



Clinical trial results:

A phase III, double-blind, randomized placebo-controlled study to evaluate the effects of dalcetrapib on cardiovascular (CV) risk in a genetically defined population with a recent Acute Coronary Syndrome (ACS): The dal-GenE trial

Summary

EudraCT number	2015-003895-65
Trial protocol	NL BE SE SK DK FI PT DE HU ES AT CZ BG RO PL GB IT
Global end of trial date	23 June 2021

Results information

Result version number	v1 (current)
This version publication date	24 September 2022
First version publication date	24 September 2022

Trial information

Trial identification

Sponsor protocol code	DAL-301
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02525939
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	DalCor Pharma UK Ltd.
Sponsor organisation address	Leatherhead, Swiss Branch, Zug Baarerstrasse 2, Zug, Switzerland, CH-6302
Public contact	Donald M. Black, DalCor Pharma, Dblack@dalcorpharma.com
Scientific contact	Donald M. Black, DalCor Pharma, Dblack@dalcorpharma.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	20 May 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	23 June 2021
Global end of trial reached?	Yes
Global end of trial date	23 June 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this trial is to evaluate the potential of dalcetrapib to reduce cardiovascular morbidity and mortality (cardiovascular death, resuscitated cardiac arrest, non-fatal myocardial infarction (MI) and non-fatal stroke) in subjects with a documented recent ACS and the AA genotype at variant rs1967309 in the ADCY9 gene.

Protection of trial subjects:

All considerations regarding the protection of human subjects were carried out in accordance with the protocol, GCP, ICH Guidelines, the ethical principles that have their origin in the Declaration of Helsinki, and all applicable regulatory requirements. The investigator (according to applicable regulatory requirements) or a person designated by the investigator and under the investigator's responsibility fully informed patients of all pertinent aspects of the clinical trial.

Background therapy:

Dalcetrapib and matching placebo were taken on a background of contemporary evidence-based medical care for status post-ACS, as individually prescribed by the treating physician.

Evidence for comparator: -

Actual start date of recruitment	13 April 2016
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	Israel: 373
Country: Number of subjects enrolled	Russian Federation: 455
Country: Number of subjects enrolled	Switzerland: 36
Country: Number of subjects enrolled	Turkey: 57
Country: Number of subjects enrolled	United Arab Emirates: 16
Country: Number of subjects enrolled	Australia: 202
Country: Number of subjects enrolled	New Zealand: 150
Country: Number of subjects enrolled	Argentina: 148
Country: Number of subjects enrolled	Brazil: 431
Country: Number of subjects enrolled	Canada: 437
Country: Number of subjects enrolled	United States: 728
Country: Number of subjects enrolled	Chile: 94
Country: Number of subjects enrolled	South Africa: 222
Country: Number of subjects enrolled	Puerto Rico: 14
Country: Number of subjects enrolled	Netherlands: 276

Country: Number of subjects enrolled	Poland: 335
Country: Number of subjects enrolled	Portugal: 54
Country: Number of subjects enrolled	Romania: 179
Country: Number of subjects enrolled	Slovakia: 48
Country: Number of subjects enrolled	Spain: 188
Country: Number of subjects enrolled	Sweden: 66
Country: Number of subjects enrolled	United Kingdom: 382
Country: Number of subjects enrolled	Austria: 50
Country: Number of subjects enrolled	Belgium: 39
Country: Number of subjects enrolled	Bulgaria: 384
Country: Number of subjects enrolled	Czechia: 152
Country: Number of subjects enrolled	Denmark: 137
Country: Number of subjects enrolled	Finland: 20
Country: Number of subjects enrolled	France: 99
Country: Number of subjects enrolled	Germany: 69
Country: Number of subjects enrolled	Hungary: 183
Country: Number of subjects enrolled	Italy: 123
Worldwide total number of subjects	6147
EEA total number of subjects	2402

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)	3711
From 65 to 84 years	2397
85 years and over	39

Subject disposition

Recruitment

Recruitment details:

Screening procedures were performed at the time of the index ACS event or anytime thereafter, with the condition that the randomization window must have occurred within the mandated window (1 to 3 months after the index event).

Pre-assignment

Screening details:

Subjects were assessed based on their medical history. Those who were likely to qualify were consented, had a blood test obtained, and underwent a cobas® ADCY9 Genotype Clinical Trial Assay. Those patients who met the genetic testing criteria, all the other inclusion criteria, and none of the exclusion criteria were eligible for randomization.

Period 1

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

Blinding implementation details:

The blind during the study was maintained by administration of 2 matching placebo tablets to patients in the placebo group. Furthermore, the project teams of DalCor, the CROs, as well as the Investigator and his or her study personnel were blinded with respect to levels of HDL-C so as not to reveal patients' assignment to 1 of the 2 treatment groups. Levels of triglycerides (TG) and LDL-C values were not blinded to allow for appropriate patient management.

Arms

Are arms mutually exclusive?	Yes
Arm title	Dalcetrapib 600 mg

Arm description:

Patients recently hospitalized for an ACS (between 1 month and 3 months after the index event). Dalcetrapib was provided as 300 mg film-coated tablets. Patients received 600 mg of dalcetrapib (2 tablets) once daily, preferably with the largest meal of the day. Dalcetrapib was taken on a background of contemporary evidence-based medical care for ACS, including aspirin, clopidogrel, beta-blockers, angiotensin-converting enzyme inhibitors, and statins; and medication for optimal control of hypertension, angina, and diabetes. Patients were allowed to reduce dose to 300 mg once daily or temporarily interrupt study drug as deemed necessary due to physician assessment.

Patients visited the clinic 1 month and 6 months after randomization and every 6 months thereafter. The study lasted until approximately 582 patients experienced a primary event, at which time the sites were contacted and asked to bring their patients in for final visits.

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

Dosage and administration details:

Dalcetrapib was provided as film-coated tablets of 300 mg.

Patients received 600 mg of dalcetrapib (2 tablets) once daily. Study medication was taken with food, preferably with the largest meal of the day. Patients were instructed to take study medication with the same meal throughout the study.

Study medication kits were dispensed at every visit. Study medication was packaged in boxes containing 7 bottles each. Each bottle contained study medication for one month, i.e., 60 pills (2 x 300 mg tablets per day). A box thus contained study medication for 7 months.

Arm title	Placebo 600 mg
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Arm description:

Patients recently hospitalized for an ACS (between 1 month and 3 months after the index event).

Matching placebo was provided as 300 mg film-coated tablets. Patients received 600 mg of matching placebo (2 tablets) once daily, preferably with the largest meal of the day.

The placebo was taken on a background of contemporary evidence-based medical care for ACS, including aspirin, clopidogrel, beta-blockers, angiotensin-converting enzyme inhibitors, and statins; and medication for optimal control of hypertension, angina, and diabetes.

Patients visited the clinic 1 month and 6 months after randomization and every 6 months thereafter. The study lasted until approximately 582 patients experienced a primary event, at which time the sites were contacted and asked to bring their patients in for final visits.

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

Dosage and administration details:

Matching placebo was provided as film-coated tablets of 300 mg.

Patients received 600 mg of matching placebo (2 tablets) once daily. Study medication was taken with food, preferably with the largest meal of the day. Patients were instructed to take study medication with the same meal throughout the study.

Study medication kits were dispensed at every visit. Study medication was packaged in boxes containing 7 bottles each. Each bottle contained study medication for one month, i.e., 60 pills (2 x 300 mg tablets per day). A box thus contained study medication for 7 months.

Number of subjects in period 1	Dalcetrapib 600 mg	Placebo 600 mg
Started	3071	3076
Completed	2840	2833
Not completed	231	243
Adverse event, serious fatal	180	179
Consent withdrawn by subject	24	39
Physician decision	-	1
Lost to follow-up	27	24

Baseline characteristics

Reporting groups

Reporting group title	Dalcetrapib 600 mg
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Reporting group description:

Patients recently hospitalized for an ACS (between 1 month and 3 months after the index event). Dalcetrapib was provided as 300 mg film-coated tablets. Patients received 600 mg of dalcetrapib (2 tablets) once daily, preferably with the largest meal of the day. Dalcetrapib was taken on a background of contemporary evidence-based medical care for ACS, including aspirin, clopidogrel, beta-blockers, angiotensin-converting enzyme inhibitors, and statins; and medication for optimal control of hypertension, angina, and diabetes. Patients were allowed to reduce dose to 300 mg once daily or temporarily interrupt study drug as deemed necessary due to physician assessment.

Patients visited the clinic 1 month and 6 months after randomization and every 6 months thereafter. The study lasted until approximately 582 patients experienced a primary event, at which time the sites were contacted and asked to bring their patients in for final visits.

Reporting group title	Placebo 600 mg
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Reporting group description:

Patients recently hospitalized for an ACS (between 1 month and 3 months after the index event). Matching placebo was provided as 300 mg film-coated tablets. Patients received 600 mg of matching placebo (2 tablets) once daily, preferably with the largest meal of the day. The placebo was taken on a background of contemporary evidence-based medical care for ACS, including aspirin, clopidogrel, beta-blockers, angiotensin-converting enzyme inhibitors, and statins; and medication for optimal control of hypertension, angina, and diabetes.

Patients visited the clinic 1 month and 6 months after randomization and every 6 months thereafter. The study lasted until approximately 582 patients experienced a primary event, at which time the sites were contacted and asked to bring their patients in for final visits.

Reporting group values	Dalcetrapib 600 mg	Placebo 600 mg	Total
Number of subjects	3071	3076	6147
Age categorical			
Units: Subjects			

Age continuous			
Units: years			
arithmetic mean	62.19	62.34	
standard deviation	± 9.16	± 9.25	-
Gender categorical			
Units: Subjects			
Female	723	672	1395
Male	2348	2404	4752

End points

End points reporting groups

Reporting group title	Dalcetrapib 600 mg
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Reporting group description:

Patients recently hospitalized for an ACS (between 1 month and 3 months after the index event). Dalcetrapib was provided as 300 mg film-coated tablets. Patients received 600 mg of dalcetrapib (2 tablets) once daily, preferably with the largest meal of the day. Dalcetrapib was taken on a background of contemporary evidence-based medical care for ACS, including aspirin, clopidogrel, beta-blockers, angiotensin-converting enzyme inhibitors, and statins; and medication for optimal control of hypertension, angina, and diabetes. Patients were allowed to reduce dose to 300 mg once daily or temporarily interrupt study drug as deemed necessary due to physician assessment. Patients visited the clinic 1 month and 6 months after randomization and every 6 months thereafter. The study lasted until approximately 582 patients experienced a primary event, at which time the sites were contacted and asked to bring their patients in for final visits.

Reporting group title	Placebo 600 mg
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Reporting group description:

Patients recently hospitalized for an ACS (between 1 month and 3 months after the index event). Matching placebo was provided as 300 mg film-coated tablets. Patients received 600 mg of matching placebo (2 tablets) once daily, preferably with the largest meal of the day. The placebo was taken on a background of contemporary evidence-based medical care for ACS, including aspirin, clopidogrel, beta-blockers, angiotensin-converting enzyme inhibitors, and statins; and medication for optimal control of hypertension, angina, and diabetes. Patients visited the clinic 1 month and 6 months after randomization and every 6 months thereafter. The study lasted until approximately 582 patients experienced a primary event, at which time the sites were contacted and asked to bring their patients in for final visits.

Primary: Primary endpoint

End point title	Primary endpoint
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End point description:

The primary endpoint of this study was the time from randomization to first occurrence of any component of the composite event as adjudicated by the Clinical Endpoints Committee (CEC). Components of the primary composite were cardiovascular (CV) death, resuscitated cardiac arrest, non-fatal myocardial infarction (MI) and non-fatal stroke. Time to event (or censoring) was calculated as the difference (in days) between the randomization date and the date of first occurrence of an adjudicated event (or censoring date in patients without event) plus 1 day. One patient population was used for analysis of data for this study, the Intent-to-Treat (ITT) population. A stratified Cox proportional hazards model was used to analyze the primary endpoint.

End point type	Primary
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End point timeframe:

There was no minimum or maximum study treatment duration defined for this study, but the expected overall duration was 54 months including recruitment and follow-up.

End point values	Dalcetrapib 600 mg	Placebo 600 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3071	3076		
Units: patients	3071	3076		

Statistical analyses

Statistical analysis title	Cox proportional hazards model
Statistical analysis description:	
A stratified Cox proportional hazards model was used to analyze the primary endpoint. Time to event started at randomization and subjects who were event-free were censored at the time that they were last known to be event-free. The null and alternative hypotheses tested with the above Cox model were: $H_0: \lambda = 1$ versus. $H_A: \lambda \neq 1$, where λ is the, assumed constant, HR for the time to occurrence of the composite events of the primary endpoint for the dalcetrapib and placebo treated groups.	
Comparison groups	Dalcetrapib 600 mg v Placebo 600 mg
Number of subjects included in analysis	6147
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.12
Method	Stratified Cox proportional hazards mode
Parameter estimate	Hazard ratio (HR)
Point estimate	0.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.75
upper limit	1.03
Variability estimate	Standard deviation

Secondary: Secondary endpoint-1

End point title	Secondary endpoint-1
End point description:	
Time to first Occurrence of any component of the composite endpoint of CV death, resuscitated cardiac arrest, non-fatal MI, non-fatal stroke, hospitalization for ACS (with ECG abnormalities) or unanticipated coronary revascularization	
Time to event (or censoring) was calculated as the difference (in days) between the randomization date and the date of first occurrence of an adjudicated event (or censoring date in patients without event) plus 1 day.	
One patient population was used for analysis of data for this study, the Intent-to-Treat (ITT) population.	
End point type	Secondary
End point timeframe:	
There was no minimum or maximum study treatment duration defined for this study, but the expected overall duration was 54 months including recruitment and follow-up.	

End point values	Dalcetrapib 600 mg	Placebo 600 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3071	3076		
Units: patients	3071	3076		

Statistical analyses

Statistical analysis title	Cox proportional hazards model
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Statistical analysis description:

A stratified Cox proportional hazards model was used to analyze the primary endpoint. Time to event started at randomization and subjects who were event-free were censored at the time that they were last known to be event-free. The null and alternative hypotheses tested with the above Cox model were: $H_0: \lambda = 1$ versus. $H_A: \lambda \neq 1$, where λ is the, assumed constant, HR for the time to occurrence of the composite events of the secondary endpoint for the dalcetrapib and placebo treated groups

Comparison groups	Placebo 600 mg v Dalcetrapib 600 mg
Number of subjects included in analysis	6147
Analysis specification	Pre-specified
Analysis type	other ^[1]
P-value	= 0.945 ^[2]
Method	Stratified Cox proportional hazards mode
Parameter estimate	Cox proportional hazard
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.13
Variability estimate	Standard deviation

Notes:

[1] - Cox proportional hazards model

[2] - Results demonstrated that patients with the AA genotype at variant rs1967309 in the ADCY9 gene experienced no reduction in the risk for any component of the composite endpoint.

Secondary: Secondary endpoint-2

End point title	Secondary endpoint-2
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End point description:

Time to first occurrence of any component of the composite endpoint of CV death, resuscitated cardiac arrest, non-fatal MI, non-fatal stroke or hospitalization for new or worsening heart failure.

Time to event (or censoring) was calculated as the difference (in days) between the randomization date and the date of first occurrence of an adjudicated event (or censoring date in patients without event) plus 1 day.

One patient population was used for analysis of data for this study, the Intent-to-Treat (ITT) population. A stratified Cox proportional hazards model was used to analyze the primary endpoint.

End point type	Secondary
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End point timeframe:

There was no minimum or maximum study treatment duration defined for this study, but the expected overall duration was 54 months including recruitment and follow-up.

End point values	Dalcetrapib 600 mg	Placebo 600 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3071	3076		
Units: patients	3071	3076		

Statistical analyses

Statistical analysis title	Cox proportional hazards model
Statistical analysis description:	
A stratified Cox proportional hazards model was used to analyze the primary endpoint. Time to event started at randomization and subjects who were event-free were censored at the time that they were last known to be event-free. The null and alternative hypotheses tested with the above Cox model were: H0: $\lambda = 1$ versus. HA: $\lambda \neq 1$, where λ is the, assumed constant, HR for the time to occurrence of the composite events of the secondary endpoint for the dalcetrapib and placebo treated groups.	
Comparison groups	Dalcetrapib 600 mg v Placebo 600 mg
Number of subjects included in analysis	6147
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.27 ^[3]
Method	Stratified Cox proportional hazards mode
Parameter estimate	Cox proportional hazard
Point estimate	0.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	1.07
Variability estimate	Standard deviation

Notes:

[3] - Treatment with dalcetrapib failed to meet the pre-specified threshold for a positive outcome in regards to the secondary endpoint-2.

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse event monitoring starts from the time the patient consents to the study until they complete the trial

Adverse event reporting additional description:

A Treatment-emergent adverse event (TEAE) was defined as an adverse event (AE) that occurred on or after the administration of the first dose of study drug.

Assessment type	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 600 mg
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Reporting group description:

Patients recently hospitalized for an ACS (between 1 month and 3 months after the index event).

Matching placebo was provided as 300 mg film-coated tablets. Patients received 600 mg of matching placebo (2 tablets) once daily, preferably with the largest meal of the day.

The placebo was taken on a background of contemporary evidence-based medical care for ACS, including aspirin, clopidogrel, beta-blockers, angiotensin-converting enzyme inhibitors, and statins; and medication for optimal control of hypertension, angina, and diabetes.

Patients visited the clinic 1 month and 6 months after randomization and every 6 months thereafter. The study lasted until approximately 582 patients experienced a primary event, at which time the sites were contacted and asked to bring their patients in for final visits.

Reporting group title	Dalcetrapib 600 mg
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Reporting group description:

Patients recently hospitalized for an ACS (between 1 month and 3 months after the index event).

Dalcetrapib was provided as 300 mg film-coated tablets. Patients received 600 mg of dalcetrapib (2 tablets) once daily, preferably with the largest meal of the day.

Dalcetrapib was taken on a background of contemporary evidence-based medical care for ACS, including aspirin, clopidogrel, beta-blockers, angiotensin-converting enzyme inhibitors, and statins; and medication for optimal control of hypertension, angina, and diabetes. Patients were allowed to reduce dose to 300 mg once daily or temporarily interrupt study drug as deemed necessary due to physician assessment.

Patients visited the clinic 1 month and 6 months after randomization and every 6 months thereafter. The study lasted until approximately 582 patients experienced a primary event, at which time the sites were contacted and asked to bring their patients in for final visits.

Serious adverse events	Placebo 600 mg	Dalcetrapib 600 mg	
Total subjects affected by serious adverse events			
subjects affected / exposed	923 / 3076 (30.01%)	900 / 3071 (29.31%)	
number of deaths (all causes)	179	180	
number of deaths resulting from adverse events	133	127	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Abdominal neoplasm			

subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute leukaemia			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Acute myeloid leukaemia			
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Adenocarcinoma			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (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	6 / 3076 (0.20%)	3 / 3071 (0.10%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
Anal squamous cell carcinoma			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atypical fibroxanthoma			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Basal cell carcinoma			
subjects affected / exposed	1 / 3076 (0.03%)	5 / 3071 (0.16%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign lung neoplasm			

subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign neoplasm of prostate			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (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	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder cancer			
subjects affected / exposed	9 / 3076 (0.29%)	3 / 3071 (0.10%)	
occurrences causally related to treatment / all	1 / 9	0 / 3	
deaths causally related to treatment / all	0 / 2	0 / 0	
Bladder neoplasm			
subjects affected / exposed	0 / 3076 (0.00%)	4 / 3071 (0.13%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder transitional cell carcinoma			
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain neoplasm			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer			
subjects affected / exposed	3 / 3076 (0.10%)	6 / 3071 (0.20%)	
occurrences causally related to treatment / all	0 / 3	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer metastatic			

subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (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 II			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cancer pain			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carcinoid tumour			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervix carcinoma			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Chest wall tumour			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholesteatoma			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic lymphocytic leukaemia			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic lymphocytic leukaemia stage 1			

subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon adenoma			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon cancer			
subjects affected / exposed	8 / 3076 (0.26%)	4 / 3071 (0.13%)	
occurrences causally related to treatment / all	0 / 8	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 1	
Colon cancer metastatic			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Colon cancer stage IV			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon neoplasm			
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colorectal cancer			
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diffuse large B-cell lymphoma			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial sarcoma			

subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Epstein-Barr virus associated lymphoma			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Extranodal marginal zone B-cell lymphoma (MALT type)			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric cancer			
subjects affected / exposed	2 / 3076 (0.07%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Giant cell tumour of tendon sheath			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glioblastoma			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Glioma			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cancer			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hepatic cancer recurrent			

subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hepatocellular carcinoma			
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hodgkin's disease			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Intestinal adenocarcinoma			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intraductal proliferative breast lesion			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (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	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal cancer			
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Laryngeal papilloma			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leiomyoma			

subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lip and/or oral cavity cancer			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lipoma			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung adenocarcinoma			
subjects affected / exposed	0 / 3076 (0.00%)	3 / 3071 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Lung adenocarcinoma metastatic			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung adenocarcinoma stage III			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung cancer metastatic			
subjects affected / exposed	3 / 3076 (0.10%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 1	
Lung neoplasm			
subjects affected / exposed	3 / 3076 (0.10%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Lung neoplasm malignant			

subjects affected / exposed	5 / 3076 (0.16%)	6 / 3071 (0.20%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 2	0 / 3	
Lymphoma			
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant melanoma			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Malignant melanoma in situ			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant polyp			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningioma			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to adrenals			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to bone			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metastases to liver			

subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Metastases to lung			
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 1	
Metastases to lymph nodes			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic carcinoma of the bladder			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metastatic neoplasm			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metastatic renal cell carcinoma			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myelodysplastic syndrome			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myeloproliferative neoplasm			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Neoplasm malignant			

subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neoplasm prostate			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuroendocrine carcinoma			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuroendocrine carcinoma metastatic			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuroendocrine tumour			
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-Hodgkin's lymphoma			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (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 metastatic			
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Oesophageal adenocarcinoma			
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Oesophageal carcinoma			

subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Oesophageal neoplasm			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oropharyngeal neoplasm			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian epithelial cancer			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pancreatic carcinoma			
subjects affected / exposed	6 / 3076 (0.20%)	3 / 3071 (0.10%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	0 / 3	0 / 1	
Pancreatic carcinoma metastatic			
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Parathyroid tumour benign			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Plasma cell myeloma			
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Plasma cell myeloma recurrent			

subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural neoplasm			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polycythaemia vera			
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer			
subjects affected / exposed	27 / 3076 (0.88%)	10 / 3071 (0.33%)	
occurrences causally related to treatment / all	1 / 28	0 / 10	
deaths causally related to treatment / all	0 / 1	0 / 0	
Prostate cancer metastatic			
subjects affected / exposed	4 / 3076 (0.13%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 3	0 / 0	
Prostate cancer recurrent			
subjects affected / exposed	5 / 3076 (0.16%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer stage I			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal adenocarcinoma			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (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	2 / 3076 (0.07%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Renal cancer			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cell carcinoma			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Renal neoplasm			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small cell lung cancer metastatic			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Small intestine carcinoma			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma			
subjects affected / exposed	2 / 3076 (0.07%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Squamous cell carcinoma of lung			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Thyroid cancer			

subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tongue neoplasm			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transitional cell cancer of the renal pelvis and ureter			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transitional cell carcinoma			
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Tumour haemorrhage			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureteral neoplasm			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine leiomyoma			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Accelerated hypertension			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic aneurysm			

subjects affected / exposed	5 / 3076 (0.16%)	4 / 3071 (0.13%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 2	
Aortic aneurysm rupture			
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic dissection			
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic intramural haematoma			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic stenosis			
subjects affected / exposed	9 / 3076 (0.29%)	4 / 3071 (0.13%)	
occurrences causally related to treatment / all	0 / 9	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial insufficiency			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Arterial occlusive disease			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial perforation			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial stenosis			

subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (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	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Arteritis			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood pressure inadequately controlled			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deep vein thrombosis			
subjects affected / exposed	1 / 3076 (0.03%)	4 / 3071 (0.13%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolism arterial			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolism venous			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extremity necrosis			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematoma			

subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertension			
subjects affected / exposed	10 / 3076 (0.33%)	7 / 3071 (0.23%)	
occurrences causally related to treatment / all	1 / 10	1 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive crisis			
subjects affected / exposed	5 / 3076 (0.16%)	6 / 3071 (0.20%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive emergency			
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			
subjects affected / exposed	7 / 3076 (0.23%)	7 / 3071 (0.23%)	
occurrences causally related to treatment / all	0 / 9	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypovolaemic shock			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intermittent claudication			
subjects affected / exposed	3 / 3076 (0.10%)	3 / 3071 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Internal haemorrhage			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemia			

subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Lymphocele			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant hypertension			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orthostatic hypotension			
subjects affected / exposed	2 / 3076 (0.07%)	5 / 3071 (0.16%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral arterial occlusive disease			
subjects affected / exposed	5 / 3076 (0.16%)	7 / 3071 (0.23%)	
occurrences causally related to treatment / all	0 / 6	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery aneurysm			
subjects affected / exposed	2 / 3076 (0.07%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery occlusion			
subjects affected / exposed	3 / 3076 (0.10%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery stenosis			
subjects affected / exposed	4 / 3076 (0.13%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 7	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral embolism			

subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral ischaemia			
subjects affected / exposed	5 / 3076 (0.16%)	4 / 3071 (0.13%)	
occurrences causally related to treatment / all	0 / 7	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	
Peripheral vascular disorder			
subjects affected / exposed	2 / 3076 (0.07%)	7 / 3071 (0.23%)	
occurrences causally related to treatment / all	0 / 4	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Phlebitis			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shock			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Shock haemorrhagic			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thromboangiitis obliterans			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombophlebitis			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombophlebitis superficial			

subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombosis			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicose vein			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vasculitis			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous thrombosis limb			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Aneurysm repair			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angioplasty			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthrodesis			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atherectomy			

subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood pressure management			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone lesion excision			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac ablation			
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac pacemaker insertion			
subjects affected / exposed	3 / 3076 (0.10%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac pacemaker replacement			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac rehabilitation therapy			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac resynchronisation therapy			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract operation			

subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystectomy			
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithotomy			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colostomy closure			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary angioplasty			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary arterial stent insertion			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery bypass			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary revascularisation			
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Finger amputation			

subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrectomy			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heart transplant			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatectomy			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hernia repair			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip arthroplasty			
subjects affected / exposed	3 / 3076 (0.10%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Implantable defibrillator insertion			
subjects affected / exposed	11 / 3076 (0.36%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 11	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Insertion of ambulatory peritoneal catheter			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Keratoplasty			

subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Knee arthroplasty			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Left atrial appendage occlusion			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb amputation			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lithotripsy			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Medical device change			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ophthalmic fluid drainage			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ossiculoplasty			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Percutaneous coronary intervention			

subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rehabilitation therapy			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal transplant			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft tissue flap operation			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stem cell transplant			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tooth extraction			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tumour excision			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral dilation procedure			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular graft			

subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitrectomy			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	2 / 3076 (0.07%)	3 / 3071 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac death			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Chest discomfort			
subjects affected / exposed	7 / 3076 (0.23%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 7	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest pain			
subjects affected / exposed	79 / 3076 (2.57%)	81 / 3071 (2.64%)	
occurrences causally related to treatment / all	0 / 93	0 / 104	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			
subjects affected / exposed	8 / 3076 (0.26%)	17 / 3071 (0.55%)	
occurrences causally related to treatment / all	0 / 8	0 / 17	
deaths causally related to treatment / all	0 / 8	0 / 17	
Drowning			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Drug intolerance			

subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Exercise tolerance decreased			
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fatigue			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General physical health deterioration			
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Generalised oedema			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Impaired self-care			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple organ dysfunction syndrome			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nodule			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-cardiac chest pain			

subjects affected / exposed	28 / 3076 (0.91%)	41 / 3071 (1.34%)	
occurrences causally related to treatment / all	0 / 40	0 / 45	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema peripheral			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pacemaker generated arrhythmia			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyp			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden cardiac death			
subjects affected / exposed	3 / 3076 (0.10%)	8 / 3071 (0.26%)	
occurrences causally related to treatment / all	0 / 3	0 / 8	
deaths causally related to treatment / all	0 / 3	0 / 8	
Sudden death			
subjects affected / exposed	14 / 3076 (0.46%)	16 / 3071 (0.52%)	
occurrences causally related to treatment / all	0 / 14	1 / 16	
deaths causally related to treatment / all	0 / 14	1 / 16	
Systemic inflammatory response syndrome			

subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent restenosis			
subjects affected / exposed	3 / 3076 (0.10%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent stenosis			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (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	1 / 3076 (0.03%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug hypersensitivity			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Food allergy			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypersensitivity			
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sarcoidosis			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Social circumstances			

Alcohol use			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sight disability			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	5 / 3076 (0.16%)	9 / 3071 (0.29%)	
occurrences causally related to treatment / all	0 / 5	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cyst			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast disorder			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial hyperplasia			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (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	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatomegaly			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Uterine polyp			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (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	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal prolapse			
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute respiratory failure			
subjects affected / exposed	8 / 3076 (0.26%)	6 / 3071 (0.20%)	
occurrences causally related to treatment / all	0 / 8	1 / 8	
deaths causally related to treatment / all	0 / 1	1 / 1	
Aspiration			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Asthma			
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchiectasis			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (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	2 / 3076 (0.07%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchopneumopathy			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchospasm			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bullous lung disease			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic obstructive pulmonary disease			
subjects affected / exposed	19 / 3076 (0.62%)	15 / 3071 (0.49%)	
occurrences causally related to treatment / all	0 / 34	0 / 18	
deaths causally related to treatment / all	0 / 2	0 / 0	
Chronic respiratory failure			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	8 / 3076 (0.26%)	16 / 3071 (0.52%)	
occurrences causally related to treatment / all	0 / 8	0 / 17	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea exertional			
subjects affected / exposed	3 / 3076 (0.10%)	3 / 3071 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epistaxis			

subjects affected / exposed	3 / 3076 (0.10%)	8 / 3071 (0.26%)	
occurrences causally related to treatment / all	0 / 3	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoptysis			
subjects affected / exposed	3 / 3076 (0.10%)	3 / 3071 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
Haemothorax			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxia			
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Interstitial lung disease			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal granuloma			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung disorder			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung infiltration			
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal obstruction			

subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-cardiogenic pulmonary oedema			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (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	2 / 3076 (0.07%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleuritic pain			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonitis			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax			
subjects affected / exposed	4 / 3076 (0.13%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax spontaneous			
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary arterial hypertension			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary congestion			

subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (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	3 / 3076 (0.10%)	7 / 3071 (0.23%)	
occurrences causally related to treatment / all	0 / 3	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pulmonary fibrosis			
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Pulmonary mass			
subjects affected / exposed	3 / 3076 (0.10%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary oedema			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Respiratory acidosis			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory failure			
subjects affected / exposed	4 / 3076 (0.13%)	8 / 3071 (0.26%)	
occurrences causally related to treatment / all	0 / 4	0 / 8	
deaths causally related to treatment / all	0 / 2	0 / 3	
Sleep apnoea syndrome			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vocal cord polyp			

subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Alcohol abuse			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol withdrawal syndrome			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcoholism			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aphasia			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Confusional state			
subjects affected / exposed	5 / 3076 (0.16%)	3 / 3071 (0.10%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Conversion disorder			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Delirium			

subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Depression			
subjects affected / exposed	3 / 3076 (0.10%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hallucinations, mixed			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mania			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mental status changes			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post-traumatic stress disorder			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychotic disorder			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Schizoaffective disorder			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Somatic symptom disorder			

subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Substance abuse			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicidal ideation			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
Device dislocation			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device material issue			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Acute hepatic failure			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct obstruction			
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stenosis			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stone			

subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary colic			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis			
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis acute			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis			
subjects affected / exposed	10 / 3076 (0.33%)	8 / 3071 (0.26%)	
occurrences causally related to treatment / all	0 / 12	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis acute			
subjects affected / exposed	4 / 3076 (0.13%)	8 / 3071 (0.26%)	
occurrences causally related to treatment / all	0 / 4	1 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis chronic			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis			
subjects affected / exposed	8 / 3076 (0.26%)	5 / 3071 (0.16%)	
occurrences causally related to treatment / all	0 / 8	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug-induced liver injury			

subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cyst			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic function abnormal			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic lesion			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis toxic			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatocellular injury			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaundice			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaundice cholestatic			

subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (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 / 3076 (0.00%)	1 / 3071 (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 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Angiogram			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriogram coronary			
subjects affected / exposed	1 / 3076 (0.03%)	4 / 3071 (0.13%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biopsy prostate			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood creatinine increased			
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood folate decreased			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood potassium increased			

subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood pressure increased			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac murmur			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac stress test abnormal			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid bruit			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Catheterisation cardiac			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Catheterisation cardiac abnormal			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystoscopy			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diagnostic procedure			

subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ejection fraction decreased			
subjects affected / exposed	3 / 3076 (0.10%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fibrin D dimer increased			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoglobin decreased			
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic enzyme increased			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (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 / 3076 (0.03%)	0 / 3071 (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 abnormal			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Occult blood positive			

subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic enzymes increased			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sleep study			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcus test positive			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stress echocardiogram abnormal			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Troponin increased			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureteroscopy			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Weight decreased			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Alcohol poisoning			

subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anastomotic complication			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anastomotic leak			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ankle fracture			
subjects affected / exposed	4 / 3076 (0.13%)	3 / 3071 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial bypass thrombosis			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial injury			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial restenosis			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stenosis traumatic			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical vertebral fracture			

subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest injury			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clavicle fracture			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Comminuted fracture			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Concussion			
subjects affected / exposed	0 / 3076 (0.00%)	3 / 3071 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Contusion			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery restenosis			
subjects affected / exposed	3 / 3076 (0.10%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Costal cartilage fracture			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Craniocerebral injury			

subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Electric shock			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Extradural haematoma			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye burns			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fall			
subjects affected / exposed	6 / 3076 (0.20%)	11 / 3071 (0.36%)	
occurrences causally related to treatment / all	0 / 6	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 1	
Femoral neck fracture			
subjects affected / exposed	4 / 3076 (0.13%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femur fracture			
subjects affected / exposed	6 / 3076 (0.20%)	5 / 3071 (0.16%)	
occurrences causally related to treatment / all	0 / 6	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fibula fracture			
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foreign body			

subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal stoma complication			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematuria traumatic			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (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	0 / 3076 (0.00%)	3 / 3071 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Head injury			
subjects affected / exposed	2 / 3076 (0.07%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip fracture			
subjects affected / exposed	1 / 3076 (0.03%)	4 / 3071 (0.13%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Humerus fracture			
subjects affected / exposed	2 / 3076 (0.07%)	3 / 3071 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incisional hernia			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incomplete spinal fusion			

subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury			
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Intentional overdose			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint dislocation			
subjects affected / exposed	0 / 3076 (0.00%)	4 / 3071 (0.13%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint injury			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ligament rupture			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ligament sprain			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (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	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower limb fracture			

subjects affected / exposed	3 / 3076 (0.10%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar vertebral fracture			
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meniscus injury			
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple injuries			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Overdose			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Patella fracture			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic fracture			
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery restenosis			
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Perirenal haematoma			

subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural bile leak			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural complication			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural discomfort			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haematoma			
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (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 / 3076 (0.03%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Postoperative respiratory failure			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural haemorrhage			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural nausea			

subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural pain			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radius fracture			
subjects affected / exposed	2 / 3076 (0.07%)	4 / 3071 (0.13%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory fume inhalation disorder			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rib fracture			
subjects affected / exposed	1 / 3076 (0.03%)	5 / 3071 (0.16%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Road traffic accident			
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Snake bite			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft tissue injury			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal fracture			

subjects affected / exposed	3 / 3076 (0.10%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stab wound			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sternal fracture			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdural haematoma			
subjects affected / exposed	3 / 3076 (0.10%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Subdural haemorrhage			
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Tendon rupture			
subjects affected / exposed	4 / 3076 (0.13%)	4 / 3071 (0.13%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thoracic vertebral fracture			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tibia fracture			

subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulna fracture			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper limb fracture			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention postoperative			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular graft stenosis			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular graft thrombosis			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular pseudoaneurysm			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (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	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound dehiscence			

subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound haemorrhage			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound secretion			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (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	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Atrial septal defect			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bicuspid aortic valve			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrocele			
subjects affected / exposed	3 / 3076 (0.10%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Adams-Stokes syndrome			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (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	50 / 3076 (1.63%)	52 / 3071 (1.69%)	
occurrences causally related to treatment / all	0 / 55	0 / 53	
deaths causally related to treatment / all	0 / 0	0 / 1	
Angina unstable			
subjects affected / exposed	23 / 3076 (0.75%)	19 / 3071 (0.62%)	
occurrences causally related to treatment / all	0 / 24	0 / 21	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve disease			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (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	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve stenosis			
subjects affected / exposed	5 / 3076 (0.16%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arrhythmia			
subjects affected / exposed	3 / 3076 (0.10%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Arteriosclerosis coronary artery			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriospasm coronary			

subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			
subjects affected / exposed	36 / 3076 (1.17%)	31 / 3071 (1.01%)	
occurrences causally related to treatment / all	1 / 47	0 / 35	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial flutter			
subjects affected / exposed	6 / 3076 (0.20%)	4 / 3071 (0.13%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial tachycardia			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block			
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block complete			
subjects affected / exposed	6 / 3076 (0.20%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 6	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block second degree			
subjects affected / exposed	3 / 3076 (0.10%)	4 / 3071 (0.13%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bradycardia			
subjects affected / exposed	3 / 3076 (0.10%)	7 / 3071 (0.23%)	
occurrences causally related to treatment / all	0 / 3	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac aneurysm			

subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac arrest			
subjects affected / exposed	5 / 3076 (0.16%)	5 / 3071 (0.16%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 5	0 / 5	
Cardiac failure			
subjects affected / exposed	4 / 3076 (0.13%)	7 / 3071 (0.23%)	
occurrences causally related to treatment / all	0 / 4	0 / 7	
deaths causally related to treatment / all	0 / 1	0 / 3	
Cardiac failure acute			
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cardiac failure chronic			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac tamponade			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac valve disease			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac ventricular thrombosis			
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardio-respiratory arrest			

subjects affected / exposed	2 / 3076 (0.07%)	4 / 3071 (0.13%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 2	0 / 4	
Cardiogenic shock			
subjects affected / exposed	3 / 3076 (0.10%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Cardiomyopathy			
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiopulmonary failure			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiovascular insufficiency			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Carditis			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest pain			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cor pulmonale			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Coronary artery disease			

subjects affected / exposed	23 / 3076 (0.75%)	30 / 3071 (0.98%)	
occurrences causally related to treatment / all	0 / 26	0 / 31	
deaths causally related to treatment / all	0 / 0	0 / 1	
Coronary artery dissection			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (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 / 3076 (0.10%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery perforation			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery stenosis			
subjects affected / exposed	7 / 3076 (0.23%)	7 / 3071 (0.23%)	
occurrences causally related to treatment / all	0 / 7	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic cardiomyopathy			
subjects affected / exposed	2 / 3076 (0.07%)	3 / 3071 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Left ventricular dysfunction			
subjects affected / exposed	3 / 3076 (0.10%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Left ventricular failure			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Long QT syndrome			

subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral valve incompetence			
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial haemorrhage			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial ischaemia			
subjects affected / exposed	12 / 3076 (0.39%)	12 / 3071 (0.39%)	
occurrences causally related to treatment / all	0 / 12	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 2	
Myocarditis			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Palpitations			
subjects affected / exposed	2 / 3076 (0.07%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial effusion			
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericarditis			
subjects affected / exposed	4 / 3076 (0.13%)	3 / 3071 (0.10%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Right ventricular failure			

subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Sinus arrest			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus bradycardia			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (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 / 3076 (0.13%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus tachycardia			
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Supraventricular extrasystoles			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Supraventricular tachycardia			
subjects affected / exposed	4 / 3076 (0.13%)	4 / 3071 (0.13%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systolic dysfunction			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachycardia			

subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (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 / 3076 (0.00%)	1 / 3071 (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 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular extrasystoles			
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular fibrillation			
subjects affected / exposed	2 / 3076 (0.07%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 2	0 / 1	
Ventricular tachycardia			
subjects affected / exposed	5 / 3076 (0.16%)	8 / 3071 (0.26%)	
occurrences causally related to treatment / all	0 / 5	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Balance disorder			
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Burning sensation			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery disease			

subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery occlusion			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (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	5 / 3076 (0.16%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carpal tunnel syndrome			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cauda equina syndrome			
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral artery stenosis			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral haematoma			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral haemorrhage			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Cerebral ischaemia			

subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular accident			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical radiculopathy			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervicobrachial syndrome			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (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 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coma			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dementia			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Dementia Alzheimer's type			
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic ketoacidotic hyperglycaemic coma			

subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disturbance in attention			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dizziness			
subjects affected / exposed	8 / 3076 (0.26%)	3 / 3071 (0.10%)	
occurrences causally related to treatment / all	0 / 8	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalopathy			
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epilepsy			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Generalised tonic-clonic seizure			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Guillain-Barre syndrome			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Headache			
subjects affected / exposed	0 / 3076 (0.00%)	5 / 3071 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hemiparesis			

subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrocephalus			
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoaesthesia			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemic coma			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (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	2 / 3076 (0.07%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Loss of consciousness			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar radiculopathy			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbosacral radiculopathy			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Memory impairment			

subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolic encephalopathy			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (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	2 / 3076 (0.07%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Monoparesis			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorder			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (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	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parkinson's disease			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyneuropathy			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Presyncope			

subjects affected / exposed	3 / 3076 (0.10%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radicular pain			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sciatica			
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			
subjects affected / exposed	3 / 3076 (0.10%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Status epilepticus			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	28 / 3076 (0.91%)	24 / 3071 (0.78%)	
occurrences causally related to treatment / all	1 / 33	0 / 28	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient ischaemic attack			
subjects affected / exposed	10 / 3076 (0.33%)	6 / 3071 (0.20%)	
occurrences causally related to treatment / all	0 / 11	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tremor			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular dementia			

subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebral artery stenosis			
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebrobasilar insufficiency			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (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	21 / 3076 (0.68%)	19 / 3071 (0.62%)	
occurrences causally related to treatment / all	0 / 21	0 / 19	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile neutropenia			
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic anaemia			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypochromic anaemia			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (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	3 / 3076 (0.10%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukocytosis			

subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukopenia			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphadenopathy			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Microcytic anaemia			
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenia			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-Hodgkin's lymphoma recurrent			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancytopenia			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenic haematoma			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenic infarction			

subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenic vein thrombosis			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Ear canal stenosis			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meniere's disease			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tinnitus			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (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 / 3076 (0.07%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo positional			
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			

Blindness transient			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lens dislocation			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Optic nerve disorder			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal detachment			
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal tear			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinopathy of prematurity			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Visual acuity reduced			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitreous haemorrhage			

subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal adhesions			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal discomfort			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal hernia			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			
subjects affected / exposed	6 / 3076 (0.20%)	7 / 3071 (0.23%)	
occurrences causally related to treatment / all	0 / 6	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain lower			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (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	5 / 3076 (0.16%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenocarcinoma pancreas			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal fissure			

subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aphthous ulcer			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (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 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Auriculotemporal syndrome			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Barrett's oesophagus			
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coeliac artery stenosis			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis ischaemic			
subjects affected / exposed	2 / 3076 (0.07%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis ulcerative			

subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Constipation			
subjects affected / exposed	0 / 3076 (0.00%)	4 / 3071 (0.13%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	2 / 3076 (0.07%)	5 / 3071 (0.16%)	
occurrences causally related to treatment / all	0 / 2	2 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticular perforation			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum intestinal			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum intestinal haemorrhagic			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer haemorrhage			
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenitis			

subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspepsia			
subjects affected / exposed	3 / 3076 (0.10%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysphagia			
subjects affected / exposed	4 / 3076 (0.13%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enteritis			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Faecaloma			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Functional gastrointestinal disorder			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric haemorrhage			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer			
subjects affected / exposed	2 / 3076 (0.07%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer haemorrhage			

subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer perforation			
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis			
subjects affected / exposed	3 / 3076 (0.10%)	3 / 3071 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis erosive			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis haemorrhagic			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal angiodysplasia			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			
subjects affected / exposed	8 / 3076 (0.26%)	5 / 3071 (0.16%)	
occurrences causally related to treatment / all	0 / 8	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 0	
Gastrointestinal necrosis			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrooesophageal reflux disease			

subjects affected / exposed	5 / 3076 (0.16%)	4 / 3071 (0.13%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gingival recession			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematemesis			
subjects affected / exposed	0 / 3076 (0.00%)	3 / 3071 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematochezia			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic erosive gastritis			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoidal haemorrhage			
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoids			
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hernial eventration			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hiatus hernia			

subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (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	2 / 3076 (0.07%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus paralytic			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (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	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inflammatory bowel disease			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (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	5 / 3076 (0.16%)	5 / 3071 (0.16%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia strangulated			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal haemorrhage			
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal ischaemia			

subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Intestinal obstruction			
subjects affected / exposed	1 / 3076 (0.03%)	3 / 3071 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal perforation			
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine polyp			
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower gastrointestinal haemorrhage			
subjects affected / exposed	3 / 3076 (0.10%)	3 / 3071 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mallory-Weiss syndrome			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Melaena			
subjects affected / exposed	4 / 3076 (0.13%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mesenteric panniculitis			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal dysplasia			

subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis			
subjects affected / exposed	3 / 3076 (0.10%)	7 / 3071 (0.23%)	
occurrences causally related to treatment / all	0 / 4	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis acute			
subjects affected / exposed	14 / 3076 (0.46%)	6 / 3071 (0.20%)	
occurrences causally related to treatment / all	1 / 16	0 / 8	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pancreatitis chronic			
subjects affected / exposed	3 / 3076 (0.10%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peptic ulcer			
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Portal venous gas			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Proctalgia			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal haemorrhage			
subjects affected / exposed	2 / 3076 (0.07%)	3 / 3071 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retroperitoneal haematoma			

subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (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	1 / 3076 (0.03%)	5 / 3071 (0.16%)	
occurrences causally related to treatment / all	0 / 1	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal ulcer haemorrhage			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subileus			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Umbilical hernia			
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	5 / 3076 (0.16%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Volvulus			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	0 / 3076 (0.00%)	4 / 3071 (0.13%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Angioedema			

subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Decubitus ulcer			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (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	2 / 3076 (0.07%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ecchymosis			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eczema			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin disorder			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin lesion			

subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin mass			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin ulcer			
subjects affected / exposed	3 / 3076 (0.10%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Swelling face			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Xanthelasma			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	20 / 3076 (0.65%)	18 / 3071 (0.59%)	
occurrences causally related to treatment / all	0 / 21	0 / 19	
deaths causally related to treatment / all	0 / 0	0 / 1	
Anuria			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder dysplasia			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus bladder			

subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus urinary			
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic kidney disease			
subjects affected / exposed	3 / 3076 (0.10%)	3 / 3071 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematuria			
subjects affected / exposed	9 / 3076 (0.29%)	13 / 3071 (0.42%)	
occurrences causally related to treatment / all	0 / 12	0 / 17	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage urinary tract			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydronephrosis			
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Micturition disorder			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrolithiasis			
subjects affected / exposed	2 / 3076 (0.07%)	7 / 3071 (0.23%)	
occurrences causally related to treatment / all	0 / 2	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvi-ureteric obstruction			

subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Proteinuria			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (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	3 / 3076 (0.10%)	3 / 3071 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure			
subjects affected / exposed	0 / 3076 (0.00%)	4 / 3071 (0.13%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal impairment			
subjects affected / exposed	1 / 3076 (0.03%)	3 / 3071 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal injury			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal pain			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureteric stenosis			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureterolithiasis			

subjects affected / exposed	1 / 3076 (0.03%)	5 / 3071 (0.16%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral haemorrhage			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral stenosis			
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary incontinence			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (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	4 / 3076 (0.13%)	9 / 3071 (0.29%)	
occurrences causally related to treatment / all	0 / 4	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract obstruction			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autoimmune thyroiditis			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cushing's syndrome			

subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperparathyroidism primary			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid mass			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxic goitre			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Ankylosing spondylitis			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthralgia			
subjects affected / exposed	3 / 3076 (0.10%)	5 / 3071 (0.16%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis			
subjects affected / exposed	3 / 3076 (0.10%)	3 / 3071 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis reactive			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain			

subjects affected / exposed	9 / 3076 (0.29%)	4 / 3071 (0.13%)	
occurrences causally related to treatment / all	0 / 9	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical spinal stenosis			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chondrocalcinosis pyrophosphate			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Facet joint syndrome			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot deformity			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gouty arthritis			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc degeneration			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc disorder			
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc protrusion			

subjects affected / exposed	2 / 3076 (0.07%)	6 / 3071 (0.20%)	
occurrences causally related to treatment / all	0 / 2	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint effusion			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Knee impingement syndrome			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb deformity			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar spinal stenosis			
subjects affected / exposed	2 / 3076 (0.07%)	4 / 3071 (0.13%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mobility decreased			
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle twitching			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscular weakness			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal chest pain			

subjects affected / exposed	9 / 3076 (0.29%)	7 / 3071 (0.23%)	
occurrences causally related to treatment / all	0 / 10	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal pain			
subjects affected / exposed	5 / 3076 (0.16%)	3 / 3071 (0.10%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myalgia			
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neck pain			
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoarthritis			
subjects affected / exposed	27 / 3076 (0.88%)	23 / 3071 (0.75%)	
occurrences causally related to treatment / all	0 / 29	0 / 25	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteolysis			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteonecrosis			
subjects affected / exposed	2 / 3076 (0.07%)	5 / 3071 (0.16%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoporosis			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain in extremity			

subjects affected / exposed	3 / 3076 (0.10%)	4 / 3071 (0.13%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain in jaw			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pathological fracture			
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polymyalgia rheumatica			
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psoriatic arthropathy			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhabdomyolysis			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rheumatoid arthritis			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rotator cuff syndrome			
subjects affected / exposed	2 / 3076 (0.07%)	7 / 3071 (0.23%)	
occurrences causally related to treatment / all	0 / 2	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal column stenosis			

subjects affected / exposed	2 / 3076 (0.07%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal disorder			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal pain			
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondylitis			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendonitis			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebral osteophyte			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess limb			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess of salivary gland			

subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess oral			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal abscess			
subjects affected / exposed	2 / 3076 (0.07%)	3 / 3071 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			
subjects affected / exposed	8 / 3076 (0.26%)	7 / 3071 (0.23%)	
occurrences causally related to treatment / all	0 / 8	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis perforated			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriosclerotic gangrene			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis bacterial			
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacteraemia			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial infection			

subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary sepsis			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain abscess			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	2 / 3076 (0.07%)	4 / 3071 (0.13%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac valve vegetation			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (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	12 / 3076 (0.39%)	12 / 3071 (0.39%)	
occurrences causally related to treatment / all	0 / 12	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis staphylococcal			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Central nervous system infection			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis infective			

subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile colitis			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile infection			
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colonic abscess			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Corona virus infection			
subjects affected / exposed	43 / 3076 (1.40%)	45 / 3071 (1.47%)	
occurrences causally related to treatment / all	0 / 44	0 / 45	
deaths causally related to treatment / all	0 / 15	0 / 11	
Creutzfeldt-Jakob disease			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cystitis			
subjects affected / exposed	0 / 3076 (0.00%)	3 / 3071 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Device related infection			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic foot infection			

subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Diarrhoea infectious			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis			
subjects affected / exposed	6 / 3076 (0.20%)	7 / 3071 (0.23%)	
occurrences causally related to treatment / all	0 / 7	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear infection			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eczema infected			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (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	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocarditis			
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Endocarditis bacterial			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epididymitis			

subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erysipelas			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia bacteraemia			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia infection			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia pyelonephritis			
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gangrene			
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer helicobacter			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis bacterial			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			

subjects affected / exposed	10 / 3076 (0.33%)	8 / 3071 (0.26%)	
occurrences causally related to treatment / all	0 / 10	1 / 8	
deaths causally related to treatment / all	0 / 1	0 / 0	
Gastroenteritis viral			
subjects affected / exposed	4 / 3076 (0.13%)	4 / 3071 (0.13%)	
occurrences causally related to treatment / all	1 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal infection			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematoma infection			
subjects affected / exposed	3 / 3076 (0.10%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemophilus bacteraemia			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Helicobacter infection			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis C			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (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 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes zoster oticus			

subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Implant site infection			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected lymphocele			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infection			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infectious colitis			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infective exacerbation of bronchiectasis			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	1 / 3076 (0.03%)	3 / 3071 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			
subjects affected / exposed	2 / 3076 (0.07%)	3 / 3071 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Klebsiella bacteraemia			

subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Klebsiella sepsis			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver abscess			
subjects affected / exposed	2 / 3076 (0.07%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Localised infection			
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower respiratory tract infection			
subjects affected / exposed	8 / 3076 (0.26%)	3 / 3071 (0.10%)	
occurrences causally related to treatment / all	0 / 8	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung abscess			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung infection			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenic sepsis			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nosocomial infection			

subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ophthalmic herpes simplex			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (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	3 / 3076 (0.10%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis			
subjects affected / exposed	4 / 3076 (0.13%)	3 / 3071 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreas infection			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parainfluenzae virus infection			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Perirectal abscess			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonitis			
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			

subjects affected / exposed	41 / 3076 (1.33%)	39 / 3071 (1.27%)	
occurrences causally related to treatment / all	0 / 50	0 / 45	
deaths causally related to treatment / all	0 / 4	0 / 3	
Pneumonia bacterial			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia escherichia			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia legionella			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia necrotising			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia staphylococcal			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia viral			
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Postoperative wound infection			

subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary tuberculosis			
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis			
subjects affected / exposed	2 / 3076 (0.07%)	7 / 3071 (0.23%)	
occurrences causally related to treatment / all	0 / 3	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis acute			
subjects affected / exposed	4 / 3076 (0.13%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis chronic			
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory syncytial virus infection			
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection			
subjects affected / exposed	5 / 3076 (0.16%)	3 / 3071 (0.10%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
Respiratory tract infection bacterial			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scrotal abscess			

subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	19 / 3076 (0.62%)	14 / 3071 (0.46%)	
occurrences causally related to treatment / all	0 / 19	0 / 16	
deaths causally related to treatment / all	0 / 5	0 / 4	
Septic shock			
subjects affected / exposed	8 / 3076 (0.26%)	10 / 3071 (0.33%)	
occurrences causally related to treatment / all	0 / 8	0 / 10	
deaths causally related to treatment / all	0 / 3	0 / 4	
Serratia bacteraemia			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shunt infection			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Sinusitis			
subjects affected / exposed	3 / 3076 (0.10%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal bacteraemia			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Streptococcal bacteraemia			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheobronchitis			

subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tuberculosis			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (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 / 3076 (0.07%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	7 / 3076 (0.23%)	17 / 3071 (0.55%)	
occurrences causally related to treatment / all	0 / 10	0 / 17	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection bacterial			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (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	8 / 3076 (0.26%)	3 / 3071 (0.10%)	
occurrences causally related to treatment / all	0 / 8	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
Vestibular neuronitis			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral infection			
subjects affected / exposed	2 / 3076 (0.07%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection			

subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (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			
Adult failure to thrive			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Decreased appetite			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			
subjects affected / exposed	5 / 3076 (0.16%)	3 / 3071 (0.10%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes mellitus			
subjects affected / exposed	6 / 3076 (0.20%)	3 / 3071 (0.10%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes mellitus inadequate control			
subjects affected / exposed	0 / 3076 (0.00%)	3 / 3071 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes with hyperosmolarity			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (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 / 3076 (0.07%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic metabolic decompensation			

subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrolyte imbalance			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Failure to thrive			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gout			
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypercalcaemia			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemia			
subjects affected / exposed	2 / 3076 (0.07%)	3 / 3071 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperkalaemia			
subjects affected / exposed	3 / 3076 (0.10%)	4 / 3071 (0.13%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperosmolar hyperglycaemic state			
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemia			

subjects affected / exposed	5 / 3076 (0.16%)	0 / 3071 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Hypokalaemia		
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hyponatraemia		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lactic acidosis		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Metabolic acidosis		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Obesity		
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Type 2 diabetes mellitus		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

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

Non-serious adverse events	Placebo 600 mg	Dalcetrapib 600 mg	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2363 / 3076 (76.82%)	2380 / 3071 (77.50%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acanthoma			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences (all)	1	1	
Acrochordon			
subjects affected / exposed	1 / 3076 (0.03%)	3 / 3071 (0.10%)	
occurrences (all)	1	3	
Adenoma benign			
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences (all)	0	2	
Adrenal adenoma			
subjects affected / exposed	2 / 3076 (0.07%)	2 / 3071 (0.07%)	
occurrences (all)	2	2	
Anogenital warts			
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)	
occurrences (all)	2	0	
Atypical fibroxanthoma			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences (all)	1	0	
Basal cell carcinoma			
subjects affected / exposed	15 / 3076 (0.49%)	26 / 3071 (0.85%)	
occurrences (all)	22	27	
Basosquamous carcinoma			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences (all)	1	0	
Benign breast neoplasm			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences (all)	0	1	
Benign gastrointestinal neoplasm			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences (all)	1	0	
Benign lymph node neoplasm			

subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Benign neoplasm of skin		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Benign neoplasm of thyroid gland		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Benign salivary gland neoplasm		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Bladder cancer		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Bowen's disease		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Breast adenoma		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Breast cancer metastatic		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Breast cancer recurrent		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Breast neoplasm		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Bronchial neoplasm		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Carcinoid tumour		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Chronic lymphocytic leukaemia		

subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Colon adenoma		
subjects affected / exposed	7 / 3076 (0.23%)	8 / 3071 (0.26%)
occurrences (all)	9	8
Colon neoplasm		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Colon cancer		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Dysplastic naevus		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Enchondromatosis		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Fibroadenoma of breast		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Fibrous histiocytoma		
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)
occurrences (all)	1	2
Haemangioma of liver		
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)
occurrences (all)	0	2
Haemangioma		
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)
occurrences (all)	1	2
Haemangioma of skin		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Hodgkin's disease		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Hypergammaglobulinaemia benign		

monoclonal		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Keratoacanthoma		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Kidney angiomyolipoma		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Large intestine benign neoplasm		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Laryngeal cancer		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Leiomyoma		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Lentigo maligna		
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)
occurrences (all)	2	1
Lip squamous cell carcinoma		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Lipoma		
subjects affected / exposed	3 / 3076 (0.10%)	5 / 3071 (0.16%)
occurrences (all)	3	5
Lung carcinoma cell type unspecified stage IV		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Malignant melanoma		
subjects affected / exposed	3 / 3076 (0.10%)	7 / 3071 (0.23%)
occurrences (all)	3	8
Malignant melanoma in situ		

subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Melanocytic naevus		
subjects affected / exposed	0 / 3076 (0.00%)	4 / 3071 (0.13%)
occurrences (all)	0	4
Metastases to bone		
subjects affected / exposed	3 / 3076 (0.10%)	0 / 3071 (0.00%)
occurrences (all)	3	0
Metastases to central nervous system		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Metastases to lung		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Metastases to thorax		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Monoclonal gammopathy		
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)
occurrences (all)	0	2
Myelodysplastic syndrome		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Neoplasm malignant		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Neoplasm skin		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Neuroma		
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)
occurrences (all)	0	2
Non-Hodgkin's lymphoma		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1

Ocular neoplasm		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Oral papilloma		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Pancreatic carcinoma metastatic		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Pancreatic neoplasm		
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)
occurrences (all)	0	2
Papilloma		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Pituitary tumour benign		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Plasma cell myeloma		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Pleural mesothelioma		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Polycythaemia vera		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Prostate cancer		
subjects affected / exposed	8 / 3076 (0.26%)	5 / 3071 (0.16%)
occurrences (all)	8	5
Prostate cancer metastatic		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Prostate cancer recurrent		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1

Prostatic adenoma		
subjects affected / exposed	1 / 3076 (0.03%)	3 / 3071 (0.10%)
occurrences (all)	1	3
Pyogenic granuloma		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Rectal cancer		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Rectal neoplasm		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Renal cell carcinoma		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Renal neoplasm		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Salivary gland neoplasm		
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)
occurrences (all)	0	2
Seborrhoeic keratosis		
subjects affected / exposed	7 / 3076 (0.23%)	6 / 3071 (0.20%)
occurrences (all)	7	6
Skin cancer		
subjects affected / exposed	5 / 3076 (0.16%)	2 / 3071 (0.07%)
occurrences (all)	5	2
Skin papilloma		
subjects affected / exposed	2 / 3076 (0.07%)	4 / 3071 (0.13%)
occurrences (all)	2	4
Small cell lung cancer		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Squamous cell carcinoma		
subjects affected / exposed	9 / 3076 (0.29%)	5 / 3071 (0.16%)
occurrences (all)	10	5

Squamous cell carcinoma of skin subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1	
Tonsil cancer subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	0 / 3071 (0.00%) 0	
Transitional cell carcinoma subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	0 / 3071 (0.00%) 0	
Uterine leiomyoma subjects affected / exposed occurrences (all)	4 / 3076 (0.13%) 4	4 / 3071 (0.13%) 4	
Vulval cancer stage 0 subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	0 / 3071 (0.00%) 0	
Vulval cancer subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	0 / 3071 (0.00%) 0	
Vascular disorders			
Accelerated hypertension subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1	
Angiopathy subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	1 / 3071 (0.03%) 1	
Angiosclerosis subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	0 / 3071 (0.00%) 0	
Aortic aneurysm subjects affected / exposed occurrences (all)	8 / 3076 (0.26%) 8	9 / 3071 (0.29%) 9	
Aortic calcification subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1	
Aortic arteriosclerosis			

subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)
occurrences (all)	2	1
Aortic dilatation		
subjects affected / exposed	1 / 3076 (0.03%)	4 / 3071 (0.13%)
occurrences (all)	1	4
Aortic dissection		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Aortic stenosis		
subjects affected / exposed	5 / 3076 (0.16%)	3 / 3071 (0.10%)
occurrences (all)	5	3
Aortic thrombosis		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Arterial disorder		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Arterial occlusive disease		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Arteriosclerosis		
subjects affected / exposed	4 / 3076 (0.13%)	6 / 3071 (0.20%)
occurrences (all)	4	6
Arteriosclerosis Moenckeberg-type		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Arteritis		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Axillary vein thrombosis		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Behcet's syndrome		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Blood pressure fluctuation		

subjects affected / exposed	4 / 3076 (0.13%)	6 / 3071 (0.20%)
occurrences (all)	4	6
Blood pressure inadequately controlled		
subjects affected / exposed	5 / 3076 (0.16%)	3 / 3071 (0.10%)
occurrences (all)	5	3
Brachiocephalic arteriosclerosis		
subjects affected / exposed	3 / 3076 (0.10%)	2 / 3071 (0.07%)
occurrences (all)	3	2
Brachiocephalic vein stenosis		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Capillary fragility		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Carotid arteriosclerosis		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Circulatory collapse		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Contusion		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Deep vein thrombosis		
subjects affected / exposed	5 / 3076 (0.16%)	4 / 3071 (0.13%)
occurrences (all)	5	4
Diastolic hypertension		
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)
occurrences (all)	2	1
Dizziness		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Dry gangrene		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0

Embolism		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Embolism venous		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Embolism arterial		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Flushing		
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)
occurrences (all)	2	1
Haematoma		
subjects affected / exposed	17 / 3076 (0.55%)	17 / 3071 (0.55%)
occurrences (all)	19	18
Haemorrhage		
subjects affected / exposed	2 / 3076 (0.07%)	2 / 3071 (0.07%)
occurrences (all)	2	2
Hot flush		
subjects affected / exposed	9 / 3076 (0.29%)	6 / 3071 (0.20%)
occurrences (all)	9	6
Hypertension		
subjects affected / exposed	266 / 3076 (8.65%)	277 / 3071 (9.02%)
occurrences (all)	312	322
Hypertensive angiopathy		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Hypertensive crisis		
subjects affected / exposed	18 / 3076 (0.59%)	24 / 3071 (0.78%)
occurrences (all)	25	25
Hypotension		
subjects affected / exposed	73 / 3076 (2.37%)	78 / 3071 (2.54%)
occurrences (all)	75	82
Intermittent claudication		
subjects affected / exposed	6 / 3076 (0.20%)	15 / 3071 (0.49%)
occurrences (all)	6	15

Ischaemia		
subjects affected / exposed	3 / 3076 (0.10%)	4 / 3071 (0.13%)
occurrences (all)	3	4
Jugular vein thrombosis		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Labile blood pressure		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Labile hypertension		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Lymphoedema		
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)
occurrences (all)	2	1
Non-dipping		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Orthostatic hypertension		
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)
occurrences (all)	2	1
Orthostatic hypotension		
subjects affected / exposed	21 / 3076 (0.68%)	14 / 3071 (0.46%)
occurrences (all)	21	14
Perineal haematoma		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Peripheral arterial occlusive disease		
subjects affected / exposed	7 / 3076 (0.23%)	8 / 3071 (0.26%)
occurrences (all)	7	8
Peripheral artery aneurysm		
subjects affected / exposed	2 / 3076 (0.07%)	2 / 3071 (0.07%)
occurrences (all)	2	2
Peripheral artery occlusion		
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)
occurrences (all)	1	2

Peripheral artery stenosis		
subjects affected / exposed	3 / 3076 (0.10%)	2 / 3071 (0.07%)
occurrences (all)	3	2
Peripheral artery thrombosis		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Peripheral coldness		
subjects affected / exposed	2 / 3076 (0.07%)	4 / 3071 (0.13%)
occurrences (all)	2	4
Peripheral ischaemia		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Peripheral venous disease		
subjects affected / exposed	3 / 3076 (0.10%)	5 / 3071 (0.16%)
occurrences (all)	3	6
Peripheral vascular disorder		
subjects affected / exposed	2 / 3076 (0.07%)	5 / 3071 (0.16%)
occurrences (all)	2	5
Phlebitis		
subjects affected / exposed	4 / 3076 (0.13%)	2 / 3071 (0.07%)
occurrences (all)	4	2
Poor peripheral circulation		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Post procedural haemorrhage		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Presyncope		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Raynaud's phenomenon		
subjects affected / exposed	5 / 3076 (0.16%)	6 / 3071 (0.20%)
occurrences (all)	5	6
Shock		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1

Subclavian artery stenosis		
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)
occurrences (all)	0	2
Subclavian steal syndrome		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Temporal arteritis		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Thrombophlebitis		
subjects affected / exposed	4 / 3076 (0.13%)	3 / 3071 (0.10%)
occurrences (all)	4	3
Thrombophlebitis superficial		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Thrombosed varicose vein		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Thrombosis		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Varicose ulceration		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Varicose vein		
subjects affected / exposed	6 / 3076 (0.20%)	8 / 3071 (0.26%)
occurrences (all)	6	8
Vasculitis		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Vasospasm		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Vasodilatation		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0

Venous thrombosis subjects affected / exposed occurrences (all)	2 / 3076 (0.07%) 2	1 / 3071 (0.03%) 1	
Surgical and medical procedures			
Abdominal cavity drainage subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 4	0 / 3071 (0.00%) 0	
Abdominal hernia repair subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	0 / 3071 (0.00%) 0	
Abscess drainage subjects affected / exposed occurrences (all)	2 / 3076 (0.07%) 2	0 / 3071 (0.00%) 0	
Acrochordon excision subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1	
Angioplasty subjects affected / exposed occurrences (all)	3 / 3076 (0.10%) 4	2 / 3071 (0.07%) 2	
Aortic surgery subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1	
Aortic valve replacement subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1	
Appendicectomy subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1	
Arterial stent insertion subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	0 / 3071 (0.00%) 0	
Arthrodesis subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1	
Arthrotomy			

subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Blepharoplasty		
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)
occurrences (all)	0	2
Breast prosthesis implantation		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Bunion operation		
subjects affected / exposed	0 / 3076 (0.00%)	3 / 3071 (0.10%)
occurrences (all)	0	3
Cardiac ablation		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Cardiac pacemaker battery replacement		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Cardiac pacemaker replacement		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Cardiac pacemaker insertion		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Cardiac rehabilitation therapy		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Cardiac resynchronisation therapy		
subjects affected / exposed	3 / 3076 (0.10%)	0 / 3071 (0.00%)
occurrences (all)	3	0
Cardioversion		
subjects affected / exposed	3 / 3076 (0.10%)	1 / 3071 (0.03%)
occurrences (all)	3	1
Carotid endarterectomy		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0

Carpal tunnel decompression subjects affected / exposed occurrences (all)	2 / 3076 (0.07%) 2	4 / 3071 (0.13%) 4
Cataract operation subjects affected / exposed occurrences (all)	12 / 3076 (0.39%) 16	24 / 3071 (0.78%) 31
Chemotherapy subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1
Cholecystectomy subjects affected / exposed occurrences (all)	2 / 3076 (0.07%) 2	1 / 3071 (0.03%) 1
Circumcision subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1
Corneal transplant subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1
Coronary angioplasty subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	1 / 3071 (0.03%) 1
Coronary artery bypass subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	2 / 3071 (0.07%) 2
Coronary revascularisation subjects affected / exposed occurrences (all)	5 / 3076 (0.16%) 6	9 / 3071 (0.29%) 9
Cyst removal subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	0 / 3071 (0.00%) 0
Dental implantation subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	1 / 3071 (0.03%) 1
Dental operation subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	0 / 3071 (0.00%) 0

Dermatofibroma removal		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Drain placement		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Elective surgery		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Endodontic procedure		
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)
occurrences (all)	0	2
Endovenous ablation		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	2
Foot operation		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Gastrointestinal endoscopic therapy		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Glaucoma surgery		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Hernia repair		
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)
occurrences (all)	2	1
Hip arthroplasty		
subjects affected / exposed	4 / 3076 (0.13%)	0 / 3071 (0.00%)
occurrences (all)	4	0
Hip surgery		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Hospitalisation		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1

Implantable cardiac monitor insertion		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Implantable defibrillator insertion		
subjects affected / exposed	2 / 3076 (0.07%)	3 / 3071 (0.10%)
occurrences (all)	2	3
Incisional drainage		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Inguinal hernia repair		
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)
occurrences (all)	1	2
Intestinal polypectomy		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Joint debridement		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Knee arthroplasty		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	2
Knee operation		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Large intestinal polypectomy		
subjects affected / exposed	2 / 3076 (0.07%)	4 / 3071 (0.13%)
occurrences (all)	3	5
Left atrial appendage occlusion		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Leg amputation		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Lens extraction		

subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	2
Lithotripsy		
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)
occurrences (all)	1	2
Mass excision		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Meniscus removal		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Mole excision		
subjects affected / exposed	0 / 3076 (0.00%)	3 / 3071 (0.10%)
occurrences (all)	0	3
Osteosynthesis		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Osteotomy		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Percutaneous coronary intervention		
subjects affected / exposed	4 / 3076 (0.13%)	5 / 3071 (0.16%)
occurrences (all)	4	5
Peripheral nerve decompression		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Peripheral nerve transposition		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Polypectomy		
subjects affected / exposed	1 / 3076 (0.03%)	4 / 3071 (0.13%)
occurrences (all)	1	4
Post procedural drainage		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Postoperative care		

subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Prostatic operation		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Pterygium operation		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Pulmonary resection		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Rectal polypectomy		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Removal of internal fixation		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Retinal laser coagulation		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Rotator cuff repair		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Skin graft		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Skin lesion excision		
subjects affected / exposed	2 / 3076 (0.07%)	4 / 3071 (0.13%)
occurrences (all)	2	4
Skin neoplasm excision		
subjects affected / exposed	3 / 3076 (0.10%)	1 / 3071 (0.03%)
occurrences (all)	4	2
Small intestinal anastomosis		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Spinal fusion surgery		

subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Spinal laminectomy		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Splenectomy		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Stent placement		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Suprapubic prostatectomy		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Suture insertion		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Tendon sheath incision		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Thyroidectomy		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Toe amputation		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Tooth extraction		
subjects affected / exposed	11 / 3076 (0.36%)	14 / 3071 (0.46%)
occurrences (all)	12	14
Tooth repair		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Trabeculectomy		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Tracheostomy		

subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1	
Transurethral prostatectomy subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	0 / 3071 (0.00%) 0	
Umbilical hernia repair subjects affected / exposed occurrences (all)	2 / 3076 (0.07%) 2	1 / 3071 (0.03%) 1	
Ureteral stent insertion subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	1 / 3071 (0.03%) 1	
Urethral dilation procedure subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	0 / 3071 (0.00%) 0	
Urethrotomy subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	0 / 3071 (0.00%) 0	
Uterine prolapse repair subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1	
Varicose vein operation subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 4	
Vitrectomy subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	1 / 3071 (0.03%) 1	
General disorders and administration site conditions			
Administration site extravasation subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1	
Adverse drug reaction subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	5 / 3071 (0.16%) 5	
Adverse reaction			

subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Application site pruritus		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Asthenia		
subjects affected / exposed	32 / 3076 (1.04%)	45 / 3071 (1.47%)
occurrences (all)	33	47
Catheter site haematoma		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Catheter site pain		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Catheter site phlebitis		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Chest discomfort		
subjects affected / exposed	38 / 3076 (1.24%)	49 / 3071 (1.60%)
occurrences (all)	41	53
Chest pain		
subjects affected / exposed	239 / 3076 (7.77%)	268 / 3071 (8.73%)
occurrences (all)	295	334
Chills		
subjects affected / exposed	4 / 3076 (0.13%)	2 / 3071 (0.07%)
occurrences (all)	4	2
Crepitations		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Cyst		
subjects affected / exposed	5 / 3076 (0.16%)	4 / 3071 (0.13%)
occurrences (all)	6	4
Discomfort		
subjects affected / exposed	5 / 3076 (0.16%)	4 / 3071 (0.13%)
occurrences (all)	5	4
Drug withdrawal syndrome		

subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Drug intolerance		
subjects affected / exposed	4 / 3076 (0.13%)	3 / 3071 (0.10%)
occurrences (all)	4	3
Dysplasia		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Early satiety		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Exercise tolerance decreased		
subjects affected / exposed	6 / 3076 (0.20%)	4 / 3071 (0.13%)
occurrences (all)	6	4
Face oedema		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Facial pain		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Fat necrosis		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Fatigue		
subjects affected / exposed	101 / 3076 (3.28%)	115 / 3071 (3.74%)
occurrences (all)	104	123
Feeling cold		
subjects affected / exposed	1 / 3076 (0.03%)	3 / 3071 (0.10%)
occurrences (all)	1	3
Feeling abnormal		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Feeling drunk		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Feeling hot		

subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Feeling jittery		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Feeling of body temperature change		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Gait disturbance		
subjects affected / exposed	3 / 3076 (0.10%)	4 / 3071 (0.13%)
occurrences (all)	3	4
General physical health deterioration		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
General symptom		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Generalised oedema		
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)
occurrences (all)	0	2
Haemorrhagic cyst		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Hernia		
subjects affected / exposed	4 / 3076 (0.13%)	2 / 3071 (0.07%)
occurrences (all)	4	2
Hernia pain		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Hunger		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Hyperhidrosis		
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)
occurrences (all)	1	2
Hypothermia		

subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Impaired healing		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Implant site haemorrhage		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Implant site pain		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Implant site swelling		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Induration		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Inflammation		
subjects affected / exposed	4 / 3076 (0.13%)	4 / 3071 (0.13%)
occurrences (all)	4	4
Influenza like illness		
subjects affected / exposed	17 / 3076 (0.55%)	13 / 3071 (0.42%)
occurrences (all)	21	16
Injection site erythema		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Injection site haematoma		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Injection site haemorrhage		
subjects affected / exposed	0 / 3076 (0.00%)	3 / 3071 (0.10%)
occurrences (all)	0	3
Local swelling		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Malaise		

subjects affected / exposed	12 / 3076 (0.39%)	7 / 3071 (0.23%)
occurrences (all)	12	7
Mass		
subjects affected / exposed	4 / 3076 (0.13%)	1 / 3071 (0.03%)
occurrences (all)	4	1
Medical device site pain		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Mucosal inflammation		
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)
occurrences (all)	2	1
Nodule		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Non-cardiac chest pain		
subjects affected / exposed	75 / 3076 (2.44%)	66 / 3071 (2.15%)
occurrences (all)	96	82
Oedema		
subjects affected / exposed	6 / 3076 (0.20%)	10 / 3071 (0.33%)
occurrences (all)	6	10
Oedema peripheral		
subjects affected / exposed	60 / 3076 (1.95%)	62 / 3071 (2.02%)
occurrences (all)	62	65
Pain		
subjects affected / exposed	25 / 3076 (0.81%)	19 / 3071 (0.62%)
occurrences (all)	26	20
Peripheral swelling		
subjects affected / exposed	20 / 3076 (0.65%)	21 / 3071 (0.68%)
occurrences (all)	21	21
Polyp		
subjects affected / exposed	2 / 3076 (0.07%)	2 / 3071 (0.07%)
occurrences (all)	2	2
Postoperative fever		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Pyrexia		

subjects affected / exposed	24 / 3076 (0.78%)	21 / 3071 (0.68%)	
occurrences (all)	24	22	
Sensation of foreign body			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences (all)	0	1	
Swelling			
subjects affected / exposed	4 / 3076 (0.13%)	1 / 3071 (0.03%)	
occurrences (all)	4	1	
Temperature intolerance			
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences (all)	0	2	
Ulcer			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences (all)	1	1	
Ulcer haemorrhage			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences (all)	1	0	
Vaccination site reaction			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences (all)	0	1	
Vascular stent restenosis			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences (all)	1	0	
Vascular stent stenosis			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences (all)	1	0	
Vessel puncture site bruise			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences (all)	0	1	
Immune system disorders			
Allergic oedema			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences (all)	1	0	
Allergy to arthropod sting			
subjects affected / exposed	0 / 3076 (0.00%)	3 / 3071 (0.10%)	
occurrences (all)	0	3	

Allergy to arthropod bite subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	0 / 3071 (0.00%) 0	
Amyloidosis subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	0 / 3071 (0.00%) 0	
Anaphylactic reaction subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	0 / 3071 (0.00%) 0	
Contrast media allergy subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	0 / 3071 (0.00%) 0	
Drug hypersensitivity subjects affected / exposed occurrences (all)	8 / 3076 (0.26%) 8	4 / 3071 (0.13%) 4	
Food allergy subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	2 / 3071 (0.07%) 2	
Hypersensitivity subjects affected / exposed occurrences (all)	11 / 3076 (0.36%) 13	7 / 3071 (0.23%) 8	
Immunisation reaction subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1	
Rhinitis allergic subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1	
Sarcoidosis subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 9	1 / 3071 (0.03%) 1	
Seasonal allergy subjects affected / exposed occurrences (all)	8 / 3076 (0.26%) 8	8 / 3071 (0.26%) 8	
Social circumstances Menopause			

subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1	
Poor personal hygiene subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	0 / 3071 (0.00%) 0	
Stress at work subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1	
Tobacco user subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	0 / 3071 (0.00%) 0	
Treatment noncompliance subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1	
Vascular device user subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1	
Reproductive system and breast disorders			
Balanoposthitis subjects affected / exposed occurrences (all)	4 / 3076 (0.13%) 4	3 / 3071 (0.10%) 3	
Benign prostatic hyperplasia subjects affected / exposed occurrences (all)	36 / 3076 (1.17%) 37	36 / 3071 (1.17%) 36	
Breast calcifications subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 2	0 / 3071 (0.00%) 0	
Breast cyst subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	3 / 3071 (0.10%) 3	
Breast mass subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	4 / 3071 (0.13%) 4	
Breast pain			

subjects affected / exposed	4 / 3076 (0.13%)	0 / 3071 (0.00%)
occurrences (all)	4	0
Breast tenderness		
subjects affected / exposed	3 / 3076 (0.10%)	0 / 3071 (0.00%)
occurrences (all)	4	0
Breast ulceration		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Cervical cyst		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Cervical dysplasia		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Cervix disorder		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Cystocele		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Dysmenorrhoea		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Ejaculation failure		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Endometrial thickening		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Epididymal cyst		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Erectile dysfunction		
subjects affected / exposed	35 / 3076 (1.14%)	34 / 3071 (1.11%)
occurrences (all)	35	34
Fibrocystic breast disease		

subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Genital atrophy		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Genital discomfort		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Genital hypoaesthesia		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Genital prolapse		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Genital rash		
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)
occurrences (all)	0	2
Gynaecomastia		
subjects affected / exposed	3 / 3076 (0.10%)	6 / 3071 (0.20%)
occurrences (all)	3	6
Haematospermia		
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)
occurrences (all)	2	1
Hydrocele female		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Menorrhagia		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Metrorrhagia		
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)
occurrences (all)	1	2
Ovarian cyst		
subjects affected / exposed	0 / 3076 (0.00%)	3 / 3071 (0.10%)
occurrences (all)	0	3
Pelvic pain		

subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Penile pain		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Peyronie's disease		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Postmenopausal haemorrhage		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Prostatic obstruction		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Prostatism		
subjects affected / exposed	1 / 3076 (0.03%)	4 / 3071 (0.13%)
occurrences (all)	1	5
Prostatitis		
subjects affected / exposed	8 / 3076 (0.26%)	9 / 3071 (0.29%)
occurrences (all)	8	10
Prostatomegaly		
subjects affected / exposed	6 / 3076 (0.20%)	7 / 3071 (0.23%)
occurrences (all)	6	7
Pruritus genital		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Rectocele		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Retrograde ejaculation		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Scrotal swelling		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Sexual dysfunction		

subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences (all)	0	2	
Testicular atrophy			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences (all)	1	0	
Testicular mass			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences (all)	1	0	
Testicular pain			
subjects affected / exposed	3 / 3076 (0.10%)	0 / 3071 (0.00%)	
occurrences (all)	3	0	
Uterine haemorrhage			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences (all)	1	0	
Uterine polyp			
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)	
occurrences (all)	1	2	
Vaginal haemorrhage			
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)	
occurrences (all)	1	2	
Vaginal prolapse			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences (all)	0	1	
Varicocele			
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences (all)	0	2	
Vulvovaginal discomfort			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences (all)	1	0	
Vulvovaginal dryness			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences (all)	0	1	
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			

subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Acute respiratory failure		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Aphonia		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Apnoea		
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)
occurrences (all)	0	2
Aspiration		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Asthma		
subjects affected / exposed	12 / 3076 (0.39%)	12 / 3071 (0.39%)
occurrences (all)	13	15
Asthmatic crisis		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Atelectasis		
subjects affected / exposed	3 / 3076 (0.10%)	2 / 3071 (0.07%)
occurrences (all)	3	2
Bendopnoea		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Bronchial hyperreactivity		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Bronchial obstruction		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Bronchiectasis		
subjects affected / exposed	4 / 3076 (0.13%)	2 / 3071 (0.07%)
occurrences (all)	5	2
Bronchitis chronic		

subjects affected / exposed	4 / 3076 (0.13%)	6 / 3071 (0.20%)
occurrences (all)	4	6
Bronchospasm		
subjects affected / exposed	3 / 3076 (0.10%)	3 / 3071 (0.10%)
occurrences (all)	3	3
Catarrh		
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)
occurrences (all)	2	1
Chronic respiratory failure		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Chronic obstructive pulmonary disease		
subjects affected / exposed	48 / 3076 (1.56%)	29 / 3071 (0.94%)
occurrences (all)	57	47
Cough		
subjects affected / exposed	95 / 3076 (3.09%)	140 / 3071 (4.56%)
occurrences (all)	101	159
Dry throat		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Dysphonia		
subjects affected / exposed	12 / 3076 (0.39%)	3 / 3071 (0.10%)
occurrences (all)	12	3
Dyspnoea		
subjects affected / exposed	155 / 3076 (5.04%)	152 / 3071 (4.95%)
occurrences (all)	168	171
Dyspnoea at rest		
subjects affected / exposed	0 / 3076 (0.00%)	3 / 3071 (0.10%)
occurrences (all)	0	3
Dyspnoea exertional		
subjects affected / exposed	59 / 3076 (1.92%)	40 / 3071 (1.30%)
occurrences (all)	59	41
Dyspnoea paroxysmal nocturnal		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1

Emphysema		
subjects affected / exposed	4 / 3076 (0.13%)	7 / 3071 (0.23%)
occurrences (all)	4	7
Eosinophilic bronchitis		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Epistaxis		
subjects affected / exposed	46 / 3076 (1.50%)	55 / 3071 (1.79%)
occurrences (all)	58	67
Haemoptysis		
subjects affected / exposed	4 / 3076 (0.13%)	11 / 3071 (0.36%)
occurrences (all)	4	11
Hiccups		
subjects affected / exposed	0 / 3076 (0.00%)	3 / 3071 (0.10%)
occurrences (all)	0	3
Hydrothorax		
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)
occurrences (all)	2	1
Hyperventilation		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	3	0
Hypoxia		
subjects affected / exposed	2 / 3076 (0.07%)	2 / 3071 (0.07%)
occurrences (all)	2	2
Increased bronchial secretion		
subjects affected / exposed	1 / 3076 (0.03%)	3 / 3071 (0.10%)
occurrences (all)	1	3
Increased upper airway secretion		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Interstitial lung disease		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Laryngeal oedema		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1

Laryngeal ulceration		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Laryngospasm		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Lung cyst		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Lung infiltration		
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)
occurrences (all)	2	1
Nasal discomfort		
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)
occurrences (all)	2	1
Nasal congestion		
subjects affected / exposed	6 / 3076 (0.20%)	9 / 3071 (0.29%)
occurrences (all)	7	9
Nasal dryness		
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)
occurrences (all)	0	2
Nasal obstruction		
subjects affected / exposed	0 / 3076 (0.00%)	3 / 3071 (0.10%)
occurrences (all)	0	3
Nasal polyps		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Nasal turbinate abnormality		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Nocturnal dyspnoea		
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)
occurrences (all)	2	1
Oropharyngeal pain		
subjects affected / exposed	6 / 3076 (0.20%)	20 / 3071 (0.65%)
occurrences (all)	6	22

Painful respiration		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Paranasal sinus discomfort		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Pharyngeal paraesthesia		
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)
occurrences (all)	2	1
Pharyngeal lesion		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Pleural adhesion		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Pleural effusion		
subjects affected / exposed	11 / 3076 (0.36%)	6 / 3071 (0.20%)
occurrences (all)	12	6
Pleuritic pain		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Pneumonia aspiration		
subjects affected / exposed	3 / 3076 (0.10%)	2 / 3071 (0.07%)
occurrences (all)	3	2
Pneumothorax		
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)
occurrences (all)	2	1
Productive cough		
subjects affected / exposed	7 / 3076 (0.23%)	6 / 3071 (0.20%)
occurrences (all)	8	6
Pulmonary embolism		
subjects affected / exposed	4 / 3076 (0.13%)	0 / 3071 (0.00%)
occurrences (all)	4	0
Pulmonary fibrosis		
subjects affected / exposed	2 / 3076 (0.07%)	3 / 3071 (0.10%)
occurrences (all)	2	3

Pulmonary haemorrhage subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	0 / 3071 (0.00%) 0
Pulmonary hypertension subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	3 / 3071 (0.10%) 3
Pulmonary infarction subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	0 / 3071 (0.00%) 0
Pulmonary mass subjects affected / exposed occurrences (all)	10 / 3076 (0.33%) 10	17 / 3071 (0.55%) 19
Pulmonary oedema subjects affected / exposed occurrences (all)	3 / 3076 (0.10%) 4	3 / 3071 (0.10%) 3
Pulmonary pain subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	1 / 3071 (0.03%) 1
Reflux laryngitis subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	3 / 3071 (0.10%) 3
Respiration abnormal subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	1 / 3071 (0.03%) 1
Respiratory acidosis subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1
Respiratory disorder subjects affected / exposed occurrences (all)	6 / 3076 (0.20%) 6	3 / 3071 (0.10%) 3
Respiratory distress subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1
Respiratory muscle weakness subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1

Respiratory failure		
subjects affected / exposed	4 / 3076 (0.13%)	2 / 3071 (0.07%)
occurrences (all)	4	2
Respiratory symptom		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Respiratory tract congestion		
subjects affected / exposed	1 / 3076 (0.03%)	5 / 3071 (0.16%)
occurrences (all)	1	5
Respiratory tract inflammation		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Rhinorrhoea		
subjects affected / exposed	15 / 3076 (0.49%)	10 / 3071 (0.33%)
occurrences (all)	15	11
Rhinitis allergic		
subjects affected / exposed	5 / 3076 (0.16%)	1 / 3071 (0.03%)
occurrences (all)	5	1
Rhonchi		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Sinus congestion		
subjects affected / exposed	0 / 3076 (0.00%)	3 / 3071 (0.10%)
occurrences (all)	0	3
Sinus disorder		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Sinus polyp		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Sleep apnoea syndrome		
subjects affected / exposed	33 / 3076 (1.07%)	28 / 3071 (0.91%)
occurrences (all)	33	28
Sneezing		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1

Sputum increased subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1	
Throat irritation subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	3 / 3071 (0.10%) 3	
Upper respiratory tract inflammation subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	0 / 3071 (0.00%) 0	
Upper-airway cough syndrome subjects affected / exposed occurrences (all)	4 / 3076 (0.13%) 4	1 / 3071 (0.03%) 1	
Wheezing subjects affected / exposed occurrences (all)	6 / 3076 (0.20%) 6	4 / 3071 (0.13%) 6	
Psychiatric disorders			
Abnormal behaviour subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	2 / 3071 (0.07%) 2	
Abnormal dreams subjects affected / exposed occurrences (all)	4 / 3076 (0.13%) 4	0 / 3071 (0.00%) 0	
Adjustment disorder subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1	
Adjustment disorder with mixed anxiety and depressed mood subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1	
Adjustment disorder with depressed mood subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1	
Affect lability subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1	
Affective disorder			

subjects affected / exposed	2 / 3076 (0.07%)	2 / 3071 (0.07%)
occurrences (all)	2	2
Aggression		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Agitation		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	2
Alcohol abuse		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Alcohol withdrawal syndrome		
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)
occurrences (all)	2	1
Alcoholism		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Anger		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Anxiety		
subjects affected / exposed	50 / 3076 (1.63%)	56 / 3071 (1.82%)
occurrences (all)	53	58
Anxiety disorder		
subjects affected / exposed	2 / 3076 (0.07%)	6 / 3071 (0.20%)
occurrences (all)	2	6
Apathy		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Attention deficit/hyperactivity disorder		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Binge drinking		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1

Bruxism		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Burnout syndrome		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Claustrophobia		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Confusional state		
subjects affected / exposed	4 / 3076 (0.13%)	5 / 3071 (0.16%)
occurrences (all)	4	7
Delirium		
subjects affected / exposed	4 / 3076 (0.13%)	6 / 3071 (0.20%)
occurrences (all)	5	6
Depressed mood		
subjects affected / exposed	3 / 3076 (0.10%)	4 / 3071 (0.13%)
occurrences (all)	3	4
Depression		
subjects affected / exposed	56 / 3076 (1.82%)	55 / 3071 (1.79%)
occurrences (all)	60	56
Disorientation		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Drug dependence		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Eating disorder		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Emotional disorder		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Generalised anxiety disorder		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1

Hallucination		
subjects affected / exposed	3 / 3076 (0.10%)	0 / 3071 (0.00%)
occurrences (all)	3	0
Impulsive behaviour		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Initial insomnia		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Insomnia		
subjects affected / exposed	36 / 3076 (1.17%)	53 / 3071 (1.73%)
occurrences (all)	40	55
Irritability		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Libido decreased		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Loss of libido		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Major depression		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Mental fatigue		
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)
occurrences (all)	2	1
Mental status changes		
subjects affected / exposed	3 / 3076 (0.10%)	0 / 3071 (0.00%)
occurrences (all)	3	0
Mood altered		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Mood swings		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1

Nervousness		
subjects affected / exposed	0 / 3076 (0.00%)	3 / 3071 (0.10%)
occurrences (all)	0	3
Nightmare		
subjects affected / exposed	2 / 3076 (0.07%)	2 / 3071 (0.07%)
occurrences (all)	2	3
Obsessive-compulsive disorder		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Panic attack		
subjects affected / exposed	3 / 3076 (0.10%)	1 / 3071 (0.03%)
occurrences (all)	3	1
Panic disorder		
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)
occurrences (all)	0	2
Panic reaction		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Persecutory delusion		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Polydipsia psychogenic		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Post-traumatic stress disorder		
subjects affected / exposed	1 / 3076 (0.03%)	3 / 3071 (0.10%)
occurrences (all)	1	3
Rapid eye movement sleep behaviour disorder		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Restlessness		
subjects affected / exposed	2 / 3076 (0.07%)	2 / 3071 (0.07%)
occurrences (all)	2	2
Sleep disorder		

subjects affected / exposed occurrences (all)	4 / 3076 (0.13%) 4	6 / 3071 (0.20%) 6	
Somnolence subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	0 / 3071 (0.00%) 0	
Stress subjects affected / exposed occurrences (all)	4 / 3076 (0.13%) 4	7 / 3071 (0.23%) 7	
Suicidal ideation subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1	
Product issues			
Device breakage subjects affected / exposed occurrences (all)	2 / 3076 (0.07%) 2	0 / 3071 (0.00%) 0	
Device dislocation subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1	
Device failure subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1	
Device issue subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1	
Device malfunction subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	1 / 3071 (0.03%) 1	
Device material opacification subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1	
Device stimulation issue subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1	
Product difficult to swallow subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	1 / 3071 (0.03%) 1	

Hepatobiliary disorders			
Alcoholic liver disease			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences (all)	1	0	
Bile duct obstruction			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences (all)	0	1	
Bile duct stone			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences (all)	1	0	
Biliary colic			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences (all)	1	0	
Biliary cyst			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences (all)	0	1	
Biliary dyskinesia			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences (all)	0	1	
Biloma			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences (all)	1	0	
Cholangitis			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences (all)	0	1	
Cholecystitis			
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)	
occurrences (all)	1	2	
Cholelithiasis			
subjects affected / exposed	22 / 3076 (0.72%)	12 / 3071 (0.39%)	
occurrences (all)	22	12	
Cholecystitis chronic			
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)	
occurrences (all)	1	2	
Cholecystitis acute			

subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Cholestasis		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Gallbladder enlargement		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Gallbladder polyp		
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)
occurrences (all)	1	2
Hepatic cirrhosis		
subjects affected / exposed	2 / 3076 (0.07%)	2 / 3071 (0.07%)
occurrences (all)	2	2
Hepatic cyst		
subjects affected / exposed	3 / 3076 (0.10%)	3 / 3071 (0.10%)
occurrences (all)	3	3
Hepatic failure		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Hepatic function abnormal		
subjects affected / exposed	2 / 3076 (0.07%)	2 / 3071 (0.07%)
occurrences (all)	2	2
Hepatic lesion		
subjects affected / exposed	2 / 3076 (0.07%)	3 / 3071 (0.10%)
occurrences (all)	2	3
Hepatic mass		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Hepatic steatosis		
subjects affected / exposed	12 / 3076 (0.39%)	9 / 3071 (0.29%)
occurrences (all)	12	9
Hepatic pain		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Hepatocellular injury		

subjects affected / exposed occurrences (all)	2 / 3076 (0.07%) 2	1 / 3071 (0.03%) 1	
Hepatomegaly subjects affected / exposed occurrences (all)	3 / 3076 (0.10%) 3	1 / 3071 (0.03%) 1	
Hepatosplenomegaly subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1	
Hyperbilirubinaemia subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1	
Hypertransaminasaemia subjects affected / exposed occurrences (all)	2 / 3076 (0.07%) 2	1 / 3071 (0.03%) 1	
Ischaemic hepatitis subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	0 / 3071 (0.00%) 0	
Liver disorder subjects affected / exposed occurrences (all)	3 / 3076 (0.10%) 3	1 / 3071 (0.03%) 1	
Non-alcoholic fatty liver subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	0 / 3071 (0.00%) 0	
Investigations			
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	6 / 3076 (0.20%) 6	4 / 3071 (0.13%) 4	
Angiogram subjects affected / exposed occurrences (all)	3 / 3076 (0.10%) 3	3 / 3071 (0.10%) 3	
Anticoagulation drug level below therapeutic subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1	
Antinuclear antibody			

subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Antinuclear antibody positive		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Arteriogram coronary		
subjects affected / exposed	5 / 3076 (0.16%)	4 / 3071 (0.13%)
occurrences (all)	5	5
Arthroscopy		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Aspartate aminotransferase increased		
subjects affected / exposed	2 / 3076 (0.07%)	2 / 3071 (0.07%)
occurrences (all)	3	2
Aspiration pleural cavity		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Biopsy liver		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Biopsy prostate		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Biopsy skin normal		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Biopsy stomach abnormal		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Bleeding time prolonged		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Blood alkaline phosphatase increased		
subjects affected / exposed	4 / 3076 (0.13%)	3 / 3071 (0.10%)
occurrences (all)	4	3

Blood bilirubin increased subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	2 / 3071 (0.07%) 2
Blood calcium decreased subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1
Blood calcium increased subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	0 / 3071 (0.00%) 0
Blood cholesterol increased subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	2 / 3071 (0.07%) 2
Blood creatine increased subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	0 / 3071 (0.00%) 0
Blood creatine phosphokinase abnormal subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 2
Blood creatine phosphokinase increased subjects affected / exposed occurrences (all)	14 / 3076 (0.46%) 15	10 / 3071 (0.33%) 10
Blood creatinine increased subjects affected / exposed occurrences (all)	12 / 3076 (0.39%) 13	15 / 3071 (0.49%) 15
Blood folate decreased subjects affected / exposed occurrences (all)	3 / 3076 (0.10%) 3	5 / 3071 (0.16%) 5
Blood glucose abnormal subjects affected / exposed occurrences (all)	2 / 3076 (0.07%) 2	0 / 3071 (0.00%) 0
Blood glucose fluctuation subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	0 / 3071 (0.00%) 0
Blood glucose increased		

subjects affected / exposed	6 / 3076 (0.20%)	18 / 3071 (0.59%)
occurrences (all)	6	18
Blood iron decreased		
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)
occurrences (all)	2	1
Blood lactic acid increased		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Blood magnesium decreased		
subjects affected / exposed	1 / 3076 (0.03%)	4 / 3071 (0.13%)
occurrences (all)	1	7
Blood potassium decreased		
subjects affected / exposed	7 / 3076 (0.23%)	6 / 3071 (0.20%)
occurrences (all)	7	6
Blood potassium increased		
subjects affected / exposed	1 / 3076 (0.03%)	3 / 3071 (0.10%)
occurrences (all)	1	3
Blood pressure abnormal		
subjects affected / exposed	0 / 3076 (0.00%)	3 / 3071 (0.10%)
occurrences (all)	0	3
Blood pressure decreased		
subjects affected / exposed	38 / 3076 (1.24%)	36 / 3071 (1.17%)
occurrences (all)	43	38
Blood pressure diastolic decreased		
subjects affected / exposed	36 / 3076 (1.17%)	36 / 3071 (1.17%)
occurrences (all)	40	41
Blood pressure diastolic increased		
subjects affected / exposed	48 / 3076 (1.56%)	31 / 3071 (1.01%)
occurrences (all)	50	32
Blood pressure difference of extremities		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Blood pressure increased		
subjects affected / exposed	71 / 3076 (2.31%)	59 / 3071 (1.92%)
occurrences (all)	79	70

Blood pressure orthostatic subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Blood pressure systolic decreased subjects affected / exposed	61 / 3076 (1.98%)	51 / 3071 (1.66%)
occurrences (all)	65	55
Blood pressure systolic increased subjects affected / exposed	64 / 3076 (2.08%)	54 / 3071 (1.76%)
occurrences (all)	65	58
Blood test abnormal subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Blood testosterone decreased subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Blood thyroid stimulating hormone abnormal subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Blood thyroid stimulating hormone decreased subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Blood thyroid stimulating hormone increased subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)
occurrences (all)	0	2
Blood triglycerides subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Blood triglycerides increased subjects affected / exposed	20 / 3076 (0.65%)	12 / 3071 (0.39%)
occurrences (all)	22	12
Blood urea increased subjects affected / exposed	0 / 3076 (0.00%)	3 / 3071 (0.10%)
occurrences (all)	0	3
Blood uric acid increased		

subjects affected / exposed	3 / 3076 (0.10%)	0 / 3071 (0.00%)
occurrences (all)	3	0
Blood urine present		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Body temperature increased		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Brain natriuretic peptide increased		
subjects affected / exposed	0 / 3076 (0.00%)	3 / 3071 (0.10%)
occurrences (all)	0	3
Breath sounds		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Breath sounds abnormal		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
C-reactive protein abnormal		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
C-reactive protein increased		
subjects affected / exposed	18 / 3076 (0.59%)	15 / 3071 (0.49%)
occurrences (all)	18	15
Cardiac imaging procedure abnormal		
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)
occurrences (all)	0	2
Cardiac murmur		
subjects affected / exposed	3 / 3076 (0.10%)	5 / 3071 (0.16%)
occurrences (all)	3	5
Cardiac stress test abnormal		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Carotid bruit		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Catheterisation cardiac		

subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)
occurrences (all)	0	2
Chest X-ray abnormal		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Colonoscopy		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Computerised tomogram thorax abnormal		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Cystoscopy		
subjects affected / exposed	3 / 3076 (0.10%)	2 / 3071 (0.07%)
occurrences (all)	8	2
Echocardiogram abnormal		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Ejection fraction decreased		
subjects affected / exposed	3 / 3076 (0.10%)	4 / 3071 (0.13%)
occurrences (all)	3	4
Electrocardiogram P wave abnormal		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Electrocardiogram PR prolongation		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Electrocardiogram QT prolonged		
subjects affected / exposed	5 / 3076 (0.16%)	0 / 3071 (0.00%)
occurrences (all)	5	0
Electrocardiogram T wave amplitude decreased		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Electrocardiogram T wave inversion		

subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Electrocardiogram abnormal		
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)
occurrences (all)	2	1
Electrocardiogram change		
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)
occurrences (all)	1	2
Faecal calprotectin increased		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Fibrin D dimer increased		
subjects affected / exposed	2 / 3076 (0.07%)	5 / 3071 (0.16%)
occurrences (all)	2	5
Fractional flow reserve		
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)
occurrences (all)	0	2
Free prostate-specific antigen increased		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Functional residual capacity decreased		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Gamma-glutamyltransferase increased		
subjects affected / exposed	5 / 3076 (0.16%)	4 / 3071 (0.13%)
occurrences (all)	5	4
General physical condition abnormal		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Glomerular filtration rate abnormal		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Glomerular filtration rate decreased		

subjects affected / exposed	2 / 3076 (0.07%)	3 / 3071 (0.10%)
occurrences (all)	2	4
Glucose tolerance increased		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Glycosylated haemoglobin increased		
subjects affected / exposed	21 / 3076 (0.68%)	18 / 3071 (0.59%)
occurrences (all)	22	18
Grip strength decreased		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
HIV test positive		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Haemoglobin decreased		
subjects affected / exposed	6 / 3076 (0.20%)	12 / 3071 (0.39%)
occurrences (all)	6	14
Heart rate abnormal		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Heart rate decreased		
subjects affected / exposed	5 / 3076 (0.16%)	17 / 3071 (0.55%)
occurrences (all)	5	17
Heart rate increased		
subjects affected / exposed	7 / 3076 (0.23%)	11 / 3071 (0.36%)
occurrences (all)	7	15
Heart rate irregular		
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)
occurrences (all)	1	2
Helicobacter test positive		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Hepatic enzyme increased		
subjects affected / exposed	9 / 3076 (0.29%)	8 / 3071 (0.26%)
occurrences (all)	10	9
High density lipoprotein decreased		

subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
International normalised ratio		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Intraocular pressure increased		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Laboratory test abnormal		
subjects affected / exposed	3 / 3076 (0.10%)	4 / 3071 (0.13%)
occurrences (all)	3	4
Lipids increased		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Liver function test abnormal		
subjects affected / exposed	4 / 3076 (0.13%)	7 / 3071 (0.23%)
occurrences (all)	5	7
Liver function test increased		
subjects affected / exposed	5 / 3076 (0.16%)	4 / 3071 (0.13%)
occurrences (all)	5	5
Low density lipoprotein decreased		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Low density lipoprotein increased		
subjects affected / exposed	5 / 3076 (0.16%)	7 / 3071 (0.23%)
occurrences (all)	5	8
Mammogram abnormal		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
N-terminal prohormone brain natriuretic peptide increased		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Norovirus test positive		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	2	0

Occult blood		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Occult blood positive		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Oesophagogastroduodenoscopy		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Optic nerve cup/disc ratio increased		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Oxygen saturation		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Oxygen saturation decreased		
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)
occurrences (all)	0	2
Pancreatic enzymes increased		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Pedal pulse decreased		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Platelet count decreased		
subjects affected / exposed	3 / 3076 (0.10%)	1 / 3071 (0.03%)
occurrences (all)	3	2
Positron emission tomogram abnormal		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Precancerous cells present		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Prohormone brain natriuretic peptide increased		

subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Prostatic specific antigen increased		
subjects affected / exposed	8 / 3076 (0.26%)	9 / 3071 (0.29%)
occurrences (all)	9	9
Pulse absent		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
QRS axis abnormal		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Radial pulse abnormal		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Radioisotope scan		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Serum ferritin decreased		
subjects affected / exposed	2 / 3076 (0.07%)	3 / 3071 (0.10%)
occurrences (all)	3	3
Serum ferritin increased		
subjects affected / exposed	2 / 3076 (0.07%)	3 / 3071 (0.10%)
occurrences (all)	2	3
Single photon emission computerised tomogram abnormal		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Streptococcus test positive		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Stress echocardiogram abnormal		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Thyroid function test abnormal		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1

Transaminases increased		
subjects affected / exposed	3 / 3076 (0.10%)	2 / 3071 (0.07%)
occurrences (all)	3	2
Treponema test		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Troponin T increased		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Troponin increased		
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)
occurrences (all)	1	2
Ultrasound Doppler abnormal		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Ultrasound prostate abnormal		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Ureteroscopy		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Urine albumin/creatinine ratio increased		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Urine output decreased		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Vital functions abnormal		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Vitamin B12 decreased		
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)
occurrences (all)	1	2
Vitamin D decreased		

subjects affected / exposed occurrences (all)	4 / 3076 (0.13%) 4	3 / 3071 (0.10%) 3	
Weight decreased subjects affected / exposed occurrences (all)	23 / 3076 (0.75%) 25	27 / 3071 (0.88%) 27	
Weight increased subjects affected / exposed occurrences (all)	19 / 3076 (0.62%) 19	25 / 3071 (0.81%) 25	
White blood cell count increased subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	0 / 3071 (0.00%) 0	
Injury, poisoning and procedural complications			
Accidental overdose subjects affected / exposed occurrences (all)	2 / 3076 (0.07%) 2	1 / 3071 (0.03%) 1	
Alcohol poisoning subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	3 / 3071 (0.10%) 3	
Anaemia postoperative subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	1 / 3071 (0.03%) 1	
Anastomotic ulcer subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 2	
Animal bite subjects affected / exposed occurrences (all)	2 / 3076 (0.07%) 2	4 / 3071 (0.13%) 4	
Ankle fracture subjects affected / exposed occurrences (all)	2 / 3076 (0.07%) 2	6 / 3071 (0.20%) 6	
Arthropod sting subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	1 / 3071 (0.03%) 1	
Arthropod bite			

subjects affected / exposed	3 / 3076 (0.10%)	7 / 3071 (0.23%)
occurrences (all)	3	8
Back injury		
subjects affected / exposed	2 / 3076 (0.07%)	5 / 3071 (0.16%)
occurrences (all)	2	6
Bone contusion		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Cartilage injury		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Cervical vertebral fracture		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Chemical burns of eye		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Chest injury		
subjects affected / exposed	2 / 3076 (0.07%)	2 / 3071 (0.07%)
occurrences (all)	2	2
Chillblains		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Clavicle fracture		
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)
occurrences (all)	2	1
Concussion		
subjects affected / exposed	3 / 3076 (0.10%)	6 / 3071 (0.20%)
occurrences (all)	3	6
Contusion		
subjects affected / exposed	37 / 3076 (1.20%)	50 / 3071 (1.63%)
occurrences (all)	41	54
Corneal abrasion		
subjects affected / exposed	3 / 3076 (0.10%)	2 / 3071 (0.07%)
occurrences (all)	3	2
Costal cartilage fracture		

subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Craniocerebral injury		
subjects affected / exposed	3 / 3076 (0.10%)	0 / 3071 (0.00%)
occurrences (all)	3	0
Cystitis radiation		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Dislocation of vertebra		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Electric shock		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Epicondylitis		
subjects affected / exposed	6 / 3076 (0.20%)	8 / 3071 (0.26%)
occurrences (all)	6	9
Eschar		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Excoriation		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Exposure to toxic agent		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Eye contusion		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Eye injury		
subjects affected / exposed	2 / 3076 (0.07%)	2 / 3071 (0.07%)
occurrences (all)	2	2
Eyelid injury		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Face injury		

subjects affected / exposed	3 / 3076 (0.10%)	1 / 3071 (0.03%)
occurrences (all)	3	1
Facial bones fracture		
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)
occurrences (all)	2	1
Fall		
subjects affected / exposed	40 / 3076 (1.30%)	40 / 3071 (1.30%)
occurrences (all)	44	44
Fibula fracture		
subjects affected / exposed	2 / 3076 (0.07%)	2 / 3071 (0.07%)
occurrences (all)	2	2
Foot fracture		
subjects affected / exposed	12 / 3076 (0.39%)	7 / 3071 (0.23%)
occurrences (all)	13	7
Forearm fracture		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Foreign body		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Foreign body in eye		
subjects affected / exposed	3 / 3076 (0.10%)	4 / 3071 (0.13%)
occurrences (all)	3	4
Fracture		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Fracture displacement		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	2
Gun shot wound		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Hand fracture		
subjects affected / exposed	6 / 3076 (0.20%)	11 / 3071 (0.36%)
occurrences (all)	6	11
Head injury		

subjects affected / exposed	8 / 3076 (0.26%)	4 / 3071 (0.13%)
occurrences (all)	8	4
Hip fracture		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Humerus fracture		
subjects affected / exposed	2 / 3076 (0.07%)	2 / 3071 (0.07%)
occurrences (all)	2	2
Immunisation reaction		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	2
Incision site haemorrhage		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Incisional hernia		
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)
occurrences (all)	1	2
Injury		
subjects affected / exposed	5 / 3076 (0.16%)	3 / 3071 (0.10%)
occurrences (all)	5	3
Injury corneal		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Joint dislocation		
subjects affected / exposed	4 / 3076 (0.13%)	5 / 3071 (0.16%)
occurrences (all)	4	5
Joint injury		
subjects affected / exposed	7 / 3076 (0.23%)	9 / 3071 (0.29%)
occurrences (all)	7	9
Laceration		
subjects affected / exposed	21 / 3076 (0.68%)	23 / 3071 (0.75%)
occurrences (all)	21	23
Ligament injury		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Ligament rupture		

subjects affected / exposed	3 / 3076 (0.10%)	2 / 3071 (0.07%)
occurrences (all)	3	2
Ligament sprain		
subjects affected / exposed	20 / 3076 (0.65%)	27 / 3071 (0.88%)
occurrences (all)	20	28
Limb crushing injury		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Limb injury		
subjects affected / exposed	17 / 3076 (0.55%)	21 / 3071 (0.68%)
occurrences (all)	18	21
Limb traumatic amputation		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Lower limb fracture		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Lumbar vertebral fracture		
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)
occurrences (all)	0	2
Medication error		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Meniscus injury		
subjects affected / exposed	2 / 3076 (0.07%)	7 / 3071 (0.23%)
occurrences (all)	2	7
Mouth injury		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Multiple fractures		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Muscle injury		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Muscle rupture		

subjects affected / exposed	3 / 3076 (0.10%)	5 / 3071 (0.16%)
occurrences (all)	3	5
Muscle strain		
subjects affected / exposed	19 / 3076 (0.62%)	14 / 3071 (0.46%)
occurrences (all)	21	14
Musculoskeletal injury		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Nasal injury		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Nerve injury		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Oesophageal injury		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Overdose		
subjects affected / exposed	1 / 3076 (0.03%)	3 / 3071 (0.10%)
occurrences (all)	1	3
Patella fracture		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Pelvic fracture		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Peripheral artery restenosis		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Peroneal nerve injury		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Post concussion syndrome		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Post procedural constipation		

subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Post procedural fistula		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Post procedural haematoma		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Post procedural haemorrhage		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Post-traumatic pain		
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)
occurrences (all)	2	1
Post-traumatic neck syndrome		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Postoperative ileus		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Postoperative thrombosis		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Postoperative wound complication		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Procedural dizziness		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Procedural haemorrhage		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Procedural hypotension		
subjects affected / exposed	4 / 3076 (0.13%)	1 / 3071 (0.03%)
occurrences (all)	4	1
Procedural pain		

subjects affected / exposed	9 / 3076 (0.29%)	1 / 3071 (0.03%)
occurrences (all)	9	1
Procedural vomiting		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Radiation pneumonitis		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Radius fracture		
subjects affected / exposed	6 / 3076 (0.20%)	3 / 3071 (0.10%)
occurrences (all)	6	3
Rib fracture		
subjects affected / exposed	8 / 3076 (0.26%)	12 / 3071 (0.39%)
occurrences (all)	8	12
Road traffic accident		
subjects affected / exposed	2 / 3076 (0.07%)	7 / 3071 (0.23%)
occurrences (all)	2	7
Rotator cuff syndrome		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Scratch		
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)
occurrences (all)	1	2
Skin abrasion		
subjects affected / exposed	0 / 3076 (0.00%)	6 / 3071 (0.20%)
occurrences (all)	0	7
Skull fracture		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Soft tissue injury		
subjects affected / exposed	1 / 3076 (0.03%)	6 / 3071 (0.20%)
occurrences (all)	1	6
Spinal column injury		
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)
occurrences (all)	2	1
Spinal compression fracture		

subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)
occurrences (all)	2	1
Spinal fracture		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Sternal fracture		
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)
occurrences (all)	0	2
Stress fracture		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Subcutaneous haematoma		
subjects affected / exposed	4 / 3076 (0.13%)	3 / 3071 (0.10%)
occurrences (all)	4	3
Subdural haematoma		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Subdural haemorrhage		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Sunburn		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Synovial rupture		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Tendon injury		
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)
occurrences (all)	2	1
Tendon rupture		
subjects affected / exposed	6 / 3076 (0.20%)	9 / 3071 (0.29%)
occurrences (all)	9	9
Thermal burn		
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)
occurrences (all)	1	2
Thoracic vertebral fracture		

subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Tibia fracture		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Tooth fracture		
subjects affected / exposed	3 / 3076 (0.10%)	3 / 3071 (0.10%)
occurrences (all)	3	3
Tooth injury		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Traumatic arthritis		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Traumatic haematoma		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Ulnar nerve injury		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Upper limb fracture		
subjects affected / exposed	2 / 3076 (0.07%)	8 / 3071 (0.26%)
occurrences (all)	2	8
Vaccination complication		
subjects affected / exposed	0 / 3076 (0.00%)	4 / 3071 (0.13%)
occurrences (all)	0	4
Vascular access site pain		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Vascular pseudoaneurysm		
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)
occurrences (all)	0	2
Vascular pseudoaneurysm thrombosis		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1

Wound			
subjects affected / exposed	9 / 3076 (0.29%)	9 / 3071 (0.29%)	
occurrences (all)	9	10	
Wound complication			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences (all)	1	0	
Wound dehiscence			
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences (all)	0	2	
Wound haemorrhage			
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences (all)	0	2	
Wound secretion			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences (all)	0	1	
Wrist fracture			
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)	
occurrences (all)	1	2	
XIIth nerve injury			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences (all)	1	0	
Congenital, familial and genetic disorders			
Atrial septal defect			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences (all)	1	0	
Congenital coronary artery malformation			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences (all)	0	2	
Congenital megaureter			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences (all)	1	0	
Congenital lip fistula			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences (all)	0	1	
Dolichocolon			

subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences (all)	1	0	
Gilbert's syndrome			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences (all)	0	1	
Heart disease congenital			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences (all)	0	1	
Hereditary haemochromatosis			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences (all)	0	1	
Hydrocele			
subjects affected / exposed	4 / 3076 (0.13%)	1 / 3071 (0.03%)	
occurrences (all)	4	1	
Myotonic dystrophy			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences (all)	0	1	
Phimosis			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences (all)	1	1	
Porokeratosis			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences (all)	0	1	
Rathke's cleft cyst			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences (all)	0	1	
Thyroglossal cyst			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences (all)	1	0	
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)	
occurrences (all)	1	2	
Angina pectoris			
subjects affected / exposed	114 / 3076 (3.71%)	109 / 3071 (3.55%)	
occurrences (all)	125	130	

Angina unstable		
subjects affected / exposed	13 / 3076 (0.42%)	10 / 3071 (0.33%)
occurrences (all)	14	11
Anginal equivalent		
subjects affected / exposed	3 / 3076 (0.10%)	0 / 3071 (0.00%)
occurrences (all)	4	0
Aortic valve calcification		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Aortic valve incompetence		
subjects affected / exposed	2 / 3076 (0.07%)	2 / 3071 (0.07%)
occurrences (all)	2	2
Aortic valve sclerosis		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Aortic valve stenosis		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Arrhythmia supraventricular		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	2
Arrhythmia		
subjects affected / exposed	2 / 3076 (0.07%)	2 / 3071 (0.07%)
occurrences (all)	2	2
Arteriospasm coronary		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	2
Atrial fibrillation		
subjects affected / exposed	70 / 3076 (2.28%)	56 / 3071 (1.82%)
occurrences (all)	84	66
Atrial flutter		
subjects affected / exposed	9 / 3076 (0.29%)	5 / 3071 (0.16%)
occurrences (all)	11	5
Atrial thrombosis		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	2	0

Atrial tachycardia		
subjects affected / exposed	0 / 3076 (0.00%)	3 / 3071 (0.10%)
occurrences (all)	0	3
Atrioventricular block complete		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Atrioventricular block second degree		
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)
occurrences (all)	2	1
Atrioventricular block first degree		
subjects affected / exposed	3 / 3076 (0.10%)	0 / 3071 (0.00%)
occurrences (all)	3	0
Bradycardia		
subjects affected / exposed	34 / 3076 (1.11%)	26 / 3071 (0.85%)
occurrences (all)	36	27
Bundle branch block left		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Bundle branch block right		
subjects affected / exposed	6 / 3076 (0.20%)	2 / 3071 (0.07%)
occurrences (all)	7	2
Cardiac failure		
subjects affected / exposed	26 / 3076 (0.85%)	33 / 3071 (1.07%)
occurrences (all)	27	35
Cardiac failure chronic		
subjects affected / exposed	5 / 3076 (0.16%)	2 / 3071 (0.07%)
occurrences (all)	6	2
Cardiac failure congestive		
subjects affected / exposed	9 / 3076 (0.29%)	9 / 3071 (0.29%)
occurrences (all)	9	11
Cardiac failure acute		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Cardiac flutter		
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)
occurrences (all)	0	2

Cardiac ventricular thrombosis subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	4 / 3071 (0.13%) 5
Cardiac valve disease subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	0 / 3071 (0.00%) 0
Cardiogenic shock subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	0 / 3071 (0.00%) 0
Cardiomegaly subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1
Cardiomyopathy subjects affected / exposed occurrences (all)	3 / 3076 (0.10%) 3	2 / 3071 (0.07%) 2
Cardiovascular disorder subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	0 / 3071 (0.00%) 0
Chest pain subjects affected / exposed occurrences (all)	4 / 3076 (0.13%) 4	4 / 3071 (0.13%) 4
Chronic left ventricular failure subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	1 / 3071 (0.03%) 1
Chronotropic incompetence subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	0 / 3071 (0.00%) 0
Conduction disorder subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	0 / 3071 (0.00%) 0
Congestive cardiomyopathy subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	2 / 3071 (0.07%) 2
Coronary artery occlusion subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	1 / 3071 (0.03%) 2

Coronary artery disease subjects affected / exposed occurrences (all)	6 / 3076 (0.20%) 7	9 / 3071 (0.29%) 9
Coronary artery stenosis subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	1 / 3071 (0.03%) 1
Cyanosis subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	3 / 3071 (0.10%) 3
Diastolic dysfunction subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	2 / 3071 (0.07%) 3
Dilatation atrial subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	0 / 3071 (0.00%) 0
Extrasystoles subjects affected / exposed occurrences (all)	4 / 3076 (0.13%) 4	4 / 3071 (0.13%) 4
Heart valve incompetence subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	1 / 3071 (0.03%) 1
Hepatojugular reflux subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1
Intracardiac thrombus subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	0 / 3071 (0.00%) 0
Ischaemic cardiomyopathy subjects affected / exposed occurrences (all)	2 / 3076 (0.07%) 2	3 / 3071 (0.10%) 3
Left ventricular dysfunction subjects affected / exposed occurrences (all)	6 / 3076 (0.20%) 6	2 / 3071 (0.07%) 2
Left ventricular failure subjects affected / exposed occurrences (all)	2 / 3076 (0.07%) 2	1 / 3071 (0.03%) 1

Left ventricular hypertrophy subjects affected / exposed occurrences (all)	2 / 3076 (0.07%) 2	1 / 3071 (0.03%) 1
Mitral valve calcification subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1
Mitral valve incompetence subjects affected / exposed occurrences (all)	3 / 3076 (0.10%) 3	4 / 3071 (0.13%) 4
Myocardial infarction subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	0 / 3071 (0.00%) 0
Myocarditis subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1
Myocardial ischaemia subjects affected / exposed occurrences (all)	5 / 3076 (0.16%) 5	8 / 3071 (0.26%) 8
Nodal arrhythmia subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	1 / 3071 (0.03%) 1
Oedema peripheral subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	1 / 3071 (0.03%) 1
Palpitations subjects affected / exposed occurrences (all)	66 / 3076 (2.15%) 70	50 / 3071 (1.63%) 55
Pericarditis subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	5 / 3071 (0.16%) 6
Pericardial effusion subjects affected / exposed occurrences (all)	2 / 3076 (0.07%) 2	0 / 3071 (0.00%) 0
Prinzmetal angina subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	0 / 3071 (0.00%) 0

Right ventricular failure subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1
Sinoatrial block subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	1 / 3071 (0.03%) 1
Sinus bradycardia subjects affected / exposed occurrences (all)	9 / 3076 (0.29%) 10	7 / 3071 (0.23%) 7
Sinus node dysfunction subjects affected / exposed occurrences (all)	2 / 3076 (0.07%) 2	1 / 3071 (0.03%) 1
Sinus tachycardia subjects affected / exposed occurrences (all)	3 / 3076 (0.10%) 3	8 / 3071 (0.26%) 11
Supraventricular extrasystoles subjects affected / exposed occurrences (all)	4 / 3076 (0.13%) 4	4 / 3071 (0.13%) 4
Supraventricular tachycardia subjects affected / exposed occurrences (all)	7 / 3076 (0.23%) 7	8 / 3071 (0.26%) 8
Tachycardia subjects affected / exposed occurrences (all)	11 / 3076 (0.36%) 13	11 / 3071 (0.36%) 11
Tricuspid valve incompetence subjects affected / exposed occurrences (all)	5 / 3076 (0.16%) 5	2 / 3071 (0.07%) 2
Ventricular arrhythmia subjects affected / exposed occurrences (all)	2 / 3076 (0.07%) 2	1 / 3071 (0.03%) 1
Ventricular extrasystoles subjects affected / exposed occurrences (all)	16 / 3076 (0.52%) 17	16 / 3071 (0.52%) 16
Ventricular fibrillation subjects affected / exposed occurrences (all)	3 / 3076 (0.10%) 3	0 / 3071 (0.00%) 0

Ventricular hypokinesia subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1	
Ventricular remodelling subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	2 / 3071 (0.07%) 2	
Ventricular tachycardia subjects affected / exposed occurrences (all)	7 / 3076 (0.23%) 8	7 / 3071 (0.23%) 8	
Wolff-Parkinson-White syndrome subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1	
Nervous system disorders			
Ageusia subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	2 / 3071 (0.07%) 2	
Altered state of consciousness subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1	
Amnesia subjects affected / exposed occurrences (all)	8 / 3076 (0.26%) 8	13 / 3071 (0.42%) 13	
Anosmia subjects affected / exposed occurrences (all)	2 / 3076 (0.07%) 2	1 / 3071 (0.03%) 1	
Aphasia subjects affected / exposed occurrences (all)	4 / 3076 (0.13%) 4	1 / 3071 (0.03%) 1	
Aphonia subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	2 / 3071 (0.07%) 2	
Ataxia subjects affected / exposed occurrences (all)	2 / 3076 (0.07%) 2	0 / 3071 (0.00%) 0	
Autonomic nervous system imbalance			

subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Balance disorder		
subjects affected / exposed	4 / 3076 (0.13%)	4 / 3071 (0.13%)
occurrences (all)	4	5
Burning sensation		
subjects affected / exposed	4 / 3076 (0.13%)	2 / 3071 (0.07%)
occurrences (all)	4	2
Carotid arteriosclerosis		
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)
occurrences (all)	2	1
Carotid artery aneurysm		
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)
occurrences (all)	0	2
Carotid artery occlusion		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Carotid artery disease		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Carotid artery insufficiency		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Carotid artery stenosis		
subjects affected / exposed	8 / 3076 (0.26%)	4 / 3071 (0.13%)
occurrences (all)	9	4
Carpal tunnel syndrome		
subjects affected / exposed	15 / 3076 (0.49%)	12 / 3071 (0.39%)
occurrences (all)	17	13
Cerebellar artery thrombosis		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Cerebellar microhaemorrhage		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Cerebral arteriosclerosis		

subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)
occurrences (all)	0	2
Cerebral atrophy		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Cerebral disorder		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Cerebral haematoma		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Cerebral ischaemia		
subjects affected / exposed	2 / 3076 (0.07%)	3 / 3071 (0.10%)
occurrences (all)	2	3
Cerebral microhaemorrhage		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Cerebrovascular disorder		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Cervical myelopathy		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Cervical radiculopathy		
subjects affected / exposed	5 / 3076 (0.16%)	1 / 3071 (0.03%)
occurrences (all)	5	1
Chronic inflammatory demyelinating polyradiculoneuropathy		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Cluster headache		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Cognitive disorder		
subjects affected / exposed	6 / 3076 (0.20%)	2 / 3071 (0.07%)
occurrences (all)	6	2

Cubital tunnel syndrome		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Dementia		
subjects affected / exposed	5 / 3076 (0.16%)	4 / 3071 (0.13%)
occurrences (all)	6	5
Dementia Alzheimer's type		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Demyelination		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Diabetic neuropathy		
subjects affected / exposed	10 / 3076 (0.33%)	8 / 3071 (0.26%)
occurrences (all)	11	8
Disturbance in attention		
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)
occurrences (all)	2	1
Dizziness		
subjects affected / exposed	138 / 3076 (4.49%)	147 / 3071 (4.79%)
occurrences (all)	151	166
Dizziness exertional		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	2	1
Dizziness postural		
subjects affected / exposed	9 / 3076 (0.29%)	8 / 3071 (0.26%)
occurrences (all)	9	8
Dysaesthesia		
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)
occurrences (all)	0	2
Dysarthria		
subjects affected / exposed	3 / 3076 (0.10%)	3 / 3071 (0.10%)
occurrences (all)	3	3
Dysgeusia		
subjects affected / exposed	9 / 3076 (0.29%)	8 / 3071 (0.26%)
occurrences (all)	10	8

Dyskinesia		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Encephalopathy		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Enlarged cerebral perivascular spaces		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Epilepsy		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Essential tremor		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Extrapyramidal disorder		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Facial neuralgia		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Facial paralysis		
subjects affected / exposed	4 / 3076 (0.13%)	3 / 3071 (0.10%)
occurrences (all)	5	3
Freezing phenomenon		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Head discomfort		
subjects affected / exposed	3 / 3076 (0.10%)	1 / 3071 (0.03%)
occurrences (all)	3	1
Headache		
subjects affected / exposed	96 / 3076 (3.12%)	142 / 3071 (4.62%)
occurrences (all)	115	165
Hemianaesthesia		

subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Hemiparesis		
subjects affected / exposed	5 / 3076 (0.16%)	1 / 3071 (0.03%)
occurrences (all)	5	1
Hemiplegia		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Hydrocephalus		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Hypoaesthesia		
subjects affected / exposed	27 / 3076 (0.88%)	36 / 3071 (1.17%)
occurrences (all)	30	36
Hypogeusia		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Hyposmia		
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)
occurrences (all)	1	2
Hypotonia		
subjects affected / exposed	2 / 3076 (0.07%)	2 / 3071 (0.07%)
occurrences (all)	2	2
IIIrd nerve paralysis		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
IVth nerve paralysis		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Intercostal neuralgia		
subjects affected / exposed	0 / 3076 (0.00%)	3 / 3071 (0.10%)
occurrences (all)	0	3
Intracranial mass		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Lethargy		

subjects affected / exposed	6 / 3076 (0.20%)	9 / 3071 (0.29%)
occurrences (all)	7	9
Leukoencephalopathy		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Loss of consciousness		
subjects affected / exposed	4 / 3076 (0.13%)	4 / 3071 (0.13%)
occurrences (all)	4	4
Lumbar radiculopathy		
subjects affected / exposed	3 / 3076 (0.10%)	4 / 3071 (0.13%)
occurrences (all)	4	4
Lumbosacral radiculopathy		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Memory impairment		
subjects affected / exposed	10 / 3076 (0.33%)	8 / 3071 (0.26%)
occurrences (all)	10	8
Meralgia paraesthetica		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Metabolic encephalopathy		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Migraine with aura		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Migraine		
subjects affected / exposed	5 / 3076 (0.16%)	8 / 3071 (0.26%)
occurrences (all)	7	8
Motor dysfunction		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Movement disorder		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Multiple sclerosis		

subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Muscle contractions involuntary		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Myelopathy		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	2	1
Myoclonus		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Nerve compression		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Nervous system disorder		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Nerve root compression		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Neuralgia		
subjects affected / exposed	2 / 3076 (0.07%)	4 / 3071 (0.13%)
occurrences (all)	2	4
Neuropathy peripheral		
subjects affected / exposed	13 / 3076 (0.42%)	12 / 3071 (0.39%)
occurrences (all)	13	12
Normal pressure hydrocephalus		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Occipital neuralgia		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Paraesthesia		
subjects affected / exposed	29 / 3076 (0.94%)	27 / 3071 (0.88%)
occurrences (all)	29	28
Paralysis		

subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Paresis		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Parkinson's disease		
subjects affected / exposed	5 / 3076 (0.16%)	4 / 3071 (0.13%)
occurrences (all)	5	4
Parkinsonism		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Parosmia		
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)
occurrences (all)	0	2
Phantom pain		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Polyneuropathy		
subjects affected / exposed	4 / 3076 (0.13%)	3 / 3071 (0.10%)
occurrences (all)	5	3
Post-traumatic headache		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Presyncope		
subjects affected / exposed	19 / 3076 (0.62%)	13 / 3071 (0.42%)
occurrences (all)	22	13
Pseudoradicular syndrome		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Psychomotor hyperactivity		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Quadrantanopia		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Radicular syndrome		

subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Radiculopathy		
subjects affected / exposed	2 / 3076 (0.07%)	3 / 3071 (0.10%)
occurrences (all)	2	3
Restless legs syndrome		
subjects affected / exposed	6 / 3076 (0.20%)	2 / 3071 (0.07%)
occurrences (all)	6	3
Sciatica		
subjects affected / exposed	27 / 3076 (0.88%)	27 / 3071 (0.88%)
occurrences (all)	27	27
Seizure		
subjects affected / exposed	2 / 3076 (0.07%)	2 / 3071 (0.07%)
occurrences (all)	2	2
Sinus headache		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	2	2
Somnolence		
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)
occurrences (all)	4	1
Speech disorder		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Spinal cord disorder		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Syncope		
subjects affected / exposed	37 / 3076 (1.20%)	32 / 3071 (1.04%)
occurrences (all)	41	35
Tension headache		
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)
occurrences (all)	2	1
Tongue biting		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Transient global amnesia		

subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences (all)	1	0	
Transient ischaemic attack			
subjects affected / exposed	5 / 3076 (0.16%)	0 / 3071 (0.00%)	
occurrences (all)	5	0	
Tremor			
subjects affected / exposed	4 / 3076 (0.13%)	10 / 3071 (0.33%)	
occurrences (all)	4	11	
Trigeminal neuralgia			
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences (all)	0	2	
Ulnar neuritis			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences (all)	1	0	
Ulnar tunnel syndrome			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences (all)	1	0	
Vascular dementia			
subjects affected / exposed	0 / 3076 (0.00%)	3 / 3071 (0.10%)	
occurrences (all)	0	3	
Vertebral artery stenosis			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences (all)	1	0	
Vertebral artery occlusion			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences (all)	1	0	
Visual field defect			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences (all)	1	0	
Vocal cord paralysis			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences (all)	0	1	
White matter lesion			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences (all)	0	2	
Blood and lymphatic system disorders			

Anaemia		
subjects affected / exposed	62 / 3076 (2.02%)	60 / 3071 (1.95%)
occurrences (all)	65	62
Anaemia macrocytic		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Anaemia of chronic disease		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Anaemia vitamin B12 deficiency		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Bone marrow oedema		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Coagulopathy		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Deficiency anaemia		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Eosinophilia		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Haemorrhagic anaemia		
subjects affected / exposed	2 / 3076 (0.07%)	3 / 3071 (0.10%)
occurrences (all)	2	3
Haemorrhagic diathesis		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Heparin-induced thrombocytopenia		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Hilar lymphadenopathy		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0

Hypochromic anaemia		
subjects affected / exposed	2 / 3076 (0.07%)	4 / 3071 (0.13%)
occurrences (all)	2	5
Immune thrombocytopenic purpura		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Increased tendency to bruise		
subjects affected / exposed	4 / 3076 (0.13%)	4 / 3071 (0.13%)
occurrences (all)	5	4
Iron deficiency anaemia		
subjects affected / exposed	18 / 3076 (0.59%)	27 / 3071 (0.88%)
occurrences (all)	18	27
Leukocytosis		
subjects affected / exposed	4 / 3076 (0.13%)	4 / 3071 (0.13%)
occurrences (all)	4	4
Leukopenia		
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)
occurrences (all)	1	2
Lymphadenopathy		
subjects affected / exposed	3 / 3076 (0.10%)	8 / 3071 (0.26%)
occurrences (all)	3	8
Lymphadenopathy mediastinal		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Lymphopenia		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Macrocytosis		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Microcytic anaemia		
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)
occurrences (all)	1	2
Neutropenia		
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)
occurrences (all)	2	1

Neutrophilia			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences (all)	0	1	
Normochromic normocytic anaemia			
subjects affected / exposed	6 / 3076 (0.20%)	4 / 3071 (0.13%)	
occurrences (all)	6	4	
Pancytopenia			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences (all)	1	1	
Pernicious anaemia			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences (all)	1	0	
Polycythaemia			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences (all)	1	0	
Spleen disorder			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences (all)	0	1	
Splenic cyst			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences (all)	0	1	
Splenomegaly			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences (all)	1	0	
Spontaneous haematoma			
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)	
occurrences (all)	2	0	
Thrombocytopenia			
subjects affected / exposed	5 / 3076 (0.16%)	6 / 3071 (0.20%)	
occurrences (all)	5	6	
Thrombocytosis			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences (all)	1	0	
Ear and labyrinth disorders			
Cerumen impaction			

subjects affected / exposed	1 / 3076 (0.03%)	5 / 3071 (0.16%)
occurrences (all)	1	5
Deafness		
subjects affected / exposed	2 / 3076 (0.07%)	4 / 3071 (0.13%)
occurrences (all)	2	4
Deafness bilateral		
subjects affected / exposed	3 / 3076 (0.10%)	4 / 3071 (0.13%)
occurrences (all)	3	5
Deafness neurosensory		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Deafness unilateral		
subjects affected / exposed	1 / 3076 (0.03%)	6 / 3071 (0.20%)
occurrences (all)	1	6
Ear discomfort		
subjects affected / exposed	2 / 3076 (0.07%)	2 / 3071 (0.07%)
occurrences (all)	2	2
Ear haemorrhage		
subjects affected / exposed	1 / 3076 (0.03%)	3 / 3071 (0.10%)
occurrences (all)	1	3
Ear pain		
subjects affected / exposed	5 / 3076 (0.16%)	10 / 3071 (0.33%)
occurrences (all)	6	11
Ear pruritus		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Ear swelling		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Eustachian tube disorder		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Eustachian tube dysfunction		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Excessive cerumen production		

subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
External ear inflammation		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Hypoacusis		
subjects affected / exposed	1 / 3076 (0.03%)	5 / 3071 (0.16%)
occurrences (all)	1	6
Inner ear disorder		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Meniere's disease		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Middle ear effusion		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Motion sickness		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Otorrhoea		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Presbycusis		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Sudden hearing loss		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Tinnitus		
subjects affected / exposed	14 / 3076 (0.46%)	15 / 3071 (0.49%)
occurrences (all)	14	15
Tympanic membrane perforation		
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)
occurrences (all)	0	2
Vertigo		

subjects affected / exposed occurrences (all)	35 / 3076 (1.14%) 38	30 / 3071 (0.98%) 31	
Vertigo positional subjects affected / exposed occurrences (all)	6 / 3076 (0.20%) 6	5 / 3071 (0.16%) 5	
Vestibular disorder subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1	
Eye disorders			
Age-related macular degeneration subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1	
Amaurosis fugax subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	0 / 3071 (0.00%) 0	
Amaurosis subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	0 / 3071 (0.00%) 0	
Arteriosclerotic retinopathy subjects affected / exposed occurrences (all)	2 / 3076 (0.07%) 2	0 / 3071 (0.00%) 0	
Astigmatism subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	0 / 3071 (0.00%) 0	
Blepharitis subjects affected / exposed occurrences (all)	3 / 3076 (0.10%) 4	2 / 3071 (0.07%) 2	
Blindness subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	0 / 3071 (0.00%) 0	
Cataract nuclear subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1	
Cataract subjects affected / exposed occurrences (all)	47 / 3076 (1.53%) 54	40 / 3071 (1.30%) 47	

Chorioretinopathy		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Conjunctival hyperaemia		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Conjunctival haemorrhage		
subjects affected / exposed	4 / 3076 (0.13%)	6 / 3071 (0.20%)
occurrences (all)	4	6
Conjunctival oedema		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Dacryostenosis acquired		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Diabetic retinopathy		
subjects affected / exposed	6 / 3076 (0.20%)	5 / 3071 (0.16%)
occurrences (all)	7	6
Diabetic retinal oedema		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	2
Diplopia		
subjects affected / exposed	6 / 3076 (0.20%)	0 / 3071 (0.00%)
occurrences (all)	6	0
Dry eye		
subjects affected / exposed	4 / 3076 (0.13%)	9 / 3071 (0.29%)
occurrences (all)	4	9
Eye allergy		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Eye colour change		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Eye discharge		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1

Eye disorder		
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)
occurrences (all)	0	2
Eye haemorrhage		
subjects affected / exposed	2 / 3076 (0.07%)	3 / 3071 (0.10%)
occurrences (all)	2	3
Eye inflammation		
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)
occurrences (all)	1	2
Eye irritation		
subjects affected / exposed	5 / 3076 (0.16%)	1 / 3071 (0.03%)
occurrences (all)	5	1
Eye oedema		
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)
occurrences (all)	1	2
Eye pruritus		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Eye pain		
subjects affected / exposed	1 / 3076 (0.03%)	3 / 3071 (0.10%)
occurrences (all)	1	3
Eye swelling		
subjects affected / exposed	0 / 3076 (0.00%)	3 / 3071 (0.10%)
occurrences (all)	0	3
Eyelid irritation		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Eyelid ptosis		
subjects affected / exposed	1 / 3076 (0.03%)	5 / 3071 (0.16%)
occurrences (all)	1	5
Eyelid oedema		
subjects affected / exposed	1 / 3076 (0.03%)	4 / 3071 (0.13%)
occurrences (all)	1	5
Foreign body sensation in eyes		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1

Glaucoma		
subjects affected / exposed	3 / 3076 (0.10%)	8 / 3071 (0.26%)
occurrences (all)	3	8
Hypermetropia		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Hyphaema		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Idiopathic orbital inflammation		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Iridocyclitis		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Keratitis		
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)
occurrences (all)	1	2
Lacrimation increased		
subjects affected / exposed	4 / 3076 (0.13%)	1 / 3071 (0.03%)
occurrences (all)	4	1
Macular degeneration		
subjects affected / exposed	3 / 3076 (0.10%)	5 / 3071 (0.16%)
occurrences (all)	3	5
Macular fibrosis		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Macular hole		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Macular oedema		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Meibomian gland dysfunction		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1

Meibomianitis		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Myopia		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Neovascular age-related macular degeneration		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Ocular hyperaemia		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	2
Ocular hypertension		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Ocular ischaemic syndrome		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Ocular vascular disorder		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Open angle glaucoma		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Ophthalmic vein thrombosis		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Panophthalmitis		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Photophobia		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Posterior capsule opacification		

subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)
occurrences (all)	1	2
Presbyopia		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Pterygium		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Retinal artery occlusion		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Retinal degeneration		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Retinal detachment		
subjects affected / exposed	5 / 3076 (0.16%)	2 / 3071 (0.07%)
occurrences (all)	6	3
Retinal disorder		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Retinal haemorrhage		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Retinal tear		
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)
occurrences (all)	0	2
Retinal vein occlusion		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Retinopathy		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Retinopathy hypertensive		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Scleral pigmentation		

subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Strabismus		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Sudden visual loss		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Trichiasis		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Ulcerative keratitis		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Vision blurred		
subjects affected / exposed	15 / 3076 (0.49%)	4 / 3071 (0.13%)
occurrences (all)	16	4
Visual acuity reduced		
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)
occurrences (all)	2	1
Visual impairment		
subjects affected / exposed	2 / 3076 (0.07%)	5 / 3071 (0.16%)
occurrences (all)	2	5
Vitreous adhesions		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Vitreous degeneration		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Vitreous detachment		
subjects affected / exposed	2 / 3076 (0.07%)	3 / 3071 (0.10%)
occurrences (all)	2	3
Vitreous floaters		
subjects affected / exposed	5 / 3076 (0.16%)	0 / 3071 (0.00%)
occurrences (all)	5	0
Vitreous haemorrhage		

subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1	
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	17 / 3076 (0.55%)	17 / 3071 (0.55%)	
occurrences (all)	18	17	
Abdominal distension			
subjects affected / exposed	17 / 3076 (0.55%)	23 / 3071 (0.75%)	
occurrences (all)	18	25	
Abdominal hernia			
subjects affected / exposed	2 / 3076 (0.07%)	2 / 3071 (0.07%)	
occurrences (all)	2	2	
Abdominal pain			
subjects affected / exposed	58 / 3076 (1.89%)	76 / 3071 (2.47%)	
occurrences (all)	67	81	
Abdominal pain lower			
subjects affected / exposed	3 / 3076 (0.10%)	5 / 3071 (0.16%)	
occurrences (all)	3	5	
Abdominal pain upper			
subjects affected / exposed	54 / 3076 (1.76%)	77 / 3071 (2.51%)	
occurrences (all)	57	89	
Abdominal tenderness			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences (all)	1	0	
Abdominal wall mass			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences (all)	1	0	
Abnormal faeces			
subjects affected / exposed	2 / 3076 (0.07%)	5 / 3071 (0.16%)	
occurrences (all)	2	5	
Anal erosion			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences (all)	1	0	
Anal fissure			
subjects affected / exposed	6 / 3076 (0.20%)	0 / 3071 (0.00%)	
occurrences (all)	6	0	

Anal fistula		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Anal haemorrhage		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Anal incontinence		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Anal pruritus		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Anorectal discomfort		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Aphthous ulcer		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Ascites		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Barrett's oesophagus		
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)
occurrences (all)	0	2
Bowel movement irregularity		
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)
occurrences (all)	1	2
Breath odour		
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)
occurrences (all)	3	1
Burning mouth syndrome		
subjects affected / exposed	0 / 3076 (0.00%)	3 / 3071 (0.10%)
occurrences (all)	0	5
Change of bowel habit		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	2	0

Chronic cheek biting subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	0 / 3071 (0.00%) 0
Chronic gastritis subjects affected / exposed occurrences (all)	6 / 3076 (0.20%) 6	5 / 3071 (0.16%) 5
Coeliac disease subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	3 / 3071 (0.10%) 3
Colitis ulcerative subjects affected / exposed occurrences (all)	4 / 3076 (0.13%) 4	4 / 3071 (0.13%) 4
Colitis subjects affected / exposed occurrences (all)	6 / 3076 (0.20%) 6	3 / 3071 (0.10%) 3
Constipation subjects affected / exposed occurrences (all)	67 / 3076 (2.18%) 71	69 / 3071 (2.25%) 75
Crohn's disease subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	3 / 3071 (0.10%) 3
Dental caries subjects affected / exposed occurrences (all)	4 / 3076 (0.13%) 4	7 / 3071 (0.23%) 8
Diarrhoea subjects affected / exposed occurrences (all)	186 / 3076 (6.05%) 220	300 / 3071 (9.77%) 378
Diarrhoea haemorrhagic subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1
Diverticulum subjects affected / exposed occurrences (all)	14 / 3076 (0.46%) 14	11 / 3071 (0.36%) 11
Diverticulum intestinal subjects affected / exposed occurrences (all)	6 / 3076 (0.20%) 6	8 / 3071 (0.26%) 8

Diverticulum oesophageal subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1
Dry mouth subjects affected / exposed occurrences (all)	11 / 3076 (0.36%) 11	6 / 3071 (0.20%) 6
Duodenitis subjects affected / exposed occurrences (all)	2 / 3076 (0.07%) 2	3 / 3071 (0.10%) 4
Duodenal ulcer subjects affected / exposed occurrences (all)	2 / 3076 (0.07%) 2	3 / 3071 (0.10%) 3
Dyschezia subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	0 / 3071 (0.00%) 0
Dyspepsia subjects affected / exposed occurrences (all)	50 / 3076 (1.63%) 55	58 / 3071 (1.89%) 64
Dysphagia subjects affected / exposed occurrences (all)	6 / 3076 (0.20%) 6	9 / 3071 (0.29%) 10
Eosinophilic oesophagitis subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	0 / 3071 (0.00%) 0
Epigastric discomfort subjects affected / exposed occurrences (all)	4 / 3076 (0.13%) 4	5 / 3071 (0.16%) 5
Epiplonic appendagitis subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1
Erosive oesophagitis subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1
Eructation subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1

Faecalith		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Faeces discoloured		
subjects affected / exposed	3 / 3076 (0.10%)	3 / 3071 (0.10%)
occurrences (all)	3	3
Faeces hard		
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)
occurrences (all)	1	2
Faeces soft		
subjects affected / exposed	6 / 3076 (0.20%)	5 / 3071 (0.16%)
occurrences (all)	6	5
Femoral hernia		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Flatulence		
subjects affected / exposed	19 / 3076 (0.62%)	15 / 3071 (0.49%)
occurrences (all)	19	15
Food poisoning		
subjects affected / exposed	3 / 3076 (0.10%)	4 / 3071 (0.13%)
occurrences (all)	4	4
Frequent bowel movements		
subjects affected / exposed	5 / 3076 (0.16%)	4 / 3071 (0.13%)
occurrences (all)	5	4
Gastric dilatation		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Gastric disorder		
subjects affected / exposed	1 / 3076 (0.03%)	6 / 3071 (0.20%)
occurrences (all)	1	6
Gastric polyps		
subjects affected / exposed	2 / 3076 (0.07%)	3 / 3071 (0.10%)
occurrences (all)	2	3
Gastric mucosal lesion		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0

Gastric ulcer		
subjects affected / exposed	10 / 3076 (0.33%)	1 / 3071 (0.03%)
occurrences (all)	10	1
Gastritis		
subjects affected / exposed	32 / 3076 (1.04%)	21 / 3071 (0.68%)
occurrences (all)	33	21
Gastritis erosive		
subjects affected / exposed	1 / 3076 (0.03%)	5 / 3071 (0.16%)
occurrences (all)	1	6
Gastritis haemorrhagic		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Gastroduodenitis		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Gastrointestinal angiodysplasia		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Gastrointestinal disorder		
subjects affected / exposed	5 / 3076 (0.16%)	4 / 3071 (0.13%)
occurrences (all)	5	8
Gastrointestinal haemorrhage		
subjects affected / exposed	3 / 3076 (0.10%)	5 / 3071 (0.16%)
occurrences (all)	3	5
Gastrointestinal motility disorder		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Gastrointestinal ulcer		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Gastrointestinal pain		
subjects affected / exposed	2 / 3076 (0.07%)	2 / 3071 (0.07%)
occurrences (all)	2	2
Gastrointestinal wall thickening		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1

Gastrooesophageal reflux disease		
subjects affected / exposed	48 / 3076 (1.56%)	51 / 3071 (1.66%)
occurrences (all)	50	51
Gastrooesophageal sphincter insufficiency		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Gingival bleeding		
subjects affected / exposed	5 / 3076 (0.16%)	6 / 3071 (0.20%)
occurrences (all)	5	6
Gingival cyst		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Gingival pain		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Haematemesis		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Haematochezia		
subjects affected / exposed	5 / 3076 (0.16%)	16 / 3071 (0.52%)
occurrences (all)	5	17
Haemorrhoidal haemorrhage		
subjects affected / exposed	4 / 3076 (0.13%)	2 / 3071 (0.07%)
occurrences (all)	4	2
Haemorrhoids		
subjects affected / exposed	16 / 3076 (0.52%)	17 / 3071 (0.55%)
occurrences (all)	16	18
Haemorrhoids thrombosed		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Hiatus hernia		
subjects affected / exposed	10 / 3076 (0.33%)	12 / 3071 (0.39%)
occurrences (all)	10	12
Hyperchlorhydria		

subjects affected / exposed	3 / 3076 (0.10%)	1 / 3071 (0.03%)
occurrences (all)	3	1
Hypoaesthesia oral		
subjects affected / exposed	2 / 3076 (0.07%)	2 / 3071 (0.07%)
occurrences (all)	2	2
Ileus		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Impaired gastric emptying		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Infrequent bowel movements		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Inguinal hernia		
subjects affected / exposed	17 / 3076 (0.55%)	10 / 3071 (0.33%)
occurrences (all)	18	10
Intestinal haemorrhage		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Intestinal polyp		
subjects affected / exposed	4 / 3076 (0.13%)	7 / 3071 (0.23%)
occurrences (all)	5	8
Intestinal prolapse		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Irritable bowel syndrome		
subjects affected / exposed	0 / 3076 (0.00%)	7 / 3071 (0.23%)
occurrences (all)	0	7
Large intestinal stenosis		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Large intestine polyp		
subjects affected / exposed	12 / 3076 (0.39%)	17 / 3071 (0.55%)
occurrences (all)	13	17
Lower gastrointestinal haemorrhage		

subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Lumbar hernia		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Melaena		
subjects affected / exposed	1 / 3076 (0.03%)	7 / 3071 (0.23%)
occurrences (all)	1	7
Mesenteric panniculitis		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Mouth haemorrhage		
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)
occurrences (all)	2	1
Mouth ulceration		
subjects affected / exposed	5 / 3076 (0.16%)	2 / 3071 (0.07%)
occurrences (all)	5	2
Nausea		
subjects affected / exposed	66 / 3076 (2.15%)	100 / 3071 (3.26%)
occurrences (all)	76	114
Noninfective gingivitis		
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)
occurrences (all)	0	2
Odynophagia		
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)
occurrences (all)	2	1
Oesophageal discomfort		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Oesophageal food impaction		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Oesophageal motility disorder		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Oesophageal spasm		

subjects affected / exposed	2 / 3076 (0.07%)	2 / 3071 (0.07%)
occurrences (all)	2	2
Oesophagitis		
subjects affected / exposed	5 / 3076 (0.16%)	8 / 3071 (0.26%)
occurrences (all)	5	8
Oesophagitis ulcerative		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Oral disorder		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Oral pain		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Palatal disorder		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Pancreatic atrophy		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Pancreatic cyst		
subjects affected / exposed	1 / 3076 (0.03%)	3 / 3071 (0.10%)
occurrences (all)	1	3
Pancreatic disorder		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Pancreatic steatosis		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Pancreatitis acute		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Pancreatitis		
subjects affected / exposed	3 / 3076 (0.10%)	0 / 3071 (0.00%)
occurrences (all)	3	0
Pancreatitis chronic		

subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Paraesthesia oral		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Peptic ulcer		
subjects affected / exposed	0 / 3076 (0.00%)	4 / 3071 (0.13%)
occurrences (all)	0	4
Periodontal disease		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Periodontal inflammation		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Pharyngo-oesophageal diverticulum		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Poor dental condition		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Portal hypertensive gastropathy		
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)
occurrences (all)	0	2
Proctalgia		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Proctitis		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Rectal haemorrhage		
subjects affected / exposed	25 / 3076 (0.81%)	13 / 3071 (0.42%)
occurrences (all)	25	13
Rectal polyp		
subjects affected / exposed	3 / 3076 (0.10%)	1 / 3071 (0.03%)
occurrences (all)	3	1
Rectal prolapse		

subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Rectal stenosis		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Reflux gastritis		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Saliva altered		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Salivary duct obstruction		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Salivary gland calculus		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	3
Salivary gland mass		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Salivary gland mucocoele		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Salivary hypersecretion		
subjects affected / exposed	2 / 3076 (0.07%)	3 / 3071 (0.10%)
occurrences (all)	2	3
Stomatitis		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Stress ulcer		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Subileus		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Swollen tongue		

subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)	
occurrences (all)	1	2	
Teeth brittle			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences (all)	0	1	
Tongue discomfort			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences (all)	1	0	
Tongue haemorrhage			
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences (all)	0	2	
Tongue ulceration			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences (all)	1	0	
Tooth disorder			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences (all)	3	1	
Tooth impacted			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences (all)	1	1	
Toothache			
subjects affected / exposed	14 / 3076 (0.46%)	12 / 3071 (0.39%)	
occurrences (all)	14	12	
Umbilical hernia			
subjects affected / exposed	7 / 3076 (0.23%)	7 / 3071 (0.23%)	
occurrences (all)	7	7	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences (all)	1	0	
Varices oesophageal			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences (all)	1	1	
Vomiting			
subjects affected / exposed	38 / 3076 (1.24%)	33 / 3071 (1.07%)	
occurrences (all)	46	40	
Skin and subcutaneous tissue disorders			

Acne		
subjects affected / exposed	3 / 3076 (0.10%)	3 / 3071 (0.10%)
occurrences (all)	3	3
Actinic keratosis		
subjects affected / exposed	8 / 3076 (0.26%)	14 / 3071 (0.46%)
occurrences (all)	11	15
Alopecia		
subjects affected / exposed	10 / 3076 (0.33%)	6 / 3071 (0.20%)
occurrences (all)	10	6
Angioedema		
subjects affected / exposed	2 / 3076 (0.07%)	4 / 3071 (0.13%)
occurrences (all)	2	4
Blister		
subjects affected / exposed	2 / 3076 (0.07%)	2 / 3071 (0.07%)
occurrences (all)	2	2
Blood blister		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Bromhidrosis		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Cold sweat		
subjects affected / exposed	3 / 3076 (0.10%)	1 / 3071 (0.03%)
occurrences (all)	3	1
Contusion		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Cutis laxa		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Decubitus ulcer		
subjects affected / exposed	3 / 3076 (0.10%)	5 / 3071 (0.16%)
occurrences (all)	3	6
Dermal cyst		
subjects affected / exposed	4 / 3076 (0.13%)	7 / 3071 (0.23%)
occurrences (all)	4	8

Dermatitis		
subjects affected / exposed	12 / 3076 (0.39%)	5 / 3071 (0.16%)
occurrences (all)	12	5
Dermatitis allergic		
subjects affected / exposed	11 / 3076 (0.36%)	1 / 3071 (0.03%)
occurrences (all)	11	1
Dermatitis atopic		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Dermatitis contact		
subjects affected / exposed	4 / 3076 (0.13%)	6 / 3071 (0.20%)
occurrences (all)	4	7
Dermatitis herpetiformis		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Diabetic foot		
subjects affected / exposed	3 / 3076 (0.10%)	1 / 3071 (0.03%)
occurrences (all)	3	1
Diabetic ulcer		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Diffuse alopecia		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Drug eruption		
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)
occurrences (all)	0	2
Dry skin		
subjects affected / exposed	7 / 3076 (0.23%)	6 / 3071 (0.20%)
occurrences (all)	8	6
Dyshidrotic eczema		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Ecchymosis		
subjects affected / exposed	13 / 3076 (0.42%)	12 / 3071 (0.39%)
occurrences (all)	13	13

Eczema		
subjects affected / exposed	11 / 3076 (0.36%)	14 / 3071 (0.46%)
occurrences (all)	11	15
Eczema asteatotic		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Eczema nummular		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Erythema		
subjects affected / exposed	8 / 3076 (0.26%)	12 / 3071 (0.39%)
occurrences (all)	9	14
Granulomatous dermatitis		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Haemorrhage subcutaneous		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Hair colour changes		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Hair disorder		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Hand dermatitis		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Hidradenitis		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Hyperhidrosis		
subjects affected / exposed	10 / 3076 (0.33%)	12 / 3071 (0.39%)
occurrences (all)	10	12
Hyperkeratosis		
subjects affected / exposed	3 / 3076 (0.10%)	5 / 3071 (0.16%)
occurrences (all)	3	7

Idiopathic urticaria		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Ingrowing nail		
subjects affected / exposed	4 / 3076 (0.13%)	1 / 3071 (0.03%)
occurrences (all)	4	1
Intertrigo		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Lichen planus		
subjects affected / exposed	3 / 3076 (0.10%)	1 / 3071 (0.03%)
occurrences (all)	3	1
Lichen sclerosus		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Lichenoid keratosis		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Miliaria		
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)
occurrences (all)	0	2
Nail discolouration		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Nail disorder		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Nail toxicity		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Night sweats		
subjects affected / exposed	5 / 3076 (0.16%)	1 / 3071 (0.03%)
occurrences (all)	5	1
Onychoclasia		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1

Pain of skin		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Papule		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Parapsoriasis		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Perivascular dermatitis		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Petechiae		
subjects affected / exposed	2 / 3076 (0.07%)	2 / 3071 (0.07%)
occurrences (all)	2	2
Photosensitivity reaction		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Pigmentation disorder		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Pityriasis rosea		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Precancerous skin lesion		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Pruritus		
subjects affected / exposed	25 / 3076 (0.81%)	35 / 3071 (1.14%)
occurrences (all)	25	41
Pruritus allergic		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Pruritus generalised		
subjects affected / exposed	5 / 3076 (0.16%)	2 / 3071 (0.07%)
occurrences (all)	5	3

Psoriasis		
subjects affected / exposed	2 / 3076 (0.07%)	12 / 3071 (0.39%)
occurrences (all)	2	12
Purpura		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Pyoderma gangrenosum		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Rash		
subjects affected / exposed	45 / 3076 (1.46%)	57 / 3071 (1.86%)
occurrences (all)	51	60
Rash erythematous		
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)
occurrences (all)	0	2
Rash follicular		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Rash generalised		
subjects affected / exposed	0 / 3076 (0.00%)	3 / 3071 (0.10%)
occurrences (all)	0	3
Rash macular		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Rash maculo-papular		
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)
occurrences (all)	0	2
Rash papular		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Rash pruritic		
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)
occurrences (all)	2	1
Rash vesicular		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	2	0

Rosacea		
subjects affected / exposed	1 / 3076 (0.03%)	3 / 3071 (0.10%)
occurrences (all)	1	3
Scab		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Sebaceous gland disorder		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Sebaceous hyperplasia		
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)
occurrences (all)	0	2
Seborrhoeic dermatitis		
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)
occurrences (all)	2	1
Skin depigmentation		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Skin discolouration		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Skin exfoliation		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Skin fissures		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Skin hyperpigmentation		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Skin irritation		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Skin lesion		
subjects affected / exposed	9 / 3076 (0.29%)	15 / 3071 (0.49%)
occurrences (all)	9	16

Skin mass			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences (all)	1	1	
Skin reaction			
subjects affected / exposed	3 / 3076 (0.10%)	0 / 3071 (0.00%)	
occurrences (all)	3	0	
Skin ulcer			
subjects affected / exposed	5 / 3076 (0.16%)	8 / 3071 (0.26%)	
occurrences (all)	15	12	
Solar dermatitis			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences (all)	1	0	
Solar lentigo			
subjects affected / exposed	3 / 3076 (0.10%)	2 / 3071 (0.07%)	
occurrences (all)	3	2	
Stasis dermatitis			
subjects affected / exposed	2 / 3076 (0.07%)	2 / 3071 (0.07%)	
occurrences (all)	2	2	
Swelling face			
subjects affected / exposed	5 / 3076 (0.16%)	3 / 3071 (0.10%)	
occurrences (all)	5	4	
Toxic skin eruption			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences (all)	1	0	
Urticaria			
subjects affected / exposed	8 / 3076 (0.26%)	10 / 3071 (0.33%)	
occurrences (all)	9	10	
Vitiligo			
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences (all)	0	2	
Yellow nail syndrome			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences (all)	0	1	
Renal and urinary disorders			
Acute kidney injury			

subjects affected / exposed	26 / 3076 (0.85%)	31 / 3071 (1.01%)
occurrences (all)	36	33
Acute prerenal failure		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Albuminuria		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Bladder discomfort		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	3	0
Bladder diverticulum		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Bladder hypertrophy		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Bladder outlet obstruction		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Bladder prolapse		
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)
occurrences (all)	2	2
Bladder spasm		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Bladder trabeculation		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Calculus bladder		
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)
occurrences (all)	2	1
Calculus urinary		
subjects affected / exposed	4 / 3076 (0.13%)	2 / 3071 (0.07%)
occurrences (all)	4	2
Chromaturia		

subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Chronic kidney disease		
subjects affected / exposed	10 / 3076 (0.33%)	10 / 3071 (0.33%)
occurrences (all)	10	10
Cystitis haemorrhagic		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Diabetic nephropathy		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Dysuria		
subjects affected / exposed	15 / 3076 (0.49%)	14 / 3071 (0.46%)
occurrences (all)	15	14
End stage renal disease		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Eosinophilic cystitis		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Haematuria		
subjects affected / exposed	36 / 3076 (1.17%)	36 / 3071 (1.17%)
occurrences (all)	37	38
Hydronephrosis		
subjects affected / exposed	5 / 3076 (0.16%)	1 / 3071 (0.03%)
occurrences (all)	5	1
Hypertensive nephropathy		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Hypertonic bladder		
subjects affected / exposed	2 / 3076 (0.07%)	2 / 3071 (0.07%)
occurrences (all)	2	3
Lower urinary tract symptoms		
subjects affected / exposed	3 / 3076 (0.10%)	3 / 3071 (0.10%)
occurrences (all)	3	3
Microalbuminuria		

subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Micturition disorder		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Micturition urgency		
subjects affected / exposed	4 / 3076 (0.13%)	4 / 3071 (0.13%)
occurrences (all)	4	4
Myoglobinuria		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Nephrectasia		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Nephrolithiasis		
subjects affected / exposed	14 / 3076 (0.46%)	16 / 3071 (0.52%)
occurrences (all)	14	16
Nephropathy		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Neurogenic bladder		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Nocturia		
subjects affected / exposed	8 / 3076 (0.26%)	6 / 3071 (0.20%)
occurrences (all)	8	6
Oliguria		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Pollakiuria		
subjects affected / exposed	9 / 3076 (0.29%)	7 / 3071 (0.23%)
occurrences (all)	9	7
Polyuria		
subjects affected / exposed	3 / 3076 (0.10%)	0 / 3071 (0.00%)
occurrences (all)	3	0
Proteinuria		

subjects affected / exposed	3 / 3076 (0.10%)	3 / 3071 (0.10%)
occurrences (all)	3	4
Pyelocaliectasis		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Renal artery stenosis		
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)
occurrences (all)	0	3
Renal cyst		
subjects affected / exposed	14 / 3076 (0.46%)	17 / 3071 (0.55%)
occurrences (all)	14	17
Renal colic		
subjects affected / exposed	9 / 3076 (0.29%)	7 / 3071 (0.23%)
occurrences (all)	10	7
Renal failure		
subjects affected / exposed	10 / 3076 (0.33%)	4 / 3071 (0.13%)
occurrences (all)	10	4
Renal disorder		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Renal impairment		
subjects affected / exposed	11 / 3076 (0.36%)	11 / 3071 (0.36%)
occurrences (all)	13	13
Renal injury		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Renal mass		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Renal pain		
subjects affected / exposed	2 / 3076 (0.07%)	3 / 3071 (0.10%)
occurrences (all)	2	3
Renal tubular dysfunction		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Stress urinary incontinence		

subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Tubulointerstitial nephritis		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Ureteric stenosis		
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)
occurrences (all)	0	2
Ureterolithiasis		
subjects affected / exposed	3 / 3076 (0.10%)	2 / 3071 (0.07%)
occurrences (all)	4	2
Urethral haemorrhage		
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)
occurrences (all)	0	2
Urethral polyp		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Urethral stenosis		
subjects affected / exposed	2 / 3076 (0.07%)	2 / 3071 (0.07%)
occurrences (all)	2	2
Urinary bladder haemorrhage		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Urinary hesitation		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Urinary retention		
subjects affected / exposed	16 / 3076 (0.52%)	21 / 3071 (0.68%)
occurrences (all)	19	22
Urinary incontinence		
subjects affected / exposed	4 / 3076 (0.13%)	8 / 3071 (0.26%)
occurrences (all)	4	9
Urinary tract disorder		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Urine abnormality		

subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1	
Endocrine disorders			
Autoimmune thyroiditis			
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences (all)	0	2	
Basedow's disease			
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences (all)	0	2	
Diabetes insipidus			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences (all)	0	1	
Euthyroid sick syndrome			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences (all)	1	0	
Goitre			
subjects affected / exposed	5 / 3076 (0.16%)	4 / 3071 (0.13%)	
occurrences (all)	5	4	
Haemorrhagic thyroid cyst			
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences (all)	0	2	
Hyperparathyroidism			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences (all)	1	1	
Hyperthyroidism			
subjects affected / exposed	5 / 3076 (0.16%)	3 / 3071 (0.10%)	
occurrences (all)	5	3	
Hypogonadism			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences (all)	0	1	
Hypogonadism male			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences (all)	1	0	
Hypothyroidism			
subjects affected / exposed	14 / 3076 (0.46%)	32 / 3071 (1.04%)	
occurrences (all)	14	32	

Myxoedema			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences (all)	1	1	
Primary hypogonadism			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences (all)	1	0	
Primary hypothyroidism			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences (all)	1	0	
Thyroid mass			
subjects affected / exposed	5 / 3076 (0.16%)	4 / 3071 (0.13%)	
occurrences (all)	5	4	
Thyroiditis			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences (all)	0	1	
Musculoskeletal and connective tissue disorders			
Ankle impingement			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences (all)	1	0	
Ankylosing spondylitis			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences (all)	1	0	
Arthralgia			
subjects affected / exposed	104 / 3076 (3.38%)	113 / 3071 (3.68%)	
occurrences (all)	112	122	
Arthritis			
subjects affected / exposed	15 / 3076 (0.49%)	11 / 3071 (0.36%)	
occurrences (all)	15	12	
Arthritis climacteric			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences (all)	1	0	
Arthropathy			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences (all)	0	1	
Back pain			

subjects affected / exposed	121 / 3076 (3.93%)	124 / 3071 (4.04%)
occurrences (all)	132	138
Bone lesion		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Bone pain		
subjects affected / exposed	3 / 3076 (0.10%)	2 / 3071 (0.07%)
occurrences (all)	3	2
Bone swelling		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Bursitis		
subjects affected / exposed	14 / 3076 (0.46%)	18 / 3071 (0.59%)
occurrences (all)	15	18
Cervical spinal stenosis		
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)
occurrences (all)	2	1
Chondrocalcinosis		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Chondromalacia		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Clubbing		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Coccydynia		
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)
occurrences (all)	0	2
Costochondritis		
subjects affected / exposed	3 / 3076 (0.10%)	3 / 3071 (0.10%)
occurrences (all)	3	3
Crystal arthropathy		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Diastasis recti abdominis		

subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Dupuytren's contracture		
subjects affected / exposed	4 / 3076 (0.13%)	2 / 3071 (0.07%)
occurrences (all)	4	2
Enthesopathy		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Exostosis		
subjects affected / exposed	7 / 3076 (0.23%)	1 / 3071 (0.03%)
occurrences (all)	7	1
Extremity contracture		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Facet joint syndrome		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Fibromyalgia		
subjects affected / exposed	1 / 3076 (0.03%)	3 / 3071 (0.10%)
occurrences (all)	1	3
Flank pain		
subjects affected / exposed	6 / 3076 (0.20%)	9 / 3071 (0.29%)
occurrences (all)	6	10
Finger deformity		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Foot deformity		
subjects affected / exposed	2 / 3076 (0.07%)	4 / 3071 (0.13%)
occurrences (all)	2	6
Gouty arthritis		
subjects affected / exposed	2 / 3076 (0.07%)	7 / 3071 (0.23%)
occurrences (all)	2	8
Groin pain		
subjects affected / exposed	4 / 3076 (0.13%)	3 / 3071 (0.10%)
occurrences (all)	4	3
Hip deformity		

subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Hypotonia		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Intervertebral disc disorder		
subjects affected / exposed	4 / 3076 (0.13%)	3 / 3071 (0.10%)
occurrences (all)	4	3
Intervertebral disc degeneration		
subjects affected / exposed	6 / 3076 (0.20%)	3 / 3071 (0.10%)
occurrences (all)	6	3
Intervertebral disc protrusion		
subjects affected / exposed	16 / 3076 (0.52%)	11 / 3071 (0.36%)
occurrences (all)	17	12
Jaw cyst		
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)
occurrences (all)	0	2
Joint crepitation		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	2	1
Joint contracture		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Joint hyperextension		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Joint effusion		
subjects affected / exposed	2 / 3076 (0.07%)	3 / 3071 (0.10%)
occurrences (all)	2	3
Joint range of motion decreased		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Joint stiffness		
subjects affected / exposed	2 / 3076 (0.07%)	3 / 3071 (0.10%)
occurrences (all)	2	3
Joint swelling		

subjects affected / exposed	15 / 3076 (0.49%)	14 / 3071 (0.46%)
occurrences (all)	16	14
Kyphosis		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Limb discomfort		
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)
occurrences (all)	2	1
Limb mass		
subjects affected / exposed	0 / 3076 (0.00%)	3 / 3071 (0.10%)
occurrences (all)	0	3
Lumbar spinal stenosis		
subjects affected / exposed	4 / 3076 (0.13%)	0 / 3071 (0.00%)
occurrences (all)	4	0
Metatarsalgia		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Mobility decreased		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Muscle atrophy		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Muscle contracture		
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)
occurrences (all)	2	1
Muscle disorder		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Muscle fatigue		
subjects affected / exposed	2 / 3076 (0.07%)	4 / 3071 (0.13%)
occurrences (all)	2	4
Muscle haemorrhage		
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)
occurrences (all)	0	2
Muscle spasms		

subjects affected / exposed	42 / 3076 (1.37%)	48 / 3071 (1.56%)
occurrences (all)	45	50
Muscle tightness		
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)
occurrences (all)	2	1
Muscular weakness		
subjects affected / exposed	9 / 3076 (0.29%)	4 / 3071 (0.13%)
occurrences (all)	10	4
Musculoskeletal chest pain		
subjects affected / exposed	30 / 3076 (0.98%)	36 / 3071 (1.17%)
occurrences (all)	31	40
Musculoskeletal discomfort		
subjects affected / exposed	6 / 3076 (0.20%)	5 / 3071 (0.16%)
occurrences (all)	7	5
Musculoskeletal pain		
subjects affected / exposed	62 / 3076 (2.02%)	63 / 3071 (2.05%)
occurrences (all)	67	67
Musculoskeletal stiffness		
subjects affected / exposed	3 / 3076 (0.10%)	6 / 3071 (0.20%)
occurrences (all)	3	6
Myalgia		
subjects affected / exposed	106 / 3076 (3.45%)	108 / 3071 (3.52%)
occurrences (all)	116	119
Myofascial pain syndrome		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Myopathy		
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)
occurrences (all)	1	2
Myositis		
subjects affected / exposed	2 / 3076 (0.07%)	2 / 3071 (0.07%)
occurrences (all)	2	2
Neck pain		
subjects affected / exposed	18 / 3076 (0.59%)	30 / 3071 (0.98%)
occurrences (all)	18	30
Osteitis		

subjects affected / exposed	3 / 3076 (0.10%)	0 / 3071 (0.00%)
occurrences (all)	3	0
Osteitis deformans		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Osteoarthritis		
subjects affected / exposed	50 / 3076 (1.63%)	51 / 3071 (1.66%)
occurrences (all)	56	55
Osteochondrosis		
subjects affected / exposed	4 / 3076 (0.13%)	1 / 3071 (0.03%)
occurrences (all)	4	1
Osteomalacia		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Osteopenia		
subjects affected / exposed	3 / 3076 (0.10%)	7 / 3071 (0.23%)
occurrences (all)	3	7
Osteonecrosis		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Osteoporosis postmenopausal		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Osteoporosis		
subjects affected / exposed	6 / 3076 (0.20%)	9 / 3071 (0.29%)
occurrences (all)	6	9
Pain in extremity		
subjects affected / exposed	94 / 3076 (3.06%)	108 / 3071 (3.52%)
occurrences (all)	105	124
Pain in jaw		
subjects affected / exposed	6 / 3076 (0.20%)	1 / 3071 (0.03%)
occurrences (all)	6	1
Patellofemoral pain syndrome		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Pathological fracture		

subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Periarthritis		
subjects affected / exposed	4 / 3076 (0.13%)	7 / 3071 (0.23%)
occurrences (all)	4	8
Peripheral arthritis		
subjects affected / exposed	3 / 3076 (0.10%)	0 / 3071 (0.00%)
occurrences (all)	3	0
Plantar fasciitis		
subjects affected / exposed	4 / 3076 (0.13%)	5 / 3071 (0.16%)
occurrences (all)	4	5
Polyarthritis		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Polymyalgia rheumatica		
subjects affected / exposed	1 / 3076 (0.03%)	3 / 3071 (0.10%)
occurrences (all)	1	3
Psoriatic arthropathy		
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)
occurrences (all)	0	2
Rhabdomyolysis		
subjects affected / exposed	3 / 3076 (0.10%)	1 / 3071 (0.03%)
occurrences (all)	3	1
Rheumatoid arthritis		
subjects affected / exposed	6 / 3076 (0.20%)	7 / 3071 (0.23%)
occurrences (all)	6	7
Rotator cuff syndrome		
subjects affected / exposed	23 / 3076 (0.75%)	12 / 3071 (0.39%)
occurrences (all)	25	15
Sacroiliitis		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Scleroderma		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	3	0
Scoliosis		

subjects affected / exposed	3 / 3076 (0.10%)	0 / 3071 (0.00%)
occurrences (all)	3	0
Senile ankylosing vertebral hyperostosis		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Sjogren's syndrome		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Somatic dysfunction		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Spinal column stenosis		
subjects affected / exposed	4 / 3076 (0.13%)	7 / 3071 (0.23%)
occurrences (all)	4	7
Spinal osteoarthritis		
subjects affected / exposed	11 / 3076 (0.36%)	11 / 3071 (0.36%)
occurrences (all)	12	13
Spinal pain		
subjects affected / exposed	4 / 3076 (0.13%)	2 / 3071 (0.07%)
occurrences (all)	6	2
Spondylitis		
subjects affected / exposed	5 / 3076 (0.16%)	0 / 3071 (0.00%)
occurrences (all)	5	0
Spondylolisthesis		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Spondylolysis		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Synovial cyst		
subjects affected / exposed	5 / 3076 (0.16%)	4 / 3071 (0.13%)
occurrences (all)	6	4
Synovitis		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	2	0

Systemic lupus erythematosus subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1	
Temporomandibular joint syndrome subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	0 / 3071 (0.00%) 0	
Tendon disorder subjects affected / exposed occurrences (all)	3 / 3076 (0.10%) 3	2 / 3071 (0.07%) 2	
Tendonitis subjects affected / exposed occurrences (all)	15 / 3076 (0.49%) 15	18 / 3071 (0.59%) 20	
Tenosynovitis subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	1 / 3071 (0.03%) 1	
Tenosynovitis stenosans subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	4 / 3071 (0.13%) 5	
Torticollis subjects affected / exposed occurrences (all)	3 / 3076 (0.10%) 3	3 / 3071 (0.10%) 3	
Trigger finger subjects affected / exposed occurrences (all)	5 / 3076 (0.16%) 5	8 / 3071 (0.26%) 9	
Vertebral foraminal stenosis subjects affected / exposed occurrences (all)	2 / 3076 (0.07%) 2	1 / 3071 (0.03%) 1	
Infections and infestations			
Abdominal infection subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	0 / 3071 (0.00%) 0	
Abscess subjects affected / exposed occurrences (all)	2 / 3076 (0.07%) 2	3 / 3071 (0.10%) 3	
Abscess bacterial			

subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Abscess limb		
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)
occurrences (all)	2	1
Abscess oral		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Acarodermatitis		
subjects affected / exposed	2 / 3076 (0.07%)	2 / 3071 (0.07%)
occurrences (all)	2	2
Acute hepatitis B		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Acute sinusitis		
subjects affected / exposed	9 / 3076 (0.29%)	14 / 3071 (0.46%)
occurrences (all)	10	19
Amoebiasis		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Anal abscess		
subjects affected / exposed	3 / 3076 (0.10%)	4 / 3071 (0.13%)
occurrences (all)	3	4
Arthritis bacterial		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Bacteraemia		
subjects affected / exposed	1 / 3076 (0.03%)	3 / 3071 (0.10%)
occurrences (all)	1	3
Bacterial vaginosis		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Bacterial infection		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Balanoposthitis infective		

subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Beta haemolytic streptococcal infection		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Body tinea		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Borrelia infection		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Bronchitis		
subjects affected / exposed	69 / 3076 (2.24%)	60 / 3071 (1.95%)
occurrences (all)	81	77
Bronchitis bacterial		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Bronchitis pneumococcal		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Bronchitis viral		
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)
occurrences (all)	1	2
Burn infection		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Campylobacter infection		
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)
occurrences (all)	1	2
Candida infection		
subjects affected / exposed	4 / 3076 (0.13%)	4 / 3071 (0.13%)
occurrences (all)	5	4
Carbuncle		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1

Catheter site infection		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Cellulitis		
subjects affected / exposed	27 / 3076 (0.88%)	24 / 3071 (0.78%)
occurrences (all)	29	27
Chorioretinitis		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Chronic sinusitis		
subjects affected / exposed	2 / 3076 (0.07%)	3 / 3071 (0.10%)
occurrences (all)	2	3
Clostridium difficile colitis		
subjects affected / exposed	0 / 3076 (0.00%)	3 / 3071 (0.10%)
occurrences (all)	0	3
Clostridium difficile infection		
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)
occurrences (all)	2	1
Conjunctivitis		
subjects affected / exposed	13 / 3076 (0.42%)	6 / 3071 (0.20%)
occurrences (all)	15	6
Conjunctivitis bacterial		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Corona virus infection		
subjects affected / exposed	84 / 3076 (2.73%)	102 / 3071 (3.32%)
occurrences (all)	84	102
Cystitis		
subjects affected / exposed	16 / 3076 (0.52%)	21 / 3071 (0.68%)
occurrences (all)	27	33
Cytomegalovirus infection		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Dacryocystitis		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0

Dengue fever		
subjects affected / exposed	4 / 3076 (0.13%)	4 / 3071 (0.13%)
occurrences (all)	4	4
Dermatophytosis		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Dermatophytosis of nail		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Device related infection		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Diarrhoea infectious		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Diverticulitis		
subjects affected / exposed	12 / 3076 (0.39%)	14 / 3071 (0.46%)
occurrences (all)	12	16
Ear infection		
subjects affected / exposed	10 / 3076 (0.33%)	8 / 3071 (0.26%)
occurrences (all)	12	9
Ear infection bacterial		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Enterococcal infection		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	2
Epididymitis		
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)
occurrences (all)	0	5
Erysipelas		
subjects affected / exposed	7 / 3076 (0.23%)	3 / 3071 (0.10%)
occurrences (all)	7	3
Escherichia infection		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0

Eye infection		
subjects affected / exposed	3 / 3076 (0.10%)	7 / 3071 (0.23%)
occurrences (all)	4	7
Eyelid infection		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Folliculitis		
subjects affected / exposed	5 / 3076 (0.16%)	1 / 3071 (0.03%)
occurrences (all)	5	1
Fungal infection		
subjects affected / exposed	5 / 3076 (0.16%)	3 / 3071 (0.10%)
occurrences (all)	5	3
Fungal skin infection		
subjects affected / exposed	4 / 3076 (0.13%)	4 / 3071 (0.13%)
occurrences (all)	4	5
Furuncle		
subjects affected / exposed	3 / 3076 (0.10%)	6 / 3071 (0.20%)
occurrences (all)	5	7
Gangrene		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Gastric infection		
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)
occurrences (all)	2	2
Gastric ulcer helicobacter		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Gastritis viral		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Gastroenteritis		
subjects affected / exposed	31 / 3076 (1.01%)	29 / 3071 (0.94%)
occurrences (all)	32	30
Gastroenteritis bacterial		
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)
occurrences (all)	2	2

Gastroenteritis norovirus subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	0 / 3071 (0.00%) 0
Gastroenteritis viral subjects affected / exposed occurrences (all)	10 / 3076 (0.33%) 11	13 / 3071 (0.42%) 14
Gastrointestinal infection subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	2 / 3071 (0.07%) 2
Gastrointestinal viral infection subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	1 / 3071 (0.03%) 1
Genital abscess subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1
Genital herpes subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1
Giardiasis subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1
Gingival abscess subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	0 / 3071 (0.00%) 0
Gingivitis subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	5 / 3071 (0.16%) 6
Groin abscess subjects affected / exposed occurrences (all)	2 / 3076 (0.07%) 4	1 / 3071 (0.03%) 1
Haemophilus infection subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	0 / 3071 (0.00%) 0
Helicobacter gastritis subjects affected / exposed occurrences (all)	2 / 3076 (0.07%) 2	1 / 3071 (0.03%) 1

Helicobacter infection		
subjects affected / exposed	4 / 3076 (0.13%)	3 / 3071 (0.10%)
occurrences (all)	4	3
Hepatitis C		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Herpes virus infection		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Herpes zoster		
subjects affected / exposed	19 / 3076 (0.62%)	28 / 3071 (0.91%)
occurrences (all)	19	28
Hordeolum		
subjects affected / exposed	3 / 3076 (0.10%)	3 / 3071 (0.10%)
occurrences (all)	4	3
Human ehrlichiosis		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Incision site infection		
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)
occurrences (all)	2	1
Infected bite		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Infected bunion		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Infected dermal cyst		
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)
occurrences (all)	1	2
Infected skin ulcer		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Infection		
subjects affected / exposed	2 / 3076 (0.07%)	4 / 3071 (0.13%)
occurrences (all)	2	4

Infectious mononucleosis		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Infection parasitic		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Influenza		
subjects affected / exposed	67 / 3076 (2.18%)	72 / 3071 (2.34%)
occurrences (all)	70	76
Kidney infection		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Labyrinthitis		
subjects affected / exposed	7 / 3076 (0.23%)	6 / 3071 (0.20%)
occurrences (all)	7	7
Laryngitis		
subjects affected / exposed	3 / 3076 (0.10%)	2 / 3071 (0.07%)
occurrences (all)	3	2
Liver abscess		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Localised infection		
subjects affected / exposed	7 / 3076 (0.23%)	10 / 3071 (0.33%)
occurrences (all)	7	10
Lower respiratory tract infection		
subjects affected / exposed	36 / 3076 (1.17%)	45 / 3071 (1.47%)
occurrences (all)	55	53
Lung abscess		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Lung infection		
subjects affected / exposed	3 / 3076 (0.10%)	3 / 3071 (0.10%)
occurrences (all)	3	3
Lyme disease		
subjects affected / exposed	2 / 3076 (0.07%)	2 / 3071 (0.07%)
occurrences (all)	2	2

Mastitis		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Mastoiditis		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Myringitis		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Nail bed infection		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Nasopharyngitis		
subjects affected / exposed	103 / 3076 (3.35%)	124 / 3071 (4.04%)
occurrences (all)	134	168
Oesophageal candidiasis		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Onychomycosis		
subjects affected / exposed	7 / 3076 (0.23%)	5 / 3071 (0.16%)
occurrences (all)	7	5
Ophthalmic herpes simplex		
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)
occurrences (all)	1	2
Oral candidiasis		
subjects affected / exposed	4 / 3076 (0.13%)	6 / 3071 (0.20%)
occurrences (all)	4	6
Oral fungal infection		
subjects affected / exposed	3 / 3076 (0.10%)	3 / 3071 (0.10%)
occurrences (all)	3	6
Oral herpes		
subjects affected / exposed	3 / 3076 (0.10%)	4 / 3071 (0.13%)
occurrences (all)	3	4
Oral infection		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0

Orchitis		
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)
occurrences (all)	4	1
Osteomyelitis		
subjects affected / exposed	0 / 3076 (0.00%)	5 / 3071 (0.16%)
occurrences (all)	0	5
Otitis externa		
subjects affected / exposed	8 / 3076 (0.26%)	3 / 3071 (0.10%)
occurrences (all)	9	3
Otitis media		
subjects affected / exposed	4 / 3076 (0.13%)	6 / 3071 (0.20%)
occurrences (all)	4	7
Otitis media acute		
subjects affected / exposed	2 / 3076 (0.07%)	2 / 3071 (0.07%)
occurrences (all)	2	2
Otitis media chronic		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Parainfluenzae virus infection		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Paronychia		
subjects affected / exposed	2 / 3076 (0.07%)	3 / 3071 (0.10%)
occurrences (all)	2	3
Parotitis		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Periodontitis		
subjects affected / exposed	4 / 3076 (0.13%)	3 / 3071 (0.10%)
occurrences (all)	5	3
Periorbital cellulitis		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Pharyngitis		
subjects affected / exposed	10 / 3076 (0.33%)	16 / 3071 (0.52%)
occurrences (all)	10	18

Pharyngitis bacterial subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1
Pharyngitis streptococcal subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	5 / 3071 (0.16%) 5
Pilonidal cyst subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 3
Pneumonia subjects affected / exposed occurrences (all)	42 / 3076 (1.37%) 44	46 / 3071 (1.50%) 51
Pneumonia bacterial subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1
Pneumonia mycoplasmal subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	0 / 3071 (0.00%) 0
Pneumonia pneumococcal subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1
Pneumonia viral subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	0 / 3071 (0.00%) 0
Post procedural infection subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	3 / 3071 (0.10%) 3
Post viral fatigue syndrome subjects affected / exposed occurrences (all)	0 / 3076 (0.00%) 0	1 / 3071 (0.03%) 1
Postoperative wound infection subjects affected / exposed occurrences (all)	3 / 3076 (0.10%) 3	4 / 3071 (0.13%) 4
Pulmonary tuberculosis subjects affected / exposed occurrences (all)	1 / 3076 (0.03%) 1	2 / 3071 (0.07%) 2

Pulpitis dental		
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)
occurrences (all)	1	2
Puncture site infection		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Pyelonephritis		
subjects affected / exposed	4 / 3076 (0.13%)	2 / 3071 (0.07%)
occurrences (all)	5	2
Pyelonephritis chronic		
subjects affected / exposed	4 / 3076 (0.13%)	2 / 3071 (0.07%)
occurrences (all)	4	2
Pyuria		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Rash pustular		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Rectal abscess		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Respiratory syncytial virus infection		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Respiratory tract infection		
subjects affected / exposed	32 / 3076 (1.04%)	32 / 3071 (1.04%)
occurrences (all)	37	33
Respiratory tract infection viral		
subjects affected / exposed	17 / 3076 (0.55%)	19 / 3071 (0.62%)
occurrences (all)	17	23
Rhinitis		
subjects affected / exposed	5 / 3076 (0.16%)	8 / 3071 (0.26%)
occurrences (all)	5	8
Rhinovirus infection		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1

Root canal infection		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Rotavirus infection		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Sepsis		
subjects affected / exposed	1 / 3076 (0.03%)	5 / 3071 (0.16%)
occurrences (all)	1	5
Severe acute respiratory syndrome		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Sexually transmitted disease		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Sialoadenitis		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Sinusitis bacterial		
subjects affected / exposed	2 / 3076 (0.07%)	2 / 3071 (0.07%)
occurrences (all)	2	3
Sinusitis		
subjects affected / exposed	35 / 3076 (1.14%)	40 / 3071 (1.30%)
occurrences (all)	50	51
Skin candida		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Skin infection		
subjects affected / exposed	2 / 3076 (0.07%)	5 / 3071 (0.16%)
occurrences (all)	3	5
Staphylococcal bacteraemia		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Staphylococcal infection		
subjects affected / exposed	3 / 3076 (0.10%)	2 / 3071 (0.07%)
occurrences (all)	3	2

Streptococcal infection		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Subcutaneous abscess		
subjects affected / exposed	2 / 3076 (0.07%)	2 / 3071 (0.07%)
occurrences (all)	2	2
Syphilis		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	2
Tinea capitis		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Tinea cruris		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Tinea infection		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Tinea pedis		
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)
occurrences (all)	2	1
Tinea versicolour		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Tonsillitis		
subjects affected / exposed	9 / 3076 (0.29%)	7 / 3071 (0.23%)
occurrences (all)	9	7
Tooth abscess		
subjects affected / exposed	10 / 3076 (0.33%)	18 / 3071 (0.59%)
occurrences (all)	11	18
Tooth infection		
subjects affected / exposed	12 / 3076 (0.39%)	13 / 3071 (0.42%)
occurrences (all)	13	14
Tracheitis		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1

Tracheobronchitis		
subjects affected / exposed	4 / 3076 (0.13%)	5 / 3071 (0.16%)
occurrences (all)	6	5
Tuberculosis		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Upper respiratory tract infection		
subjects affected / exposed	69 / 3076 (2.24%)	81 / 3071 (2.64%)
occurrences (all)	83	92
Urethritis		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Urinary tract infection		
subjects affected / exposed	88 / 3076 (2.86%)	100 / 3071 (3.26%)
occurrences (all)	112	135
Urinary tract infection enterococcal		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Urosepsis		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Vaginal infection		
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)
occurrences (all)	3	1
Varicella		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Varicella zoster virus infection		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Viral infection		
subjects affected / exposed	15 / 3076 (0.49%)	25 / 3071 (0.81%)
occurrences (all)	16	28
Vestibular neuronitis		
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)
occurrences (all)	2	1

Viral pharyngitis			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences (all)	0	1	
Viral rhinitis			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences (all)	0	1	
Viral sinusitis			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences (all)	1	0	
Viral upper respiratory tract infection			
subjects affected / exposed	9 / 3076 (0.29%)	6 / 3071 (0.20%)	
occurrences (all)	11	6	
Vulvitis			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences (all)	1	0	
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences (all)	0	1	
Vulvovaginal mycotic infection			
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)	
occurrences (all)	1	1	
Vulvovaginitis			
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)	
occurrences (all)	0	1	
Wound infection			
subjects affected / exposed	5 / 3076 (0.16%)	9 / 3071 (0.29%)	
occurrences (all)	6	10	
Metabolism and nutrition disorders			
Abnormal loss of weight			
subjects affected / exposed	0 / 3076 (0.00%)	2 / 3071 (0.07%)	
occurrences (all)	0	2	
Cachexia			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences (all)	1	0	
Decreased appetite			

subjects affected / exposed	11 / 3076 (0.36%)	20 / 3071 (0.65%)
occurrences (all)	12	20
Dehydration		
subjects affected / exposed	11 / 3076 (0.36%)	11 / 3071 (0.36%)
occurrences (all)	12	11
Diabetes mellitus		
subjects affected / exposed	82 / 3076 (2.67%)	63 / 3071 (2.05%)
occurrences (all)	85	65
Diabetes mellitus inadequate control		
subjects affected / exposed	6 / 3076 (0.20%)	15 / 3071 (0.49%)
occurrences (all)	6	16
Diabetic ketoacidosis		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Diabetic metabolic decompensation		
subjects affected / exposed	5 / 3076 (0.16%)	3 / 3071 (0.10%)
occurrences (all)	5	3
Dyslipidaemia		
subjects affected / exposed	12 / 3076 (0.39%)	10 / 3071 (0.33%)
occurrences (all)	12	11
Electrolyte imbalance		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Fluid overload		
subjects affected / exposed	1 / 3076 (0.03%)	3 / 3071 (0.10%)
occurrences (all)	1	3
Fluid retention		
subjects affected / exposed	2 / 3076 (0.07%)	1 / 3071 (0.03%)
occurrences (all)	2	1
Folate deficiency		
subjects affected / exposed	8 / 3076 (0.26%)	12 / 3071 (0.39%)
occurrences (all)	8	12
Food aversion		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Food intolerance		

subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Fructose intolerance		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Glucose tolerance impaired		
subjects affected / exposed	24 / 3076 (0.78%)	15 / 3071 (0.49%)
occurrences (all)	24	15
Gout		
subjects affected / exposed	33 / 3076 (1.07%)	35 / 3071 (1.14%)
occurrences (all)	38	46
Haemochromatosis		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Hypercalcaemia		
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)
occurrences (all)	1	2
Hyperglycaemia		
subjects affected / exposed	16 / 3076 (0.52%)	9 / 3071 (0.29%)
occurrences (all)	16	11
Hypercholesterolaemia		
subjects affected / exposed	6 / 3076 (0.20%)	3 / 3071 (0.10%)
occurrences (all)	6	3
Hyperinsulinaemic hypoglycaemia		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Hyperkalaemia		
subjects affected / exposed	15 / 3076 (0.49%)	11 / 3071 (0.36%)
occurrences (all)	15	11
Hyperlipidaemia		
subjects affected / exposed	0 / 3076 (0.00%)	4 / 3071 (0.13%)
occurrences (all)	0	4
Hypernatraemia		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Hypertriglyceridaemia		

subjects affected / exposed	10 / 3076 (0.33%)	15 / 3071 (0.49%)
occurrences (all)	10	15
Hyperuricaemia		
subjects affected / exposed	13 / 3076 (0.42%)	14 / 3071 (0.46%)
occurrences (all)	14	14
Hypervolaemia		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Hypoalbuminaemia		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Hypocalcaemia		
subjects affected / exposed	6 / 3076 (0.20%)	2 / 3071 (0.07%)
occurrences (all)	7	2
Hypocholesterolaemia		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Hypoglycaemia		
subjects affected / exposed	17 / 3076 (0.55%)	17 / 3071 (0.55%)
occurrences (all)	20	20
Hypokalaemia		
subjects affected / exposed	24 / 3076 (0.78%)	23 / 3071 (0.75%)
occurrences (all)	28	24
Hypomagnesaemia		
subjects affected / exposed	10 / 3076 (0.33%)	8 / 3071 (0.26%)
occurrences (all)	11	8
Hyponatraemia		
subjects affected / exposed	11 / 3076 (0.36%)	4 / 3071 (0.13%)
occurrences (all)	11	4
Hypophosphataemia		
subjects affected / exposed	3 / 3076 (0.10%)	3 / 3071 (0.10%)
occurrences (all)	4	3
Hypovolaemia		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Impaired fasting glucose		

subjects affected / exposed	3 / 3076 (0.10%)	3 / 3071 (0.10%)
occurrences (all)	3	3
Increased appetite		
subjects affected / exposed	2 / 3076 (0.07%)	0 / 3071 (0.00%)
occurrences (all)	2	0
Insulin resistance		
subjects affected / exposed	1 / 3076 (0.03%)	1 / 3071 (0.03%)
occurrences (all)	1	1
Iron deficiency		
subjects affected / exposed	10 / 3076 (0.33%)	8 / 3071 (0.26%)
occurrences (all)	10	8
Iron deficiency anaemia		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Lactic acidosis		
subjects affected / exposed	1 / 3076 (0.03%)	2 / 3071 (0.07%)
occurrences (all)	1	2
Malnutrition		
subjects affected / exposed	4 / 3076 (0.13%)	2 / 3071 (0.07%)
occurrences (all)	4	2
Metabolic acidosis		
subjects affected / exposed	3 / 3076 (0.10%)	2 / 3071 (0.07%)
occurrences (all)	4	2
Obesity		
subjects affected / exposed	5 / 3076 (0.16%)	7 / 3071 (0.23%)
occurrences (all)	5	7
Overweight		
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)
occurrences (all)	1	0
Polydipsia		
subjects affected / exposed	3 / 3076 (0.10%)	0 / 3071 (0.00%)
occurrences (all)	3	0
Type 1 diabetes mellitus		
subjects affected / exposed	0 / 3076 (0.00%)	1 / 3071 (0.03%)
occurrences (all)	0	1
Type 2 diabetes mellitus		

subjects affected / exposed	32 / 3076 (1.04%)	40 / 3071 (1.30%)	
occurrences (all)	32	40	
Vitamin B12 deficiency			
subjects affected / exposed	5 / 3076 (0.16%)	6 / 3071 (0.20%)	
occurrences (all)	5	6	
Vitamin D deficiency			
subjects affected / exposed	7 / 3076 (0.23%)	22 / 3071 (0.72%)	
occurrences (all)	7	22	
Vitamin K deficiency			
subjects affected / exposed	1 / 3076 (0.03%)	0 / 3071 (0.00%)	
occurrences (all)	1	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
07 September 2017	<p>The original protocol, dated 18 August 2015, was implemented globally. Subsequently, this global protocol was amended 4 times.</p> <p>Protocol Version 2 dated 07 September 2017: In the original protocol DAL-301, women of childbearing potential who were not simultaneously using two effective contraceptive methods, one of which being a barrier method, were excluded from participating, as noted in the minutes from the FDA End-of-Phase 2 meeting on June 16, 2015 and in agency email communication on July 22, 2015, pending the results from an additional hamster embryo-fetal development (EFD) study. On the basis of the completion and results of the additional requested testing in hamsters, as well as the prior testing that evaluated the embryo-fetal effects of dalcetrapib in rats and rabbits, the protocol was amended to allow women of childbearing potential to be included in the study if using only one (rather than two) forms of contraception.</p> <p>Protocol Version 2 was implemented globally with the following exceptions. Canada did not accept the change of allowing women of childbearing potential to enter the study using one instead of two forms of contraception. Belgium and Germany requested the addition of the word "highly" to the description of the requirement for at least one effective method of contraception to be used and required a separate version of the protocol as a result of that request.</p>
23 February 2018	<p>The original DAL-301 sample size and anticipated treatment effect was based on the pharmacogenomics evaluation in the dal-OUTCOMES study that demonstrated a 39% reduction in CV risk in subjects with the AA genotype at variant rs1967309 in the ADCY9 gene with dalcetrapib compared to placebo. The initial design of DAL-301 proposed that a 25% reduction was appropriate as a conservative estimate for this prospective study. The study protocol was subsequently amended to change the target number of patients with a primary endpoint from 434 to 582, so that the study would have 85% power (two-sided alpha of 0.05) to detect a relative risk reduction of 22%. The minimally detectable risk reduction under this plan is 15%. A 15% relative risk reduction has been used in the design of other cardiovascular endpoint studies, including other CETP trials, since this level of risk reduction would provide clinically significant medical benefit on top of statin therapy.</p>
04 August 2020	<p>The public health and safety concerns resulting from the COVID-19 pandemic resulted in challenges adhering to DAL-301 protocol-mandated study visits and corresponding study drug dispensation. Modifications to the protocol were made to help protect patient safety, while maintaining compliance with Good Clinical Practice Guidelines and minimizing risks to study integrity. These included allowing in-person patient visits to be replaced by phone visits or virtual visits, and for patient communication to occur through email and text message. Sponsor approval was required for patients taking study medication without blood pressure, pulse, or weight assessments for more than one year. Study medication was permitted to be dispensed within a study visit window or in advance through a secure delivery method. All study medication was appropriately handled and tracked to ensure compliance with stability parameters. Patients were provided directions to save their unused study medication materials (used and unused drug supply containers) to return at their next on-site visit. Study medication was also allowed to be returned by the patient to the site through a secure delivery method. Additionally, monitors were allowed to perform monitoring visits virtually when access to sites in-person was not available.</p>

11 February 2021	Additional modifications to the protocol were made in response to the COVID-19 pandemic. The physical exam and vital signs (blood pressure, pulse, and weight) at the EOS Visit were made optional, performed whenever possible. This was done to ensure the safety of patients and study staff and in light of significant safety data already available on dalcetrapib. The physical exam and vital signs were also allowed to be performed outside of the clinical site (i.e., a remote location, the patient's home, etc.) due to many sites that were closed or had limited access during the pandemic.
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Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/32087417>