



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
Arm title	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.

Arm title	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.

Number of subjects in period 1	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
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
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
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).

Serious adverse events	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	
Adenosquamous Cell Lung Cancer			
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-Cell Lymphoma			
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	
Basal Cell Carcinoma			
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	
Benign Lung Neoplasm			
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	
Benign Neoplasm			
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	
Benign Neoplasm of Thyroid Gland			
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	
Bile Duct 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 / 1	
Bladder Cancer			

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	
Bladder Cancer Recurrent			
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	
Bladder Transitional Cell Carcinoma			
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	
Bowen'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	
Breast 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	
Breast Cancer			
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	
Breast 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	
Breast Cancer Stage Ii			
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	
Breast Cancer Stage Iii			

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	
Mediastinum Neoplasm			
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	
Meningioma Benign			
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	
Metastases to Central Nervous System			
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	
Metastases to Liver			
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	
Neuroendocrine Carcinoma Metastatic			
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	
Neuroendocrine Tumour			
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	
Non-Hodgkin's Lymphoma			
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	
Non-Small Cell Lung Cancer			

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	
Oesophageal Squamous Cell Carcinoma			
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	
Ovarian Cancer Metastatic			
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	
Pancreatic Carcinoma			
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	
Papillary Cystadenoma Lymphomatosum			
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	
Papillary Thyroid 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	
Plasma Cell Myeloma			
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	
Prostate Cancer			
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	
Prostate 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 / 0	
Rectal Cancer			
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	
Renal 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	
Schwannoma			
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	
Serous Cystadenocarcinoma of Pancreas			
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	
Small Cell Lung Cancer Metastatic			
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	
Squamous Cell Carcinoma			
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	
Squamous Cell Carcinoma of Lung			
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	
Squamous Cell Carcinoma of Skin			

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	
Squamous Cell Carcinoma of the Oral Cavity			
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	
Squamous Cell Carcinoma of the Tongue			
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	
Tongue Neoplasm Malignant Stage Unspecified			
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	
Ureteric Cancer			
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	
Uterine Cancer			
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	
Uterine Leiomyoma			
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	
Vascular disorders			
Aortic Aneurysm			
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	
Post Thrombotic 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	
Vascular Insufficiency			
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	
Surgical and medical procedures			
Coronary Arterial Stent Insertion			
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	
Hospitalisation			
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	
Stent Placement			
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	
General disorders and administration site conditions			
Adverse Drug Reaction			
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	
Cardiac Death			
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	
Malaise			
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	
Non-Cardiac Chest Pain			
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	
Oedema Peripheral			
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	
Peripheral Swelling			
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	
Pyrexia			
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	
Sudden Cardiac Death			
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	
Sudden Death			
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	
Vascular Stent Restenosis			

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	
Prostatomegaly			
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	
Uterine Polyp			
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	
Uterine Prolapse			
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	
Respiratory, thoracic and mediastinal disorders			
Acute Pulmonary Oedema			
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	
Acute Respiratory Distress Syndrome			
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	
Acute Respiratory Failure			
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	
Asthma			
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	
Asthmatic Crisis			

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	
Atelectasis			
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	
Bronchitis Chronic			
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	
Bronchospasm			
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	
Chronic Obstructive Pulmonary Disease			
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	
Cough			
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	
Dyspnoea			
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	
Epistaxis			
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	
Haemoptysis			

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	
Haemothorax			
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	
Hypoventilation			
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	
Mediastinal Effusion			
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	
Nasal Obstruction			
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	
Pleural Effusion			
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	
Pneumonia Aspiration			
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	
Pneumothorax			
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 Embolism			

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	
Pulmonary 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	
Pulmonary Mass			
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 Oedema			
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	
Pulmonary Sarcoidosis			
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	
Respiratory Acidosis			
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	
Respiratory Alkalosis			
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	
Respiratory Failure			
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	
Sleep Apnoea Syndrome			

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	
Major 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	
Psychotic 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	
Suicidal Ideation			
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	
Suicide Attempt			
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	
Product issues			
Device Breakage			
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	
Device Loosening			
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 Malfunction			
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	
Patient-Device Incompatibility			

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	
Hepatobiliary disorders			
Bile Duct Stone			
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	
Biliary Colic			
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	
Cholangitis			
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	
Cholangitis 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	
Cholecystitis			
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	
Cholecystitis Acute			
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	
Cholelithiasis			
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	
Cholelithiasis Obstructive			

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	
Gallbladder Polyp			
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	
Haemobilia			
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	
Hepatic Cirrhosis			
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	
Hepatic Lesion			
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	
Hydrocholecystis			
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	
Jaundice Cholestatic			
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 Injury			
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	
Non-Alcoholic Steatohepatitis			

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	
Investigations			
Arteriogram Coronary			
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	
Blood Creatinine 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	
Blood Glucose Increased			
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	
Ejection Fraction 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	
Electrocardiogram QT Prolonged			
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	
Electrocardiogram St-T Change			
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	
Electrocardiogram T Wave Inversion			
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	
International Normalised Ratio Increased			

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	
Craniocerebral 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	
Femur Fracture			
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	
Fibula 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	
Foot Fracture			
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	
Fractured Coccyx			
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	
Hand Fracture			
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	
Head Injury			
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	
Hip Fracture			
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	
Humerus Fracture			

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	
Jaw 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	
Joint Dislocation			
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	
Laceration			
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	
Ligament Sprain			
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	
Limb Crushing Injury			
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	
Limb Injury			
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	
Lumbar Vertebral Fracture			
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	
Meniscus Injury			

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	
Patella 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	
Pneumocephalus			
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	
Post Laminectomy 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	
Post Procedural Haematoma			
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 Haematuria			
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	
Post Procedural Haemorrhage			
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	
Postoperative Hernia			
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	
Postoperative Respiratory Failure			

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	
Subdural 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	
Suture Related Complication			
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	
Tendon 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	
Tendon Rupture			
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	
Thermal Burn			
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	
Thoracic Vertebral 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	
Tibia Fracture			
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	
Toxicity to Various Agents			

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	
Aortic Valve Incompetence			
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	
Arrhythmia			
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	
Arteriosclerosis Coronary Artery			
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	
Atrial Fibrillation			
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	
Atrial Flutter			
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	
Atrial Tachycardia			
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	
Atrioventricular Block Complete			
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	
Atrioventricular Block Second Degree			

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	
Bradycardia			
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	
Cardiac Arrest			
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	
Cardiac 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	
Cardiac Failure			
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	
Cardiac Failure Acute			
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	
Cardiac Failure Chronic			
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	
Cardiac Failure Congestive			
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	
Cardiac Valve Disease			

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	
Cardio-Respiratory Arrest			
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	
Cardiogenic Shock			
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	
Cardiopulmonary Failure			
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	
Conduction 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	
Congestive 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 / 0	0 / 0	
Coronary Artery Disease			
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	
Coronary Artery Insufficiency			
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	
Coronary Artery Occlusion			

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	
Myocardial Ischaemia			
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	
Pericardial Effusion			
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	
Pericarditis			
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	
Prinzmetal Angina			
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	
Right Ventricular Failure			
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	
Sinus Bradycardia			
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	
Sinus Node Dysfunction			
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	
Supraventricular Tachycardia			

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	
Brain Injury			
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	
Brain Stem Infarction			
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	
Brain Stem Stroke			
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	
Carotid Arteriosclerosis			
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	
Carotid 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	
Carotid Artery Stenosis			
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	
Carpal Tunnel Syndrome			
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	
Cerebellar Infarction			

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	
Cerebral Haematoma			
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 Haemorrhage			
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	
Cerebral Infarction			
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	
Cerebral Ischaemia			
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	
Cerebrovascular Accident			
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	
Cervicobrachial Syndrome			
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	
Cognitive Disorder			
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	
Diabetic Mononeuropathy			

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	
Nerve Compression			
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	
Neuralgia			
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	
Paraesthesia			
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 Nerve Paresis			
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	
Presyncope			
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	
Radiculopathy			
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	
Sciatica			
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	
Seizure			

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	
Sensory Loss			
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	
Spinal Cord Compression			
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	
Syncope			
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	
Thalamic 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	
Toxic Encephalopathy			
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	
Transient Ischaemic Attack			
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	
Tremor			
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	
Trigeminal Neuralgia			

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 Encephalopathy			
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 Headache			
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	
Vertebral 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	
Vertebrobasilar Insufficiency			
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	
Vocal Cord Paralysis			
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	
Blood and lymphatic system disorders			
Anaemia			
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	
Febrile Neutropenia			
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	
Iron Deficiency Anaemia			

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	
Polycythaemia			
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	
Thrombocytopenia			
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	
Ear and labyrinth disorders			
Haematotympanum			
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	
Hypoacusis			
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	
Vertigo			
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	
Eye disorders			
Amaurosis Fugax			
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	
Cataract			
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	
Diabetic Retinopathy			

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	
Bowel Movement Irregularity			
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	
Colitis			
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	
Colitis Ischaemic			
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	
Colitis Microscopic			
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	
Colitis Ulcerative			
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	
Colonic Pseudo-Obstruction			
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	
Constipation			
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	
Diarrhoea			

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	
Intestinal Ischaemia			
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	
Intestinal Obstruction			
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	
Intestinal 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	
Large Intestine Perforation			
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	
Lower Gastrointestinal Haemorrhage			
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	
Melaena			
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	
Mesenteric Arterial Occlusion			
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	
Mesenteric Vein Thrombosis			

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	
Oesophageal Obstruction			
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	
Pancreatitis			
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	
Pancreatitis Acute			
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	
Peptic Ulcer			
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	
Pneumoperitoneum			
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	
Rectal Tenesmus			
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	
Salivary Gland Calculus			
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	
Salivary Gland Fistula			

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	
Small Intestinal Obstruction			
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	
Swollen Tongue			
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	
Tooth 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	
Umbilical Hernia			
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	
Upper Gastrointestinal Haemorrhage			
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	
Volvulus			
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	
Skin and subcutaneous tissue disorders			
Angioedema			
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	
Dermatitis Allergic			

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 Foot			
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	
Diabetic 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	
Skin Fissures			
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	
Skin Necrosis			
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	
Skin Ulcer			
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	
Urticaria			
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	
Renal and urinary disorders			
Acute Kidney Injury			
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	
Bladder Obstruction			

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	
Nephrotic Syndrome			
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	
Pelvi-Ureteric Obstruction			
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	
Pollakiuria			
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	
Proteinuria			
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	
Renal Colic			
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	
Renal Failure			
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	
Renal Haematoma			
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	
Renal Impairment			

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	
Renal Injury			
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	
Stress Urinary Incontinence			
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	
Tubulointerstitial Nephritis			
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	
Ureterolithiasis			
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	
Urethral 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	
Urinary Incontinence			
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	
Urinary Retention			
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	
Endocrine disorders			
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	
Cervical Spinal 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	
Costochondritis			
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	
Dactylitis			
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	
Dupuytren's Contracture			
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	
Extremity Contracture			
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	
Foot Deformity			
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	
Intervertebral Disc Compression			
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	
Intervertebral Disc Disorder			

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	
Intervertebral Disc Protrusion			
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	
Knee Deformity			
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	
Lumbar Spinal Stenosis			
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	
Muscular Weakness			
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	
Musculoskeletal Chest Pain			
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	
Musculoskeletal Pain			
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	
Osteitis			
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	
Osteoarthritis			

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	
Osteonecrosis			
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	
Pathological 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	
Plantar Fasciitis			
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	
Polymyalgia Rheumatica			
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	
Rhabdomyolysis			
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	
Rotator Cuff Syndrome			
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	
Sacroiliitis			
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	
Spinal Column Stenosis			

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	
Spinal Osteoarthritis			
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	
Spinal Pain			
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	
Spondylolisthesis			
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	
Synovial 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	
Tendonitis			
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	
Tenosynovitis			
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	
Tenosynovitis Stenosans			
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	
Trigger Finger			

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	
Infections and infestations			
Abscess			
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	
Abscess Limb			
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	
Abscess Neck			
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	
Appendicitis			
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	
Arthritis Bacterial			
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	
Bronchitis			
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	
Campylobacter Gastroenteritis			
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	
Carbuncle			

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	
Diverticulitis			
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	
Ear 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	
Empyema			
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	
Endocarditis			
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	
Epididymitis			
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	
Erysipelas			
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	
Escherichia 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	
Escherichia Sepsis			

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	
Escherichia Urinary Tract Infection			
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	
Eye 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	
Gangrene			
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	
Gastroenteritis			
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	
Gastroenteritis Viral			
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	
Genital Infection Fungal			
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	
Hepatitis 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	
Herpes Zoster			

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	
Hiv 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	
Infected Dermal 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	
Infected Skin Ulcer			
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	
Infection			
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	
Infective Exacerbation of Chronic Obstructive Airways Disease			
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	
Influenza			
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	
Intervertebral Discitis			
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	
Laryngitis			

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	
Parasitic Gastroenteritis			
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	
Paronychia			
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	
Pelvic Abscess			
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	
Penile Abscess			
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	
Perinephric Abscess			
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	
Peritonsillar Abscess			
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	
Pharyngotonsillitis			
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	
Pneumococcal 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	
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	
Pyelonephritis			
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	
Pyelonephritis Acute			
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	
Respiratory Tract Infection			
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	
Scrotal 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	
Scrotal 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	
Sepsis			
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	
Septic Shock			
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	
Sinusitis			

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	
Diabetes Mellitus			
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	
Diabetes Mellitus Inadequate Control			
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	
Diabetic 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	
Diabetic Ketoacidosis			
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	
Electrolyte Imbalance			
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	
Fluid Overload			
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	
Gout			
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	
Hyperglycaemia			

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	
Metabolic Acidosis			
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	
Obesity			
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	
Type 2 Diabetes Mellitus			
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 %

Non-serious adverse events	Placebo	Canagliflozin	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	25 / 2903 (0.86%)	94 / 2904 (3.24%)	
Reproductive system and breast disorders			
Balanoposthitis			
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:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported