

**Clinical trial results:****A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Effect of Long-Term Treatment with BELVIQ (Iorcaserin HCl) on the Incidence of Major Adverse Cardiovascular Events and Conversion to Type 2 Diabetes Mellitus in Obese and Overweight Subjects with Cardiovascular Disease or Multiple Cardiovascular Risk Factors****Summary**

EudraCT number	2013-000324-34
Trial protocol	PL
Global end of trial date	14 May 2018

Results information

Result version number	v1
This version publication date	30 May 2019
First version publication date	30 May 2019

Trial information**Trial identification**

Sponsor protocol code	APD356-G000-401
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02019264
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Eisai Ltd.
Sponsor organisation address	European Knowledge Centre, Mosquito Way, Hatfield, Hertfordshire, United Kingdom, AL10 9SN
Public contact	Eisai Medical Information, Eisai Ltd., +1 888-274-2378, esi_medinfo@eisai.com
Scientific contact	Eisai Medical Information, Eisai Ltd., +1 888-274-2378, esi_medinfo@eisai.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	14 May 2018
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	14 May 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate that, in obese and overweight subjects with cardiovascular (CV) disease and/or multiple CV risk factors, lorcaserin hydrochloride (HCl) 10 milligram (mg) administered twice daily (BID) does not increase the incidence of major adverse cardiovascular events (MACE) (myocardial infarction [MI], or stroke, or CV death) compared to placebo, with a noninferiority margin for the hazard ratio (HR) of 1.4, and in obese and overweight subjects with CV disease and/or multiple CV risk factors, lorcaserin HCl 10 mg BID reduces the incidence of MACE+ (MACE or hospitalization for unstable angina or heart failure [HF], or any coronary revascularization) compared to placebo

Protection of trial subjects:

This study was conducted in accordance with standard operating procedures (SOPs) of the sponsor (or designee), which are designed to ensure adherence to Good Clinical Practice (GCP) guidelines as required by the following:

- Principles of the World Medical Association Declaration of Helsinki (World Medical Association, 2008)
- International Council on Harmonisation (ICH) E6 Guideline for GCP (CPMP/ICH/135/95) of the European Agency for the Evaluation of Medicinal Products, Committee for Proprietary Medicinal Products, International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
- Title 21 of the United States (US) Code of Federal Regulations (US 21 CFR) regarding clinical studies, including Part 50 and Part 56 concerning informed subject consent and Institutional Review Board (IRB) regulations and applicable sections of US 21 CFR Part 312
- European Good Clinical Practice Directive 2005/28/EC and Clinical Trial Directive 2001/20/EC for studies conducted within any European Union (EU) country. All suspected unexpected serious adverse reactions were reported, as required, to the Competent Authorities of all involved EU member states.
- Article 14, Paragraph 3, and Article 80-2 of the Pharmaceutical Affairs Law (Law No. 145, 1960) for studies conducted in Japan, in addition to Japan's GCP Subject Information and Informed Consent.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	24 January 2014
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	Australia: 535
Country: Number of subjects enrolled	Bahamas: 10
Country: Number of subjects enrolled	Canada: 1165
Country: Number of subjects enrolled	Chile: 107
Country: Number of subjects enrolled	Mexico: 255
Country: Number of subjects enrolled	New Zealand: 316

Country: Number of subjects enrolled	Poland: 985
Country: Number of subjects enrolled	United States: 8627
Worldwide total number of subjects	12000
EEA total number of subjects	985

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	6257
From 65 to 84 years	5699
85 years and over	44

Subject disposition

Recruitment

Recruitment details:

Subjects took part in the study at investigative sites in the United States, Bahamas, Canada, Mexico, Chile, New Zealand, Poland, and Australia from 24 Jan 2014 to 14 May 2018.

Pre-assignment

Screening details:

A total of 14,673 subjects were screened and enrolled, of which 2673 subjects were screen failures and 12,000 were randomized to receive lorcaserin HCl or placebo.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Subjects received lorcaserin HCL placebo-matching, tablets, orally, twice daily for up to 52 months.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Lorcaserin HCL placebo-matching, tablets, orally, twice daily for up to 52 months.

Arm title	Lorcaserin 10 mg
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Arm description:

Subjects received lorcaserin HCL 10 mg, tablets, orally, twice daily for up to 52 months.

Arm type	Experimental
Investigational medicinal product name	Lorcaserin
Investigational medicinal product code	
Other name	APD356, BELVIQ
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Lorcaserin HCL 10 mg, tablets, orally, twice daily for up to 52 months.

Number of subjects in period 1	Placebo	Lorcaserin 10 mg
Started	6000	6000
Completed	5752	5793
Not completed	248	207
Not Treated	6	4
Withdrawal by subjects	142	117
Lost to follow-up	50	47
Missing	14	11
Administrative reason	36	28

Baseline characteristics

Reporting groups

Reporting group title	Placebo
Reporting group description:	
Subjects received lorcaserin HCL placebo-matching, tablets, orally, twice daily for up to 52 months.	
Reporting group title	Lorcaserin 10 mg
Reporting group description:	
Subjects received lorcaserin HCL 10 mg, tablets, orally, twice daily for up to 52 months.	

Reporting group values	Placebo	Lorcaserin 10 mg	Total
Number of subjects	6000	6000	12000
Age categorical			
Units: Subjects			
In utero			0
Preterm newborn infants (gestational age < 37 wks)			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)			0
From 65-84 years			0
85 years and over			0
Age continuous			
Units: years			
arithmetic mean	63.7	63.5	
standard deviation	± 8.31	± 8.33	-
Gender categorical			
Units: Subjects			
Female	2186	2112	4298
Male	3814	3888	7702
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	536	502	1038
Not Hispanic or Latino	5464	5498	10962
Unknown or Not Reported	0	0	0
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	21	26	47
Asian	74	85	159
Native Hawaiian or Other Pacific Islander	23	30	53
Black or African American	466	454	920
White	5331	5309	10640
More than one race	85	96	181
Unknown or Not Reported	0	0	0

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Subjects received lorcaserin HCL placebo-matching, tablets, orally, twice daily for up to 52 months.	
Reporting group title	Lorcaserin 10 mg
Reporting group description:	
Subjects received lorcaserin HCL 10 mg, tablets, orally, twice daily for up to 52 months.	

Primary: Time From Randomization to First Occurrence of Major Adverse Cardiovascular Events (MACE) at Interim Analysis

End point title	Time From Randomization to First Occurrence of Major Adverse Cardiovascular Events (MACE) at Interim Analysis
End point description:	
The MACE events involved MI, stroke, or CV death. The outcome data was assessed using Kaplan-Meier estimate and Greenwood Formula. The total time analysis set using the intent-to-treat (ITT) set, events were counted that occurred while subjects were on and off treatment. Subjects with no events were censored at their last study contact or at the visit following sponsor notification of study completion, whichever occurred first. Here "99999" refers to median time and 95% confidence interval which could not be calculated since quartile was not estimable due to higher number of censored subjects.	
End point type	Primary
End point timeframe:	
Baseline up to Month 42	

End point values	Placebo	Lorcaserin 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6000	6000		
Units: days				
median (confidence interval 95%)	99999 (99999 to 99999)	99999 (99999 to 99999)		

Statistical analyses

Statistical analysis title	Placebo, Lorcaserin 10 mg
Comparison groups	Placebo v Lorcaserin 10 mg
Number of subjects included in analysis	12000
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[1]
P-value	< 0.0001
Method	Primary Analytic Method
Parameter estimate	Hazard ratio (HR)
Point estimate	1.005

Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	0.842
upper limit	1.198

Notes:

[1] - Hazard ratio was based on Cox-regression model including treatment and CV strata as covariates. MACE met non-inferiority when the one-sided upper bound of 97.5% confidence interval of the HR was less than (<) 1.4 (the non-inferiority margin).

Primary: Time From Randomization to First Occurrence of MACE+

End point title	Time From Randomization to First Occurrence of MACE+
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End point description:

The MACE+ events involved MI, stroke, or CV death or hospitalization for unstable angina or heart failure (HF), or any coronary revascularization. The outcome data was assessed using Kaplan-Meier estimate and Greenwood Formula. The total time analysis set used the ITT set, events were counted that occurred while subjects were on and off treatment. Subjects with no events were censored at their last study contact or at the visit following Sponsor Notification of Study Completion, whichever occurred first. Here "99999" refers to median time and 95% confidence interval which could not be calculated since quartile was not estimable due to higher number of censored subjects.

End point type	Primary
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End point timeframe:

Baseline up to end of study (Month 56)

End point values	Placebo	Lorcaserin 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6000	6000		
Units: days				
median (confidence interval 95%)	99999 (99999 to 99999)	99999 (99999 to 99999)		

Statistical analyses

Statistical analysis title	Placebo, Lorcaserin 10 mg
Comparison groups	Placebo v Lorcaserin 10 mg
Number of subjects included in analysis	12000
Analysis specification	Pre-specified
Analysis type	superiority ^[2]
P-value	= 0.5464
Method	Primary Analytic Method
Parameter estimate	Hazard ratio (HR)
Point estimate	0.969
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.873
upper limit	1.074

Notes:

[2] - Hazard ratio was based on Cox-regression model including treatment and CV strata as covariates.

Secondary: Time From Randomization to Conversion to Type 2 Diabetes Mellitus (T2DM) for Subjects With Prediabetes at Baseline

End point title	Time From Randomization to Conversion to Type 2 Diabetes Mellitus (T2DM) for Subjects With Prediabetes at Baseline
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End point description:

Time from randomization to conversion to T2DM was defined as first occurrence of any component of the 2013 American Diabetes Association (ADA) Diagnostic Criteria (ADA, 2013) in subjects with prediabetes at baseline. The outcome data was assessed using Kaplan-Meier estimate and Greenwood Formula. Prediabetes and total time analysis set used ITT set: without a history of any type of diabetes and who were prediabetic at baseline; events were counted that occurred while subjects were on, off treatment; subjects with no events were censored at last study contact/at visit after notification of study completion, whichever occurred first. Here "99999" refers to median time and 95% confidence interval which could not be calculated since quartile was not estimable due to higher number of censored subjects.

End point type	Secondary
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End point timeframe:

Baseline up to end of study (Month 56)

End point values	Placebo	Lorcaserin 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1976	2015		
Units: days				
median (confidence interval 95%)	99999 (99999 to 99999)	99999 (99999 to 99999)		

Statistical analyses

Statistical analysis title	Placebo, Lorcaserin 10 mg
Comparison groups	Placebo v Lorcaserin 10 mg
Number of subjects included in analysis	3991
Analysis specification	Pre-specified
Analysis type	superiority ^[3]
P-value	= 0.038
Method	Primary Analytic Method
Parameter estimate	Hazard ratio (HR)
Point estimate	0.807
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.659
upper limit	0.988

Notes:

[3] - Hazard ratio was based on Cox-regression model including treatment as covariate.

Secondary: Time From Randomization to First Occurrence of the Individual Components of MACE+

End point title	Time From Randomization to First Occurrence of the Individual Components of MACE+
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End point description:

The MACE+ events involved MI, stroke, or CV death or hospitalization for unstable angina or HF, or any coronary revascularization. The outcome data was assessed using Kaplan-Meier estimate and Greenwood Formula. The total time analysis set used the ITT set, events counted occurred while subjects were on and off treatment. Subjects with no events were censored at last study contact or at the visit following Sponsor Notification of Study Completion, whichever first. Here "99999" refers to median time and 95% confidence interval which could not be calculated since quartile was not estimable due to higher number of censored subjects.

End point type	Secondary
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End point timeframe:

Baseline up to end of study (Month 56)

End point values	Placebo	Lorcaserin 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6000	6000		
Units: days				
arithmetic mean (confidence interval 95%)				
MI	99999 (99999 to 99999)	99999 (99999 to 99999)		
Stroke	99999 (99999 to 99999)	99999 (99999 to 99999)		
CV death	99999 (99999 to 99999)	99999 (99999 to 99999)		
Hospitalization for unstable angina	99999 (99999 to 99999)	99999 (99999 to 99999)		
HF	99999 (99999 to 99999)	99999 (99999 to 99999)		
Coronary revascularization	99999 (99999 to 99999)	99999 (99999 to 99999)		

Statistical analyses

Statistical analysis title	Placebo, Lorcaserin 10 mg
Comparison groups	Placebo v Lorcaserin 10 mg
Number of subjects included in analysis	12000
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[4]
P-value	= 0.0001
Method	Primary Analytic Method
Parameter estimate	Hazard ratio (HR)
Point estimate	0.991

Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	0.824
upper limit	1.191

Notes:

[4] - MI: Hazard ratio was based on Cox-regression model including treatment and CV strata as covariates. 97.5% confidence interval refers to the upper limit of the displayed 2-sided 95% confidence interval.

Statistical analysis title	Placebo, Lorcaserin 10 mg
Comparison groups	Placebo v Lorcaserin 10 mg
Number of subjects included in analysis	12000
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[5]
P-value	= 0.0005
Method	Primary Analytic Method
Parameter estimate	Hazard ratio (HR)
Point estimate	0.856
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	0.639
upper limit	1.145

Notes:

[5] - Time to Stroke: Hazard ratio was based on Cox-regression model including treatment and CV strata as covariates. 97.5% confidence interval refers to the upper limit of the displayed 2-sided 95% confidence interval.

Statistical analysis title	Placebo, Lorcaserin 10 mg
Comparison groups	Placebo v Lorcaserin 10 mg
Number of subjects included in analysis	12000
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[6]
P-value	= 0.0262
Method	Primary Analytic Method
Parameter estimate	Hazard ratio (HR)
Point estimate	1.045
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	0.778
upper limit	1.404

Notes:

[6] - Cardiovascular Death: Hazard ratio was based on Cox-regression model including treatment and CV strata as covariates. 97.5% confidence interval refers to the upper limit of the displayed 2-sided 95% confidence interval.

Statistical analysis title	Placebo, Lorcaserin 10 mg
Comparison groups	Placebo v Lorcaserin 10 mg

Number of subjects included in analysis	12000
Analysis specification	Pre-specified
Analysis type	superiority ^[7]
P-value	= 0.3243
Method	Primary Analytic Method
Parameter estimate	Hazard ratio (HR)
Point estimate	1.163
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.861
upper limit	1.571

Notes:

[7] - Hospitalization for Unstable Angina: Hazard ratio was based on Cox-regression model including treatment and CV strata as covariates.

Statistical analysis title	Placebo, Lorcaserin 10 mg
Comparison groups	Placebo v Lorcaserin 10 mg
Number of subjects included in analysis	12000
Analysis specification	Pre-specified
Analysis type	superiority ^[8]
P-value	= 0.6758
Method	Primary Analytic Method
Parameter estimate	Hazard ratio (HR)
Point estimate	0.952
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.757
upper limit	1.197

Notes:

[8] - HF: Hazard ratio was based on Cox-regression model including treatment and CV strata as covariates.

Statistical analysis title	Placebo, Lorcaserin 10 mg
Comparison groups	Placebo v Lorcaserin 10 mg
Number of subjects included in analysis	12000
Analysis specification	Pre-specified
Analysis type	superiority ^[9]
P-value	= 0.7817
Method	Primary Analytic Method
Parameter estimate	Hazard ratio (HR)
Point estimate	0.981
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.856
upper limit	1.125

Notes:

[9] - Coronary Revascularization: Hazard ratio was based on Cox-regression model including treatment and CV strata as covariates.

Secondary: Time From Randomization to Event of All-cause Mortality

End point title	Time From Randomization to Event of All-cause Mortality
End point description:	
The outcome data was assessed using Kaplan-Meier estimate and Greenwood Formula. The total time analysis set used the ITT set, events were counted that occurred while subjects were on and off treatment. Subjects with no events were censored at their last study contact or at the visit following Sponsor Notification of Study Completion, whichever occurred first. Here "99999" refers to median time and 95% confidence interval which could not be calculated since quartile was not estimable due to higher number of censored subjects.	
End point type	Secondary
End point timeframe:	
Baseline up to end of study (Month 56)	

End point values	Placebo	Lorcaserin 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6000	6000		
Units: days				
median (confidence interval 95%)	99999 (99999 to 99999)	99999 (99999 to 99999)		

Statistical analyses

Statistical analysis title	Placebo, Lorcaserin 10 mg
Comparison groups	Placebo v Lorcaserin 10 mg
Number of subjects included in analysis	12000
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4212
Method	Primary Analytic Method
Parameter estimate	Hazard ratio (HR)
Point estimate	1.082
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.893
upper limit	1.31

Secondary: Time From Randomization to Conversion to Normal Glucose Homeostasis in Subjects With Prediabetes at Baseline

End point title	Time From Randomization to Conversion to Normal Glucose Homeostasis in Subjects With Prediabetes at Baseline
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End point description:

Normal glucose homeostasis was defined as glycosylated hemoglobin (HbA1c) less than or equal to (\leq) 5.6% and fasting plasma glucose (FPG) $<$ 100 milligram per deciliter (mg/dL) without any antidiabetic treatment. The outcome data was assessed using Kaplan-Meier estimate and Greenwood Formula. The prediabetes analysis set included all subjects in the ITT set without a history of any type of diabetes and who were prediabetic at baseline. Here "99999" refers to median time and 95% confidence interval which could not be calculated since quartile was not estimable due to higher number of

censored subjects.

End point type	Secondary
End point timeframe:	
Baseline up to end of study (Month 56)	

End point values	Placebo	Lorcaserin 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1976	2015		
Units: days				
median (confidence interval 95%)	99999 (99999 to 99999)	99999 (99999 to 99999)		

Statistical analyses

Statistical analysis title	Placebo, Lorcaserin 10 mg
Comparison groups	Placebo v Lorcaserin 10 mg
Number of subjects included in analysis	3991
Analysis specification	Pre-specified
Analysis type	superiority ^[10]
P-value	= 0.181
Method	Primary Analytic Method
Parameter estimate	Hazard ratio (HR)
Point estimate	1.124
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.947
upper limit	1.333

Notes:

[10] - Hazard ratio was based on a Cox regression model including treatment as covariate.

Secondary: Time From Randomization to Conversion to T2DM for Subjects Without Any Type of Diabetes at Baseline

End point title	Time From Randomization to Conversion to T2DM for Subjects Without Any Type of Diabetes at Baseline
End point description:	
	The outcome data was assessed using Kaplan-Meier estimate and Greenwood Formula. The nondiabetes analysis set included all subjects in the ITT set without a history of any type of diabetes at baseline. Here "99999" refers to median time and 95% confidence interval which could not be calculated since quartile was not estimable due to higher number of censored subjects.
End point type	Secondary
End point timeframe:	
Baseline up to end of study (Month 56)	

End point values	Placebo	Lorcaserin 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2569	2615		
Units: days				
median (confidence interval 95%)	99999 (99999 to 99999)	99999 (99999 to 99999)		

Statistical analyses

Statistical analysis title	Placebo, Lorcaserin 10 mg
Comparison groups	Placebo v Lorcaserin 10 mg
Number of subjects included in analysis	5184
Analysis specification	Pre-specified
Analysis type	superiority ^[11]
P-value	= 0.0116
Method	Primary Analytic Method
Parameter estimate	Hazard ratio (HR)
Point estimate	0.773
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.633
upper limit	0.944

Notes:

[11] - Hazard ratio was based on a Cox regression model including treatment as covariate.

Secondary: Change From Baseline in HbA1c at Month 6 in Subjects With T2DM at Baseline

End point title	Change From Baseline in HbA1c at Month 6 in Subjects With T2DM at Baseline
End point description:	The T2DM analysis set included all subjects in the ITT set who had T2DM at baseline. Here "n" was the T2DM analysis set where data was available at specified time points.
End point type	Secondary
End point timeframe:	Baseline, and Month 6

End point values	Placebo	Lorcaserin 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3403	3362		
Units: percentage of HbA1c				
arithmetic mean (standard deviation)				
Baseline (n=3403, 3362)	6.99 (± 1.066)	7.01 (± 1.082)		
Change at Month 6 (n=3087, 3035)	0.06 (± 0.777)	-0.33 (± 0.785)		

Statistical analyses

Statistical analysis title	Placebo, Lorcaserin 10 mg
Comparison groups	Placebo v Lorcaserin 10 mg
Number of subjects included in analysis	6765
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [12]
Method	ANCOVA
Parameter estimate	Least square (LS) Mean Difference (Net)
Point estimate	-0.39
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.43
upper limit	-0.35

Notes:

[12] - P-value was based on analysis of covariance (ANCOVA) model with treatment and stratification variable (presence of established CV disease or CV risk factors without established CV disease) as factors, and baseline HbA1c, as a covariate.

Secondary: Time From Randomization to Event of New Onset Renal Impairment or Worsening Existing Renal Impairment in All Subjects

End point title	Time From Randomization to Event of New Onset Renal Impairment or Worsening Existing Renal Impairment in All Subjects
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End point description:

New onset/worsening of existing renal impairment was first occurrence of any events: microalbuminuria and macroalbuminuria, worsening albuminuria (microalbuminuria at Baseline developed macroalbuminuria, ACR increased $\geq 30\%$ from Baseline during treatment), newly developed chronic kidney disease (CKD) or worsening of CKD (based on National Kidney Foundation [NKF] Guidelines [2002]) worsened to higher CKD stages during treatment), or doubling of serum creatinine (creatinine value at least 2 times Baseline value and ≥ 1.5 mg/dL during treatment.), or any of following: end-stage renal disease, renal transplant, renal death. Outcome data was assessed using Kaplan-Meier estimate and Greenwood Formula. ITT set included all randomized subjects regardless of whether they took study drug or not. This set was the same as full analysis set. "99999": Median time and 95% confidence interval which could not be calculated since quartile was not estimable due to higher number of censored subjects.

End point type	Secondary
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End point timeframe:

Baseline up to end of study (Month 56)

End point values	Placebo	Lorcaserin 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6000	6000		
Units: days				
median (confidence interval 95%)	99999 (99999 to 99999)	99999 (99999 to 99999)		

Statistical analyses

Statistical analysis title	Placebo, Lorcaserin 10 mg
Comparison groups	Placebo v Lorcaserin 10 mg
Number of subjects included in analysis	12000
Analysis specification	Pre-specified
Analysis type	superiority ^[13]
P-value	= 0.0054
Method	Primary Analytic Method
Parameter estimate	Hazard ratio (HR)
Point estimate	0.869
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.787
upper limit	0.959

Notes:

[13] - Hazard ratio was based on Cox-regression model including treatment and CV strata as covariates.

Secondary: Time From Randomization to Event of New Onset Renal Impairment or Worsening Existing Renal Impairment in Subjects With Prediabetes at Baseline

End point title	Time From Randomization to Event of New Onset Renal Impairment or Worsening Existing Renal Impairment in Subjects With Prediabetes at Baseline
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End point description:

New onset/worsening of existing renal impairment was first occurrence of any events: microalbuminuria and macroalbuminuria, worsening albuminuria (microalbuminuria at Baseline developed macroalbuminuria, ACR increased $\geq 30\%$ from baseline during treatment), CKD as per NKF Guidelines [2002]) or worsening of CKD (CKD Stage1/higher as per NKF Guidelines [2002] worsened to higher CKD stages during treatment), or doubling serum creatinine(creatinine value at least twice baseline value and ≥ 1.5 mg/dL during treatment.), or any of: end stage renal disease, renal transplant, renal death. Outcome data was assessed using Kaplan-Meier estimate and Greenwood Formula. ITT set included all subjects without a history of any type of diabetes and were prediabetic at baseline. This set was the same as full analysis set. Here "99999" refers to median time and 95% confidence interval which could not be calculated since quartile was not estimable due to higher number of censored subjects.

End point type	Secondary
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End point timeframe:

Baseline up to end of study (Month 56)

End point values	Placebo	Lorcaserin 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1976	2015		
Units: days				
median (confidence interval 95%)	99999 (99999 to 99999)	99999 (99999 to 99999)		

Statistical analyses

Statistical analysis title	Placebo, Lorcaserin 10 mg
Comparison groups	Placebo v Lorcaserin 10 mg
Number of subjects included in analysis	3991
Analysis specification	Pre-specified
Analysis type	superiority ^[14]
P-value	= 0.3661
Method	Primary Analytic Method
Parameter estimate	Hazard ratio (HR)
Point estimate	0.904
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.727
upper limit	1.125

Notes:

[14] - Hazard ratio on a Cox regression model including treatment as covariate.

Secondary: Time From Randomization to Event of New Onset Renal Impairment or Worsening Existing Renal Impairment in Subjects With T2DM at Baseline

End point title	Time From Randomization to Event of New Onset Renal Impairment or Worsening Existing Renal Impairment in Subjects With T2DM at Baseline
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End point description:

New onset/worsening of existing renal impairment was first occurrence of any events: microalbuminuria and macroalbuminuria, worsening albuminuria (microalbuminuria at baseline developed macroalbuminuria, ACR increased $\geq 30\%$ from baseline during treatment), CKD as per NKF Guidelines [2002]) or worsening of CKD (CKD Stage 1/higher as per NKF Guidelines [2002] worsened to higher CKD stages during treatment), or doubling of serum creatinine (creatinine value at least 2 times baseline value and ≥ 1.5 mg/dL during treatment.), or any of the following: end-stage renal disease, renal transplant, renal death. The outcome data was assessed using Kaplan-Meier estimate and Greenwood Formula. The T2DM analysis set had all subjects in the ITT set who had T2DM at baseline. Here "99999" refers to median time and 95% confidence interval which could not be calculated since quartile was not estimable due to higher number of censored subjects.

End point type	Secondary
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End point timeframe:

Baseline up to end of study (Month 56)

End point values	Placebo	Lorcaserin 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3403	3362		
Units: days				
median (confidence interval 95%)	99999 (99999 to 99999)	99999 (99999 to 99999)		

Statistical analyses

Statistical analysis title	Placebo, Lorcaserin 10 mg
Comparison groups	Placebo v Lorcaserin 10 mg
Number of subjects included in analysis	6765
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0082
Method	Primary Analytic Method
Parameter estimate	Hazard ratio (HR)
Point estimate	0.855
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.762
upper limit	0.96

Secondary: Time From Randomization to Event of Improvement in Renal Function in Subjects With T2DM at Baseline

End point title	Time From Randomization to Event of Improvement in Renal Function in Subjects With T2DM at Baseline
End point description:	Improvement in renal function: first occurrence of regression of albuminuria/regression of CKD. Regression of albuminuria: when subjects with macroalbuminuria at baseline developed microalbuminuria or nonalbuminuria, or subjects with microalbuminuria at baseline became nonalbuminuric, and ACR value decreased \geq 30% from previous assessment in treatment. Regression of CKD: when subjects with CKD Stage 1/higher at baseline improved to normal/lower stages by NKF guidelines in treatment. The outcome data was assessed using Kaplan-Meier estimate and Greenwood Formula. The T2DM analysis set included all subjects in ITT set who had T2DM at baseline. Here "99999" refers to median time and 95% confidence interval which could not be calculated since quartile was not estimable due to higher number of censored subjects.
End point type	Secondary
End point timeframe:	Baseline up to end of study (Month 56)

End point values	Placebo	Lorcaserin 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3403	3362		
Units: days				
median (confidence interval 95%)	99999 (99999 to 99999)	99999 (99999 to 99999)		

Statistical analyses

Statistical analysis title	Placebo, Lorcaserin 10 mg
Comparison groups	Placebo v Lorcaserin 10 mg
Number of subjects included in analysis	6765
Analysis specification	Pre-specified
Analysis type	superiority ^[15]
P-value	= 0.0297
Method	Primary Analytic Method
Parameter estimate	Hazard ratio (HR)
Point estimate	1.182
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.017
upper limit	1.375

Notes:

[15] - Hazard ratio was based on Cox-regression model including treatment and CV strata as covariates.

Secondary: Percentage of Subjects Who Met FDA-Defined Valvulopathy in Echocardiographically Determined Heart Valve Changes

End point title	Percentage of Subjects Who Met FDA-Defined Valvulopathy in Echocardiographically Determined Heart Valve Changes
End point description:	The FDA-defined valvulopathy analysis set included all subjects in the ITT set without FDA-defined valvulopathy at baseline. Here "n" was the FDA-defined valvulopathy analysis set where data was available at specified time point.
End point type	Secondary
End point timeframe:	
Month 12	

End point values	Placebo	Lorcaserin 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1935	1925		
Units: percentage of subjects				
number (not applicable)				
Month 6 (n=1683, 1681)	1.4	2.1		
Month 12 (n=1564, 1579)	1.5	1.8		

Statistical analyses

Statistical analysis title	Placebo, Lorcaserin 10 mg
Comparison groups	Placebo v Lorcaserin 10 mg
Number of subjects included in analysis	3860
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5015 ^[16]
Method	Primary Analytic Method
Parameter estimate	Odds ratio (OR)
Point estimate	1.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.69
upper limit	2.11

Notes:

[16] - P-value was based on logistic regression including treatment as a factor and baseline body mass index (BMI) as a covariate.

Secondary: Percentage of Subjects With FDA-Defined Valvulopathy at Baseline Who Demonstrated Worsened FDA-Defined Valvulopathy

End point title	Percentage of Subjects With FDA-Defined Valvulopathy at Baseline Who Demonstrated Worsened FDA-Defined Valvulopathy
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End point description:

The ITT analysis set in subjects with FDA-defined valvulopathy at baseline was used. Here "n" was the FDA-defined valvulopathy analysis set where data was available at specified time point.

End point type	Secondary
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End point timeframe:

Month 12

End point values	Placebo	Lorcaserin 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	228	225		
Units: percentage of subjects				
number (not applicable)				
Month 6 (n=194, 201)	2.1	3.5		
Month 12 (n=180, 189)	1.7	2.1		

Statistical analyses

Statistical analysis title	Placebo, Lorcaserin 10 mg
Comparison groups	Placebo v Lorcaserin 10 mg
Number of subjects included in analysis	453
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7249 ^[17]
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.29
upper limit	5.98

Notes:

[17] - P-value was based on logistic regression including treatment as a factor and baseline BMI as a covariate.

Secondary: Change From Baseline in Echocardiographically-Determined Pulmonary Arterial Systolic Pressure

End point title	Change From Baseline in Echocardiographically-Determined Pulmonary Arterial Systolic Pressure
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End point description:

The ITT analysis set-subjects in ECHO substudy included all randomized subjects regardless of whether they took study drug or not and data from the ECHO substudy was pooled with the ECHO data from the 3 pivotal lorcaserin HCl studies. Here "n" was the ITT analysis set-subjects in the ECHO substudy, where data was available at specified time points.

End point type	Secondary
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End point timeframe:

Baseline, Month 12

End point values	Placebo	Lorcaserin 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2167	2151		
Units: Millimeter of mercury (mmHg)				
arithmetic mean (standard deviation)				
Baseline (n=1368, 1358)	26.4354 (± 7.66312)	26.2029 (± 7.54123)		
Change at Month 12 (n=882, 893)	-0.6418 (± 6.81716)	-0.8223 (± 7.23770)		

Statistical analyses

Statistical analysis title	Placebo, Lorcaserin 10 mg
Comparison groups	Lorcaserin 10 mg v Placebo

Number of subjects included in analysis	4318
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2976 ^[18]
Method	Mixed-effects model
Parameter estimate	Mean difference (net)
Point estimate	-0.9036
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.2908
upper limit	-0.5163

Notes:

[18] - P value was based on a mixed-effects model (unstructured covariance matrix) with repeated measures with treatment, month and treatment by month interaction as factors and baseline pulmonary arterial systolic pressure and baseline BMI as covariates.

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From baseline up to 30 days after last dose of study drug (approximately 56 months)

Adverse event reporting additional description:

Adverse events were collected for the subject who were in the safety analysis set (all subjects who received at least 1 dose of study drug and had at least one post dose safety assessment).

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	19.0
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Reporting groups

Reporting group title	Placebo
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Reporting group description:

Subjects received lorcaserin HCL placebo-matching, tablets, orally, twice daily for up to 52 months.

Reporting group title	Lorcaserin 10 mg
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Reporting group description:

Subjects received lorcaserin HCL 10 mg, tablets, orally, twice daily for up to 52 months.

Serious adverse events	Placebo	Lorcaserin 10 mg	
Total subjects affected by serious adverse events			
subjects affected / exposed	2021 / 5992 (33.73%)	1974 / 5995 (32.93%)	
number of deaths (all causes)	202	219	
number of deaths resulting from adverse events	121	132	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute leukaemia			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute myeloid leukaemia			
subjects affected / exposed	1 / 5992 (0.02%)	2 / 5995 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenocarcinoma			
subjects affected / exposed	1 / 5992 (0.02%)	2 / 5995 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

Adenocarcinoma gastric			
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenocarcinoma of appendix			
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Adenocarcinoma of colon			
subjects affected / exposed	4 / 5992 (0.07%)	6 / 5995 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenocarcinoma pancreas			
subjects affected / exposed	1 / 5992 (0.02%)	2 / 5995 (0.03%)	
occurrences causally related to treatment / all	0 / 1	1 / 2	
deaths causally related to treatment / all	0 / 1	1 / 1	
Adrenal adenoma			
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adrenal gland cancer			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adrenal neoplasm			
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal squamous cell carcinoma			
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angiomyolipoma			

subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Appendix cancer		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Atypical fibroxanthoma		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
B-cell lymphoma		
subjects affected / exposed	2 / 5992 (0.03%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
B-cell lymphoma stage III		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Basal cell carcinoma		
subjects affected / exposed	4 / 5992 (0.07%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Benign gastric neoplasm		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Benign neoplasm of ampulla of Vater		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Benign neoplasm of bladder		

subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Benign neoplasm of thyroid gland		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign renal neoplasm		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Benign small intestinal neoplasm		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Biliary neoplasm		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder cancer		
subjects affected / exposed	5 / 5992 (0.08%)	4 / 5995 (0.07%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder cancer recurrent		
subjects affected / exposed	2 / 5992 (0.03%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder neoplasm		
subjects affected / exposed	2 / 5992 (0.03%)	4 / 5995 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder transitional cell carcinoma		

subjects affected / exposed	2 / 5992 (0.03%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder transitional cell carcinoma recurrent		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bone cancer		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bone cancer metastatic		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Brain cancer metastatic		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Brain neoplasm		
subjects affected / exposed	0 / 5992 (0.00%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Breast cancer		
subjects affected / exposed	9 / 5992 (0.15%)	11 / 5995 (0.18%)
occurrences causally related to treatment / all	0 / 9	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Breast cancer in situ		
subjects affected / exposed	1 / 5992 (0.02%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Breast cancer metastatic		

subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cervix carcinoma		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cervix carcinoma stage IV		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Cholangiocarcinoma		
subjects affected / exposed	1 / 5992 (0.02%)	4 / 5995 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 2
Choroid melanoma		
subjects affected / exposed	1 / 5992 (0.02%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Choroid neoplasm		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic lymphocytic leukaemia		
subjects affected / exposed	3 / 5992 (0.05%)	5 / 5995 (0.08%)
occurrences causally related to treatment / all	1 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1
Chronic myeloid leukaemia		
subjects affected / exposed	1 / 5992 (0.02%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Clear cell renal cell carcinoma		

subjects affected / exposed	3 / 5992 (0.05%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	1 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Colon adenoma		
subjects affected / exposed	11 / 5992 (0.18%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	2 / 12	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colon cancer		
subjects affected / exposed	7 / 5992 (0.12%)	9 / 5995 (0.15%)
occurrences causally related to treatment / all	0 / 7	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Colon cancer metastatic		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colon neoplasm		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colorectal adenocarcinoma		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colorectal cancer stage IV		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (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	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Endometrial adenocarcinoma		

subjects affected / exposed	5 / 5992 (0.08%)	4 / 5995 (0.07%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Endometrial cancer		
subjects affected / exposed	7 / 5992 (0.12%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 7	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Extranodal marginal zone B-cell lymphoma (MALT type)		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Fibroadenoma of breast		
subjects affected / exposed	1 / 5992 (0.02%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Fibroma		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Follicular thyroid cancer		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric cancer		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric cancer stage 0		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal stromal tumour		

subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glioblastoma			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Glioblastoma multiforme			
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Hepatic cancer			
subjects affected / exposed	2 / 5992 (0.03%)	2 / 5995 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Hepatic cancer metastatic			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hepatocellular carcinoma			
subjects affected / exposed	2 / 5992 (0.03%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hodgkin's disease			
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal adenocarcinoma			
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intraductal papillary mucinous neoplasm			

subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intraductal papillary-mucinous carcinoma of pancreas		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intraductal papilloma of breast		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (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	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Invasive breast carcinoma		
subjects affected / exposed	3 / 5992 (0.05%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Invasive ductal breast carcinoma		
subjects affected / exposed	8 / 5992 (0.13%)	4 / 5995 (0.07%)
occurrences causally related to treatment / all	0 / 9	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Keratoacanthoma		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Kidney angiomyolipoma		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lipoma		

subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung adenocarcinoma		
subjects affected / exposed	3 / 5992 (0.05%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 1
Lung adenocarcinoma stage 0		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung adenocarcinoma stage IV		
subjects affected / exposed	1 / 5992 (0.02%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1
Lung cancer metastatic		
subjects affected / exposed	3 / 5992 (0.05%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1
Lung carcinoma cell type unspecified stage III		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
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	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lung neoplasm malignant		
subjects affected / exposed	6 / 5992 (0.10%)	13 / 5995 (0.22%)
occurrences causally related to treatment / all	0 / 6	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 1
Lung squamous cell carcinoma stage II		

subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphoma		
subjects affected / exposed	4 / 5992 (0.07%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant melanoma		
subjects affected / exposed	17 / 5992 (0.28%)	20 / 5995 (0.33%)
occurrences causally related to treatment / all	0 / 21	0 / 24
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant melanoma in situ		
subjects affected / exposed	3 / 5992 (0.05%)	5 / 5995 (0.08%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant melanoma stage I		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant neoplasm of ampulla of Vater		
subjects affected / exposed	0 / 5992 (0.00%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Malignant neoplasm of spinal cord		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant neoplasm of unknown primary site		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Malignant sweat gland neoplasm		

subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Melanocytic naevus		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Meningioma		
subjects affected / exposed	0 / 5992 (0.00%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Meningioma benign		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to bone		
subjects affected / exposed	6 / 5992 (0.10%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Metastases to liver		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Metastases to lung		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to lymph nodes		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Metastasis		

subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
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 / 5992 (0.02%)	0 / 5995 (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	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Metastatic renal cell carcinoma		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metastatic squamous cell carcinoma		
subjects affected / exposed	0 / 5992 (0.00%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Mucinous cystadenocarcinoma ovary		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Mycosis fungoides		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Myelodysplastic syndrome		
subjects affected / exposed	2 / 5992 (0.03%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Myxofibrosarcoma		

subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasopharyngeal cancer			
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neoplasm prostate			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neoplasm skin			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuroendocrine carcinoma metastatic			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuroendocrine tumour			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nodular melanoma			
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-Hodgkin's lymphoma			
subjects affected / exposed	2 / 5992 (0.03%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-small cell lung cancer			

subjects affected / exposed	3 / 5992 (0.05%)	5 / 5995 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 1
Non-small cell lung cancer stage I		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal adenocarcinoma		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Oesophageal adenocarcinoma metastatic		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Oesophageal carcinoma		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Oropharyngeal cancer		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian adenoma		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian cancer metastatic		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Pancreatic carcinoma		

subjects affected / exposed	0 / 5992 (0.00%)	5 / 5995 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 4
Pancreatic carcinoma metastatic		
subjects affected / exposed	0 / 5992 (0.00%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 3
Pancreatic neuroendocrine tumour		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Papillary serous endometrial carcinoma		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (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 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peritoneal carcinoma metastatic		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Pharyngeal cancer		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pituitary tumour benign		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Plasma cell myeloma		

subjects affected / exposed	1 / 5992 (0.02%)	5 / 5995 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 2
Polycythaemia vera		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate cancer		
subjects affected / exposed	51 / 5992 (0.85%)	50 / 5995 (0.83%)
occurrences causally related to treatment / all	0 / 51	1 / 50
deaths causally related to treatment / all	0 / 1	0 / 1
Prostate cancer metastatic		
subjects affected / exposed	2 / 5992 (0.03%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Prostate cancer recurrent		
subjects affected / exposed	6 / 5992 (0.10%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Prostate cancer stage II		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatic adenoma		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal adenocarcinoma		
subjects affected / exposed	0 / 5992 (0.00%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal cancer		

subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal cancer metastatic		
subjects affected / exposed	0 / 5992 (0.00%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Rectosigmoid cancer		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cancer		
subjects affected / exposed	0 / 5992 (0.00%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cell carcinoma		
subjects affected / exposed	7 / 5992 (0.12%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	0 / 7	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Renal neoplasm		
subjects affected / exposed	1 / 5992 (0.02%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Salivary gland adenoma		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Salivary gland cancer		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Skin cancer		

subjects affected / exposed	1 / 5992 (0.02%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Skin squamous cell carcinoma metastatic		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Small cell carcinoma		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Small cell lung cancer		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Small cell lung cancer extensive stage		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Small cell lung cancer metastatic		
subjects affected / exposed	2 / 5992 (0.03%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Squamous cell carcinoma		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma of head and neck		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Squamous cell carcinoma of lung		

subjects affected / exposed	0 / 5992 (0.00%)	6 / 5995 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 2
Squamous cell carcinoma of skin		
subjects affected / exposed	5 / 5992 (0.08%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma of the oral cavity		
subjects affected / exposed	0 / 5992 (0.00%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma of the tongue		
subjects affected / exposed	2 / 5992 (0.03%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tongue neoplasm malignant stage unspecified		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tonsil cancer		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
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	4 / 5992 (0.07%)	5 / 5995 (0.08%)
occurrences causally related to treatment / all	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Ureteral neoplasm		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Urethral cancer		

subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine cancer			
subjects affected / exposed	2 / 5992 (0.03%)	2 / 5995 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine leiomyoma			
subjects affected / exposed	3 / 5992 (0.05%)	4 / 5995 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulval cancer stage 0			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Waldenstrom's macroglobulinaemia			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Accelerated hypertension			
subjects affected / exposed	2 / 5992 (0.03%)	4 / 5995 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic aneurysm			
subjects affected / exposed	11 / 5992 (0.18%)	6 / 5995 (0.10%)	
occurrences causally related to treatment / all	0 / 11	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic dissection			
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Aortic stenosis			

subjects affected / exposed	7 / 5992 (0.12%)	14 / 5995 (0.23%)
occurrences causally related to treatment / all	0 / 7	1 / 15
deaths causally related to treatment / all	0 / 0	0 / 1
Arterial occlusive disease		
subjects affected / exposed	2 / 5992 (0.03%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Arterial stenosis		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arteriosclerosis		
subjects affected / exposed	1 / 5992 (0.02%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Arteriovenous fistula		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
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	0 / 5992 (0.00%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Deep vein thrombosis		
subjects affected / exposed	13 / 5992 (0.22%)	12 / 5995 (0.20%)
occurrences causally related to treatment / all	0 / 16	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Dry gangrene		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haematoma		

subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertension		
subjects affected / exposed	14 / 5992 (0.23%)	10 / 5995 (0.17%)
occurrences causally related to treatment / all	0 / 19	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 1
Hypertensive crisis		
subjects affected / exposed	7 / 5992 (0.12%)	8 / 5995 (0.13%)
occurrences causally related to treatment / all	0 / 7	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive emergency		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypotension		
subjects affected / exposed	10 / 5992 (0.17%)	16 / 5995 (0.27%)
occurrences causally related to treatment / all	0 / 10	0 / 16
deaths causally related to treatment / all	0 / 0	0 / 0
Hypovolaemic shock		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Iliac artery disease		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Intermittent claudication		
subjects affected / exposed	2 / 5992 (0.03%)	6 / 5995 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemia		

subjects affected / exposed	2 / 5992 (0.03%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Leriche syndrome		
subjects affected / exposed	0 / 5992 (0.00%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphoedema		
subjects affected / exposed	1 / 5992 (0.02%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant hypertension		
subjects affected / exposed	3 / 5992 (0.05%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Microscopic polyangiitis		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Orthostatic hypotension		
subjects affected / exposed	1 / 5992 (0.02%)	5 / 5995 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral arterial occlusive disease		
subjects affected / exposed	11 / 5992 (0.18%)	14 / 5995 (0.23%)
occurrences causally related to treatment / all	0 / 11	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 1
Peripheral artery aneurysm		
subjects affected / exposed	1 / 5992 (0.02%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery dissection		

subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery occlusion		
subjects affected / exposed	4 / 5992 (0.07%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery stenosis		
subjects affected / exposed	4 / 5992 (0.07%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	0 / 7	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery thrombosis		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral ischaemia		
subjects affected / exposed	2 / 5992 (0.03%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral vascular disorder		
subjects affected / exposed	7 / 5992 (0.12%)	6 / 5995 (0.10%)
occurrences causally related to treatment / all	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral venous disease		
subjects affected / exposed	0 / 5992 (0.00%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Poor peripheral circulation		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Reperfusion injury		

subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shock haemorrhagic			
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (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	1 / 5992 (0.02%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subclavian vein thrombosis			
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombophlebitis superficial			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombosis			
subjects affected / exposed	2 / 5992 (0.03%)	3 / 5995 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous thrombosis			
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous thrombosis limb			
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (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			
Adverse drug reaction			

subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Asthenia		
subjects affected / exposed	5 / 5992 (0.08%)	9 / 5995 (0.15%)
occurrences causally related to treatment / all	0 / 5	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac death		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Chest discomfort		
subjects affected / exposed	7 / 5992 (0.12%)	6 / 5995 (0.10%)
occurrences causally related to treatment / all	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Chest pain		
subjects affected / exposed	21 / 5992 (0.35%)	16 / 5995 (0.27%)
occurrences causally related to treatment / all	0 / 22	0 / 16
deaths causally related to treatment / all	0 / 0	0 / 0
Complication associated with device		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cyst		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Death		
subjects affected / exposed	12 / 5992 (0.20%)	16 / 5995 (0.27%)
occurrences causally related to treatment / all	1 / 12	2 / 16
deaths causally related to treatment / all	1 / 12	2 / 16
Drug withdrawal syndrome		

subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Exercise tolerance decreased		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Fatigue		
subjects affected / exposed	1 / 5992 (0.02%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	1 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gait disturbance		
subjects affected / exposed	2 / 5992 (0.03%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal complication associated with device		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Generalised oedema		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hernia pain		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypothermia		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Impaired healing		

subjects affected / exposed	2 / 5992 (0.03%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Implant site erosion		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Incarcerated hernia		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infusion site extravasation		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Localised oedema		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (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	2 / 5992 (0.03%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Medical device site haemorrhage		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple organ dysfunction syndrome		
subjects affected / exposed	2 / 5992 (0.03%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Non-cardiac chest pain		

subjects affected / exposed	132 / 5992 (2.20%)	133 / 5995 (2.22%)
occurrences causally related to treatment / all	0 / 153	1 / 164
deaths causally related to treatment / all	0 / 0	0 / 0
Oedema peripheral		
subjects affected / exposed	4 / 5992 (0.07%)	4 / 5995 (0.07%)
occurrences causally related to treatment / all	1 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Pain		
subjects affected / exposed	0 / 5992 (0.00%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral swelling		
subjects affected / exposed	2 / 5992 (0.03%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pyrexia		
subjects affected / exposed	2 / 5992 (0.03%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Stent-graft endoleak		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sudden cardiac death		
subjects affected / exposed	2 / 5992 (0.03%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 2
Sudden death		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Systemic inflammatory response syndrome		

subjects affected / exposed	1 / 5992 (0.02%)	2 / 5995 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent occlusion			
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent restenosis			
subjects affected / exposed	2 / 5992 (0.03%)	3 / 5995 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent thrombosis			
subjects affected / exposed	0 / 5992 (0.00%)	2 / 5995 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	4 / 5992 (0.07%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	1 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaphylactic shock			
subjects affected / exposed	0 / 5992 (0.00%)	2 / 5995 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug hypersensitivity			
subjects affected / exposed	2 / 5992 (0.03%)	3 / 5995 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypersensitivity			
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Social circumstances			

Convalescent			
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Spousal abuse			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Acquired hydrocele			
subjects affected / exposed	1 / 5992 (0.02%)	3 / 5995 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adnexa uteri mass			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
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	10 / 5992 (0.17%)	7 / 5995 (0.12%)	
occurrences causally related to treatment / all	0 / 12	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast enlargement			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast fibrosis			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast hyperplasia			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Breast pain			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast ulceration			
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (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	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial hyperplasia			
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erectile dysfunction			
subjects affected / exposed	1 / 5992 (0.02%)	2 / 5995 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Female genital tract fistula			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Mastoptosis			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orchitis noninfective			
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Organic erectile dysfunction			

subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian cyst		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic pain		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic prolapse		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Penis disorder		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Postmenopausal haemorrhage		
subjects affected / exposed	2 / 5992 (0.03%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Priapism		
subjects affected / exposed	2 / 5992 (0.03%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	2 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatism		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatitis		

subjects affected / exposed	2 / 5992 (0.03%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatomegaly			
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scrotal haematocoele			
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine polyp			
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine prolapse			
subjects affected / exposed	4 / 5992 (0.07%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal haemorrhage			
subjects affected / exposed	0 / 5992 (0.00%)	2 / 5995 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal prolapse			
subjects affected / exposed	0 / 5992 (0.00%)	3 / 5995 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	3 / 5992 (0.05%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute respiratory distress syndrome			

subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Acute respiratory failure		
subjects affected / exposed	28 / 5992 (0.47%)	35 / 5995 (0.58%)
occurrences causally related to treatment / all	1 / 31	0 / 37
deaths causally related to treatment / all	1 / 3	0 / 5
Allergic bronchitis		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Aspiration		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Asthma		
subjects affected / exposed	9 / 5992 (0.15%)	12 / 5995 (0.20%)
occurrences causally related to treatment / all	0 / 11	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Atelectasis		
subjects affected / exposed	4 / 5992 (0.07%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchial hyperreactivity		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchitis chronic		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchospasm		

subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic obstructive pulmonary disease		
subjects affected / exposed	43 / 5992 (0.72%)	39 / 5995 (0.65%)
occurrences causally related to treatment / all	0 / 53	0 / 58
deaths causally related to treatment / all	0 / 3	0 / 0
Chronic respiratory failure		
subjects affected / exposed	2 / 5992 (0.03%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cough		
subjects affected / exposed	3 / 5992 (0.05%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dyspnoea		
subjects affected / exposed	38 / 5992 (0.63%)	27 / 5995 (0.45%)
occurrences causally related to treatment / all	1 / 40	0 / 27
deaths causally related to treatment / all	0 / 1	0 / 0
Dyspnoea exertional		
subjects affected / exposed	11 / 5992 (0.18%)	5 / 5995 (0.08%)
occurrences causally related to treatment / all	0 / 11	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Emphysema		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Epistaxis		
subjects affected / exposed	3 / 5992 (0.05%)	5 / 5995 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Haemoptysis		

subjects affected / exposed	2 / 5992 (0.03%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemothorax		
subjects affected / exposed	0 / 5992 (0.00%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hiccups		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypercapnia		
subjects affected / exposed	1 / 5992 (0.02%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoxia		
subjects affected / exposed	6 / 5992 (0.10%)	8 / 5995 (0.13%)
occurrences causally related to treatment / all	0 / 6	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Idiopathic pulmonary fibrosis		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Interstitial lung disease		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngeal granuloma		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngeal mass		

subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
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	1 / 5992 (0.02%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Mediastinal haematoma			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mediastinal haemorrhage			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal obstruction			
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal polyps			
subjects affected / exposed	0 / 5992 (0.00%)	2 / 5995 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstructive airways disorder			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngeal fistula			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pickwickian syndrome			

subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pleural effusion		
subjects affected / exposed	10 / 5992 (0.17%)	12 / 5995 (0.20%)
occurrences causally related to treatment / all	0 / 10	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Pleurisy		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pleuritic pain		
subjects affected / exposed	2 / 5992 (0.03%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia aspiration		
subjects affected / exposed	4 / 5992 (0.07%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0
Pneumonitis		
subjects affected / exposed	0 / 5992 (0.00%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumothorax		
subjects affected / exposed	4 / 5992 (0.07%)	5 / 5995 (0.08%)
occurrences causally related to treatment / all	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 1
Pulmonary arterial hypertension		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary embolism		

subjects affected / exposed	26 / 5992 (0.43%)	20 / 5995 (0.33%)
occurrences causally related to treatment / all	1 / 27	0 / 21
deaths causally related to treatment / all	0 / 1	0 / 3
Pulmonary fibrosis		
subjects affected / exposed	1 / 5992 (0.02%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Pulmonary granuloma		
subjects affected / exposed	0 / 5992 (0.00%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary haemorrhage		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary hypertension		
subjects affected / exposed	14 / 5992 (0.23%)	14 / 5995 (0.23%)
occurrences causally related to treatment / all	4 / 14	1 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary mass		
subjects affected / exposed	4 / 5992 (0.07%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary oedema		
subjects affected / exposed	8 / 5992 (0.13%)	5 / 5995 (0.08%)
occurrences causally related to treatment / all	0 / 8	0 / 5
deaths causally related to treatment / all	0 / 2	0 / 0
Pulmonary sarcoidosis		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory arrest		

subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory distress			
subjects affected / exposed	3 / 5992 (0.05%)	4 / 5995 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	
Respiratory failure			
subjects affected / exposed	14 / 5992 (0.23%)	14 / 5995 (0.23%)	
occurrences causally related to treatment / all	1 / 14	0 / 15	
deaths causally related to treatment / all	0 / 2	0 / 1	
Sleep apnoea syndrome			
subjects affected / exposed	2 / 5992 (0.03%)	2 / 5995 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachypnoea			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsillar hypertrophy			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 5992 (0.00%)	2 / 5995 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol abuse			
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol withdrawal syndrome			

subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Anger		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anxiety		
subjects affected / exposed	4 / 5992 (0.07%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Confusional state		
subjects affected / exposed	3 / 5992 (0.05%)	12 / 5995 (0.20%)
occurrences causally related to treatment / all	0 / 3	1 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Delirium		
subjects affected / exposed	3 / 5992 (0.05%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Depression		
subjects affected / exposed	5 / 5992 (0.08%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 5	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hallucination		
subjects affected / exposed	2 / 5992 (0.03%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Insomnia		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Major depression		

subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mental disorder due to a general medical condition		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mental status changes		
subjects affected / exposed	6 / 5992 (0.10%)	10 / 5995 (0.17%)
occurrences causally related to treatment / all	0 / 6	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Nightmare		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post-traumatic stress disorder		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Psychotic disorder		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Somatic delusion		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Suicidal ideation		
subjects affected / exposed	4 / 5992 (0.07%)	9 / 5995 (0.15%)
occurrences causally related to treatment / all	3 / 4	6 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Suicide attempt		

subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
Device dislocation			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device failure			
subjects affected / exposed	2 / 5992 (0.03%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device loosening			
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device malfunction			
subjects affected / exposed	1 / 5992 (0.02%)	2 / 5995 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device pacing issue			
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lead dislodgement			
subjects affected / exposed	0 / 5992 (0.00%)	3 / 5995 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Autoimmune hepatitis			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct obstruction			

subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
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 / 5992 (0.03%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Biliary colic		
subjects affected / exposed	2 / 5992 (0.03%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Biliary dyskinesia		
subjects affected / exposed	1 / 5992 (0.02%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cholangitis		
subjects affected / exposed	3 / 5992 (0.05%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	1 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis		
subjects affected / exposed	14 / 5992 (0.23%)	10 / 5995 (0.17%)
occurrences causally related to treatment / all	1 / 14	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis acute		
subjects affected / exposed	14 / 5992 (0.23%)	12 / 5995 (0.20%)
occurrences causally related to treatment / all	0 / 14	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis chronic		
subjects affected / exposed	1 / 5992 (0.02%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cholelithiasis		

subjects affected / exposed	24 / 5992 (0.40%)	14 / 5995 (0.23%)
occurrences causally related to treatment / all	0 / 25	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Cholelithiasis obstructive		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic hepatic failure		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Cirrhosis alcoholic		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cryptogenic cirrhosis		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Drug-induced liver injury		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic cirrhosis		
subjects affected / exposed	2 / 5992 (0.03%)	4 / 5995 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 2
Hepatic cyst		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic function abnormal		

subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic mass			
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic steatosis			
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic vascular thrombosis			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver disorder			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver injury			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-alcoholic fatty liver			
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Portal vein thrombosis			
subjects affected / exposed	0 / 5992 (0.00%)	2 / 5995 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Ammonia increased			

subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic bruit		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Blood calcium decreased		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (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	2 / 5992 (0.03%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Blood glucose increased		
subjects affected / exposed	2 / 5992 (0.03%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Blood immunoglobulin G decreased		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Blood potassium increased		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Blood pressure increased		
subjects affected / exposed	2 / 5992 (0.03%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Blood sodium increased		

subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Blood urea increased		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Blood urine present		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Body temperature increased		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac stress test abnormal		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Coagulation test abnormal		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
ECG signs of myocardial ischaemia		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ejection fraction decreased		
subjects affected / exposed	1 / 5992 (0.02%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	1 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Electrocardiogram QT prolonged		

subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Electrocardiogram ST segment depression		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Electrocardiogram abnormal		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Glycosylated haemoglobin increased		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemoglobin decreased		
subjects affected / exposed	2 / 5992 (0.03%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Heart rate decreased		
subjects affected / exposed	2 / 5992 (0.03%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic enzyme increased		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
International normalised ratio abnormal		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
International normalised ratio increased		

subjects affected / exposed	2 / 5992 (0.03%)	3 / 5995 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver function test abnormal			
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver function test increased			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
N-terminal prohormone brain natriuretic peptide increased			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oxygen saturation decreased			
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Platelet count decreased			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
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	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prothrombin time prolonged			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary arterial pressure increased			

subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Troponin T increased			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Troponin increased			
subjects affected / exposed	8 / 5992 (0.13%)	6 / 5995 (0.10%)	
occurrences causally related to treatment / all	0 / 8	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
White blood cell count increased			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Abdominal injury			
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Accidental overdose			
subjects affected / exposed	1 / 5992 (0.02%)	3 / 5995 (0.05%)	
occurrences causally related to treatment / all	0 / 1	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol poisoning			
subjects affected / exposed	2 / 5992 (0.03%)	4 / 5995 (0.07%)	
occurrences causally related to treatment / all	0 / 2	1 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia postoperative			
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anastomotic ulcer haemorrhage			

subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Animal bite		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ankle fracture		
subjects affected / exposed	4 / 5992 (0.07%)	6 / 5995 (0.10%)
occurrences causally related to treatment / all	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Arterial bypass thrombosis		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arterial injury		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder injury		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Brain contusion		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Cardiac contusion		
subjects affected / exposed	0 / 5992 (0.00%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac valve replacement complication		

subjects affected / exposed	2 / 5992 (0.03%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cartilage injury		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cervical vertebral fracture		
subjects affected / exposed	2 / 5992 (0.03%)	5 / 5995 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Chest injury		
subjects affected / exposed	2 / 5992 (0.03%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Clavicle fracture		
subjects affected / exposed	1 / 5992 (0.02%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Concussion		
subjects affected / exposed	1 / 5992 (0.02%)	4 / 5995 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Contusion		
subjects affected / exposed	3 / 5992 (0.05%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Craniocerebral injury		
subjects affected / exposed	1 / 5992 (0.02%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis radiation		

subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Delayed recovery from anaesthesia		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Extradural haematoma		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
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	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fall		
subjects affected / exposed	15 / 5992 (0.25%)	21 / 5995 (0.35%)
occurrences causally related to treatment / all	0 / 17	0 / 21
deaths causally related to treatment / all	0 / 0	0 / 0
Femoral neck fracture		
subjects affected / exposed	4 / 5992 (0.07%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Femur fracture		
subjects affected / exposed	2 / 5992 (0.03%)	10 / 5995 (0.17%)
occurrences causally related to treatment / all	0 / 2	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Fibula fracture		
subjects affected / exposed	3 / 5992 (0.05%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Foot fracture		

subjects affected / exposed	3 / 5992 (0.05%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Forearm fracture		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fractured sacrum		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal stoma complication		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hand fracture		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Head injury		
subjects affected / exposed	2 / 5992 (0.03%)	4 / 5995 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Hip fracture		
subjects affected / exposed	5 / 5992 (0.08%)	10 / 5995 (0.17%)
occurrences causally related to treatment / all	0 / 5	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Humerus fracture		
subjects affected / exposed	6 / 5992 (0.10%)	6 / 5995 (0.10%)
occurrences causally related to treatment / all	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Ilium fracture		

subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Incarcerated incisional hernia		
subjects affected / exposed	0 / 5992 (0.00%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Incision site complication		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Incision site haemorrhage		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Incisional hernia		
subjects affected / exposed	3 / 5992 (0.05%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Incomplete spinal fusion		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intentional overdose		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal anastomosis complication		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Jaw fracture		

subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Joint capsule rupture		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (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	3 / 5992 (0.05%)	4 / 5995 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Joint dislocation postoperative		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Joint injury		
subjects affected / exposed	2 / 5992 (0.03%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Kidney contusion		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
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 / 5992 (0.02%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Ligament rupture		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ligament sprain		

subjects affected / exposed	2 / 5992 (0.03%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Limb injury		
subjects affected / exposed	3 / 5992 (0.05%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Limb traumatic amputation		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Liver contusion		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lower limb fracture		
subjects affected / exposed	2 / 5992 (0.03%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar vertebral fracture		
subjects affected / exposed	1 / 5992 (0.02%)	4 / 5995 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Meniscus injury		
subjects affected / exposed	2 / 5992 (0.03%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mental status changes postoperative		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple fractures		

subjects affected / exposed	2 / 5992 (0.03%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple injuries		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Muscle strain		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Patella fracture		
subjects affected / exposed	2 / 5992 (0.03%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic fracture		
subjects affected / exposed	3 / 5992 (0.05%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Periprosthetic fracture		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonitis chemical		
subjects affected / exposed	0 / 5992 (0.00%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumothorax traumatic		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post laminectomy syndrome		

subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural bile leak		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
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	3 / 5992 (0.05%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Post procedural discharge		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural haematoma		
subjects affected / exposed	2 / 5992 (0.03%)	6 / 5995 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural haematuria		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (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	3 / 5992 (0.05%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural myocardial infarction		
subjects affected / exposed	3 / 5992 (0.05%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural swelling		

subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative fever		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative ileus		
subjects affected / exposed	1 / 5992 (0.02%)	5 / 5995 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative renal failure		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative respiratory failure		
subjects affected / exposed	2 / 5992 (0.03%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative thoracic procedure complication		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative wound complication		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Postpericardiotomy syndrome		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural complication		

subjects affected / exposed	0 / 5992 (0.00%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural haemorrhage		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural hypotension		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural pain		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural pneumothorax		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pubis fracture		
subjects affected / exposed	2 / 5992 (0.03%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary contusion		
subjects affected / exposed	0 / 5992 (0.00%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Radius fracture		
subjects affected / exposed	2 / 5992 (0.03%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rib fracture		

subjects affected / exposed	9 / 5992 (0.15%)	9 / 5995 (0.15%)	
occurrences causally related to treatment / all	0 / 9	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Road traffic accident			
subjects affected / exposed	9 / 5992 (0.15%)	5 / 5995 (0.08%)	
occurrences causally related to treatment / all	1 / 9	0 / 5	
deaths causally related to treatment / all	0 / 2	0 / 3	
Scapula fracture			
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seroma			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shunt malfunction			
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shunt occlusion			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin abrasion			
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skull fracture			
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal compression fracture			

subjects affected / exposed	0 / 5992 (0.00%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal fracture		
subjects affected / exposed	3 / 5992 (0.05%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Splenic rupture		
subjects affected / exposed	1 / 5992 (0.02%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Stab wound		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Subdural haematoma		
subjects affected / exposed	7 / 5992 (0.12%)	5 / 5995 (0.08%)
occurrences causally related to treatment / all	0 / 8	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 0
Tendon rupture		
subjects affected / exposed	1 / 5992 (0.02%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Tibia fracture		
subjects affected / exposed	3 / 5992 (0.05%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic arthritis		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic haematoma		

subjects affected / exposed	4 / 5992 (0.07%)	4 / 5995 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic haemorrhage		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic haemothorax		
subjects affected / exposed	3 / 5992 (0.05%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic intracranial haemorrhage		
subjects affected / exposed	2 / 5992 (0.03%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Upper limb fracture		
subjects affected / exposed	4 / 5992 (0.07%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary retention postoperative		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular pseudoaneurysm		
subjects affected / exposed	2 / 5992 (0.03%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular pseudoaneurysm ruptured		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Weaning failure		

subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (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 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound dehiscence			
subjects affected / exposed	1 / 5992 (0.02%)	2 / 5995 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Wound haematoma			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wrist fracture			
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Atrial septal defect			
subjects affected / exposed	1 / 5992 (0.02%)	2 / 5995 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Choledochal cyst			
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Developmental hip dysplasia			
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal arteriovenous malformation			

subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrocele			
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertrophic cardiomyopathy			
subjects affected / exposed	2 / 5992 (0.03%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Microgenia			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	14 / 5992 (0.23%)	11 / 5995 (0.18%)	
occurrences causally related to treatment / all	0 / 14	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute left ventricular failure			
subjects affected / exposed	3 / 5992 (0.05%)	3 / 5995 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute myocardial infarction			
subjects affected / exposed	117 / 5992 (1.95%)	105 / 5995 (1.75%)	
occurrences causally related to treatment / all	1 / 131	0 / 118	
deaths causally related to treatment / all	1 / 7	0 / 3	
Angina pectoris			
subjects affected / exposed	123 / 5992 (2.05%)	142 / 5995 (2.37%)	
occurrences causally related to treatment / all	0 / 136	0 / 152	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina unstable			

subjects affected / exposed	106 / 5992 (1.77%)	113 / 5995 (1.88%)
occurrences causally related to treatment / all	1 / 115	0 / 129
deaths causally related to treatment / all	0 / 1	0 / 0
Anginal equivalent		
subjects affected / exposed	2 / 5992 (0.03%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic valve disease		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic valve incompetence		
subjects affected / exposed	4 / 5992 (0.07%)	6 / 5995 (0.10%)
occurrences causally related to treatment / all	1 / 4	2 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic valve stenosis		
subjects affected / exposed	2 / 5992 (0.03%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	1 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Arrhythmia		
subjects affected / exposed	2 / 5992 (0.03%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0
Arteriosclerosis coronary artery		
subjects affected / exposed	1 / 5992 (0.02%)	9 / 5995 (0.15%)
occurrences causally related to treatment / all	0 / 1	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 1
Arteriospasm coronary		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (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	102 / 5992 (1.70%)	105 / 5995 (1.75%)
occurrences causally related to treatment / all	2 / 122	3 / 120
deaths causally related to treatment / all	0 / 0	0 / 0
Atrial flutter		
subjects affected / exposed	22 / 5992 (0.37%)	21 / 5995 (0.35%)
occurrences causally related to treatment / all	0 / 28	3 / 23
deaths causally related to treatment / all	0 / 0	0 / 0
Atrial tachycardia		
subjects affected / exposed	2 / 5992 (0.03%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block		
subjects affected / exposed	0 / 5992 (0.00%)	4 / 5995 (0.07%)
occurrences causally related to treatment / all	0 / 0	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block complete		
subjects affected / exposed	7 / 5992 (0.12%)	4 / 5995 (0.07%)
occurrences causally related to treatment / all	1 / 7	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block first degree		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block second degree		
subjects affected / exposed	3 / 5992 (0.05%)	7 / 5995 (0.12%)
occurrences causally related to treatment / all	1 / 3	1 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Bradyarrhythmia		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bradycardia		

subjects affected / exposed	17 / 5992 (0.28%)	18 / 5995 (0.30%)
occurrences causally related to treatment / all	0 / 17	0 / 18
deaths causally related to treatment / all	0 / 0	0 / 1
Bundle branch block bilateral		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bundle branch block left		
subjects affected / exposed	1 / 5992 (0.02%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bundle branch block right		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac aneurysm		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac arrest		
subjects affected / exposed	19 / 5992 (0.32%)	17 / 5995 (0.28%)
occurrences causally related to treatment / all	0 / 19	0 / 17
deaths causally related to treatment / all	0 / 11	0 / 11
Cardiac discomfort		
subjects affected / exposed	7 / 5992 (0.12%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	0 / 7	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac disorder		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Cardiac failure		

subjects affected / exposed	21 / 5992 (0.35%)	18 / 5995 (0.30%)
occurrences causally related to treatment / all	0 / 25	0 / 19
deaths causally related to treatment / all	0 / 1	0 / 1
Cardiac failure acute		
subjects affected / exposed	5 / 5992 (0.08%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac failure chronic		
subjects affected / exposed	2 / 5992 (0.03%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac failure congestive		
subjects affected / exposed	106 / 5992 (1.77%)	91 / 5995 (1.52%)
occurrences causally related to treatment / all	2 / 139	3 / 124
deaths causally related to treatment / all	1 / 3	0 / 1
Cardiac perforation		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac tamponade		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac valve disease		
subjects affected / exposed	0 / 5992 (0.00%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac ventricular thrombosis		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardio-respiratory arrest		

subjects affected / exposed	6 / 5992 (0.10%)	7 / 5995 (0.12%)
occurrences causally related to treatment / all	0 / 6	1 / 7
deaths causally related to treatment / all	0 / 5	1 / 6
Cardiogenic shock		
subjects affected / exposed	5 / 5992 (0.08%)	4 / 5995 (0.07%)
occurrences causally related to treatment / all	1 / 5	0 / 4
deaths causally related to treatment / all	1 / 3	0 / 2
Cardiomyopathy		
subjects affected / exposed	4 / 5992 (0.07%)	5 / 5995 (0.08%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiopulmonary failure		
subjects affected / exposed	2 / 5992 (0.03%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 1
Cardiovascular disorder		
subjects affected / exposed	2 / 5992 (0.03%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Cardiovascular insufficiency		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cor pulmonale		
subjects affected / exposed	1 / 5992 (0.02%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Cor pulmonale acute		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cor pulmonale chronic		

subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery disease		
subjects affected / exposed	78 / 5992 (1.30%)	87 / 5995 (1.45%)
occurrences causally related to treatment / all	0 / 80	3 / 92
deaths causally related to treatment / all	0 / 0	0 / 8
Coronary artery occlusion		
subjects affected / exposed	6 / 5992 (0.10%)	8 / 5995 (0.13%)
occurrences causally related to treatment / all	0 / 6	1 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery perforation		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery stenosis		
subjects affected / exposed	13 / 5992 (0.22%)	17 / 5995 (0.28%)
occurrences causally related to treatment / all	0 / 13	1 / 17
deaths causally related to treatment / all	0 / 0	0 / 0
Diastolic dysfunction		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperdynamic left ventricle		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive heart disease		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Intracardiac thrombus		

subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic cardiomyopathy		
subjects affected / exposed	4 / 5992 (0.07%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Kounis syndrome		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Left atrial dilatation		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Left ventricular dysfunction		
subjects affected / exposed	3 / 5992 (0.05%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	1 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Left ventricular failure		
subjects affected / exposed	2 / 5992 (0.03%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Microvascular coronary artery disease		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Mitral valve disease		
subjects affected / exposed	2 / 5992 (0.03%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mitral valve incompetence		

subjects affected / exposed	12 / 5992 (0.20%)	12 / 5995 (0.20%)
occurrences causally related to treatment / all	3 / 12	4 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Mitral valve prolapse		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mitral valve stenosis		
subjects affected / exposed	2 / 5992 (0.03%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Myocardial infarction		
subjects affected / exposed	31 / 5992 (0.52%)	36 / 5995 (0.60%)
occurrences causally related to treatment / all	2 / 31	0 / 38
deaths causally related to treatment / all	1 / 9	0 / 4
Myocardial ischaemia		
subjects affected / exposed	16 / 5992 (0.27%)	14 / 5995 (0.23%)
occurrences causally related to treatment / all	1 / 17	1 / 14
deaths causally related to treatment / all	0 / 0	1 / 3
Palpitations		
subjects affected / exposed	5 / 5992 (0.08%)	6 / 5995 (0.10%)
occurrences causally related to treatment / all	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Pericardial cyst		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (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 / 5992 (0.00%)	4 / 5995 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Pericardial haemorrhage		

subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pericarditis		
subjects affected / exposed	2 / 5992 (0.03%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pericarditis constrictive		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Prinzmetal angina		
subjects affected / exposed	2 / 5992 (0.03%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary valve incompetence		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
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	2 / 5992 (0.03%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 2	1 / 1
deaths causally related to treatment / all	0 / 1	1 / 1
Right ventricular failure		
subjects affected / exposed	1 / 5992 (0.02%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	0 / 1	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus bradycardia		
subjects affected / exposed	2 / 5992 (0.03%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus node dysfunction		

subjects affected / exposed	6 / 5992 (0.10%)	15 / 5995 (0.25%)
occurrences causally related to treatment / all	0 / 6	0 / 17
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus tachycardia		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Stress cardiomyopathy		
subjects affected / exposed	0 / 5992 (0.00%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Supraventricular tachycardia		
subjects affected / exposed	9 / 5992 (0.15%)	11 / 5995 (0.18%)
occurrences causally related to treatment / all	0 / 9	1 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Systolic dysfunction		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
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 / 5992 (0.02%)	5 / 5995 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Tricuspid valve incompetence		
subjects affected / exposed	7 / 5992 (0.12%)	6 / 5995 (0.10%)
occurrences causally related to treatment / all	3 / 7	2 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Ventricular arrhythmia		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ventricular extrasystoles		

subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular fibrillation			
subjects affected / exposed	8 / 5992 (0.13%)	3 / 5995 (0.05%)	
occurrences causally related to treatment / all	0 / 8	0 / 4	
deaths causally related to treatment / all	0 / 2	0 / 0	
Ventricular tachyarrhythmia			
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular tachycardia			
subjects affected / exposed	22 / 5992 (0.37%)	13 / 5995 (0.22%)	
occurrences causally related to treatment / all	0 / 27	0 / 14	
deaths causally related to treatment / all	0 / 1	0 / 0	
Nervous system disorders			
Amnesia			
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ataxia			
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Balance disorder			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Basal ganglia haemorrhage			
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Basal ganglia infarction			

subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bickerstaff's encephalitis		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Brain injury		
subjects affected / exposed	3 / 5992 (0.05%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 1
Brain stem haemorrhage		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Brain stem infarction		
subjects affected / exposed	0 / 5992 (0.00%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Brain stem stroke		
subjects affected / exposed	3 / 5992 (0.05%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid artery disease		
subjects affected / exposed	2 / 5992 (0.03%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid artery occlusion		
subjects affected / exposed	2 / 5992 (0.03%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid artery stenosis		

subjects affected / exposed	17 / 5992 (0.28%)	15 / 5995 (0.25%)
occurrences causally related to treatment / all	0 / 19	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid sinus syndrome		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Carpal tunnel syndrome		
subjects affected / exposed	0 / 5992 (0.00%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Central nervous system necrosis		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebellar infarction		
subjects affected / exposed	1 / 5992 (0.02%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral circulatory failure		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral haemorrhage		
subjects affected / exposed	2 / 5992 (0.03%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral infarction		
subjects affected / exposed	4 / 5992 (0.07%)	9 / 5995 (0.15%)
occurrences causally related to treatment / all	0 / 4	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebrospinal fluid leakage		

subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebrovascular accident		
subjects affected / exposed	41 / 5992 (0.68%)	29 / 5995 (0.48%)
occurrences causally related to treatment / all	3 / 42	1 / 31
deaths causally related to treatment / all	0 / 3	0 / 2
Cerebrovascular disorder		
subjects affected / exposed	2 / 5992 (0.03%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cervical cord compression		
subjects affected / exposed	1 / 5992 (0.02%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cervical myelopathy		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cervical radiculopathy		
subjects affected / exposed	2 / 5992 (0.03%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cervicogenic headache		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Complex partial seizures		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cranial nerve palsies multiple		

subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cubital tunnel syndrome		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dementia		
subjects affected / exposed	2 / 5992 (0.03%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Dementia Alzheimer's type		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic coma		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Dizziness		
subjects affected / exposed	9 / 5992 (0.15%)	14 / 5995 (0.23%)
occurrences causally related to treatment / all	0 / 9	2 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Dizziness postural		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dysarthria		
subjects affected / exposed	1 / 5992 (0.02%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Embolic cerebral infarction		

subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Embolitic stroke		
subjects affected / exposed	2 / 5992 (0.03%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Encephalopathy		
subjects affected / exposed	2 / 5992 (0.03%)	4 / 5995 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Epilepsy		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
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	1 / 5992 (0.02%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Frontal lobe epilepsy		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Guillain-Barre syndrome		
subjects affected / exposed	0 / 5992 (0.00%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhage intracranial		
subjects affected / exposed	2 / 5992 (0.03%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhagic stroke		

subjects affected / exposed	1 / 5992 (0.02%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 2
Headache		
subjects affected / exposed	9 / 5992 (0.15%)	5 / 5995 (0.08%)
occurrences causally related to treatment / all	1 / 10	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Hemiparesis		
subjects affected / exposed	2 / 5992 (0.03%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic encephalopathy		
subjects affected / exposed	0 / 5992 (0.00%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive encephalopathy		
subjects affected / exposed	2 / 5992 (0.03%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoaesthesia		
subjects affected / exposed	5 / 5992 (0.08%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoxic-ischaemic encephalopathy		
subjects affected / exposed	0 / 5992 (0.00%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	1 / 1
IIIrd nerve paralysis		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intracranial aneurysm		

subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Ischaemic stroke		
subjects affected / exposed	14 / 5992 (0.23%)	13 / 5995 (0.22%)
occurrences causally related to treatment / all	0 / 14	1 / 14
deaths causally related to treatment / all	0 / 1	0 / 1
Lacunar infarction		
subjects affected / exposed	2 / 5992 (0.03%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Loss of consciousness		
subjects affected / exposed	3 / 5992 (0.05%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar radiculopathy		
subjects affected / exposed	4 / 5992 (0.07%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbosacral radiculopathy		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Metabolic encephalopathy		
subjects affected / exposed	2 / 5992 (0.03%)	5 / 5995 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Migraine		
subjects affected / exposed	5 / 5992 (0.08%)	5 / 5995 (0.08%)
occurrences causally related to treatment / all	0 / 5	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Migraine with aura		

subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Motor neurone disease		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Myasthenia gravis		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Myelomalacia		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Myelopathy		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Myoclonus		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nerve compression		
subjects affected / exposed	0 / 5992 (0.00%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Nerve root compression		
subjects affected / exposed	2 / 5992 (0.03%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neuralgia		

subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neuromyelitis optica spectrum disorder		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
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	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Normal pressure hydrocephalus		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Paraesthesia		
subjects affected / exposed	1 / 5992 (0.02%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Parkinson's disease		
subjects affected / exposed	2 / 5992 (0.03%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Parkinsonism		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral sensory neuropathy		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peroneal nerve palsy		

subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Petit mal epilepsy		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Presyncope		
subjects affected / exposed	13 / 5992 (0.22%)	9 / 5995 (0.15%)
occurrences causally related to treatment / all	0 / 13	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Radial nerve palsy		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Radicular pain		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sciatica		
subjects affected / exposed	7 / 5992 (0.12%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 7	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Seizure		
subjects affected / exposed	4 / 5992 (0.07%)	10 / 5995 (0.17%)
occurrences causally related to treatment / all	0 / 4	0 / 13
deaths causally related to treatment / all	0 / 1	0 / 0
Serotonin syndrome		
subjects affected / exposed	3 / 5992 (0.05%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	4 / 4	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Simple partial seizures		

subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Slow speech		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Somnolence		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal claudication		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal cord disorder		
subjects affected / exposed	0 / 5992 (0.00%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Spondylitic myelopathy		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
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	2 / 5992 (0.03%)	9 / 5995 (0.15%)
occurrences causally related to treatment / all	0 / 2	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 2
Superficial siderosis of central nervous system		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Superior sagittal sinus thrombosis		

subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Syncope		
subjects affected / exposed	49 / 5992 (0.82%)	54 / 5995 (0.90%)
occurrences causally related to treatment / all	3 / 51	1 / 62
deaths causally related to treatment / all	0 / 0	0 / 1
Thalamus haemorrhage		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Toxic encephalopathy		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Transient global amnesia		
subjects affected / exposed	2 / 5992 (0.03%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	1 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Transient ischaemic attack		
subjects affected / exposed	38 / 5992 (0.63%)	46 / 5995 (0.77%)
occurrences causally related to treatment / all	0 / 39	3 / 55
deaths causally related to treatment / all	0 / 0	0 / 0
Transverse sinus thrombosis		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tremor		
subjects affected / exposed	0 / 5992 (0.00%)	4 / 5995 (0.07%)
occurrences causally related to treatment / all	0 / 0	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Trigeminal neuralgia		

subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Unresponsive to stimuli			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vlith nerve paralysis			
subjects affected / exposed	0 / 5992 (0.00%)	2 / 5995 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebral artery dissection			
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebral artery thrombosis			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebrobasilar insufficiency			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vocal cord paralysis			
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Abdominal lymphadenopathy			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia			

subjects affected / exposed	19 / 5992 (0.32%)	12 / 5995 (0.20%)
occurrences causally related to treatment / all	0 / 19	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Anaemia macrocytic		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (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	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Disseminated intravascular coagulation		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Febrile neutropenia		
subjects affected / exposed	1 / 5992 (0.02%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhagic anaemia		
subjects affected / exposed	7 / 5992 (0.12%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	0 / 7	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Iron deficiency anaemia		
subjects affected / exposed	2 / 5992 (0.03%)	4 / 5995 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Leukocytosis		
subjects affected / exposed	3 / 5992 (0.05%)	5 / 5995 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Leukopenia		

subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphadenopathy		
subjects affected / exposed	2 / 5992 (0.03%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Microcytic anaemia		
subjects affected / exposed	2 / 5992 (0.03%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neutropenia		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Normochromic normocytic anaemia		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Splenic haematoma		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Splenic infarction		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spontaneous haematoma		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombocytopenia		

subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Tympanic membrane perforation			
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo			
subjects affected / exposed	8 / 5992 (0.13%)	9 / 5995 (0.15%)	
occurrences causally related to treatment / all	0 / 8	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo positional			
subjects affected / exposed	1 / 5992 (0.02%)	5 / 5995 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Cataract			
subjects affected / exposed	3 / 5992 (0.05%)	2 / 5995 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Charles Bonnet syndrome			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deformity of orbit			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Macular oedema			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oscillopsia			

subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
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 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal vascular thrombosis			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vision blurred			
subjects affected / exposed	0 / 5992 (0.00%)	2 / 5995 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitreous adhesions			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitreous haemorrhage			
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal adhesions			
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal discomfort			
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal distension			

subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal fat apron		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal hernia		
subjects affected / exposed	10 / 5992 (0.17%)	7 / 5995 (0.12%)
occurrences causally related to treatment / all	0 / 10	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal hernia obstructive		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal incarcerated hernia		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
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	11 / 5992 (0.18%)	9 / 5995 (0.15%)
occurrences causally related to treatment / all	1 / 11	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal pain upper		
subjects affected / exposed	7 / 5992 (0.12%)	6 / 5995 (0.10%)
occurrences causally related to treatment / all	0 / 7	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal wall haematoma		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anal fissure		

subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Anal incontinence		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Anorectal varices		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ascites		
subjects affected / exposed	2 / 5992 (0.03%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Coeliac artery stenosis		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis		
subjects affected / exposed	8 / 5992 (0.13%)	4 / 5995 (0.07%)
occurrences causally related to treatment / all	0 / 8	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis ischaemic		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis microscopic		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis ulcerative		

subjects affected / exposed	0 / 5992 (0.00%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Colonic pseudo-obstruction		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Constipation		
subjects affected / exposed	6 / 5992 (0.10%)	8 / 5995 (0.13%)
occurrences causally related to treatment / all	0 / 7	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Crohn's disease		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diarrhoea		
subjects affected / exposed	6 / 5992 (0.10%)	8 / 5995 (0.13%)
occurrences causally related to treatment / all	1 / 6	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Dieulafoy's vascular malformation		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticular perforation		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum		
subjects affected / exposed	4 / 5992 (0.07%)	6 / 5995 (0.10%)
occurrences causally related to treatment / all	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum intestinal haemorrhagic		

subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
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	2 / 5992 (0.03%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal ulcer haemorrhage		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal ulcer perforation		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenitis		
subjects affected / exposed	2 / 5992 (0.03%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenogastric reflux		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dyspepsia		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dysphagia		
subjects affected / exposed	6 / 5992 (0.10%)	4 / 5995 (0.07%)
occurrences causally related to treatment / all	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Enteritis		

subjects affected / exposed	0 / 5992 (0.00%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Enteroceles		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Erosive duodenitis		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Erosive oesophagitis		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Faecaloma		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Food poisoning		
subjects affected / exposed	0 / 5992 (0.00%)	2 / 5995 (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 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric disorder		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
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	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Gastric perforation		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric polyps		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer		
subjects affected / exposed	5 / 5992 (0.08%)	5 / 5995 (0.08%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer haemorrhage		
subjects affected / exposed	1 / 5992 (0.02%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis		
subjects affected / exposed	6 / 5992 (0.10%)	6 / 5995 (0.10%)
occurrences causally related to treatment / all	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis erosive		
subjects affected / exposed	3 / 5992 (0.05%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal angiodysplasia haemorrhagic		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal haemorrhage		

subjects affected / exposed	27 / 5992 (0.45%)	29 / 5995 (0.48%)
occurrences causally related to treatment / all	0 / 30	0 / 29
deaths causally related to treatment / all	0 / 1	0 / 1
Gastrointestinal necrosis		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal ulcer haemorrhage		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrooesophageal reflux disease		
subjects affected / exposed	9 / 5992 (0.15%)	11 / 5995 (0.18%)
occurrences causally related to treatment / all	0 / 10	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Haematochezia		
subjects affected / exposed	2 / 5992 (0.03%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhoidal haemorrhage		
subjects affected / exposed	2 / 5992 (0.03%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhoids		
subjects affected / exposed	2 / 5992 (0.03%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hiatus hernia		
subjects affected / exposed	5 / 5992 (0.08%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ileus		

subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Impaired gastric emptying			
subjects affected / exposed	0 / 5992 (0.00%)	2 / 5995 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incarcerated umbilical hernia			
subjects affected / exposed	1 / 5992 (0.02%)	2 / 5995 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia			
subjects affected / exposed	9 / 5992 (0.15%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 9	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal dilatation			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal haemorrhage			
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal ischaemia			
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal obstruction			
subjects affected / exposed	3 / 5992 (0.05%)	7 / 5995 (0.12%)	
occurrences causally related to treatment / all	0 / 3	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal perforation			

subjects affected / exposed	3 / 5992 (0.05%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intra-abdominal haematoma		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Irritable bowel syndrome		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestinal haemorrhage		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestinal ulcer		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestine perforation		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestine polyp		
subjects affected / exposed	2 / 5992 (0.03%)	5 / 5995 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Lower gastrointestinal haemorrhage		
subjects affected / exposed	9 / 5992 (0.15%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 9	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Megacolon		

subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Melaena		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mesenteric artery stenosis		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mesenteric panniculitis		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (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	3 / 5992 (0.05%)	8 / 5995 (0.13%)
occurrences causally related to treatment / all	0 / 3	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Obstruction gastric		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Odynophagia		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal food impaction		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal pain		

subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal spasm		
subjects affected / exposed	0 / 5992 (0.00%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal stenosis		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal varices haemorrhage		
subjects affected / exposed	0 / 5992 (0.00%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophagitis		
subjects affected / exposed	2 / 5992 (0.03%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Omental infarction		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis		
subjects affected / exposed	14 / 5992 (0.23%)	13 / 5995 (0.22%)
occurrences causally related to treatment / all	5 / 15	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis acute		
subjects affected / exposed	15 / 5992 (0.25%)	9 / 5995 (0.15%)
occurrences causally related to treatment / all	0 / 17	0 / 9
deaths causally related to treatment / all	0 / 1	0 / 0
Pancreatitis chronic		

subjects affected / exposed	0 / 5992 (0.00%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis relapsing		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peptic ulcer		
subjects affected / exposed	3 / 5992 (0.05%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peptic ulcer haemorrhage		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal haemorrhage		
subjects affected / exposed	6 / 5992 (0.10%)	8 / 5995 (0.13%)
occurrences causally related to treatment / all	0 / 6	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal polyp		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Retroperitoneal haemorrhage		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Salivary gland mass		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Small intestinal obstruction		

subjects affected / exposed	18 / 5992 (0.30%)	11 / 5995 (0.18%)	
occurrences causally related to treatment / all	0 / 22	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tongue disorder			
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Umbilical hernia			
subjects affected / exposed	7 / 5992 (0.12%)	6 / 5995 (0.10%)	
occurrences causally related to treatment / all	0 / 7	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	5 / 5992 (0.08%)	3 / 5995 (0.05%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uvulitis			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Visceroptosis			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	7 / 5992 (0.12%)	6 / 5995 (0.10%)	
occurrences causally related to treatment / all	0 / 7	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	2 / 5992 (0.03%)	3 / 5995 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Decubitus ulcer			

subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dermatitis atopic		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic foot		
subjects affected / exposed	4 / 5992 (0.07%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic ulcer		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Drug reaction with eosinophilia and systemic symptoms		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Excessive skin		
subjects affected / exposed	0 / 5992 (0.00%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperhidrosis		
subjects affected / exposed	1 / 5992 (0.02%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hypersensitivity vasculitis		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neutrophilic dermatosis		

subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Petechiae		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pruritus		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rash		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rash erythematous		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Skin necrosis		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Skin ulcer		
subjects affected / exposed	5 / 5992 (0.08%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Telangiectasia		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urticaria		

subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	57 / 5992 (0.95%)	57 / 5995 (0.95%)	
occurrences causally related to treatment / all	1 / 64	0 / 61	
deaths causally related to treatment / all	0 / 2	0 / 1	
Acute prerenal failure			
subjects affected / exposed	3 / 5992 (0.05%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Albuminuria			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Azotaemia			
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder disorder			
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder dysfunction			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder neck obstruction			
subjects affected / exposed	3 / 5992 (0.05%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder necrosis			

subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder outlet obstruction		
subjects affected / exposed	0 / 5992 (0.00%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder prolapse		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder stenosis		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Calculus urinary		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic kidney disease		
subjects affected / exposed	5 / 5992 (0.08%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Cystitis haemorrhagic		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic nephropathy		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
End stage renal disease		

subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haematuria		
subjects affected / exposed	7 / 5992 (0.12%)	5 / 5995 (0.08%)
occurrences causally related to treatment / all	0 / 10	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhage urinary tract		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hydronephrosis		
subjects affected / exposed	1 / 5992 (0.02%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lower urinary tract symptoms		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nephrolithiasis		
subjects affected / exposed	18 / 5992 (0.30%)	11 / 5995 (0.18%)
occurrences causally related to treatment / all	0 / 18	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Obstructive uropathy		
subjects affected / exposed	0 / 5992 (0.00%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Oliguria		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Proteinuria		

subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal artery stenosis		
subjects affected / exposed	0 / 5992 (0.00%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Renal colic		
subjects affected / exposed	2 / 5992 (0.03%)	5 / 5995 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Renal failure		
subjects affected / exposed	3 / 5992 (0.05%)	4 / 5995 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0
Renal haemorrhage		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal impairment		
subjects affected / exposed	2 / 5992 (0.03%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal infarct		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal mass		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal tubular necrosis		

subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureteral disorder			
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureterocele			
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (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	6 / 5992 (0.10%)	7 / 5995 (0.12%)	
occurrences causally related to treatment / all	0 / 6	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral stenosis			
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary bladder haemorrhage			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention			
subjects affected / exposed	6 / 5992 (0.10%)	6 / 5995 (0.10%)	
occurrences causally related to treatment / all	0 / 9	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract obstruction			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Adrenal insufficiency			

subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Goitre			
subjects affected / exposed	1 / 5992 (0.02%)	5 / 5995 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperparathyroidism			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperthyroidism			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypothyroidism			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid mass			
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyrotoxic crisis			
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	25 / 5992 (0.42%)	25 / 5995 (0.42%)	
occurrences causally related to treatment / all	0 / 26	0 / 26	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis			

subjects affected / exposed	16 / 5992 (0.27%)	19 / 5995 (0.32%)
occurrences causally related to treatment / all	0 / 19	0 / 20
deaths causally related to treatment / all	0 / 0	0 / 0
Arthritis reactive		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Arthropathy		
subjects affected / exposed	2 / 5992 (0.03%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Back pain		
subjects affected / exposed	15 / 5992 (0.25%)	16 / 5995 (0.27%)
occurrences causally related to treatment / all	0 / 15	0 / 16
deaths causally related to treatment / all	0 / 0	0 / 0
Bursitis		
subjects affected / exposed	2 / 5992 (0.03%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cervical spinal stenosis		
subjects affected / exposed	8 / 5992 (0.13%)	5 / 5995 (0.08%)
occurrences causally related to treatment / all	0 / 8	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Chondrocalcinosis pyrophosphate		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Costochondritis		
subjects affected / exposed	0 / 5992 (0.00%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Exostosis		

subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Fibromyalgia		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Flank pain		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Foot deformity		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fracture delayed union		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fracture malunion		
subjects affected / exposed	1 / 5992 (0.02%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Fracture nonunion		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
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	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haemarthrosis		

subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc compression		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
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	5 / 5992 (0.08%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc displacement		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc protrusion		
subjects affected / exposed	15 / 5992 (0.25%)	6 / 5995 (0.10%)
occurrences causally related to treatment / all	0 / 15	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc space narrowing		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Limb discomfort		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar spinal stenosis		
subjects affected / exposed	13 / 5992 (0.22%)	12 / 5995 (0.20%)
occurrences causally related to treatment / all	0 / 13	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Mobility decreased		

subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Monarthritis		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Muscle spasms		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Muscular weakness		
subjects affected / exposed	2 / 5992 (0.03%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Musculoskeletal chest pain		
subjects affected / exposed	13 / 5992 (0.22%)	10 / 5995 (0.17%)
occurrences causally related to treatment / all	0 / 13	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Musculoskeletal pain		
subjects affected / exposed	7 / 5992 (0.12%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 7	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Myalgia		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Myositis		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neck mass		

subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neck pain		
subjects affected / exposed	3 / 5992 (0.05%)	4 / 5995 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Neuropathic arthropathy		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Osteoarthritis		
subjects affected / exposed	109 / 5992 (1.82%)	93 / 5995 (1.55%)
occurrences causally related to treatment / all	0 / 121	0 / 97
deaths causally related to treatment / all	0 / 0	0 / 0
Osteoarthropathy		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Osteolysis		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Osteonecrosis		
subjects affected / exposed	2 / 5992 (0.03%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Osteoporosis		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pain in extremity		

subjects affected / exposed	1 / 5992 (0.02%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pain in jaw		
subjects affected / exposed	1 / 5992 (0.02%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pathological fracture		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Plantar fasciitis		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Polyarthritis		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Polymyalgia rheumatica		
subjects affected / exposed	2 / 5992 (0.03%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rhabdomyolysis		
subjects affected / exposed	3 / 5992 (0.05%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	0 / 3	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Rheumatoid arthritis		
subjects affected / exposed	1 / 5992 (0.02%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Rotator cuff syndrome		

subjects affected / exposed	10 / 5992 (0.17%)	6 / 5995 (0.10%)
occurrences causally related to treatment / all	0 / 10	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Scoliosis		
subjects affected / exposed	0 / 5992 (0.00%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Soft tissue mass		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal column stenosis		
subjects affected / exposed	10 / 5992 (0.17%)	5 / 5995 (0.08%)
occurrences causally related to treatment / all	0 / 11	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal osteoarthritis		
subjects affected / exposed	7 / 5992 (0.12%)	10 / 5995 (0.17%)
occurrences causally related to treatment / all	0 / 8	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal pain		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spondylitis		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spondylolisthesis		
subjects affected / exposed	5 / 5992 (0.08%)	6 / 5995 (0.10%)
occurrences causally related to treatment / all	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Synovial cyst		

subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebral foraminal stenosis			
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebral osteophyte			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	3 / 5992 (0.05%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal wall abscess			
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess limb			
subjects affected / exposed	2 / 5992 (0.03%)	3 / 5995 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess neck			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess of salivary gland			
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute sinusitis			

subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anal abscess		
subjects affected / exposed	2 / 5992 (0.03%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Appendicitis		
subjects affected / exposed	9 / 5992 (0.15%)	9 / 5995 (0.15%)
occurrences causally related to treatment / all	0 / 9	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Appendicitis perforated		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arthritis bacterial		
subjects affected / exposed	1 / 5992 (0.02%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Arthritis infective		
subjects affected / exposed	2 / 5992 (0.03%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bacteraemia		
subjects affected / exposed	6 / 5992 (0.10%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Bacterial infection		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bacterial sepsis		

subjects affected / exposed	2 / 5992 (0.03%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bone abscess		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchiolitis		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchitis		
subjects affected / exposed	26 / 5992 (0.43%)	18 / 5995 (0.30%)
occurrences causally related to treatment / all	0 / 26	0 / 19
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchitis viral		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Campylobacter infection		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Campylobacter sepsis		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Catheter site infection		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cellulitis		

subjects affected / exposed	71 / 5992 (1.18%)	48 / 5995 (0.80%)
occurrences causally related to treatment / all	0 / 81	2 / 52
deaths causally related to treatment / all	0 / 0	0 / 0
Cellulitis pasteurella		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cellulitis staphylococcal		
subjects affected / exposed	0 / 5992 (0.00%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cellulitis streptococcal		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis infective		
subjects affected / exposed	1 / 5992 (0.02%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic sinusitis		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic tonsillitis		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Clostridium difficile colitis		
subjects affected / exposed	2 / 5992 (0.03%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Clostridium difficile infection		

subjects affected / exposed	2 / 5992 (0.03%)	4 / 5995 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Colonic abscess		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis		
subjects affected / exposed	2 / 5992 (0.03%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dengue fever		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Device related infection		
subjects affected / exposed	7 / 5992 (0.12%)	4 / 5995 (0.07%)
occurrences causally related to treatment / all	0 / 8	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Device related sepsis		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic foot infection		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic gangrene		
subjects affected / exposed	2 / 5992 (0.03%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diarrhoea infectious		

subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulitis		
subjects affected / exposed	17 / 5992 (0.28%)	23 / 5995 (0.38%)
occurrences causally related to treatment / all	0 / 22	0 / 26
deaths causally related to treatment / all	0 / 0	0 / 0
Emphysematous cystitis		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Empyema		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Encephalitis		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Endocarditis		
subjects affected / exposed	1 / 5992 (0.02%)	4 / 5995 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Enterococcal bacteraemia		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Epididymitis		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia bacteraemia		

subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia infection		
subjects affected / exposed	2 / 5992 (0.03%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia sepsis		
subjects affected / exposed	2 / 5992 (0.03%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia urinary tract infection		
subjects affected / exposed	2 / 5992 (0.03%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Extradural abscess		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gangrene		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis		
subjects affected / exposed	13 / 5992 (0.22%)	10 / 5995 (0.17%)
occurrences causally related to treatment / all	0 / 13	1 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis bacterial		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis viral		

subjects affected / exposed	3 / 5992 (0.05%)	7 / 5995 (0.12%)
occurrences causally related to treatment / all	0 / 3	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Groin abscess		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Groin infection		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
H1N1 influenza		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis A		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis B		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Herpes zoster		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Human anaplasmosis		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Human ehrlichiosis		

subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Implant site infection		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Incision site abscess		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Incision site infection		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
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	3 / 5992 (0.05%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infectious colitis		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infectious pleural effusion		
subjects affected / exposed	2 / 5992 (0.03%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Infective exacerbation of chronic obstructive airways disease		
subjects affected / exposed	2 / 5992 (0.03%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Infective tenosynovitis		

subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (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	10 / 5992 (0.17%)	12 / 5995 (0.20%)
occurrences causally related to treatment / all	0 / 10	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Kidney infection		
subjects affected / exposed	2 / 5992 (0.03%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Klebsiella bacteraemia		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Labyrinthitis		
subjects affected / exposed	1 / 5992 (0.02%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngitis		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Localised infection		
subjects affected / exposed	5 / 5992 (0.08%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Lower respiratory tract infection		
subjects affected / exposed	3 / 5992 (0.05%)	4 / 5995 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Lower respiratory tract infection viral		

subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lyme disease		
subjects affected / exposed	2 / 5992 (0.03%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphangitis		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mastoiditis		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Necrotising fasciitis		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neutropenic sepsis		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal candidiasis		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Orchitis		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Osteomyelitis		

subjects affected / exposed	13 / 5992 (0.22%)	11 / 5995 (0.18%)
occurrences causally related to treatment / all	0 / 14	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Osteomyelitis acute		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Parainfluenzae virus infection		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Paraspinal abscess		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic abscess		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Perirectal abscess		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peritonitis bacterial		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pharyngeal abscess		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pharyngitis		

subjects affected / exposed	2 / 5992 (0.03%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia		
subjects affected / exposed	86 / 5992 (1.44%)	92 / 5995 (1.53%)
occurrences causally related to treatment / all	1 / 90	0 / 105
deaths causally related to treatment / all	0 / 3	0 / 2
Pneumonia bacterial		
subjects affected / exposed	3 / 5992 (0.05%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia legionella		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia mycoplasmal		
subjects affected / exposed	2 / 5992 (0.03%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia pneumococcal		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia staphylococcal		
subjects affected / exposed	3 / 5992 (0.05%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia streptococcal		
subjects affected / exposed	2 / 5992 (0.03%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia viral		

subjects affected / exposed	4 / 5992 (0.07%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural cellulitis		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural infection		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative abscess		
subjects affected / exposed	2 / 5992 (0.03%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative wound infection		
subjects affected / exposed	1 / 5992 (0.02%)	5 / 5995 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1
Pulmonary sepsis		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (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	4 / 5992 (0.07%)	6 / 5995 (0.10%)
occurrences causally related to treatment / all	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis acute		
subjects affected / exposed	4 / 5992 (0.07%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory moniliasis		

subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory syncytial virus infection		
subjects affected / exposed	0 / 5992 (0.00%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory tract infection		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory tract infection viral		
subjects affected / exposed	2 / 5992 (0.03%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rocky mountain spotted fever		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rotavirus infection		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Scrotal abscess		
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sepsis		
subjects affected / exposed	27 / 5992 (0.45%)	37 / 5995 (0.62%)
occurrences causally related to treatment / all	0 / 27	0 / 39
deaths causally related to treatment / all	0 / 3	0 / 4
Sepsis syndrome		

subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Septic arthritis staphylococcal		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Septic embolus		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Septic shock		
subjects affected / exposed	5 / 5992 (0.08%)	7 / 5995 (0.12%)
occurrences causally related to treatment / all	0 / 5	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 2
Sialoadenitis		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sinusitis		
subjects affected / exposed	3 / 5992 (0.05%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal bacteraemia		
subjects affected / exposed	2 / 5992 (0.03%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal infection		
subjects affected / exposed	3 / 5992 (0.05%)	6 / 5995 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal osteomyelitis		

subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal sepsis		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal skin infection		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Streptococcal bacteraemia		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Streptococcal infection		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Subcutaneous abscess		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tonsillitis		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tooth abscess		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tooth infection		

subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (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 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Upper respiratory tract infection		
subjects affected / exposed	3 / 5992 (0.05%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	1 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract infection		
subjects affected / exposed	40 / 5992 (0.67%)	30 / 5995 (0.50%)
occurrences causally related to treatment / all	2 / 41	0 / 30
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract infection bacterial		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (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 enterococcal		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Urosepsis		
subjects affected / exposed	7 / 5992 (0.12%)	13 / 5995 (0.22%)
occurrences causally related to treatment / all	0 / 7	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular stent infection		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vestibular neuronitis		

subjects affected / exposed	0 / 5992 (0.00%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Viral infection		
subjects affected / exposed	2 / 5992 (0.03%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Viral upper respiratory tract infection		
subjects affected / exposed	2 / 5992 (0.03%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vulvitis		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
West Nile viral infection		
subjects affected / exposed	0 / 5992 (0.00%)	2 / 5995 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Wound abscess		
subjects affected / exposed	1 / 5992 (0.02%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Wound infection		
subjects affected / exposed	4 / 5992 (0.07%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Wound infection pseudomonas		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Wound infection staphylococcal		

subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Acidosis			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholesterosis			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Decreased appetite			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			
subjects affected / exposed	21 / 5992 (0.35%)	13 / 5995 (0.22%)	
occurrences causally related to treatment / all	0 / 21	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes mellitus			
subjects affected / exposed	13 / 5992 (0.22%)	11 / 5995 (0.18%)	
occurrences causally related to treatment / all	0 / 13	1 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes mellitus inadequate control			
subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic ketoacidosis			
subjects affected / exposed	4 / 5992 (0.07%)	5 / 5995 (0.08%)	
occurrences causally related to treatment / all	0 / 5	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 1	
Electrolyte imbalance			

subjects affected / exposed	2 / 5992 (0.03%)	0 / 5995 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Fluid overload		
subjects affected / exposed	5 / 5992 (0.08%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gout		
subjects affected / exposed	6 / 5992 (0.10%)	6 / 5995 (0.10%)
occurrences causally related to treatment / all	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Hypercalcaemia		
subjects affected / exposed	0 / 5992 (0.00%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperglycaemia		
subjects affected / exposed	1 / 5992 (0.02%)	5 / 5995 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperkalaemia		
subjects affected / exposed	11 / 5992 (0.18%)	6 / 5995 (0.10%)
occurrences causally related to treatment / all	1 / 11	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 0
Hyperosmolar hyperglycaemic state		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperosmolar state		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperphosphataemia		

subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypocalcaemia		
subjects affected / exposed	0 / 5992 (0.00%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoglycaemia		
subjects affected / exposed	7 / 5992 (0.12%)	18 / 5995 (0.30%)
occurrences causally related to treatment / all	1 / 7	3 / 19
deaths causally related to treatment / all	0 / 0	0 / 0
Hypokalaemia		
subjects affected / exposed	5 / 5992 (0.08%)	10 / 5995 (0.17%)
occurrences causally related to treatment / all	0 / 6	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Hypomagnesaemia		
subjects affected / exposed	1 / 5992 (0.02%)	4 / 5995 (0.07%)
occurrences causally related to treatment / all	1 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Hyponatraemia		
subjects affected / exposed	4 / 5992 (0.07%)	5 / 5995 (0.08%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Hypophagia		
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypovolaemia		
subjects affected / exposed	0 / 5992 (0.00%)	3 / 5995 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Lactic acidosis		

subjects affected / exposed	1 / 5992 (0.02%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malnutrition			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolic acidosis			
subjects affected / exposed	2 / 5992 (0.03%)	0 / 5995 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obesity			
subjects affected / exposed	12 / 5992 (0.20%)	12 / 5995 (0.20%)	
occurrences causally related to treatment / all	0 / 12	0 / 12	
deaths causally related to treatment / all	0 / 1	0 / 0	
Type 2 diabetes mellitus			
subjects affected / exposed	11 / 5992 (0.18%)	7 / 5995 (0.12%)	
occurrences causally related to treatment / all	0 / 11	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitamin D deficiency			
subjects affected / exposed	0 / 5992 (0.00%)	1 / 5995 (0.02%)	
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 %

Non-serious adverse events	Placebo	Lorcaserin 10 mg	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4788 / 5992 (79.91%)	4946 / 5995 (82.50%)	
Nervous system disorders			
Dizziness			
subjects affected / exposed	340 / 5992 (5.67%)	537 / 5995 (8.96%)	
occurrences (all)	407	640	
Headache			

subjects affected / exposed occurrences (all)	274 / 5992 (4.57%) 316	383 / 5995 (6.39%) 445	
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	302 / 5992 (5.04%)	496 / 5995 (8.27%)	
occurrences (all)	329	548	
Oedema peripheral			
subjects affected / exposed	340 / 5992 (5.67%)	267 / 5995 (4.45%)	
occurrences (all)	385	294	
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	248 / 5992 (4.14%)	336 / 5995 (5.60%)	
occurrences (all)	268	362	
Diarrhoea			
subjects affected / exposed	324 / 5992 (5.41%)	419 / 5995 (6.99%)	
occurrences (all)	362	478	
Nausea			
subjects affected / exposed	286 / 5992 (4.77%)	356 / 5995 (5.94%)	
occurrences (all)	329	398	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	303 / 5992 (5.06%)	376 / 5995 (6.27%)	
occurrences (all)	351	431	
Dyspnoea			
subjects affected / exposed	310 / 5992 (5.17%)	285 / 5995 (4.75%)	
occurrences (all)	347	312	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	452 / 5992 (7.54%)	457 / 5995 (7.62%)	
occurrences (all)	542	544	
Back pain			
subjects affected / exposed	452 / 5992 (7.54%)	457 / 5995 (7.62%)	
occurrences (all)	496	496	
Infections and infestations			

Bronchitis		
subjects affected / exposed	468 / 5992 (7.81%)	455 / 5995 (7.59%)
occurrences (all)	584	536
Nasopharyngitis		
subjects affected / exposed	338 / 5992 (5.64%)	353 / 5995 (5.89%)
occurrences (all)	418	426
Upper respiratory tract infection		
subjects affected / exposed	567 / 5992 (9.46%)	528 / 5995 (8.81%)
occurrences (all)	690	659
Urinary tract infection		
subjects affected / exposed	400 / 5992 (6.68%)	440 / 5995 (7.34%)
occurrences (all)	575	593

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
06 August 2015	Amendment 01: The secondary objective related to glycemic control was reclassified. The exploratory objective was added. Instructions that the first dose should be taken at Visit 2. Inclusion and exclusion criteria's were updated. Renal impairment: defined with reference to estimated glomerular filtration rate rather than clearance. Cyproheptadine, amoxapine, tricyclic antidepressants, and mirtazapine was deleted from the list of drugs increasing the risk for cardiac valvulopathy/PH. List of prohibited drugs was revised and the restrictions on serotonergic drugs was clarified. An analysis of subjects having worsened valvulopathy at 1 year and yearly and had FDA-defined valvulopathy at Baseline was added as a secondary endpoint. Study population for conversion to diabetes was changed to prediabetes population. Confirmatory test was needed for subjects with new onset of diabetes. Dosing instructions was modified. It was clarified that nicotine use was not exclusionary. Hospitalizations for administration of study drug or insertion of access for administration of study drug was removed from the list of hospitalization that are not SAEs because it was not applicable to the study. Clarification on subjects who permanently discontinued study drug were to complete the EOT visit within 30 days. Euphoria and suicidal ideation was moved from study-specific AEs of interest to 'SAEs and Events Associated with Special Situations'. It was added that renal function parameters and glycemic profile should be collected at all visits. It was specified that SAE collection for 30 days after the last drug dose applied only to subjects taking study drug at the time of study completion, since some subjects may have discontinued study drug before study completion. Revised footnote b in Schedule of Procedures/Assessments pertaining to unscheduled visits for assessments required by state-controlled substance requirements.
30 March 2017	Amendment 02: The primary objective of conversion to T2DM was changed to a secondary objective because the timelines to demonstrate the primary endpoint for conversion to Type 2 diabetes were not as initially projected, due to the low rate of conversion, Removed HbA1c from the exploratory objective in order to have a broader assessment of glycemic benefit in subjects with diabetes, Added FPG, fasting insulin levels, and homeostatic model assessment-insulin resistance (HOMA-IR) to better assess lorcaserin glycemic benefit, Multiple testing procedure was updated to reflect the change in the primary objective, The renal objective for the overall population was added and reorganized for clarification, Details of the interim analysis was outlined in the Study Integrity Charter, Removed the clarification of major adverse cardiovascular events (MACE)+ events accruing after 11 months after 460 MACE events have occurred, Updated the timing of the interim analysis date.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported