



## Clinical trial results:

### A Randomized, Multicenter, Double-Blind, Parallel, Placebo-Controlled Study of the Effects of Canagliflozin on Renal Endpoints in Adult Subjects With Type 2 Diabetes Mellitus

#### Summary

EudraCT number	2013-003050-25
Trial protocol	SE BE IT NL ES HU CZ GB FR
Global end of trial date	23 February 2017

#### Results information

Result version number	v1 (current)
This version publication date	11 March 2018
First version publication date	11 March 2018

#### Trial information

##### Trial identification

Sponsor protocol code	28431754DIA4003
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##### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01989754
WHO universal trial number (UTN)	-

Notes:

##### Sponsors

Sponsor organisation name	Janssen-Cilag International NV
Sponsor organisation address	Turnhoutseweg 30, Beerse, Belgium, B-2340
Public contact	Clinical Registry group, Janssen-Cilag International NV, ClinicalTrialsEU@its.jnj.com
Scientific contact	Clinical Registry group, Janssen-Cilag International NV, ClinicalTrialsEU@its.jnj.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	23 February 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	23 February 2017
Global end of trial reached?	Yes
Global end of trial date	23 February 2017
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

The main objective of the study was to assess the effect of canagliflozin compared to placebo on progression of albuminuria in subjects with Type 2 diabetes mellitus (T2DM) receiving standard care, but had inadequate glycemic control and were at elevated risk of cardiovascular (CV) events. Furthermore, study DIA4003 together with study DIA3008, constitutes the CANVAS program. An integrated analysis of CANVAS for cardiovascular safety was to use all subjects in DIA4003 and DIA3008 to show that a canagliflozin-associated risk in the CV risk ratio (if any), was significantly less than 1.3 using the two-sided 95% confidence interval of the risk ratio.

Protection of trial subjects:

Several monitoring and adjudication committees were commissioned for this study, including an Academic Research Organization (ARO) which provided scientific and academic oversight and site monitoring for some sites; a Steering Committee of external scientific experts; an Independent Data Monitoring Committee (IDMC); an independent Endpoint Adjudication Committee (EAC), which reviewed blinded data for selected specific events; separate adjudication committees, which were employed to review cases of diabetic ketoacidosis (DKA), fracture, renal events, and pancreatitis; and a company internal Medical Safety Review Committee (MSRC).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	17 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	Argentina: 305
Country: Number of subjects enrolled	Australia: 109
Country: Number of subjects enrolled	Belgium: 152
Country: Number of subjects enrolled	Brazil: 549
Country: Number of subjects enrolled	Canada: 282
Country: Number of subjects enrolled	China: 92
Country: Number of subjects enrolled	Czech Republic: 139
Country: Number of subjects enrolled	Germany: 101
Country: Number of subjects enrolled	Spain: 496
Country: Number of subjects enrolled	France: 124
Country: Number of subjects enrolled	United Kingdom: 151
Country: Number of subjects enrolled	Hungary: 179
Country: Number of subjects enrolled	Italy: 98
Country: Number of subjects enrolled	Korea, Republic of: 167

Country: Number of subjects enrolled	Mexico: 228
Country: Number of subjects enrolled	Malaysia: 92
Country: Number of subjects enrolled	Netherlands: 249
Country: Number of subjects enrolled	New Zealand: 105
Country: Number of subjects enrolled	Poland: 363
Country: Number of subjects enrolled	Russian Federation: 412
Country: Number of subjects enrolled	Sweden: 221
Country: Number of subjects enrolled	Taiwan: 76
Country: Number of subjects enrolled	Ukraine: 449
Country: Number of subjects enrolled	United States: 673
Worldwide total number of subjects	5812
EEA total number of subjects	2273

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)	2976
From 65 to 84 years	2810
85 years and over	26

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

A total of 5,813 subjects were randomized; however, 1 subject was randomized twice and only the first randomization was included in the Intent-to-treat (ITT) analysis set. Thus 2,905 and 2,907 subjects were randomly assigned to the placebo and canagliflozin groups in the ITT analysis set, respectively.

### 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	Investigator, Monitor, Carer, Data analyst, Assessor, Subject

### Arms

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

Arm description:

Subjects received one capsule of matching placebo orally once daily for the duration of the study or until early discontinuation from treatment.

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

Dosage and administration details:

Subjects received one capsule of placebo orally once daily for the duration of the study or until early discontinuation from treatment.

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

Subjects received canagliflozin (JNJ-28431754) 100 milligram (mg) once daily during the first 13 weeks, then the dose was increased to 300 mg once daily (if the subject required additional glycemic control, provided the 100-mg dose was well tolerated).

Arm type	Experimental
Investigational medicinal product name	Canagliflozin 100 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Subjects received canagliflozin (JNJ-28431754) 100 mg once daily during the first 13 weeks.

Investigational medicinal product name	Canagliflozin 300 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Subjects received canagliflozin (JNJ-28431754) 300 mg once daily after the first 13 weeks.

<b>Number of subjects in period 1</b>	Placebo	Canagliflozin
Started	2905	2907
Completed	2866	2872
Not completed	39	35
Consent withdrawn by subject	10	14
Other - closed site	1	1
Lost to follow-up	28	20

## Baseline characteristics

### Reporting groups

Reporting group title	Placebo
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Reporting group description:

Subjects received one capsule of matching placebo orally once daily for the duration of the study or until early discontinuation from treatment.

Reporting group title	Canagliflozin
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Reporting group description:

Subjects received canagliflozin (JNJ-28431754) 100 milligram (mg) once daily during the first 13 weeks, then the dose was increased to 300 mg once daily (if the subject required additional glycemic control, provided the 100-mg dose was well tolerated).

Reporting group values	Placebo	Canagliflozin	Total
Number of subjects	2905	2907	5812
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	1479	1497	2976
From 65 to 84 years	1413	1397	2810
85 years and over	13	13	26
Title for AgeContinuous Units: years			
arithmetic mean	64	63.9	-
standard deviation	± 8.28	± 8.42	-
Title for Gender Units: subjects			
Female	1111	1053	2164
Male	1794	1854	3648

## End points

### End points reporting groups

Reporting group title	Placebo
Reporting group description: Subjects received one capsule of matching placebo orally once daily for the duration of the study or until early discontinuation from treatment.	
Reporting group title	Canagliflozin
Reporting group description: Subjects received canagliflozin (JNJ-28431754) 100 milligram (mg) once daily during the first 13 weeks, then the dose was increased to 300 mg once daily (if the subject required additional glycemic control, provided the 100-mg dose was well tolerated).	

### Primary: Time to the First Occurrence of Progression of Albuminuria

End point title	Time to the First Occurrence of Progression of Albuminuria
End point description: Event rate was estimated based on the time to the first occurrence of the event. Progression defined as the development of micro-albuminuria (UACR 30 to 300 milligram per gram [mg/g]) or macroalbuminuria (Albumin/creatinine ratio [ACR] of > 300 mg/g) in a subject with baseline normoalbuminuria (ACR less than [ $<$ ] 30 mg/g) or the development of macro-albuminuria in a subject with baseline microalbuminuria with an ACR increase greater than or equal to ( $\geq$ ) 30 percent from baseline. The intent to treat (ITT) population included all the randomized subjects. Here 'N' signifies number of subjects who were evaluable for this endpoint. Subjects with macroalbuminuria at baseline (ACR>300 mg/g) are excluded from the analysis.	
End point type	Primary
End point timeframe: Up to 3 years	

End point values	Placebo	Canagliflozin		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2518	2541		
Units: Events per 1000 patient-year				
number (not applicable)	153.01	99.80		

### Statistical analyses

Statistical analysis title	Statistical analysis 1
Statistical analysis description: Comparison for canagliflozin versus placebo is reported here.	
Comparison groups	Placebo v Canagliflozin

Number of subjects included in analysis	5059
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Cox proportional hazard method
Parameter estimate	Hazard ratio (HR)
Point estimate	0.64
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.57
upper limit	0.73

### Secondary: Time to the First Occurrence of Composite of Cardiovascular (CV) Death Events or Hospitalization for Heart Failure

End point title	Time to the First Occurrence of Composite of Cardiovascular (CV) Death Events or Hospitalization for Heart Failure
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End point description:

Event rate was estimated based on the time to the first occurrence of the event. Analyses were using adjudicated events, i.e. CV death events or hospitalization due to heart failure, and adjudication of these outcomes by the Endpoint Adjudication Committee (EAC) were done in a blinded fashion. The ITT Analysis Set included the randomized subjects.

End point type	Secondary
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End point timeframe:

Approximately 3 years

End point values	Placebo	Canagliflozin		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2905	2907		
Units: Events per 1000 patient-years				
number (not applicable)	21.91	15.85		

### Statistical analyses

Statistical analysis title	Statistical analysis
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Statistical analysis description:

Comparison for canagliflozin versus placebo is reported here.

Comparison groups	Placebo v Canagliflozin
Number of subjects included in analysis	5812
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0148
Method	Stratified Cox proportional hazard
Parameter estimate	Hazard ratio (HR)
Point estimate	0.72

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.55
upper limit	0.94

### Secondary: Time to the First Occurrence of CV Death

End point title	Time to the First Occurrence of CV Death
End point description:	
Event rate was estimated based on the time to the first occurrence of the event. Analyses were using adjudicated events, i.e. CV death events, and adjudication of these outcomes by the Endpoint Adjudication Committee (EAC) were done in a blinded fashion. The ITT Analysis Set included the randomized subjects.	
End point type	Secondary
End point timeframe:	
Approximately 3 years	

End point values	Placebo	Canagliflozin		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2905	2907		
Units: Events per 1000 patient-years				
number (not applicable)	11.60	10.06		

### Statistical analyses

Statistical analysis title	Statistical analysis 1
Statistical analysis description:	
Comparison for canagliflozin versus placebo is reported here.	
Comparison groups	Placebo v Canagliflozin
Number of subjects included in analysis	5812
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4067
Method	Stratified Cox proportional hazard
Parameter estimate	Hazard ratio (HR)
Point estimate	0.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.61
upper limit	1.22

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Approximately 3 years

Adverse event reporting additional description:

On-treatment analysis set included all randomized subjects who were treated and received at least 1 dose of study drug. The number of deaths (all causes) reported here is adjudicated death that occurred within 30 days of the last dose of the study drug.

Assessment type	Non-systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	19.1
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### Reporting groups

Reporting group title	Placebo
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Reporting group description:

Subjects received one capsule of placebo orally once daily for the duration of the study or until early discontinuation from treatment.

Reporting group title	Canagliflozin
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Reporting group description:

Subjects received canagliflozin (JNJ-28431754) 100 milligram (mg) once daily during the first 13 weeks, then the dose was increased to 300 mg once daily (if the subject required additional glycemic control, provided the 100-mg dose was well tolerated).

<b>Serious adverse events</b>	Placebo	Canagliflozin	
Total subjects affected by serious adverse events			
subjects affected / exposed	775 / 2903 (26.70%)	714 / 2904 (24.59%)	
number of deaths (all causes)	71	68	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute Myeloid Leukaemia			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Adenocarcinoma Gastric			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenocarcinoma of Colon			

subjects affected / exposed	3 / 2903 (0.10%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Adenosquamous Cell Lung Cancer</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>B-Cell Lymphoma</b>		
subjects affected / exposed	2 / 2903 (0.07%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0
deaths causally related to treatment / all	1 / 2	0 / 0
<b>Basal Cell Carcinoma</b>		
subjects affected / exposed	2 / 2903 (0.07%)	2 / 2904 (0.07%)
occurrences causally related to treatment / all	0 / 7	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Benign Lung Neoplasm</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Benign Neoplasm</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Benign Neoplasm of Thyroid Gland</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bile Duct Cancer</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Bladder Cancer</b>		

subjects affected / exposed	4 / 2903 (0.14%)	4 / 2904 (0.14%)
occurrences causally related to treatment / all	4 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bladder Cancer Recurrent</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bladder Transitional Cell Carcinoma</b>		
subjects affected / exposed	2 / 2903 (0.07%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bowen's Disease</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Breast Adenoma</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Breast Cancer</b>		
subjects affected / exposed	2 / 2903 (0.07%)	3 / 2904 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Breast Cancer Metastatic</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Breast Cancer Stage Ii</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Breast Cancer Stage Iii</b>		

subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral Hygroma		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cholangiocarcinoma		
subjects affected / exposed	2 / 2903 (0.07%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Chronic Myeloid Leukaemia		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Colon Adenoma		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colon Cancer		
subjects affected / exposed	0 / 2903 (0.00%)	4 / 2904 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
Colon Cancer Metastatic		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Colorectal Adenocarcinoma		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Colorectal Cancer		

subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diffuse Large B-Cell Lymphoma		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric Cancer		
subjects affected / exposed	1 / 2903 (0.03%)	2 / 2904 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Glioblastoma		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Hodgkin's Disease		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Invasive Ductal Breast Carcinoma		
subjects affected / exposed	2 / 2903 (0.07%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Large Cell Lung Cancer		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngeal Cancer		
subjects affected / exposed	1 / 2903 (0.03%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lipoma		

subjects affected / exposed	2 / 2903 (0.07%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lung Adenocarcinoma		
subjects affected / exposed	2 / 2903 (0.07%)	4 / 2904 (0.14%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 2
Lung Adenocarcinoma Metastatic		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Lung Cancer Metastatic		
subjects affected / exposed	1 / 2903 (0.03%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung Neoplasm Malignant		
subjects affected / exposed	6 / 2903 (0.21%)	6 / 2904 (0.21%)
occurrences causally related to treatment / all	0 / 6	0 / 7
deaths causally related to treatment / all	0 / 4	0 / 0
Lymphoma		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant Melanoma		
subjects affected / exposed	0 / 2903 (0.00%)	3 / 2904 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant Melanoma in Situ		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
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	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Mediastinum Neoplasm</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Meningioma Benign</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Metastases to Central Nervous System</b>		
subjects affected / exposed	0 / 2903 (0.00%)	2 / 2904 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Metastases to Liver</b>		
subjects affected / exposed	1 / 2903 (0.03%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Neuroendocrine Carcinoma Metastatic</b>		
subjects affected / exposed	1 / 2903 (0.03%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 1	1 / 1
<b>Neuroendocrine Tumour</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Non-Hodgkin's Lymphoma</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Non-Small Cell Lung Cancer</b>		

subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Oesophageal Squamous Cell Carcinoma</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Ovarian Cancer Metastatic</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Pancreatic Carcinoma</b>		
subjects affected / exposed	6 / 2903 (0.21%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 7	0 / 1
deaths causally related to treatment / all	0 / 4	0 / 1
<b>Papillary Cystadenoma Lymphomatosum</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Papillary Thyroid Cancer</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Plasma Cell Myeloma</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Prostate Cancer</b>		
subjects affected / exposed	8 / 2903 (0.28%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	2 / 8	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Prostate Cancer Metastatic</b>		

subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Rectal Cancer</b>			
subjects affected / exposed	3 / 2903 (0.10%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Renal Cancer</b>			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Schwannoma</b>			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Serous Cystadenocarcinoma of Pancreas</b>			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Small Cell Lung Cancer Metastatic</b>			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Squamous Cell Carcinoma</b>			
subjects affected / exposed	1 / 2903 (0.03%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 8	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Squamous Cell Carcinoma of Lung</b>			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Squamous Cell Carcinoma of Skin</b>			

subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Squamous Cell Carcinoma of the Oral Cavity</b>			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Squamous Cell Carcinoma of the Tongue</b>			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Tongue Neoplasm Malignant Stage Unspecified</b>			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Ureteric Cancer</b>			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Uterine Cancer</b>			
subjects affected / exposed	2 / 2903 (0.07%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Uterine Leiomyoma</b>			
subjects affected / exposed	1 / 2903 (0.03%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Vascular disorders</b>			
<b>Aortic Aneurysm</b>			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Aortic Arteriosclerosis			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic Stenosis			
subjects affected / exposed	4 / 2903 (0.14%)	5 / 2904 (0.17%)	
occurrences causally related to treatment / all	0 / 6	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial Thrombosis			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriosclerosis			
subjects affected / exposed	2 / 2903 (0.07%)	2 / 2904 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Circulatory Collapse			
subjects affected / exposed	1 / 2903 (0.03%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Deep Vein Thrombosis			
subjects affected / exposed	2 / 2903 (0.07%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Diabetic Vascular Disorder			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extremity Necrosis			
subjects affected / exposed	5 / 2903 (0.17%)	3 / 2904 (0.10%)	
occurrences causally related to treatment / all	1 / 5	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematoma			

subjects affected / exposed	1 / 2903 (0.03%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertension		
subjects affected / exposed	4 / 2903 (0.14%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive Crisis		
subjects affected / exposed	6 / 2903 (0.21%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypotension		
subjects affected / exposed	3 / 2903 (0.10%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypovolaemic Shock		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Iliac Artery Occlusion		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
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	3 / 2903 (0.10%)	4 / 2904 (0.14%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Orthostatic Hypotension		
subjects affected / exposed	4 / 2903 (0.14%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	2 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral Arterial Occlusive Disease		

subjects affected / exposed	9 / 2903 (0.31%)	9 / 2904 (0.31%)
occurrences causally related to treatment / all	1 / 9	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral Artery Occlusion		
subjects affected / exposed	1 / 2903 (0.03%)	4 / 2904 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral Artery Stenosis		
subjects affected / exposed	2 / 2903 (0.07%)	8 / 2904 (0.28%)
occurrences causally related to treatment / all	0 / 2	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral Artery Thrombosis		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral Embolism		
subjects affected / exposed	1 / 2903 (0.03%)	1 / 2904 (0.03%)
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	5 / 2903 (0.17%)	7 / 2904 (0.24%)
occurrences causally related to treatment / all	1 / 7	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral Vascular Disorder		
subjects affected / exposed	4 / 2903 (0.14%)	9 / 2904 (0.31%)
occurrences causally related to treatment / all	0 / 5	1 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral Venous Disease		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Poor Peripheral Circulation		

subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
<b>Post Thrombotic Syndrome</b>			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Vascular Insufficiency</b>			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
<b>Surgical and medical procedures</b>			
<b>Coronary Arterial Stent Insertion</b>			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Hospitalisation</b>			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Stent Placement</b>			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>General disorders and administration site conditions</b>			
<b>Adverse Drug Reaction</b>			
subjects affected / exposed	1 / 2903 (0.03%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Cardiac Death</b>			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	

Chest Discomfort			
subjects affected / exposed	2 / 2903 (0.07%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest Pain			
subjects affected / exposed	17 / 2903 (0.59%)	22 / 2904 (0.76%)	
occurrences causally related to treatment / all	0 / 17	0 / 22	
deaths causally related to treatment / all	0 / 0	0 / 1	
Complication Associated with Device			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cyst			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			
subjects affected / exposed	7 / 2903 (0.24%)	5 / 2904 (0.17%)	
occurrences causally related to treatment / all	1 / 7	0 / 5	
deaths causally related to treatment / all	1 / 7	0 / 5	
Drug Intolerance			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gait Disturbance			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
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	1 / 2903 (0.03%)	0 / 2904 (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	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Malaise</b>		
subjects affected / exposed	1 / 2903 (0.03%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Non-Cardiac Chest Pain</b>		
subjects affected / exposed	7 / 2903 (0.24%)	9 / 2904 (0.31%)
occurrences causally related to treatment / all	0 / 7	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Oedema Peripheral</b>		
subjects affected / exposed	2 / 2903 (0.07%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Peripheral Swelling</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pyrexia</b>		
subjects affected / exposed	3 / 2903 (0.10%)	2 / 2904 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Sudden Cardiac Death</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Sudden Death</b>		
subjects affected / exposed	6 / 2903 (0.21%)	6 / 2904 (0.21%)
occurrences causally related to treatment / all	0 / 6	1 / 6
deaths causally related to treatment / all	0 / 6	1 / 6
<b>Vascular Stent Restenosis</b>		

subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular Stent Thrombosis			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Anaphylactic Reaction			
subjects affected / exposed	2 / 2903 (0.07%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug Hypersensitivity			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sarcoidosis			
subjects affected / exposed	1 / 2903 (0.03%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Social circumstances			
Penile Prosthesis User			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Victim of Homicide			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Reproductive system and breast disorders			
Balanoposthitis			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Benign Prostatic Hyperplasia			
subjects affected / exposed	5 / 2903 (0.17%)	4 / 2904 (0.14%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial Hyperplasia			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial Hypertrophy			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epididymal Disorder			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erectile Dysfunction			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fallopian Tube Cyst			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metrorrhagia			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peyronie's Disease			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatitis			

subjects affected / exposed	3 / 2903 (0.10%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 3	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Prostatomegaly</b>			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Uterine Polyp</b>			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Uterine Prolapse</b>			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Respiratory, thoracic and mediastinal disorders</b>			
<b>Acute Pulmonary Oedema</b>			
subjects affected / exposed	5 / 2903 (0.17%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
<b>Acute Respiratory Distress Syndrome</b>			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
<b>Acute Respiratory Failure</b>			
subjects affected / exposed	3 / 2903 (0.10%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 3	1 / 1	
deaths causally related to treatment / all	0 / 2	0 / 0	
<b>Asthma</b>			
subjects affected / exposed	2 / 2903 (0.07%)	3 / 2904 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Asthmatic Crisis</b>			

subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Atelectasis</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bronchitis Chronic</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bronchospasm</b>		
subjects affected / exposed	2 / 2903 (0.07%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Chronic Obstructive Pulmonary Disease</b>		
subjects affected / exposed	11 / 2903 (0.38%)	2 / 2904 (0.07%)
occurrences causally related to treatment / all	0 / 26	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cough</b>		
subjects affected / exposed	1 / 2903 (0.03%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Dyspnoea</b>		
subjects affected / exposed	8 / 2903 (0.28%)	8 / 2904 (0.28%)
occurrences causally related to treatment / all	0 / 11	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Epistaxis</b>		
subjects affected / exposed	0 / 2903 (0.00%)	3 / 2904 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Haemoptysis</b>		

subjects affected / exposed	2 / 2903 (0.07%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Haemothorax</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hypoventilation</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Mediastinal Effusion</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Nasal Obstruction</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pleural Effusion</b>		
subjects affected / exposed	5 / 2903 (0.17%)	2 / 2904 (0.07%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Pneumonia Aspiration</b>		
subjects affected / exposed	2 / 2903 (0.07%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Pneumothorax</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pulmonary Embolism</b>		

subjects affected / exposed	5 / 2903 (0.17%)	6 / 2904 (0.21%)
occurrences causally related to treatment / all	1 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 2
<b>Pulmonary Fibrosis</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Pulmonary Mass</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pulmonary Oedema</b>		
subjects affected / exposed	6 / 2903 (0.21%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0
<b>Pulmonary Sarcoidosis</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Respiratory Acidosis</b>		
subjects affected / exposed	1 / 2903 (0.03%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Respiratory Alkalosis</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Respiratory Failure</b>		
subjects affected / exposed	3 / 2903 (0.10%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
<b>Sleep Apnoea Syndrome</b>		

subjects affected / exposed	1 / 2903 (0.03%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vocal Cord Leukoplakia			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Bipolar Disorder			
subjects affected / exposed	2 / 2903 (0.07%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Completed Suicide			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Confusional State			
subjects affected / exposed	2 / 2903 (0.07%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Delirium			
subjects affected / exposed	2 / 2903 (0.07%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depression			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depression Suicidal			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Emotional Disorder			

subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Major Depression</b>			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Psychotic Disorder</b>			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Suicidal Ideation</b>			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Suicide Attempt</b>			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Product issues</b>			
<b>Device Breakage</b>			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Device Loosening</b>			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Device Malfunction</b>			
subjects affected / exposed	2 / 2903 (0.07%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Patient-Device Incompatibility</b>			

subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Hepatobiliary disorders</b>			
<b>Bile Duct Stone</b>			
subjects affected / exposed	2 / 2903 (0.07%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Biliary Colic</b>			
subjects affected / exposed	1 / 2903 (0.03%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Cholangitis</b>			
subjects affected / exposed	0 / 2903 (0.00%)	2 / 2904 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Cholangitis Acute</b>			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Cholecystitis</b>			
subjects affected / exposed	3 / 2903 (0.10%)	3 / 2904 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Cholecystitis Acute</b>			
subjects affected / exposed	1 / 2903 (0.03%)	2 / 2904 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Cholelithiasis</b>			
subjects affected / exposed	7 / 2903 (0.24%)	5 / 2904 (0.17%)	
occurrences causally related to treatment / all	0 / 7	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Cholelithiasis Obstructive</b>			

subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Gallbladder Polyp</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Haemobilia</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hepatic Cirrhosis</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hepatic Lesion</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hydrocholecystis</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Jaundice Cholestatic</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Liver Injury</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Non-Alcoholic Steatohepatitis</b>		

subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Investigations</b>			
<b>Arteriogram Coronary</b>			
subjects affected / exposed	2 / 2903 (0.07%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Blood Creatinine Increased</b>			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Blood Glucose Increased</b>			
subjects affected / exposed	3 / 2903 (0.10%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Ejection Fraction Decreased</b>			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Electrocardiogram QT Prolonged</b>			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Electrocardiogram St-T Change</b>			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Electrocardiogram T Wave Inversion</b>			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>International Normalised Ratio Increased</b>			

subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver Function Test Increased			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Platelet Count Decreased			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
White Blood Cell Count Decreased			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
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			
Ankle Fracture			
subjects affected / exposed	2 / 2903 (0.07%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial Bypass Stenosis			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid Artery Restenosis			
subjects affected / exposed	0 / 2903 (0.00%)	2 / 2904 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract Operation Complication			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clavicle Fracture			

subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Concussion		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Contusion		
subjects affected / exposed	3 / 2903 (0.10%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cranio-cerebral Injury		
subjects affected / exposed	0 / 2903 (0.00%)	2 / 2904 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2
Epiphyseal Fracture		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Eye Injury		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Facial Bones Fracture		
subjects affected / exposed	1 / 2903 (0.03%)	3 / 2904 (0.10%)
occurrences causally related to treatment / all	0 / 1	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Fall		
subjects affected / exposed	4 / 2903 (0.14%)	5 / 2904 (0.17%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Femoral Neck Fracture		

subjects affected / exposed	2 / 2903 (0.07%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Femur Fracture</b>		
subjects affected / exposed	6 / 2903 (0.21%)	4 / 2904 (0.14%)
occurrences causally related to treatment / all	1 / 6	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Fibula Fracture</b>		
subjects affected / exposed	1 / 2903 (0.03%)	2 / 2904 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Foot Fracture</b>		
subjects affected / exposed	1 / 2903 (0.03%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Fractured Coccyx</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hand Fracture</b>		
subjects affected / exposed	1 / 2903 (0.03%)	2 / 2904 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Head Injury</b>		
subjects affected / exposed	2 / 2903 (0.07%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hip Fracture</b>		
subjects affected / exposed	5 / 2903 (0.17%)	3 / 2904 (0.10%)
occurrences causally related to treatment / all	1 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Humerus Fracture</b>		

subjects affected / exposed	2 / 2903 (0.07%)	3 / 2904 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Jaw Fracture</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Joint Dislocation</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Laceration</b>		
subjects affected / exposed	0 / 2903 (0.00%)	2 / 2904 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Ligament Sprain</b>		
subjects affected / exposed	2 / 2903 (0.07%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Limb Crushing Injury</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Limb Injury</b>		
subjects affected / exposed	2 / 2903 (0.07%)	5 / 2904 (0.17%)
occurrences causally related to treatment / all	1 / 3	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Lumbar Vertebral Fracture</b>		
subjects affected / exposed	1 / 2903 (0.03%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Meniscus Injury</b>		

subjects affected / exposed	0 / 2903 (0.00%)	2 / 2904 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Patella Fracture</b>			
subjects affected / exposed	2 / 2903 (0.07%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Pneumocephalus</b>			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Post Laminectomy Syndrome</b>			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Post Procedural Haematoma</b>			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Post Procedural Haematuria</b>			
subjects affected / exposed	0 / 2903 (0.00%)	2 / 2904 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Post Procedural Haemorrhage</b>			
subjects affected / exposed	1 / 2903 (0.03%)	2 / 2904 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Postoperative Hernia</b>			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Postoperative Respiratory Failure</b>			

subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural Headache		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
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	0 / 2903 (0.00%)	1 / 2904 (0.03%)
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	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Radius Fracture		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rib Fracture		
subjects affected / exposed	4 / 2903 (0.14%)	4 / 2904 (0.14%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Road Traffic Accident		
subjects affected / exposed	0 / 2903 (0.00%)	2 / 2904 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Spinal Fracture		
subjects affected / exposed	0 / 2903 (0.00%)	2 / 2904 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Subarachnoid Haemorrhage		

subjects affected / exposed	2 / 2903 (0.07%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Subdural Haematoma</b>		
subjects affected / exposed	1 / 2903 (0.03%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Suture Related Complication</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Tendon Injury</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Tendon Rupture</b>		
subjects affected / exposed	2 / 2903 (0.07%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Thermal Burn</b>		
subjects affected / exposed	1 / 2903 (0.03%)	2 / 2904 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Thoracic Vertebral Fracture</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Tibia Fracture</b>		
subjects affected / exposed	1 / 2903 (0.03%)	4 / 2904 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Toxicity to Various Agents</b>		

subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Traumatic Fracture		
subjects affected / exposed	0 / 2903 (0.00%)	2 / 2904 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic Ulcer		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ulna Fracture		
subjects affected / exposed	1 / 2903 (0.03%)	2 / 2904 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Upper Limb Fracture		
subjects affected / exposed	2 / 2903 (0.07%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular Graft Stenosis		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (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 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Wound Dehiscence		
subjects affected / exposed	1 / 2903 (0.03%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Wound Necrosis		

subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
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 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute Coronary Syndrome			
subjects affected / exposed	11 / 2903 (0.38%)	4 / 2904 (0.14%)	
occurrences causally related to treatment / all	0 / 12	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute Left Ventricular Failure			
subjects affected / exposed	1 / 2903 (0.03%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute Myocardial Infarction			
subjects affected / exposed	26 / 2903 (0.90%)	32 / 2904 (1.10%)	
occurrences causally related to treatment / all	0 / 31	1 / 35	
deaths causally related to treatment / all	0 / 3	0 / 6	
Adams-Stokes Syndrome			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina Pectoris			
subjects affected / exposed	33 / 2903 (1.14%)	22 / 2904 (0.76%)	
occurrences causally related to treatment / all	0 / 34	0 / 24	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina Unstable			
subjects affected / exposed	42 / 2903 (1.45%)	42 / 2904 (1.45%)	
occurrences causally related to treatment / all	0 / 54	0 / 47	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic Valve Disease			

subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Aortic Valve Incompetence</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Arrhythmia</b>		
subjects affected / exposed	1 / 2903 (0.03%)	2 / 2904 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Arteriosclerosis Coronary Artery</b>		
subjects affected / exposed	5 / 2903 (0.17%)	3 / 2904 (0.10%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Atrial Fibrillation</b>		
subjects affected / exposed	18 / 2903 (0.62%)	14 / 2904 (0.48%)
occurrences causally related to treatment / all	1 / 22	0 / 17
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Atrial Flutter</b>		
subjects affected / exposed	7 / 2903 (0.24%)	5 / 2904 (0.17%)
occurrences causally related to treatment / all	0 / 7	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Atrial Tachycardia</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Atrioventricular Block Complete</b>		
subjects affected / exposed	1 / 2903 (0.03%)	3 / 2904 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Atrioventricular Block Second Degree</b>		

subjects affected / exposed	1 / 2903 (0.03%)	2 / 2904 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bradycardia</b>		
subjects affected / exposed	1 / 2903 (0.03%)	2 / 2904 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cardiac Arrest</b>		
subjects affected / exposed	9 / 2903 (0.31%)	5 / 2904 (0.17%)
occurrences causally related to treatment / all	0 / 10	0 / 5
deaths causally related to treatment / all	0 / 8	0 / 3
<b>Cardiac Disorder</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cardiac Failure</b>		
subjects affected / exposed	41 / 2903 (1.41%)	19 / 2904 (0.65%)
occurrences causally related to treatment / all	0 / 47	2 / 21
deaths causally related to treatment / all	0 / 5	0 / 1
<b>Cardiac Failure Acute</b>		
subjects affected / exposed	3 / 2903 (0.10%)	2 / 2904 (0.07%)
occurrences causally related to treatment / all	0 / 7	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cardiac Failure Chronic</b>		
subjects affected / exposed	3 / 2903 (0.10%)	4 / 2904 (0.14%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 1
<b>Cardiac Failure Congestive</b>		
subjects affected / exposed	18 / 2903 (0.62%)	11 / 2904 (0.38%)
occurrences causally related to treatment / all	0 / 25	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Cardiac Valve Disease</b>		

subjects affected / exposed	2 / 2903 (0.07%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cardio-Respiratory Arrest</b>		
subjects affected / exposed	1 / 2903 (0.03%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
<b>Cardiogenic Shock</b>		
subjects affected / exposed	2 / 2903 (0.07%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0
<b>Cardiopulmonary Failure</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Conduction Disorder</b>		
subjects affected / exposed	2 / 2903 (0.07%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Congestive Cardiomyopathy</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Coronary Artery Disease</b>		
subjects affected / exposed	29 / 2903 (1.00%)	34 / 2904 (1.17%)
occurrences causally related to treatment / all	1 / 30	0 / 36
deaths causally related to treatment / all	0 / 2	0 / 2
<b>Coronary Artery Insufficiency</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Coronary Artery Occlusion</b>		

subjects affected / exposed	3 / 2903 (0.10%)	4 / 2904 (0.14%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary Artery Stenosis		
subjects affected / exposed	8 / 2903 (0.28%)	5 / 2904 (0.17%)
occurrences causally related to treatment / all	0 / 8	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic Cardiomyopathy		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Ischaemic Cardiomyopathy		
subjects affected / exposed	4 / 2903 (0.14%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	1 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Left Ventricular Dysfunction		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Left Ventricular Failure		
subjects affected / exposed	1 / 2903 (0.03%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Mitral Valve Stenosis		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Myocardial Fibrosis		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Myocardial Infarction		

subjects affected / exposed	24 / 2903 (0.83%)	31 / 2904 (1.07%)
occurrences causally related to treatment / all	1 / 24	1 / 34
deaths causally related to treatment / all	0 / 1	0 / 8
<b>Myocardial Ischaemia</b>		
subjects affected / exposed	9 / 2903 (0.31%)	7 / 2904 (0.24%)
occurrences causally related to treatment / all	0 / 10	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pericardial Effusion</b>		
subjects affected / exposed	0 / 2903 (0.00%)	2 / 2904 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pericarditis</b>		
subjects affected / exposed	3 / 2903 (0.10%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Prinzmetal Angina</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Right Ventricular Failure</b>		
subjects affected / exposed	2 / 2903 (0.07%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Sinus Bradycardia</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Sinus Node Dysfunction</b>		
subjects affected / exposed	4 / 2903 (0.14%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Supraventricular Tachycardia</b>		

subjects affected / exposed	1 / 2903 (0.03%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachycardia			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tricuspid Valve Incompetence			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular Arrhythmia			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular Asystole			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Ventricular Extrasystoles			
subjects affected / exposed	1 / 2903 (0.03%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular Fibrillation			
subjects affected / exposed	0 / 2903 (0.00%)	2 / 2904 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular Tachycardia			
subjects affected / exposed	2 / 2903 (0.07%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Basilar Artery Occlusion			

subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Brain Injury</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Brain Stem Infarction</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Brain Stem Stroke</b>		
subjects affected / exposed	0 / 2903 (0.00%)	2 / 2904 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Carotid Arteriosclerosis</b>		
subjects affected / exposed	2 / 2903 (0.07%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Carotid Artery Occlusion</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Carotid Artery Stenosis</b>		
subjects affected / exposed	7 / 2903 (0.24%)	9 / 2904 (0.31%)
occurrences causally related to treatment / all	0 / 7	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Carpal Tunnel Syndrome</b>		
subjects affected / exposed	1 / 2903 (0.03%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cerebellar Infarction</b>		

subjects affected / exposed	1 / 2903 (0.03%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cerebral Haematoma</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cerebral Haemorrhage</b>		
subjects affected / exposed	1 / 2903 (0.03%)	3 / 2904 (0.10%)
occurrences causally related to treatment / all	0 / 1	1 / 3
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Cerebral Infarction</b>		
subjects affected / exposed	5 / 2903 (0.17%)	4 / 2904 (0.14%)
occurrences causally related to treatment / all	1 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cerebral Ischaemia</b>		
subjects affected / exposed	1 / 2903 (0.03%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cerebrovascular Accident</b>		
subjects affected / exposed	37 / 2903 (1.27%)	15 / 2904 (0.52%)
occurrences causally related to treatment / all	2 / 41	0 / 17
deaths causally related to treatment / all	0 / 3	0 / 1
<b>Cervicobrachial Syndrome</b>		
subjects affected / exposed	1 / 2903 (0.03%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cognitive Disorder</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Diabetic Mononeuropathy</b>		

subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic Neuropathy		
subjects affected / exposed	1 / 2903 (0.03%)	2 / 2904 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Dizziness Postural		
subjects affected / exposed	2 / 2903 (0.07%)	2 / 2904 (0.07%)
occurrences causally related to treatment / all	0 / 2	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Embolic Stroke		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Epilepsy		
subjects affected / exposed	1 / 2903 (0.03%)	2 / 2904 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Facial Nerve Disorder		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Generalised Tonic-Clonic Seizure		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhagic Stroke		
subjects affected / exposed	4 / 2903 (0.14%)	2 / 2904 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 1
Headache		

subjects affected / exposed	1 / 2903 (0.03%)	2 / 2904 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hemiparesis		
subjects affected / exposed	0 / 2903 (0.00%)	2 / 2904 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hydrocephalus		
subjects affected / exposed	1 / 2903 (0.03%)	2 / 2904 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive Encephalopathy		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoxic-Ischaemic Encephalopathy		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intraventricular Haemorrhage		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic Cerebral Infarction		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic Stroke		
subjects affected / exposed	12 / 2903 (0.41%)	20 / 2904 (0.69%)
occurrences causally related to treatment / all	0 / 12	0 / 21
deaths causally related to treatment / all	0 / 2	0 / 3
Lacunar Infarction		

subjects affected / exposed	2 / 2903 (0.07%)	2 / 2904 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lacunar Stroke		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lethargy		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Loss of Consciousness		
subjects affected / exposed	0 / 2903 (0.00%)	2 / 2904 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar Radiculopathy		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metabolic Encephalopathy		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Migraine		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Myasthenia Gravis		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Myasthenia Gravis Crisis		

subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Nerve Compression</b>			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Neuralgia</b>			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Paraesthesia</b>			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Peripheral Nerve Paresis</b>			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Presyncope</b>			
subjects affected / exposed	1 / 2903 (0.03%)	3 / 2904 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Radiculopathy</b>			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Sciatica</b>			
subjects affected / exposed	2 / 2903 (0.07%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Seizure</b>			

subjects affected / exposed	2 / 2903 (0.07%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Sensory Loss</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Spinal Cord Compression</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Syncope</b>		
subjects affected / exposed	8 / 2903 (0.28%)	10 / 2904 (0.34%)
occurrences causally related to treatment / all	0 / 8	2 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Thalamic Infarction</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Toxic Encephalopathy</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Transient Ischaemic Attack</b>		
subjects affected / exposed	10 / 2903 (0.34%)	8 / 2904 (0.28%)
occurrences causally related to treatment / all	0 / 13	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Tremor</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Trigeminal Neuralgia</b>		

subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Vascular Encephalopathy</b>			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Vascular Headache</b>			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Vertebral Artery Occlusion</b>			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Vertebrobasilar Insufficiency</b>			
subjects affected / exposed	1 / 2903 (0.03%)	2 / 2904 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Vocal Cord Paralysis</b>			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Blood and lymphatic system disorders</b>			
<b>Anaemia</b>			
subjects affected / exposed	6 / 2903 (0.21%)	10 / 2904 (0.34%)	
occurrences causally related to treatment / all	0 / 8	2 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Febrile Neutropenia</b>			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Iron Deficiency Anaemia</b>			

subjects affected / exposed	2 / 2903 (0.07%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Polycythaemia</b>			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Thrombocytopenia</b>			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Ear and labyrinth disorders</b>			
<b>Haematotympanum</b>			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Hypoacusis</b>			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Vertigo</b>			
subjects affected / exposed	2 / 2903 (0.07%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	1 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Eye disorders</b>			
<b>Amaurosis Fugax</b>			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Cataract</b>			
subjects affected / exposed	3 / 2903 (0.10%)	10 / 2904 (0.34%)	
occurrences causally related to treatment / all	0 / 3	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Diabetic Retinopathy</b>			

subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diplopia		
subjects affected / exposed	1 / 2903 (0.03%)	2 / 2904 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Eye Haemorrhage		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Eye Pain		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Eyelid Ptosis		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Glaucoma		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Macular Fibrosis		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal Artery Occlusion		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal Detachment		

subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinopathy			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (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 Hernia			
subjects affected / exposed	3 / 2903 (0.10%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal Pain			
subjects affected / exposed	5 / 2903 (0.17%)	2 / 2904 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal Pain Lower			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal Pain Upper			
subjects affected / exposed	2 / 2903 (0.07%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal Fistula			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ascites			
subjects affected / exposed	1 / 2903 (0.03%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Barrett's Oesophagus			

subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bowel Movement Irregularity</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Colitis</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Colitis Ischaemic</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Colitis Microscopic</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Colitis Ulcerative</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Colonic Pseudo-Obstruction</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Constipation</b>		
subjects affected / exposed	1 / 2903 (0.03%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Diarrhoea</b>		

subjects affected / exposed	4 / 2903 (0.14%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticular Perforation		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum		
subjects affected / exposed	0 / 2903 (0.00%)	2 / 2904 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum Intestinal		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal Ulcer		
subjects affected / exposed	1 / 2903 (0.03%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal Ulcer Haemorrhage		
subjects affected / exposed	2 / 2903 (0.07%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal Ulcer Perforation		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Enterocolitis		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Food Poisoning		

subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric Polyps		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroduodenitis		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
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	3 / 2903 (0.10%)	3 / 2904 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Haematemesis		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ileus		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Impaired Gastric Emptying		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Inguinal Hernia		
subjects affected / exposed	4 / 2903 (0.14%)	2 / 2904 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal Haemorrhage		

subjects affected / exposed	2 / 2903 (0.07%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Intestinal Ischaemia</b>		
subjects affected / exposed	3 / 2903 (0.10%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0
<b>Intestinal Obstruction</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Intestinal Ulcer Perforation</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Large Intestine Perforation</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Lower Gastrointestinal Haemorrhage</b>		
subjects affected / exposed	1 / 2903 (0.03%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Melaena</b>		
subjects affected / exposed	0 / 2903 (0.00%)	2 / 2904 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Mesenteric Arterial Occlusion</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Mesenteric Vein Thrombosis</b>		

subjects affected / exposed	2 / 2903 (0.07%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Oesophageal Obstruction</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pancreatitis</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pancreatitis Acute</b>		
subjects affected / exposed	2 / 2903 (0.07%)	3 / 2904 (0.10%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Peptic Ulcer</b>		
subjects affected / exposed	1 / 2903 (0.03%)	2 / 2904 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pneumoperitoneum</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Rectal Tenesmus</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Salivary Gland Calculus</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Salivary Gland Fistula</b>		

subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Small Intestinal Obstruction</b>			
subjects affected / exposed	0 / 2903 (0.00%)	2 / 2904 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Swollen Tongue</b>			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Tooth Disorder</b>			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Umbilical Hernia</b>			
subjects affected / exposed	1 / 2903 (0.03%)	6 / 2904 (0.21%)	
occurrences causally related to treatment / all	0 / 1	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Upper Gastrointestinal Haemorrhage</b>			
subjects affected / exposed	2 / 2903 (0.07%)	3 / 2904 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Volvulus</b>			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Skin and subcutaneous tissue disorders</b>			
<b>Angioedema</b>			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Dermatitis Allergic</b>			

subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Diabetic Foot</b>			
subjects affected / exposed	9 / 2903 (0.31%)	10 / 2904 (0.34%)	
occurrences causally related to treatment / all	1 / 9	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Diabetic Ulcer</b>			
subjects affected / exposed	1 / 2903 (0.03%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Skin Fissures</b>			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Skin Necrosis</b>			
subjects affected / exposed	0 / 2903 (0.00%)	2 / 2904 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Skin Ulcer</b>			
subjects affected / exposed	5 / 2903 (0.17%)	7 / 2904 (0.24%)	
occurrences causally related to treatment / all	1 / 5	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Urticaria</b>			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Renal and urinary disorders</b>			
<b>Acute Kidney Injury</b>			
subjects affected / exposed	15 / 2903 (0.52%)	7 / 2904 (0.24%)	
occurrences causally related to treatment / all	2 / 17	3 / 7	
deaths causally related to treatment / all	0 / 0	1 / 2	
<b>Bladder Obstruction</b>			

subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic Kidney Disease		
subjects affected / exposed	2 / 2903 (0.07%)	3 / 2904 (0.10%)
occurrences causally related to treatment / all	1 / 2	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0
Diabetic Nephropathy		
subjects affected / exposed	1 / 2903 (0.03%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haematuria		
subjects affected / exposed	1 / 2903 (0.03%)	3 / 2904 (0.10%)
occurrences causally related to treatment / all	1 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hydronephrosis		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ketonuria		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nephrolithiasis		
subjects affected / exposed	2 / 2903 (0.07%)	8 / 2904 (0.28%)
occurrences causally related to treatment / all	0 / 2	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Nephropathy		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nephropathy Toxic		

subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Nephrotic Syndrome</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pelvi-Ureteric Obstruction</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pollakiuria</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Proteinuria</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Renal Colic</b>		
subjects affected / exposed	0 / 2903 (0.00%)	2 / 2904 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Renal Failure</b>		
subjects affected / exposed	2 / 2903 (0.07%)	2 / 2904 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Renal Haematoma</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Renal Impairment</b>		

subjects affected / exposed	2 / 2903 (0.07%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
<b>Renal Injury</b>			
subjects affected / exposed	3 / 2903 (0.10%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	2 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Stress Urinary Incontinence</b>			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Tubulointerstitial Nephritis</b>			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Ureterolithiasis</b>			
subjects affected / exposed	1 / 2903 (0.03%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Urethral Stenosis</b>			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Urinary Incontinence</b>			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Urinary Retention</b>			
subjects affected / exposed	2 / 2903 (0.07%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Endocrine disorders</b>			
Basedow's Disease			

subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperparathyroidism			
subjects affected / exposed	2 / 2903 (0.07%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperparathyroidism Primary			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperthyroidism			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (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	3 / 2903 (0.10%)	4 / 2904 (0.14%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis			
subjects affected / exposed	2 / 2903 (0.07%)	2 / 2904 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthropathy			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back Pain			
subjects affected / exposed	11 / 2903 (0.38%)	2 / 2904 (0.07%)	
occurrences causally related to treatment / all	0 / 12	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bursitis			

subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cervical Spinal Stenosis</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Costochondritis</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Dactylitis</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Dupuytren's Contracture</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Extremity Contracture</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Foot Deformity</b>		
subjects affected / exposed	0 / 2903 (0.00%)	2 / 2904 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Intervertebral Disc Compression</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Intervertebral Disc Disorder</b>		

subjects affected / exposed	1 / 2903 (0.03%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Intervertebral Disc Protrusion</b>			
subjects affected / exposed	5 / 2903 (0.17%)	7 / 2904 (0.24%)	
occurrences causally related to treatment / all	0 / 6	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Knee Deformity</b>			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Lumbar Spinal Stenosis</b>			
subjects affected / exposed	4 / 2903 (0.14%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Muscular Weakness</b>			
subjects affected / exposed	2 / 2903 (0.07%)	2 / 2904 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Musculoskeletal Chest Pain</b>			
subjects affected / exposed	2 / 2903 (0.07%)	2 / 2904 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Musculoskeletal Pain</b>			
subjects affected / exposed	2 / 2903 (0.07%)	2 / 2904 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Osteitis</b>			
subjects affected / exposed	1 / 2903 (0.03%)	2 / 2904 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Osteoarthritis</b>			

subjects affected / exposed	16 / 2903 (0.55%)	13 / 2904 (0.45%)
occurrences causally related to treatment / all	0 / 17	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Osteonecrosis</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pathological Fracture</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Plantar Fasciitis</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Polymyalgia Rheumatica</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Rhabdomyolysis</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Rotator Cuff Syndrome</b>		
subjects affected / exposed	1 / 2903 (0.03%)	4 / 2904 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Sacroiliitis</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Spinal Column Stenosis</b>		

subjects affected / exposed	1 / 2903 (0.03%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Spinal Osteoarthritis</b>		
subjects affected / exposed	4 / 2903 (0.14%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Spinal Pain</b>		
subjects affected / exposed	3 / 2903 (0.10%)	3 / 2904 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Spondylolisthesis</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Synovial Cyst</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Tendonitis</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Tenosynovitis</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Tenosynovitis Stenosans</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Trigger Finger</b>		

subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Infections and infestations</b>			
<b>Abscess</b>			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Abscess Limb</b>			
subjects affected / exposed	2 / 2903 (0.07%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Abscess Neck</b>			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Appendicitis</b>			
subjects affected / exposed	2 / 2903 (0.07%)	6 / 2904 (0.21%)	
occurrences causally related to treatment / all	0 / 2	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Arthritis Bacterial</b>			
subjects affected / exposed	1 / 2903 (0.03%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Bronchitis</b>			
subjects affected / exposed	3 / 2903 (0.10%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Campylobacter Gastroenteritis</b>			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Carbuncle</b>			

subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (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	11 / 2903 (0.38%)	9 / 2904 (0.31%)
occurrences causally related to treatment / all	0 / 14	1 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Cellulitis Staphylococcal		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cellulitis Streptococcal		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis Infective		
subjects affected / exposed	1 / 2903 (0.03%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colonic Abscess		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
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	1 / 2903 (0.03%)	2 / 2904 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic Foot Infection		
subjects affected / exposed	4 / 2903 (0.14%)	3 / 2904 (0.10%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic Gangrene		

subjects affected / exposed	2 / 2903 (0.07%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Diverticulitis</b>		
subjects affected / exposed	3 / 2903 (0.10%)	3 / 2904 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Ear Infection</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Empyema</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Endocarditis</b>		
subjects affected / exposed	0 / 2903 (0.00%)	2 / 2904 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Epididymitis</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Erysipelas</b>		
subjects affected / exposed	5 / 2903 (0.17%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Escherichia Infection</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Escherichia Sepsis</b>		

subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Escherichia Urinary Tract Infection</b>		
subjects affected / exposed	1 / 2903 (0.03%)	2 / 2904 (0.07%)
occurrences causally related to treatment / all	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Eye Infection</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Gangrene</b>		
subjects affected / exposed	2 / 2903 (0.07%)	5 / 2904 (0.17%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Gastroenteritis</b>		
subjects affected / exposed	9 / 2903 (0.31%)	8 / 2904 (0.28%)
occurrences causally related to treatment / all	0 / 9	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Gastroenteritis Viral</b>		
subjects affected / exposed	1 / 2903 (0.03%)	2 / 2904 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Genital Infection Fungal</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hepatitis B</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Herpes Zoster</b>		

subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hiv Infection</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Infected Dermal Cyst</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Infected Skin Ulcer</b>		
subjects affected / exposed	1 / 2903 (0.03%)	3 / 2904 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Infection</b>		
subjects affected / exposed	1 / 2903 (0.03%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Infective Exacerbation of Chronic Obstructive Airways Disease</b>		
subjects affected / exposed	2 / 2903 (0.07%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Influenza</b>		
subjects affected / exposed	1 / 2903 (0.03%)	5 / 2904 (0.17%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Intervertebral Discitis</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Laryngitis</b>		

subjects affected / exposed	0 / 2903 (0.00%)	2 / 2904 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Localised Infection		
subjects affected / exposed	6 / 2903 (0.21%)	5 / 2904 (0.17%)
occurrences causally related to treatment / all	1 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Lower Respiratory Tract Infection		
subjects affected / exposed	6 / 2903 (0.21%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung Abscess		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
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 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Orchitis		
subjects affected / exposed	2 / 2903 (0.07%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Osteomyelitis		
subjects affected / exposed	5 / 2903 (0.17%)	6 / 2904 (0.21%)
occurrences causally related to treatment / all	0 / 6	2 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Osteomyelitis Chronic		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Otitis Media Acute		

subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Parasitic Gastroenteritis</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Paronychia</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pelvic Abscess</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Penile Abscess</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Perinephric Abscess</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Peritonsillar Abscess</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pharyngotonsillitis</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pneumococcal Sepsis</b>		

subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia		
subjects affected / exposed	31 / 2903 (1.07%)	26 / 2904 (0.90%)
occurrences causally related to treatment / all	1 / 33	0 / 27
deaths causally related to treatment / all	0 / 1	0 / 5
Pneumonia Legionella		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia Pneumococcal		
subjects affected / exposed	2 / 2903 (0.07%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post Procedural Infection		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post Procedural Sepsis		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative Wound Infection		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary Sepsis		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Pulmonary Tuberculosis		

subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pyelonephritis</b>		
subjects affected / exposed	2 / 2903 (0.07%)	5 / 2904 (0.17%)
occurrences causally related to treatment / all	0 / 2	3 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pyelonephritis Acute</b>		
subjects affected / exposed	3 / 2903 (0.10%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 3	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Respiratory Tract Infection</b>		
subjects affected / exposed	13 / 2903 (0.45%)	5 / 2904 (0.17%)
occurrences causally related to treatment / all	0 / 16	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Scrotal Abscess</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Scrotal Infection</b>		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Sepsis</b>		
subjects affected / exposed	9 / 2903 (0.31%)	4 / 2904 (0.14%)
occurrences causally related to treatment / all	1 / 9	0 / 4
deaths causally related to treatment / all	0 / 4	0 / 0
<b>Septic Shock</b>		
subjects affected / exposed	6 / 2903 (0.21%)	4 / 2904 (0.14%)
occurrences causally related to treatment / all	1 / 6	1 / 4
deaths causally related to treatment / all	0 / 3	0 / 2
<b>Sinusitis</b>		

subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Soft Tissue Infection		
subjects affected / exposed	0 / 2903 (0.00%)	2 / 2904 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal Infection		
subjects affected / exposed	2 / 2903 (0.07%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal Sepsis		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Stenotrophomonas Infection		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subcutaneous Abscess		
subjects affected / exposed	2 / 2903 (0.07%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tooth Abscess		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
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 / 2903 (0.03%)	0 / 2904 (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 / 2903 (0.00%)	1 / 2904 (0.03%)	
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	2 / 2903 (0.07%)	2 / 2904 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary Tract Infection			
subjects affected / exposed	13 / 2903 (0.45%)	11 / 2904 (0.38%)	
occurrences causally related to treatment / all	6 / 13	4 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary Tract Infection Enterococcal			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			
subjects affected / exposed	1 / 2903 (0.03%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound Infection			
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Acidosis			
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cachexia			
subjects affected / exposed	1 / 2903 (0.03%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			

subjects affected / exposed	2 / 2903 (0.07%)	3 / 2904 (0.10%)
occurrences causally related to treatment / all	2 / 2	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Diabetes Mellitus</b>		
subjects affected / exposed	18 / 2903 (0.62%)	5 / 2904 (0.17%)
occurrences causally related to treatment / all	0 / 19	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Diabetes Mellitus Inadequate Control</b>		
subjects affected / exposed	12 / 2903 (0.41%)	6 / 2904 (0.21%)
occurrences causally related to treatment / all	0 / 14	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Diabetic Complication</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Diabetic Ketoacidosis</b>		
subjects affected / exposed	2 / 2903 (0.07%)	5 / 2904 (0.17%)
occurrences causally related to treatment / all	0 / 2	5 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Electrolyte Imbalance</b>		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Fluid Overload</b>		
subjects affected / exposed	2 / 2903 (0.07%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Gout</b>		
subjects affected / exposed	1 / 2903 (0.03%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hyperglycaemia</b>		

subjects affected / exposed	11 / 2903 (0.38%)	5 / 2904 (0.17%)
occurrences causally related to treatment / all	0 / 11	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperkalaemia		
subjects affected / exposed	5 / 2903 (0.17%)	2 / 2904 (0.07%)
occurrences causally related to treatment / all	2 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperosmolar Hyperglycaemic State		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertriglyceridaemia		
subjects affected / exposed	0 / 2903 (0.00%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoglycaemia		
subjects affected / exposed	9 / 2903 (0.31%)	6 / 2904 (0.21%)
occurrences causally related to treatment / all	2 / 10	2 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Hypokalaemia		
subjects affected / exposed	1 / 2903 (0.03%)	0 / 2904 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hyponatraemia		
subjects affected / exposed	4 / 2903 (0.14%)	3 / 2904 (0.10%)
occurrences causally related to treatment / all	3 / 5	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hypovolaemia		
subjects affected / exposed	2 / 2903 (0.07%)	1 / 2904 (0.03%)
occurrences causally related to treatment / all	1 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lactic Acidosis		

subjects affected / exposed	0 / 2903 (0.00%)	2 / 2904 (0.07%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	1 / 1	
<b>Metabolic Acidosis</b>			
subjects affected / exposed	1 / 2903 (0.03%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Obesity</b>			
subjects affected / exposed	3 / 2903 (0.10%)	2 / 2904 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Type 2 Diabetes Mellitus</b>			
subjects affected / exposed	1 / 2903 (0.03%)	1 / 2904 (0.03%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 2 %

<b>Non-serious adverse events</b>	Placebo	Canagliflozin	
<b>Total subjects affected by non-serious adverse events</b>			
subjects affected / exposed	25 / 2903 (0.86%)	94 / 2904 (3.24%)	
<b>Reproductive system and breast disorders</b>			
<b>Balanoposthitis</b>			
subjects affected / exposed	25 / 2903 (0.86%)	94 / 2904 (3.24%)	
occurrences (all)	29	125	

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
17 September 2015	The primary reason was to incorporate a request by Health Authorities to include diabetic ketoacidosis (DKA) safety information and handling of subjects surrounding this event.
05 May 2016	The primary reason to amend the study protocol was to include new safety information and guidance regarding subject management surrounding the event of lower extremity amputations.
01 September 2016	The primary reason to amend the study protocol was to add secondary cardiovascular objectives and exploratory renal objectives.

Notes:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported