Clinical trial results:
International Breast Cancer Intervention Study II (DCIS). An international multi-centre trial of tamoxifen v anastrozole in post-menopausal women with ductal carcinoma in situ.

Summary

EudraCT number	2004-003992-35
Trial protocol	SE
Global end of trial date	31 May 2021

Results information

Result version number	v1 (current)
This version publication date	12 May 2022
First version publication date	12 May 2022

Trial information

Trial identification

Sponsor protocol code	MREC02/8/71

Additional study identifiers

ISRCTN number	ISRCTN37546358
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Queen Mary University London
Sponsor organisation address	Wolfson Institute of Population Health, London, United Kingdom, EC1M 6BQ
Public contact	Professor Jack Cuzick, Queen Mary University London, j.cuzick@qmul.ac.uk
Scientific contact	Professor Jack Cuzick, Queen Mary University London, j.cuzick@qmul.ac.uk

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	31 May 2021
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	31 May 2021
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To determine if anastrozole is at least as effective as tamoxifen in local control and prevention of contralateral disease in women with locally excised ER or PgR+ve DCIS and to compare side effect profiles of tamoxifen and anastrozole.

Protection of trial subjects:

Eligibility criteria were risk-based, varied by age, and defined in the protocol to ensure protection of participants. Participants were informed of potential side-effects prior to study entry and if new side-effects were added to the Summary of Product Characteristics (SmPC) after randomisation, women were informed at their next clinic appointment. Women were informed of their right to withdraw at any point.

Only post-menopausal women diagnosed with locally excised, hormone-receptor-positive DCIS were eligible. Women aged 60 without a uterus were eligible if they had FSH levels >30 IU/L and if taking HRT, an 8 week wash-out period was required prior to a FSH test being performed. Due to potential concerns over the effects of the trial interventions on pre-existing conditions associated with low bone mineral density, women with osteoporosis were excluded and a DXA scan and spinal radiograph within the last two years was required prior to randomisation.
Advice on maintaining healthy bones was offered to women in the trial. Treatment with bisphosphonates was considered where necessary. If serious menopausal symptoms developed during treatment, management followed a protocolised approach including details on when to reduce dosing of the trial intervention. Circumstances which indicated cessation of the IMP were listed in the protocol. A codebreak procedure to unblind clinicians and participants was active throughout the study. Adverse events were collected and reviewed regularly by the Trial team and Steering Committee.

Background therapy: -

Evidence for comparator:

IBIS-II (DCIS) is designed to continue the work started in IBIS-I in determining whether a chemo preventive strategy towards breast cancer is beneficial. IBIS-I was set up to investigate the use of tamoxifen as a preventive agent for women with moderate to increased risk of getting breast cancer. IBIS-II (DCIS) is a randomized double blind control trial which will compare tamoxifen versus anastrozole in women with locally excised ER or PgR positive Ductal Carcinoma In-Situ (ER or PgR+ve DCIS).

Actual start date of recruitment	03 March 2003
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy, Scientific research
Long term follow-up duration	5 Years
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Sweden: 8
Country: Number of subjects enrolled	United Kingdom: 889
Country: Number of subjects enrolled	Italy: 323

Country: Number of subjects enrolled	Australia: 168
Country: Number of subjects enrolled	Switzerland: 45
Country: Number of subjects enrolled	Belgium: 104
Country: Number of subjects enrolled	Chile: 17
Country: Number of subjects enrolled	Finland: 7
Country: Number of subjects enrolled	Ireland: 78
Country: Number of subjects enrolled	France: 426
Country: Number of subjects enrolled	Germany: 779
Country: Number of subjects enrolled	Hungary: 15
Country: Number of subjects enrolled	Malta: 4
Country: Number of subjects enrolled	New Zealand: 10
Country: Number of subjects enrolled	Turkey: 15
Country: Number of subjects enrolled	Austria: 90
Country: Number of subjects enrolled	India: 2
Worldwide total number of subjects	2980
EEA total number of subjects	1834

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)	2310
From 65 to 84 years	670
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Between March 3, 2003, and Feb 8, 2012, women who had been diagnosed with locally excised, hormone-receptor-positive DCIS were recruited from 236 centres in 17 countries (Sweden, UK, Italy, Australia, Switzerland, Belgium, Chile, Finland, Ireland, France, Germany, Hungary, Malta, New Zealand, Turkey, Austria, India).

Pre-assignment

Screening details:

Potentially eligible women were given an information sheet. Informed consent was taken from interested patients and pre-randomisation eligibility assessment was conducted. Eligibility criteria were clearly listed in the protocol.

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, Monitor

Arms

Are arms mutually exclusive?	Yes
Arm title	Anastrozole

Arm description: -

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

Dosage and administration details:

Anastrozole 1mg + Tamoxifen placebo. All treatment will be on a daily basis for 5 years and all women will take 2 tablets/day. One will contain tamoxifen or placebo. The second tablet will contain either anastrozole or placebo. Tablets will be supplied in numbered light-proof containers containing a 6-month supply. Each container will have extra tablets to allow for some delay in the next appointment.

Arm title	Tamoxifen

Arm description: -

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

Dosage and administration details:

Tamoxifen 20mg + Anastrozole placebo. All treatment will be on a daily basis for 5 years and all women will take 2 tablets/day. One will contain tamoxifen or placebo. The second tablet will contain either anastrozole or placebo. Tablets will be supplied in numbered light-proof containers containing a 6-month supply. Each container will have extra tablets to allow for some delay in the next appointment.

Number of subjects in period 1	Anastrozole	Tamoxifen
Started	1471	1509
Completed	1449	1489
Not completed	22	20
Consent withdrawn by subject	22	20

Baseline characteristics

Reporting groups	
Reporting group title	Anastrozole
Reporting group description: -	
Reporting group title	Tamoxifen
Reporting group description: -	

Reporting group values	Anastrozole	Tamoxifen	Total
Number of subjects	1471	1509	2980
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	1139	1171	2310
From 65-84 years	332	338	670
85 years and over	0	0	0
Age continuous Units: years			
median	60.4	60.3	
inter-quartile range (Q1-Q3)	56.4 to 64.7	55.8 to 64.5	-
Gender categorical Units: Subjects			
Female	1471	1509	2980
Male	0	0	0

End points

End points reporting groups

Reporting group title	Anastrozole
Reporting group description: -	
Reporting group title	Tamoxifen
Reporting group description: -	

Primary: Breast cancer recurrence, including recurrent DCIS and new contralateral tumours

End point title	Breast cancer recurrence, including recurrent DCIS and new contralateral tumours
End point description:	
End point type	Primary
End point timeframe:	
From 3 March 2003 to 31 May 2021.	

End point values	Anastrozole	Tamoxifen		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1449	1489		
Units: Breast cancer recurrence	103	120		

Statistical analyses

Statistical analysis title	Univariate Cox Model
Comparison groups	Anastrozole v Tamoxifen
Number of subjects included in analysis	2938
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.33
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.67
upper limit	1.14
Variability estimate	Standard deviation
Dispersion value	0.12

Statistical analysis title	Multivariate Cox Model

Statistical analysis description:

The following baseline characteristics will be included in the Cox proportional hazard models adjusting for baseline covariates for the incidence of breast cancer. The covariates will be included in the models regardless of statistical significance: • Hormone Replacement Therapy (HRT) use • Age • Body Mass Index (BMI) • Use of radiotherapy • Extent of margins • Grade (categorical: low, medium, high)

Comparison groups	Anastrozole v Tamoxifen
Number of subjects included in analysis	2938
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.33
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.66
upper limit	1.15
Variability estimate	Standard deviation
Dispersion value	0.12

Secondary: ER+ breast cancer recurrence, including recurrent DCIS and new contralateral tumours

End point title	ER+ breast cancer recurrence, including recurrent DCIS and new contralateral tumours

End point description:

End point type	Secondary

End point timeframe:

From 3 March 2003 to 31 May 2021.

End point values	Anastrozole	Tamoxifen		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1449	1489		
Units: ER+ breast cancer recurrence	58	82		

Statistical analyses

Statistical analysis title	Univariate Cox Model
Comparison groups	Anastrozole v Tamoxifen
Number of subjects included in analysis	2938
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.06
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.72
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.52
upper limit	1.01
Variability estimate	Standard deviation
Dispersion value	0.12

Statistical analysis title	Multivariate Cox Model

Statistical analysis description:

The following baseline characteristics will be included in the Cox proportional hazard models adjusting for baseline covariates for the incidence of ER+ breast cancer. The covariates will be included in the models regardless of statistical significance: • Hormone Replacement Therapy (HRT) use • Age • Body Mass Index (BMI) • Use of radiotherapy • Extent of margins • Grade (categorical: low, medium, high)

Comparison groups	Anastrozole v Tamoxifen
Number of subjects included in analysis	2938
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.09
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.52
upper limit	1.05
Variability estimate	Standard deviation
Dispersion value	0.13

Secondary: ER- breast cancer recurrence

End point title	ER- breast cancer recurrence

End point description:

End point type	Secondary

End point timeframe:

From 3 March 2003 to 31 May 2021.

End point values	Anastrozole	Tamoxifen		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1449	1489		
Units: ER- breast cancer recurrence	24	15		

Statistical analyses

Statistical analysis title	Univariate Cox Model
Comparison groups	Anastrozole v Tamoxifen
Number of subjects included in analysis	2938
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.13
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	1.64
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.86
upper limit	3.12
Variability estimate	Standard deviation
Dispersion value	0.54

Statistical analysis title	Multivariate Cox Model

Statistical analysis description:

The following baseline characteristics will be included in the Cox proportional hazard models adjusting for baseline covariates for the incidence of ER- breast cancer. The covariates will be included in the models regardless of statistical significance: • Hormone Replacement Therapy (HRT) use • Age • Body Mass Index (BMI) • Use of radiotherapy • Extent of margins • Grade (categorical: low, medium, high)

Comparison groups	Anastrozole v Tamoxifen
Number of subjects included in analysis	2938
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.26
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	1.46
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.75
upper limit	2.84

Variability estimate	Standard deviation
Dispersion value	0.5

Secondary: Breast cancer mortality	
End point title	Breast cancer mortality
End point description:	

End point type	Secondary
End point timeframe:	
From 3 March 2003 to 31 May 2021.	

End point values	Anastrozole	Tamoxifen		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1449	1489		
Units: Breast cancer mortality	3	3		

Statistical analyses

Statistical analysis title	Univariate Cox Model
Comparison groups	Anastrozole v Tamoxifen
Number of subjects included in analysis	2938
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.97
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	1.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.21
upper limit	5.11
Variability estimate	Standard deviation
Dispersion value	0.84

Statistical analysis title	Multivariate Cox Model
Statistical analysis description:	
The following baseline characteristics will be included in the Cox proportional hazard models adjusting for baseline covariates for the incidence of breast cancer mortality. The covariates will be included in the models regardless of statistical significance: • Hormone Replacement Therapy (HRT) use • Age • Body Mass Index (BMI) • Use of radiotherapy • Extent of margins • Grade (categorical: low, medium, high)	
Comparison groups	Anastrozole v Tamoxifen

Number of subjects included in analysis	2938
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.93
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	1.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.22
upper limit	5.36
Variability estimate	Standard deviation
Dispersion value	0.88

Secondary: Non-breast cancer mortality

End point title	Non-breast cancer mortality
End point description:	
End point type	Secondary
End point timeframe:	
From 3 March 2003 to 31 May 2021.	

End point values	Anastrozole	Tamoxifen		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1449	1489		
Units: Non-breast cancer mortality	59	65		

Statistical analyses

Statistical analysis title	Univariate Cox Model
Comparison groups	Tamoxifen v Anastrozole
Number of subjects included in analysis	2938
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.67
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.93

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.65
upper limit	1.32
Variability estimate	Standard deviation
Dispersion value	0.17

Statistical analysis title	Multivariate Cox Model

Statistical analysis description:

The following baseline characteristics will be included in the Cox proportional hazard models adjusting for baseline covariates for the incidence of non-breast cancer mortality. The covariates will be included in the models regardless of statistical significance: • Hormone Replacement Therapy (HRT) use • Age • Body Mass Index (BMI) • Use of radiotherapy • Extent of margins • Grade (categorical: low, medium, high)

Comparison groups	Anastrozole v Tamoxifen
Number of subjects included in analysis	2938
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.38
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.59
upper limit	1.22
Variability estimate	Standard deviation
Dispersion value	0.16

Adverse events

Adverse events information	
Timeframe for reporting adverse events: From 3 March 2003 to 31 May 2021.	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	19

Reporting groups	
Reporting group title	Anastrozole
Reporting group description: -	
Reporting group title	Tamoxifen
Reporting group description: -	

Serious adverse events	Anastrozole	Tamoxifen	
Total subjects affected by serious adverse events			
subjects affected / exposed	333 / 1449 (22.98%)	371 / 1489 (24.92%)	
number of deaths (all causes)	62	69	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Intraductal papilloma of breast			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast angiosarcoma			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer in situ			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer metastatic			

subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paget's disease of the breast			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Melanocytic naevus			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
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 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parathyroid tumour benign			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pituitary tumour benign			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid adenoma			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carcinoid tumour of the caecum			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuroendocrine tumour			

subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Phaeochromocytoma			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid cancer			
subjects affected / exposed	3 / 1449 (0.21%)	2 / 1489 (0.13%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon adenoma			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salivary gland adenoma			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenocarcinoma pancreas			
subjects affected / exposed	0 / 1449 (0.00%)	3 / 1489 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Anal cancer			
subjects affected / exposed	3 / 1449 (0.21%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon cancer			
subjects affected / exposed	3 / 1449 (0.21%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 3	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon cancer metastatic			

subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Colorectal cancer			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colorectal cancer metastatic			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Gastric cancer			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Gastrointestinal carcinoma			
subjects affected / exposed	0 / 1449 (0.00%)	3 / 1489 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal neoplasm			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Gastrooesophageal cancer			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Lip and/or oral cavity cancer			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Malignant palate neoplasm			

subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant peritoneal neoplasm			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal adenocarcinoma			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Oesophageal carcinoma			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Oral cavity cancer metastatic			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pancreatic carcinoma			
subjects affected / exposed	1 / 1449 (0.07%)	2 / 1489 (0.13%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 2	
Pancreatic carcinoma metastatic			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Rectal cancer			
subjects affected / exposed	5 / 1449 (0.35%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Rectal cancer metastatic			

subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectosigmoid cancer recurrent			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Salivary gland cancer			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Essential thrombocythaemia			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematological malignancy			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Myeloproliferative disorder			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Focal nodular hyperplasia			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct cancer			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hepatic cancer			

subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cancer metastatic			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hepatocellular carcinoma			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute myeloid leukaemia			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic lymphocytic leukaemia			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic myeloid leukaemia			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hairy cell leukaemia			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphoma			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-Hodgkin's lymphoma			

subjects affected / exposed	2 / 1449 (0.14%)	2 / 1489 (0.13%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Mesothelioma			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pleural mesothelioma			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural mesothelioma malignant			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metastases to bone			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to central nervous system			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to liver			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metastases to lung			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Metastases to peritoneum			

subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to spine			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Adenoma benign			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign neoplasm			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemangioma			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenocarcinoma			
subjects affected / exposed	4 / 1449 (0.28%)	2 / 1489 (0.13%)	
occurrences causally related to treatment / all	0 / 4	1 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Malignant neoplasm of unknown primary site			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic neoplasm			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Metastatic squamous cell carcinoma			

subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neoplasm			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neoplasm malignant			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Squamous cell carcinoma			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain neoplasm			
subjects affected / exposed	1 / 1449 (0.07%)	2 / 1489 (0.13%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Meningeal neoplasm			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningioma			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intraocular melanoma			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple myeloma			

subjects affected / exposed	1 / 1449 (0.07%)	4 / 1489 (0.27%)	
occurrences causally related to treatment / all	0 / 1	1 / 4	
deaths causally related to treatment / all	0 / 1	0 / 2	
Bladder cancer			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder transitional cell carcinoma			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cancer			
subjects affected / exposed	5 / 1449 (0.35%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Renal cell carcinoma			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transitional cell carcinoma			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign ovarian tumour			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian adenoma			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine leiomyoma			

subjects affected / exposed	1 / 1449 (0.07%)	6 / 1489 (0.40%)	
occurrences causally related to treatment / all	0 / 1	3 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine polyp			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cervix carcinoma recurrent			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial cancer			
subjects affected / exposed	1 / 1449 (0.07%)	8 / 1489 (0.54%)	
occurrences causally related to treatment / all	1 / 1	5 / 8	
deaths causally related to treatment / all	0 / 0	0 / 2	
Endometrial cancer metastatic			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Endometrial cancer stage I			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial neoplasm			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fallopian tube cancer			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian cancer			

subjects affected / exposed	1 / 1449 (0.07%)	7 / 1489 (0.47%)	
occurrences causally related to treatment / all	0 / 1	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 2	
Bronchial carcinoma			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Lung adenocarcinoma			
subjects affected / exposed	2 / 1449 (0.14%)	3 / 1489 (0.20%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 3	
Lung adenocarcinoma metastatic			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Lung cancer metastatic			
subjects affected / exposed	1 / 1449 (0.07%)	3 / 1489 (0.20%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 3	
Lung neoplasm			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung neoplasm malignant			
subjects affected / exposed	8 / 1449 (0.55%)	2 / 1489 (0.13%)	
occurrences causally related to treatment / all	0 / 8	0 / 2	
deaths causally related to treatment / all	0 / 4	0 / 0	
Non-small cell lung cancer			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Small cell lung cancer recurrent			

subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Small cell lung cancer stage unspecified			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Tonsil cancer			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (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 / 1449 (0.07%)	5 / 1489 (0.34%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant melanoma			
subjects affected / exposed	1 / 1449 (0.07%)	5 / 1489 (0.34%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 2	
Melanoma recurrent			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metastatic malignant melanoma			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Angiomyolipoma			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leiomyoma			

subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inflammatory myofibroblastic tumour			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sarcoma			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sarcoma uterus			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Aortic dissection			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Arterial stenosis			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (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	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Infarction			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous insufficiency			

subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial thrombosis limb			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deep vein thrombosis			
subjects affected / exposed	5 / 1449 (0.35%)	14 / 1489 (0.94%)	
occurrences causally related to treatment / all	3 / 5	8 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic venous thrombosis			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombophlebitis superficial			
subjects affected / exposed	1 / 1449 (0.07%)	4 / 1489 (0.27%)	
occurrences causally related to treatment / all	0 / 1	2 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombosis			
subjects affected / exposed	2 / 1449 (0.14%)	5 / 1489 (0.34%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous thrombosis			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (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	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hot flush			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematoma			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertension			
subjects affected / exposed	1 / 1449 (0.07%)	4 / 1489 (0.27%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Phlebitis			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicose ulceration			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicose vein			
subjects affected / exposed	3 / 1449 (0.21%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 3	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Bunion operation			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip arthroplasty			

subjects affected / exposed	2 / 1449 (0.14%)	5 / 1489 (0.34%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint arthroplasty			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (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	3 / 1449 (0.21%)	2 / 1489 (0.13%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rotator cuff repair			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mammoplasty			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve replacement			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cardiac pacemaker insertion			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral valve replacement			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid operation			

subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroidectomy			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye operation			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal hernia repair			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicectomy			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colectomy			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
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 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laparotomy			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal prolapse repair			

subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystectomy			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningioma surgery			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal laminectomy			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal operation			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hysterectomy			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oophorectomy			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oophorectomy bilateral			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salpingo-oophorectomy bilateral			

subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine dilation and curettage			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine operation			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine tumour excision			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrectomy			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Removal of inert matter from skin or subcutaneous tissue			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scar excision			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin graft			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cancer surgery			

subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Debridement			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Elective surgery			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lesion excision			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant tumour excision			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound closure			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
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 / 1449 (0.07%)	0 / 1489 (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			
Pyrexia			
subjects affected / exposed	2 / 1449 (0.14%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac death			

subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Death			
subjects affected / exposed	14 / 1449 (0.97%)	10 / 1489 (0.67%)	
occurrences causally related to treatment / all	0 / 14	0 / 10	
deaths causally related to treatment / all	0 / 14	0 / 10	
Asthenia			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest discomfort			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
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	2 / 1449 (0.14%)	6 / 1489 (0.40%)	
occurrences causally related to treatment / all	0 / 2	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disease progression			
subjects affected / exposed	2 / 1449 (0.14%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Fatigue			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hernia			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malaise			

subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multi-organ failure			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Pain			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyp			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Swelling			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic mass			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden cardiac death			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Immune system disorders			
Allergy to arthropod bite			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypersensitivity			

subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Breast haematoma			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast necrosis			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast pain			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical cyst			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical dysplasia			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical polyp			
subjects affected / exposed	0 / 1449 (0.00%)	3 / 1489 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postmenopausal haemorrhage			
subjects affected / exposed	1 / 1449 (0.07%)	6 / 1489 (0.40%)	
occurrences causally related to treatment / all	1 / 1	4 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metrorrhagia			

subjects affected / exposed	1 / 1449 (0.07%)	2 / 1489 (0.13%)	
occurrences causally related to treatment / all	0 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian atrophy			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian cyst			
subjects affected / exposed	0 / 1449 (0.00%)	3 / 1489 (0.20%)	
occurrences causally related to treatment / all	0 / 0	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Female genital tract fistula			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystocele			
subjects affected / exposed	2 / 1449 (0.14%)	4 / 1489 (0.27%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial disorder			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial dysplasia			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial hyperplasia			
subjects affected / exposed	1 / 1449 (0.07%)	12 / 1489 (0.81%)	
occurrences causally related to treatment / all	0 / 1	6 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial hypertrophy			

subjects affected / exposed	0 / 1449 (0.00%)	5 / 1489 (0.34%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectocele			
subjects affected / exposed	1 / 1449 (0.07%)	2 / 1489 (0.13%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine atrophy			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine polyp			
subjects affected / exposed	1 / 1449 (0.07%)	15 / 1489 (1.01%)	
occurrences causally related to treatment / all	1 / 1	9 / 15	
deaths causally related to treatment / all	0 / 0	0 / 1	
Uterine prolapse			
subjects affected / exposed	1 / 1449 (0.07%)	3 / 1489 (0.20%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterovaginal prolapse			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal prolapse			
subjects affected / exposed	3 / 1449 (0.21%)	3 / 1489 (0.20%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal disorder			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal haemorrhage			

subjects affected / exposed	3 / 1449 (0.21%)	4 / 1489 (0.27%)	
occurrences causally related to treatment / all	0 / 3	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal polyp			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulvovaginal discomfort			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	1 / 1449 (0.07%)	2 / 1489 (0.13%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic obstructive pulmonary disease			
subjects affected / exposed	2 / 1449 (0.14%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute respiratory distress syndrome			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia aspiration			
subjects affected / exposed	3 / 1449 (0.21%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Pulmonary fibrosis			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pleural effusion			

subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	5 / 1449 (0.35%)	9 / 1489 (0.60%)	
occurrences causally related to treatment / all	0 / 5	6 / 9	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cough			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	1 / 1449 (0.07%)	3 / 1489 (0.20%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoptysis			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (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	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Productive cough			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary mass			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory arrest			

subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Respiratory failure			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Sleep apnoea syndrome			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epistaxis			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal haemorrhage			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Nasal septum deviation			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsillar disorder			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Anxiety			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Panic attack			

subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Panic disorder			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Confusional state			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depression			
subjects affected / exposed	4 / 1449 (0.28%)	4 / 1489 (0.27%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hallucination			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug abuse			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sleep disorder			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Completed suicide			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Suicide attempt			

subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Ejection fraction decreased			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heart rate increased			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (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	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alanine aminotransferase increased			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic enzyme increased			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigation			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood glucose fluctuation			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood glucose increased			

subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthroscopy			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intraocular pressure increased			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Body temperature increased			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
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	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystoscopy			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hysteroscopy			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Smear cervix abnormal			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Acetabulum fracture			

subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (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	10 / 1449 (0.69%)	11 / 1489 (0.74%)	
occurrences causally related to treatment / all	0 / 10	2 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cartilage injury			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Facial bones fracture			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral neck fracture			
subjects affected / exposed	3 / 1449 (0.21%)	4 / 1489 (0.27%)	
occurrences causally related to treatment / all	1 / 3	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femur fracture			
subjects affected / exposed	3 / 1449 (0.21%)	2 / 1489 (0.13%)	
occurrences causally related to treatment / all	0 / 3	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fibula fracture			
subjects affected / exposed	1 / 1449 (0.07%)	3 / 1489 (0.20%)	
occurrences causally related to treatment / all	0 / 1	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot fracture			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Forearm fracture			

subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fracture			
subjects affected / exposed	2 / 1449 (0.14%)	2 / 1489 (0.13%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hand fracture			
subjects affected / exposed	2 / 1449 (0.14%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	1 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip fracture			
subjects affected / exposed	4 / 1449 (0.28%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Humerus fracture			
subjects affected / exposed	4 / 1449 (0.28%)	3 / 1489 (0.20%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint dislocation			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint sprain			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
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	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower limb fracture			

subjects affected / exposed	3 / 1449 (0.21%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar vertebral fracture			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meniscus lesion			
subjects affected / exposed	3 / 1449 (0.21%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Patella fracture			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic fracture			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radius fracture			
subjects affected / exposed	3 / 1449 (0.21%)	2 / 1489 (0.13%)	
occurrences causally related to treatment / all	2 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rib fracture			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (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	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sternal fracture			

subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thoracic vertebral fracture			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tibia fracture			
subjects affected / exposed	0 / 1449 (0.00%)	3 / 1489 (0.20%)	
occurrences causally related to treatment / all	0 / 0	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulna fracture			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper limb fracture			
subjects affected / exposed	2 / 1449 (0.14%)	3 / 1489 (0.20%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wrist fracture			
subjects affected / exposed	4 / 1449 (0.28%)	4 / 1489 (0.27%)	
occurrences causally related to treatment / all	1 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol poisoning			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radiation fibrosis - lung			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radiation necrosis			

subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radiation pneumonitis			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thermal burn			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fall			
subjects affected / exposed	6 / 1449 (0.41%)	2 / 1489 (0.13%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Head injury			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Ligament injury			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ligament rupture			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple injuries			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Road traffic accident			

subjects affected / exposed	1 / 1449 (0.07%)	2 / 1489 (0.13%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Tendon rupture			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic anuria			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intentional overdose			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple drug overdose			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dislocation of joint prosthesis			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incisional hernia			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haemorrhage			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural pulmonary embolism			

subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seroma			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound decomposition			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	5 / 1449 (0.35%)	4 / 1489 (0.27%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial flutter			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Bradycardia			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bundle branch block left			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bundle branch block right			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (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	2 / 1449 (0.14%)	2 / 1489 (0.13%)	
occurrences causally related to treatment / all	1 / 2	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 2	
Extrasystoles			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Supraventricular tachycardia			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (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 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular tachycardia			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (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	0 / 1449 (0.00%)	3 / 1489 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve incompetence			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute coronary syndrome			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute myocardial infarctioncardial			

subjects affected / exposed	1 / 1449 (0.07%)	3 / 1489 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Angina pectoris			
subjects affected / exposed	2 / 1449 (0.14%)	4 / 1489 (0.27%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 1	
Angina unstable			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery disease			
subjects affected / exposed	2 / 1449 (0.14%)	3 / 1489 (0.20%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery occlusion			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery stenosis			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial infarction			
subjects affected / exposed	4 / 1449 (0.28%)	6 / 1489 (0.40%)	
occurrences causally related to treatment / all	1 / 4	2 / 6	
deaths causally related to treatment / all	0 / 1	0 / 2	
Cardiac failure			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cardiac failure congestive			

subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Left ventricular failure			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Nervous system disorders			
Arachnoiditis			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalitis			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain stem stroke			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery occlusion			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery stenosis			
subjects affected / exposed	1 / 1449 (0.07%)	2 / 1489 (0.13%)	
occurrences causally related to treatment / all	0 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral haemorrhage			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral infarction			

subjects affected / exposed	4 / 1449 (0.28%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Cerebral ischaemia			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular accident			
subjects affected / exposed	10 / 1449 (0.69%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	2 / 10	1 / 1	
deaths causally related to treatment / all	0 / 2	0 / 0	
Ischaemic stroke			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (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 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient ischaemic attack			
subjects affected / exposed	10 / 1449 (0.69%)	3 / 1489 (0.20%)	
occurrences causally related to treatment / all	1 / 10	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Trigeminal neuralgia			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple sclerosis			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Headache			

subjects affected / exposed	1 / 1449 (0.07%)	2 / 1489 (0.13%)	
occurrences causally related to treatment / all	1 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Migraine			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Amnesia			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dementia Alzheimer's type			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hemiparesis			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paresis			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parkinson's disease			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tremor			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Altered state of consciousness			

subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic hyperosmolar coma			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dizziness			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lethargy			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Loss of consciousness			
subjects affected / exposed	1 / 1449 (0.07%)	2 / 1489 (0.13%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraesthesia			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Presyncope			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	4 / 1449 (0.28%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autonomic nervous system imbalance			

subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Motor neurone disease			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Carpal tunnel syndrome			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic nephropathy			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Guillain-Barre syndrome			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nerve compression			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervicobrachial syndrome			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sciatica			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
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	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iron deficiency anaemia			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphadenopathy			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Deafness unilateral			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tinnitus			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (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	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Cataract			
subjects affected / exposed	5 / 1449 (0.35%)	2 / 1489 (0.13%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract cortical			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glaucoma			

subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ocular hypertension			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Open angle glaucoma			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Optic ischaemic neuropathy			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye irritation			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Keratitis			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Macular hole			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Papilloedema			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal detachment			

subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal tear			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal vein occlusion			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blindness unilateral			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vision blurred			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal hernia			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocele			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
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 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colonic polyp			

subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gingival hypoplasia			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum intestinal			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic disorder			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pancreatitis			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis acute			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal fistula			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric haemorrhage			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			

subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematemesis			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
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	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			
subjects affected / exposed	0 / 1449 (0.00%)	3 / 1489 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis ischaemic			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis ulcerative			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Crohn's disease			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenitis			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis			

subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrooesophagitis			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileitis			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophagitis			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Constipation			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	1 / 1449 (0.07%)	2 / 1489 (0.13%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Frequent bowel movements			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
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 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			
subjects affected / exposed	2 / 1449 (0.14%)	4 / 1489 (0.27%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain lower			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
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	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspepsia			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysphagia			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	2 / 1449 (0.14%)	4 / 1489 (0.27%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal obstruction			

subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Volvulus of small bowel			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer			
subjects affected / exposed	1 / 1449 (0.07%)	2 / 1489 (0.13%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal ulcer			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peptic ulcer			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoids			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenic artery aneurysm			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varices oesophageal			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (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	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hepatobiliary disorders			
Biliary colic			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis			
subjects affected / exposed	2 / 1449 (0.14%)	4 / 1489 (0.27%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis acute			
subjects affected / exposed	3 / 1449 (0.21%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis chronic			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis			
subjects affected / exposed	3 / 1449 (0.21%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder polyp			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cirrhosis alcoholic			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hepatic cirrhosis			

subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hepatic cyst			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Urticaria			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pruritus			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 1449 (0.07%)	3 / 1489 (0.20%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hydronephrosis			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Kidney enlargement			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal artery thrombosis			

subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cyst			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Renal failure acute			
subjects affected / exposed	1 / 1449 (0.07%)	3 / 1489 (0.20%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Renal impairment			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral disorder			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematuria			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incontinence			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mixed incontinence			

subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (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	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stress urinary incontinence			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary incontinence			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrolithiasis			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Autoimmune thyroiditis			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Goitre			
subjects affected / exposed	3 / 1449 (0.21%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperthyroidism			

subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroiditis			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
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			
Bone pain			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteopenia			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoporosis			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain in jaw			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sjogren's syndrome			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fracture nonunion			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (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	5 / 1449 (0.35%)	4 / 1489 (0.27%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis			
subjects affected / exposed	3 / 1449 (0.21%)	3 / 1489 (0.20%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoarthritis			
subjects affected / exposed	15 / 1449 (1.04%)	11 / 1489 (0.74%)	
occurrences causally related to treatment / all	3 / 15	2 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rheumatoid arthritis			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rotator cuff syndrome			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal osteoarthritis			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle spasms			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
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 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Trismus			

subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical spinal stenosis			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot deformity			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc disorder			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc protrusion			
subjects affected / exposed	2 / 1449 (0.14%)	3 / 1489 (0.20%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar spine flattening			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal column stenosis			
subjects affected / exposed	3 / 1449 (0.21%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back disorder			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
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	2 / 1449 (0.14%)	3 / 1489 (0.20%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dupuytren's contracture			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Groin pain			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal chest pain			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal pain			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
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	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain in extremity			
subjects affected / exposed	3 / 1449 (0.21%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	1 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Synovitis			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tenosynovitis stenosans			

subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chondropathy			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tenosynovitis			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (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			
Arthritis bacterial			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cellulitis			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	2 / 1449 (0.14%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia infection			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia sepsis			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumococcal sepsis			

subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia pneumococcal			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Streptococcal sepsis			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal infection			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Appendicitis			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis infective			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast abscess			

subjects affected / exposed	1 / 1449 (0.07%)	4 / 1489 (0.27%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchiectasis			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
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 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchopneumonia			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis			
subjects affected / exposed	5 / 1449 (0.35%)	3 / 1489 (0.20%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocarditis			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (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	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infection			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Kidney infection			

subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Localised infection			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mastitis			
subjects affected / exposed	3 / 1449 (0.21%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nail infection			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	5 / 1449 (0.35%)	10 / 1489 (0.67%)	
occurrences causally related to treatment / all	0 / 5	0 / 10	
deaths causally related to treatment / all	0 / 1	0 / 2	
Postoperative wound infection			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection			

subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (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	2 / 1449 (0.14%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 0	
Sialoadenitis			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	4 / 1449 (0.28%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Urosepsis			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection			
subjects affected / exposed	1 / 1449 (0.07%)	2 / 1489 (0.13%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes ophthalmic			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (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	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vestibular neuronitis			

subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral infection			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (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	1 / 1449 (0.07%)	0 / 1489 (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	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes mellitus			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Folate deficiency			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Anastrozole	Tamoxifen	
Total subjects affected by non-serious adverse events subjects affected / exposed	1323 / 1449 (91.30%)	1380 / 1489 (92.68%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign breast neoplasm			
subjects affected / exposed	10 / 1449 (0.69%)	11 / 1489 (0.74%)	
occurrences (all)	10	11	
Breast cyst			
subjects affected / exposed	4 / 1449 (0.28%)	2 / 1489 (0.13%)	
occurrences (all)	4	2	
Fibroadenoma of breast			
subjects affected / exposed	6 / 1449 (0.41%)	8 / 1489 (0.54%)	
occurrences (all)	6	8	
Breast cancer in situ			
subjects affected / exposed	3 / 1449 (0.21%)	2 / 1489 (0.13%)	
occurrences (all)	3	2	
Breast cancer metastatic			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
Breast cancer recurrent			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences (all)	2	0	
Melanocytic naevus			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Seborrhoeic keratosis			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
Skin papilloma			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Adrenal adenoma			

subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Thyroid cyst			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Neuroendocrine carcinoma			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Anal polyp			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Colon adenoma			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Gastric polyps			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Anal cancer			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Colon cancer			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences (all)	0	2	
Colorectal cancer stage IV			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal cancer metastatic			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal carcinoma			
subjects affected / exposed	1 / 1449 (0.07%)	2 / 1489 (0.13%)	
occurrences (all)	1	2	
Intestinal adenocarcinoma			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Lip and/or oral cavity cancer			

subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Oesophageal carcinoma			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Rectal cancer			
subjects affected / exposed	2 / 1449 (0.14%)	1 / 1489 (0.07%)	
occurrences (all)	2	1	
Focal nodular hyperplasia			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Hepatic cancer			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Myelodysplastic syndrome			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Lymphoma			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Non-Hodgkin's lymphoma			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Mesothelioma			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Metastases to bone			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Metastases to liver			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences (all)	2	0	
Metastases to lung			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
Metastases to lymph nodes			

subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
Metastases to peritoneum			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Metastases to skin			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Metastasis			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Adenoma benign			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Cholesteatoma			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Cyst			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Polyp			
subjects affected / exposed	0 / 1449 (0.00%)	3 / 1489 (0.20%)	
occurrences (all)	0	3	
Adenoid cystic carcinoma			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Angiosarcoma			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Carcinoma in situ			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Head and neck cancer			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Malignant neoplasm of unknown			

primary site			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Metastatic neoplasm			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Recurrent cancer			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Squamous cell carcinoma			
subjects affected / exposed	2 / 1449 (0.14%)	2 / 1489 (0.13%)	
occurrences (all)	2	2	
Neuroma			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Intracranial meningioma malignant			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences (all)	0	2	
Meningioma			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Gammopathy			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Renal cancer			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Genital cyst			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Cervical polyp			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
Degeneration of uterine fibroid			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	

Ovarian cyst			
subjects affected / exposed	3 / 1449 (0.21%)	3 / 1489 (0.20%)	
occurrences (all)	3	3	
Uterine cyst			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Uterine leiomyoma			
subjects affected / exposed	0 / 1449 (0.00%)	6 / 1489 (0.40%)	
occurrences (all)	0	6	
Uterine polyp			
subjects affected / exposed	3 / 1449 (0.21%)	3 / 1489 (0.20%)	
occurrences (all)	3	3	
Vaginal polyp			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Vulval polyp			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Endometrial cancer stage I			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Ovarian cancer			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences (all)	0	2	
Uterine cancer			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences (all)	0	2	
Vulval neoplasm			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Benign lung neoplasm			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Nasal polyps			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	

Adenosquamous cell lung cancer				
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)		
occurrences (all)	0	1		
Bronchial carcinoma				
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)		
occurrences (all)	0	1		
Lung adenocarcinoma				
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)		
occurrences (all)	0	1		
Lung carcinoma cell type unspecified recurrent				
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)		
occurrences (all)	0	2		
Lung carcinoma cell type unspecified stage 0				
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)		
occurrences (all)	0	1		
Thymoma				
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)		
occurrences (all)	0	1		
Tonsil cancer				
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)		
occurrences (all)	0	1		
Basal cell carcinoma				
subjects affected / exposed	8 / 1449 (0.55%)	9 / 1489 (0.60%)		
occurrences (all)	8	9		
Bowen's disease				
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)		
occurrences (all)	1	0		
Malignant melanoma				
subjects affected / exposed	4 / 1449 (0.28%)	1 / 1489 (0.07%)		
occurrences (all)	4	1		
Malignant melanoma in situ				
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)		
occurrences (all)	0	1		
Melanoma recurrent				

subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Skin cancer			
subjects affected / exposed	0 / 1449 (0.00%)	4 / 1489 (0.27%)	
occurrences (all)	0	4	
Superficial spreading melanoma stage unspecified			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Lipoma			
subjects affected / exposed	3 / 1449 (0.21%)	1 / 1489 (0.07%)	
occurrences (all)	3	1	
Vascular disorders			
Accelerated hypertension			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Aneurysm			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Angina unstable			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Aortic stenosis			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
Carotid artery occlusion			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Carotid artery stenosis			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Cerebrovascular accident			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Circulatory collapse			

subjects affected / exposed	1 / 1449 (0.07%)	2 / 1489 (0.13%)	
occurrences (all)	1	2	
Coronary artery disease			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Deep vein thrombosis			
subjects affected / exposed	5 / 1449 (0.35%)	3 / 1489 (0.20%)	
occurrences (all)	5	3	
Dizziness			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Embolism			
subjects affected / exposed	2 / 1449 (0.14%)	5 / 1489 (0.34%)	
occurrences (all)	2	5	
Epistaxis			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Essential hypertension			
subjects affected / exposed	68 / 1449 (4.69%)	54 / 1489 (3.63%)	
occurrences (all)	68	54	
Femoral artery aneurysm			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Haematoma			
subjects affected / exposed	4 / 1449 (0.28%)	8 / 1489 (0.54%)	
occurrences (all)	4	8	
Haemorrhage intracranial			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Hot flush			
subjects affected / exposed	161 / 1449 (11.11%)	184 / 1489 (12.36%)	
occurrences (all)	161	184	
Hypertension			
subjects affected / exposed	28 / 1449 (1.93%)	22 / 1489 (1.48%)	
occurrences (all)	28	22	

Hypotension			
subjects affected / exposed	2 / 1449 (0.14%)	3 / 1489 (0.20%)	
occurrences (all)	2	3	
Ischaemia			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Ischaemic stroke			
subjects affected / exposed	1 / 1449 (0.07%)	2 / 1489 (0.13%)	
occurrences (all)	1	2	
Lymphoedema			
subjects affected / exposed	4 / 1449 (0.28%)	8 / 1489 (0.54%)	
occurrences (all)	4	8	
Malignant hypertension			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Orthostatic hypotension			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Peripheral coldness			
subjects affected / exposed	3 / 1449 (0.21%)	3 / 1489 (0.20%)	
occurrences (all)	3	3	
Peripheral vascular disorder			
subjects affected / exposed	2 / 1449 (0.14%)	1 / 1489 (0.07%)	
occurrences (all)	2	1	
Phlebitis			
subjects affected / exposed	3 / 1449 (0.21%)	7 / 1489 (0.47%)	
occurrences (all)	3	7	
Postmenopausal haemorrhage			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Presyncope			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Pulmonary embolism			
subjects affected / exposed	3 / 1449 (0.21%)	2 / 1489 (0.13%)	
occurrences (all)	3	2	

Spider vein			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Syncope			
subjects affected / exposed	1 / 1449 (0.07%)	2 / 1489 (0.13%)	
occurrences (all)	1	2	
Temporal arteritis			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences (all)	0	2	
Thrombophlebitis superficial			
subjects affected / exposed	1 / 1449 (0.07%)	6 / 1489 (0.40%)	
occurrences (all)	1	6	
Thrombosis			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Transient ischaemic attack			
subjects affected / exposed	7 / 1449 (0.48%)	2 / 1489 (0.13%)	
occurrences (all)	7	2	
Varicose ulceration			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Varicose vein			
subjects affected / exposed	7 / 1449 (0.48%)	9 / 1489 (0.60%)	
occurrences (all)	7	9	
Vasculitis			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Venous insufficiency			
subjects affected / exposed	3 / 1449 (0.21%)	0 / 1489 (0.00%)	
occurrences (all)	3	0	
Venous thrombosis			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Surgical and medical procedures			
Abscess drainage			

subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Acupuncture			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Adrenal gland operation			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Anal polypectomy			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Angioplasty			
subjects affected / exposed	2 / 1449 (0.14%)	2 / 1489 (0.13%)	
occurrences (all)	2	2	
Ankle operation			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Aortic valve replacement			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Appendicectomy			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Arterial stent insertion			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Arthroscopic surgery			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Bladder operation			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Bone lesion excision			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Bone operation			

subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Breast cyst drainage			
subjects affected / exposed	1 / 1449 (0.07%)	2 / 1489 (0.13%)	
occurrences (all)	1	2	
Breast lump removal			
subjects affected / exposed	1 / 1449 (0.07%)	3 / 1489 (0.20%)	
occurrences (all)	1	3	
Breast reconstruction			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Bunion operation			
subjects affected / exposed	6 / 1449 (0.41%)	8 / 1489 (0.54%)	
occurrences (all)	6	8	
Cancer surgery			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Cardiac ablation			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences (all)	0	2	
Cardiac operation			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Cardiac pacemaker insertion			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Cardiac resynchronisation therapy			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Cardioversion			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Carpal tunnel decompression			
subjects affected / exposed	13 / 1449 (0.90%)	3 / 1489 (0.20%)	
occurrences (all)	13	3	
Cataract operation			

subjects affected / exposed	18 / 1449 (1.24%)	26 / 1489 (1.75%)	
occurrences (all)	18	26	
Cervical polypectomy			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
Chemotherapy			
subjects affected / exposed	1 / 1449 (0.07%)	2 / 1489 (0.13%)	
occurrences (all)	1	2	
Chiropractic			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Cholecystectomy			
subjects affected / exposed	9 / 1449 (0.62%)	7 / 1489 (0.47%)	
occurrences (all)	9	7	
Colon operation			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Colon polypectomy			
subjects affected / exposed	3 / 1449 (0.21%)	6 / 1489 (0.40%)	
occurrences (all)	3	6	
Colonoscopy			
subjects affected / exposed	1 / 1449 (0.07%)	4 / 1489 (0.27%)	
occurrences (all)	1	4	
Colostomy			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences (all)	0	2	
Colporrhaphy			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Coronary artery bypass			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
Cyst removal			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Debridement			

subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Dental care			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Dental implantation			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Dupuytren's contracture operation			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Ear operation			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Elbow operation			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Elective surgery			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Emergency care			
subjects affected / exposed	1 / 1449 (0.07%)	3 / 1489 (0.20%)	
occurrences (all)	1	3	
Endocervical curettage			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Ethmoid sinus surgery			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Eye operation			
subjects affected / exposed	3 / 1449 (0.21%)	3 / 1489 (0.20%)	
occurrences (all)	3	3	
Foot operation			
subjects affected / exposed	2 / 1449 (0.14%)	2 / 1489 (0.13%)	
occurrences (all)	2	2	
Gallbladder operation			

subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Haemorrhoid operation			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Hand repair operation			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Heart valve replacement			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences (all)	0	2	
Hernia repair			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
High frequency ablation			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Hip arthroplasty			
subjects affected / exposed	14 / 1449 (0.97%)	10 / 1489 (0.67%)	
occurrences (all)	14	10	
Hip surgery			
subjects affected / exposed	6 / 1449 (0.41%)	4 / 1489 (0.27%)	
occurrences (all)	6	4	
Hospitalisation			
subjects affected / exposed	3 / 1449 (0.21%)	3 / 1489 (0.20%)	
occurrences (all)	3	3	
Hysterectomy			
subjects affected / exposed	4 / 1449 (0.28%)	17 / 1489 (1.14%)	
occurrences (all)	4	17	
Ileostomy			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Incisional hernia repair			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences (all)	0	2	
Inguinal hernia repair			

subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Intervertebral disc operation			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Intestinal resection			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Intraocular lens implant			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Intra-uterine contraceptive device			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Jaw operation			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Joint manipulation			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Joint surgery			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Knee arthroplasty			
subjects affected / exposed	12 / 1449 (0.83%)	13 / 1489 (0.87%)	
occurrences (all)	12	13	
Knee operation			
subjects affected / exposed	8 / 1449 (0.55%)	3 / 1489 (0.20%)	
occurrences (all)	8	3	
Large intestine operation			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Laryngeal polypectomy			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Lesion excision			

subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Limb operation			
subjects affected / exposed	1 / 1449 (0.07%)	3 / 1489 (0.20%)	
occurrences (all)	1	3	
Lipoma excision			
subjects affected / exposed	0 / 1449 (0.00%)	7 / 1489 (0.47%)	
occurrences (all)	0	7	
Local anaesthesia			
subjects affected / exposed	3 / 1449 (0.21%)	0 / 1489 (0.00%)	
occurrences (all)	3	0	
Lung lobectomy			
subjects affected / exposed	2 / 1449 (0.14%)	1 / 1489 (0.07%)	
occurrences (all)	2	1	
Lymphadenectomy			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Mammoplasty			
subjects affected / exposed	3 / 1449 (0.21%)	4 / 1489 (0.27%)	
occurrences (all)	3	4	
Mastectomy			
subjects affected / exposed	2 / 1449 (0.14%)	4 / 1489 (0.27%)	
occurrences (all)	2	4	
Meningioma surgery			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Meniscus removal			
subjects affected / exposed	2 / 1449 (0.14%)	3 / 1489 (0.20%)	
occurrences (all)	2	3	
Mitral valve replacement			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Mole excision			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Muscle operation			

subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Nail operation			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences (all)	2	0	
Nasal operation			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Nephrectomy			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Nerve block			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Oophorectomy			
subjects affected / exposed	0 / 1449 (0.00%)	3 / 1489 (0.20%)	
occurrences (all)	0	3	
Oophorectomy bilateral			
subjects affected / exposed	2 / 1449 (0.14%)	5 / 1489 (0.34%)	
occurrences (all)	2	5	
Open reduction of fracture			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Ovarian cystectomy			
subjects affected / exposed	3 / 1449 (0.21%)	1 / 1489 (0.07%)	
occurrences (all)	3	1	
Parathyroidectomy			
subjects affected / exposed	2 / 1449 (0.14%)	1 / 1489 (0.07%)	
occurrences (all)	2	1	
Pelvic floor repair			
subjects affected / exposed	1 / 1449 (0.07%)	4 / 1489 (0.27%)	
occurrences (all)	1	4	
Physiotherapy			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Plastic surgery			

subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
Polypectomy			
subjects affected / exposed	1 / 1449 (0.07%)	12 / 1489 (0.81%)	
occurrences (all)	1	12	
Prolapse repair			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Prosthesis implantation			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Radical mastectomy			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Radiotherapy			
subjects affected / exposed	1 / 1449 (0.07%)	2 / 1489 (0.13%)	
occurrences (all)	1	2	
Renal cyst excision			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Retinal laser coagulation			
subjects affected / exposed	2 / 1449 (0.14%)	1 / 1489 (0.07%)	
occurrences (all)	2	1	
Retinal operation			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences (all)	0	2	
Salpingectomy			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences (all)	0	2	
Salpingo-oophorectomy			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Salpingo-oophorectomy bilateral			
subjects affected / exposed	1 / 1449 (0.07%)	2 / 1489 (0.13%)	
occurrences (all)	1	2	
Sclerotherapy			

subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Shoulder arthroplasty			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Shoulder operation			
subjects affected / exposed	6 / 1449 (0.41%)	3 / 1489 (0.20%)	
occurrences (all)	6	3	
Simple mastectomy			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Sinus operation			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Skin graft			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Skin lesion excision			
subjects affected / exposed	5 / 1449 (0.35%)	3 / 1489 (0.20%)	
occurrences (all)	5	3	
Skin neoplasm excision			
subjects affected / exposed	2 / 1449 (0.14%)	4 / 1489 (0.27%)	
occurrences (all)	2	4	
Spinal decompression			
subjects affected / exposed	1 / 1449 (0.07%)	2 / 1489 (0.13%)	
occurrences (all)	1	2	
Spinal laminectomy			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Spinal operation			
subjects affected / exposed	2 / 1449 (0.14%)	2 / 1489 (0.13%)	
occurrences (all)	2	2	
Stent placement			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences (all)	2	0	
Steroid therapy			

subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Surgery			
subjects affected / exposed	4 / 1449 (0.28%)	4 / 1489 (0.27%)	
occurrences (all)	4	4	
Tendon operation			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Tendon sheath lesion excision			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Therapeutic skin care topical			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Thoracotomy			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Thyroid operation			
subjects affected / exposed	3 / 1449 (0.21%)	1 / 1489 (0.07%)	
occurrences (all)	3	1	
Thyroidectomy			
subjects affected / exposed	1 / 1449 (0.07%)	3 / 1489 (0.20%)	
occurrences (all)	1	3	
Toe amputation			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Toe operation			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Tooth extraction			
subjects affected / exposed	2 / 1449 (0.14%)	6 / 1489 (0.40%)	
occurrences (all)	2	6	
Trabeculectomy			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Transfusion			

subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Tumour excision			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Umbilical hernia repair			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Uterine cervix dilation procedure			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Uterine cystectomy			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Uterine dilation and curettage			
subjects affected / exposed	3 / 1449 (0.21%)	4 / 1489 (0.27%)	
occurrences (all)	3	4	
Uterine polypectomy			
subjects affected / exposed	3 / 1449 (0.21%)	0 / 1489 (0.00%)	
occurrences (all)	3	0	
Uterine prolapse repair			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Varicose vein operation			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Venous ligation			
subjects affected / exposed	1 / 1449 (0.07%)	2 / 1489 (0.13%)	
occurrences (all)	1	2	
Venous operation			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Vocal cordectomy			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
General disorders and administration			

site conditions				
Pyrexia				
subjects affected / exposed	3 / 1449 (0.21%)	6 / 1489 (0.40%)		
occurrences (all)	3	6		
Asthenia				
subjects affected / exposed	23 / 1449 (1.59%)	25 / 1489 (1.68%)		
occurrences (all)	23	25		
Axillary pain				
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)		
occurrences (all)	0	1		
Chest discomfort				
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)		
occurrences (all)	0	2		
Chest pain				
subjects affected / exposed	4 / 1449 (0.28%)	6 / 1489 (0.40%)		
occurrences (all)	4	6		
Chills				
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)		
occurrences (all)	0	1		
Disease recurrence				
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)		
occurrences (all)	0	1		
Facial pain				
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)		
occurrences (all)	2	0		
Fatigue				
subjects affected / exposed	1 / 1449 (0.07%)	2 / 1489 (0.13%)		
occurrences (all)	1	2		
Gait disturbance				
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)		
occurrences (all)	1	0		
Hernia				
subjects affected / exposed	2 / 1449 (0.14%)	2 / 1489 (0.13%)		
occurrences (all)	2	2		
Hot flush				

subjects affected / exposed	19 / 1449 (1.31%)	14 / 1489 (0.94%)	
occurrences (all)	19	14	
Inflammation			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Influenza like illness			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Irritability			
subjects affected / exposed	6 / 1449 (0.41%)	1 / 1489 (0.07%)	
occurrences (all)	6	1	
Lethargy			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Malaise			
subjects affected / exposed	165 / 1449 (11.39%)	177 / 1489 (11.89%)	
occurrences (all)	165	177	
Night sweats			
subjects affected / exposed	5 / 1449 (0.35%)	3 / 1489 (0.20%)	
occurrences (all)	5	3	
Oedema			
subjects affected / exposed	21 / 1449 (1.45%)	28 / 1489 (1.88%)	
occurrences (all)	21	28	
Oedema peripheral			
subjects affected / exposed	18 / 1449 (1.24%)	9 / 1489 (0.60%)	
occurrences (all)	18	9	
Pain			
subjects affected / exposed	1 / 1449 (0.07%)	2 / 1489 (0.13%)	
occurrences (all)	1	2	
Polyp			
subjects affected / exposed	2 / 1449 (0.14%)	6 / 1489 (0.40%)	
occurrences (all)	2	6	
Thirst			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	

Adverse drug reaction			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Adverse reaction			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences (all)	2	0	
Cyst			
subjects affected / exposed	2 / 1449 (0.14%)	2 / 1489 (0.13%)	
occurrences (all)	2	2	
Dysplasia			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Fat necrosis			
subjects affected / exposed	2 / 1449 (0.14%)	1 / 1489 (0.07%)	
occurrences (all)	2	1	
Fibrosis			
subjects affected / exposed	6 / 1449 (0.41%)	3 / 1489 (0.20%)	
occurrences (all)	6	3	
Hyperplasia			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Immune system disorders			
Asthma			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences (all)	2	0	
Drug hypersensitivity			
subjects affected / exposed	5 / 1449 (0.35%)	0 / 1489 (0.00%)	
occurrences (all)	5	0	
Hypersensitivity			
subjects affected / exposed	3 / 1449 (0.21%)	10 / 1489 (0.67%)	
occurrences (all)	3	10	
Multiple allergies			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Antiphospholipid syndrome			

subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Polymyalgia rheumatica			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
Rheumatoid arthritis			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Polyarteritis nodosa			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Temporal arteritis			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Social circumstances			
Bereavement			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Ex-tobacco user			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Reproductive system and breast disorders			
Adnexa uteri pain			
subjects affected / exposed	1 / 1449 (0.07%)	3 / 1489 (0.20%)	
occurrences (all)	1	3	
Arthritis climacteric			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Benign breast neoplasm			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Breast abscess			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Breast calcifications			

subjects affected / exposed	4 / 1449 (0.28%)	4 / 1489 (0.27%)	
occurrences (all)	4	4	
Breast cancer in situ			
subjects affected / exposed	1 / 1449 (0.07%)	3 / 1489 (0.20%)	
occurrences (all)	1	3	
Breast cancer metastatic			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Breast cancer recurrent			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Breast cyst			
subjects affected / exposed	10 / 1449 (0.69%)	7 / 1489 (0.47%)	
occurrences (all)	10	7	
Breast discharge			
subjects affected / exposed	6 / 1449 (0.41%)	5 / 1489 (0.34%)	
occurrences (all)	6	5	
Breast discomfort			
subjects affected / exposed	3 / 1449 (0.21%)	0 / 1489 (0.00%)	
occurrences (all)	3	0	
Breast disorder			
subjects affected / exposed	7 / 1449 (0.48%)	18 / 1489 (1.21%)	
occurrences (all)	7	18	
Breast hyperplasia			
subjects affected / exposed	2 / 1449 (0.14%)	1 / 1489 (0.07%)	
occurrences (all)	2	1	
Breast infection			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Breast necrosis			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Breast pain			
subjects affected / exposed	70 / 1449 (4.83%)	66 / 1489 (4.43%)	
occurrences (all)	70	66	
Breast swelling			

subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Cervical dysplasia			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences (all)	2	0	
Cervical polyp			
subjects affected / exposed	2 / 1449 (0.14%)	11 / 1489 (0.74%)	
occurrences (all)	2	11	
Cystocele			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
Dysmenorrhoea			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Dyspareunia			
subjects affected / exposed	11 / 1449 (0.76%)	11 / 1489 (0.74%)	
occurrences (all)	11	11	
Endometrial disorder			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Endometrial hyperplasia			
subjects affected / exposed	0 / 1449 (0.00%)	18 / 1489 (1.21%)	
occurrences (all)	0	18	
Endometrial hypertrophy			
subjects affected / exposed	2 / 1449 (0.14%)	34 / 1489 (2.28%)	
occurrences (all)	2	34	
Endometriosis			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
Fibrocystic breast disease			
subjects affected / exposed	4 / 1449 (0.28%)	8 / 1489 (0.54%)	
occurrences (all)	4	8	
Galactorrhoea			
subjects affected / exposed	1 / 1449 (0.07%)	2 / 1489 (0.13%)	
occurrences (all)	1	2	
Gynaecomastia			

subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences (all)	2	0	
Hot flush			
subjects affected / exposed	815 / 1449 (56.25%)	898 / 1489 (60.31%)	
occurrences (all)	815	898	
Intraductal papilloma of breast			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Mastitis			
subjects affected / exposed	3 / 1449 (0.21%)	0 / 1489 (0.00%)	
occurrences (all)	3	0	
Menopausal symptoms			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
Menorrhagia			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Metrorrhagia			
subjects affected / exposed	13 / 1449 (0.90%)	20 / 1489 (1.34%)	
occurrences (all)	13	20	
Night sweats			
subjects affected / exposed	70 / 1449 (4.83%)	74 / 1489 (4.97%)	
occurrences (all)	70	74	
Nipple disorder			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Nipple pain			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Ovarian cyst			
subjects affected / exposed	10 / 1449 (0.69%)	9 / 1489 (0.60%)	
occurrences (all)	10	9	
Ovarian mass			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	

Pelvic pain			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Perineal pain			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Postmenopausal haemorrhage			
subjects affected / exposed	13 / 1449 (0.90%)	12 / 1489 (0.81%)	
occurrences (all)	13	12	
Premenstrual syndrome			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Sexual dysfunction			
subjects affected / exposed	1 / 1449 (0.07%)	2 / 1489 (0.13%)	
occurrences (all)	1	2	
Uterine atrophy			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Uterine cyst			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Uterine fibrosis			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
Uterine haemorrhage			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Uterine leiomyoma			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Uterine polyp			
subjects affected / exposed	9 / 1449 (0.62%)	25 / 1489 (1.68%)	
occurrences (all)	9	25	
Uterine prolapse			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	

Uterine spasm			
subjects affected / exposed	1 / 1449 (0.07%)	3 / 1489 (0.20%)	
occurrences (all)	1	3	
Vaginal cyst			
subjects affected / exposed	1 / 1449 (0.07%)	2 / 1489 (0.13%)	
occurrences (all)	1	2	
Vaginal discharge			
subjects affected / exposed	31 / 1449 (2.14%)	140 / 1489 (9.40%)	
occurrences (all)	31	140	
Vaginal disorder			
subjects affected / exposed	20 / 1449 (1.38%)	22 / 1489 (1.48%)	
occurrences (all)	20	22	
Vaginal haemorrhage			
subjects affected / exposed	32 / 1449 (2.21%)	78 / 1489 (5.24%)	
occurrences (all)	32	78	
Vaginal inflammation			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences (all)	0	2	
Vaginal polyp			
subjects affected / exposed	1 / 1449 (0.07%)	2 / 1489 (0.13%)	
occurrences (all)	1	2	
Vaginal prolapse			
subjects affected / exposed	8 / 1449 (0.55%)	11 / 1489 (0.74%)	
occurrences (all)	8	11	
Vaginal swelling			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Vulval abscess			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Vulval neoplasm			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Vulval polyp			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	

Vulvovaginal dryness			
subjects affected / exposed	201 / 1449 (13.87%)	166 / 1489 (11.15%)	
occurrences (all)	201	166	
Vulvovaginal pain			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Vulvovaginal pruritus			
subjects affected / exposed	19 / 1449 (1.31%)	47 / 1489 (3.16%)	
occurrences (all)	19	47	
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	10 / 1449 (0.69%)	12 / 1489 (0.81%)	
occurrences (all)	10	12	
Bronchitis chronic			
subjects affected / exposed	1 / 1449 (0.07%)	2 / 1489 (0.13%)	
occurrences (all)	1	2	
Chest discomfort			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Chest pain			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Chronic obstructive pulmonary disease			
subjects affected / exposed	4 / 1449 (0.28%)	6 / 1489 (0.40%)	
occurrences (all)	4	6	
Cough			
subjects affected / exposed	16 / 1449 (1.10%)	24 / 1489 (1.61%)	
occurrences (all)	16	24	
Dry throat			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Dyspnoea			
subjects affected / exposed	21 / 1449 (1.45%)	30 / 1489 (2.01%)	
occurrences (all)	21	30	
Dyspnoea exertional			

subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences (all)	2	0	
Emphysema			
subjects affected / exposed	3 / 1449 (0.21%)	0 / 1489 (0.00%)	
occurrences (all)	3	0	
Epistaxis			
subjects affected / exposed	5 / 1449 (0.35%)	3 / 1489 (0.20%)	
occurrences (all)	5	3	
Haemoptysis			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Increased upper airway secretion			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
Lobar pneumonia			
subjects affected / exposed	2 / 1449 (0.14%)	1 / 1489 (0.07%)	
occurrences (all)	2	1	
Lower respiratory tract infection			
subjects affected / exposed	22 / 1449 (1.52%)	53 / 1489 (3.56%)	
occurrences (all)	22	53	
Lung cancer metastatic			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Lung disorder			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences (all)	2	0	
Multifocal micronodular pneumocyte hyperplasia			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Nasal congestion			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Nasal discomfort			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences (all)	0	2	

Nasal dryness			
subjects affected / exposed	2 / 1449 (0.14%)	1 / 1489 (0.07%)	
occurrences (all)	2	1	
Nasal polyps			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Pertussis			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Pleurisy			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Pleuritic pain			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Pneumonia			
subjects affected / exposed	7 / 1449 (0.48%)	3 / 1489 (0.20%)	
occurrences (all)	7	3	
Pulmonary arterial hypertension			
subjects affected / exposed	4 / 1449 (0.28%)	4 / 1489 (0.27%)	
occurrences (all)	4	4	
Pulmonary embolism			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences (all)	0	2	
Pulmonary hypertension			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Respiratory disorder			
subjects affected / exposed	2 / 1449 (0.14%)	4 / 1489 (0.27%)	
occurrences (all)	2	4	
Respiratory distress			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Rhinitis allergic			
subjects affected / exposed	2 / 1449 (0.14%)	5 / 1489 (0.34%)	
occurrences (all)	2	5	

Rhinorrhoea			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Sinusitis			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Sleep apnoea syndrome			
subjects affected / exposed	24 / 1449 (1.66%)	25 / 1489 (1.68%)	
occurrences (all)	24	25	
Throat tightness			
subjects affected / exposed	1 / 1449 (0.07%)	2 / 1489 (0.13%)	
occurrences (all)	1	2	
Tonsillar disorder			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Tonsillitis			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Upper respiratory tract infection			
subjects affected / exposed	4 / 1449 (0.28%)	7 / 1489 (0.47%)	
occurrences (all)	4	7	
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences (all)	0	2	
Amnesia			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences (all)	2	0	
Aggression			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Alcohol problem			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Anxiety			

subjects affected / exposed	15 / 1449 (1.04%)	22 / 1489 (1.48%)	
occurrences (all)	15	22	
Bipolar I disorder			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Cognitive disorder			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Depression			
subjects affected / exposed	67 / 1449 (4.62%)	70 / 1489 (4.70%)	
occurrences (all)	67	70	
Eating disorder			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Emotional disorder			
subjects affected / exposed	27 / 1449 (1.86%)	36 / 1489 (2.42%)	
occurrences (all)	27	36	
Hallucination			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Insomnia			
subjects affected / exposed	109 / 1449 (7.52%)	93 / 1489 (6.25%)	
occurrences (all)	109	93	
Loss of libido			
subjects affected / exposed	10 / 1449 (0.69%)	12 / 1489 (0.81%)	
occurrences (all)	10	12	
Mental disorder			
subjects affected / exposed	2 / 1449 (0.14%)	3 / 1489 (0.20%)	
occurrences (all)	2	3	
Nervousness			
subjects affected / exposed	3 / 1449 (0.21%)	2 / 1489 (0.13%)	
occurrences (all)	3	2	
Neurosis			
subjects affected / exposed	0 / 1449 (0.00%)	5 / 1489 (0.34%)	
occurrences (all)	0	5	
Nightmare			

subjects affected / exposed	1 / 1449 (0.07%)	2 / 1489 (0.13%)	
occurrences (all)	1	2	
Personality disorder			
subjects affected / exposed	3 / 1449 (0.21%)	0 / 1489 (0.00%)	
occurrences (all)	3	0	
Phobia			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Restlessness			
subjects affected / exposed	2 / 1449 (0.14%)	3 / 1489 (0.20%)	
occurrences (all)	2	3	
Sleep disorder			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Somnolence			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Stress			
subjects affected / exposed	4 / 1449 (0.28%)	5 / 1489 (0.34%)	
occurrences (all)	4	5	
Suicidal ideation			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Cholecystitis acute			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Cholecystitis chronic			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Cholelithiasis			
subjects affected / exposed	4 / 1449 (0.28%)	8 / 1489 (0.54%)	
occurrences (all)	4	8	

Gallbladder disorder			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Haemochromatosis			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences (all)	0	2	
Hepatic cirrhosis			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Hepatitis			
subjects affected / exposed	1 / 1449 (0.07%)	3 / 1489 (0.20%)	
occurrences (all)	1	3	
Liver disorder			
subjects affected / exposed	3 / 1449 (0.21%)	3 / 1489 (0.20%)	
occurrences (all)	3	3	
Hepatobiliary carcinoma in situ			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Investigations			
Biopsy lymph gland			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
Angiogram			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Arteriogram coronary			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
Blood pressure			
subjects affected / exposed	2 / 1449 (0.14%)	2 / 1489 (0.13%)	
occurrences (all)	2	2	
Blood pressure abnormal			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Blood pressure increased			

subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Cardiac murmur			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Cardiovascular evaluation			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Catheterisation cardiac			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Echocardiogram			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Electrocardiogram			
subjects affected / exposed	3 / 1449 (0.21%)	2 / 1489 (0.13%)	
occurrences (all)	3	2	
Electrocardiogram abnormal			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences (all)	0	2	
Electrocardiogram ST segment depression			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Heart rate decreased			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Heart rate irregular			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
Scan myocardial perfusion			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Ultrasound Doppler			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences (all)	0	2	

Venogram			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Gene mutation identification test positive			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Biopsy thyroid gland			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Thyroid function test abnormal			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Barium enema			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Barium swallow			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Biopsy colon abnormal			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Biopsy oesophagus			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Colonoscopy			
subjects affected / exposed	0 / 1449 (0.00%)	5 / 1489 (0.34%)	
occurrences (all)	0	5	
Endoscopy upper gastrointestinal tract			
subjects affected / exposed	2 / 1449 (0.14%)	5 / 1489 (0.34%)	
occurrences (all)	2	5	
Oesophagogastrectomy			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Sigmoidoscopy			

subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
Ultrasound abdomen			
subjects affected / exposed	1 / 1449 (0.07%)	2 / 1489 (0.13%)	
occurrences (all)	1	2	
White blood cell count decreased			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Red blood cell count			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences (all)	2	0	
Biopsy liver			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Hepatic enzyme increased			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Liver function test abnormal			
subjects affected / exposed	17 / 1449 (1.17%)	21 / 1489 (1.41%)	
occurrences (all)	17	21	
Ultrasound biliary tract			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Biopsy			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Computerised tomogram			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Endoscopy			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	

Imaging procedure				
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)		
occurrences (all)	1	0		
Investigation				
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)		
occurrences (all)	2	0		
Needle biopsy site unspecified normal				
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)		
occurrences (all)	1	0		
Nuclear magnetic resonance imaging				
subjects affected / exposed	4 / 1449 (0.28%)	2 / 1489 (0.13%)		
occurrences (all)	4	2		
X-ray				
subjects affected / exposed	4 / 1449 (0.28%)	2 / 1489 (0.13%)		
occurrences (all)	4	2		
Free fatty acids increased				
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)		
occurrences (all)	0	1		
Glucose tolerance test				
subjects affected / exposed	5 / 1449 (0.35%)	3 / 1489 (0.20%)		
occurrences (all)	5	3		
Arthroscopy				
subjects affected / exposed	6 / 1449 (0.41%)	7 / 1489 (0.47%)		
occurrences (all)	6	7		
Bone densitometry				
subjects affected / exposed	4 / 1449 (0.28%)	3 / 1489 (0.20%)		
occurrences (all)	4	3		
Bone density decreased				
subjects affected / exposed	56 / 1449 (3.86%)	42 / 1489 (2.82%)		
occurrences (all)	56	42		
Acoustic stimulation tests				
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)		
occurrences (all)	0	1		
Brain scan normal				

subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Scan brain			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Body height decreased			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Body temperature increased			
subjects affected / exposed	4 / 1449 (0.28%)	1 / 1489 (0.07%)	
occurrences (all)	4	1	
Gastrointestinal examination			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
Gynaecological examination			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
Neurological examination			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Ophthalmological examination			
subjects affected / exposed	4 / 1449 (0.28%)	4 / 1489 (0.27%)	
occurrences (all)	4	4	
Orthopaedic examination			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences (all)	0	2	
Weight decreased			
subjects affected / exposed	23 / 1449 (1.59%)	15 / 1489 (1.01%)	
occurrences (all)	23	15	
Weight increased			
subjects affected / exposed	126 / 1449 (8.70%)	133 / 1489 (8.93%)	
occurrences (all)	126	133	
Cystoscopy			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences (all)	0	2	
Ultrasound kidney			

subjects affected / exposed	2 / 1449 (0.14%)	1 / 1489 (0.07%)	
occurrences (all)	2	1	
Aspiration breast			
subjects affected / exposed	3 / 1449 (0.21%)	3 / 1489 (0.20%)	
occurrences (all)	3	3	
Biopsy breast			
subjects affected / exposed	8 / 1449 (0.55%)	12 / 1489 (0.81%)	
occurrences (all)	8	12	
Biopsy breast normal			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Biopsy cervix			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
Biopsy endometrium			
subjects affected / exposed	2 / 1449 (0.14%)	7 / 1489 (0.47%)	
occurrences (all)	2	7	
Biopsy endometrium normal			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Biopsy testes normal			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Biopsy uterus			
subjects affected / exposed	0 / 1449 (0.00%)	3 / 1489 (0.20%)	
occurrences (all)	0	3	
Biopsy vagina			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Hysteroscopy			
subjects affected / exposed	4 / 1449 (0.28%)	16 / 1489 (1.07%)	
occurrences (all)	4	16	
Mammogram			
subjects affected / exposed	3 / 1449 (0.21%)	3 / 1489 (0.20%)	
occurrences (all)	3	3	
Mammogram abnormal			

subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Mammogram normal			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences (all)	0	2	
Smear cervix			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Smear cervix abnormal			
subjects affected / exposed	1 / 1449 (0.07%)	6 / 1489 (0.40%)	
occurrences (all)	1	6	
Ultrasound breast			
subjects affected / exposed	2 / 1449 (0.14%)	10 / 1489 (0.67%)	
occurrences (all)	2	10	
Ultrasound pelvis			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Ultrasound scan vagina			
subjects affected / exposed	0 / 1449 (0.00%)	4 / 1489 (0.27%)	
occurrences (all)	0	4	
Ultrasound uterus			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences (all)	0	2	
Chest X-ray			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
Computerised tomogram thorax			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Laryngoscopy			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Sclerotherapy			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Serum ferritin increased			

subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	9 / 1449 (0.62%)	10 / 1489 (0.67%)	
occurrences (all)	9	10	
Bone fragmentation			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Bursa injury			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Cartilage injury			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
Cervical vertebral fracture			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Clavicle fracture			
subjects affected / exposed	0 / 1449 (0.00%)	4 / 1489 (0.27%)	
occurrences (all)	0	4	
Facial bones fracture			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Femoral neck fracture			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences (all)	2	0	
Femur fracture			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences (all)	2	0	
Fibula fracture			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Foot fracture			

subjects affected / exposed	14 / 1449 (0.97%)	17 / 1489 (1.14%)	
occurrences (all)	14	17	
Forearm fracture			
subjects affected / exposed	3 / 1449 (0.21%)	1 / 1489 (0.07%)	
occurrences (all)	3	1	
Fracture			
subjects affected / exposed	5 / 1449 (0.35%)	5 / 1489 (0.34%)	
occurrences (all)	5	5	
Fracture displacement			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Fractured coccyx			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
Fractured sacrum			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Haemarthrosis			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Hand fracture			
subjects affected / exposed	7 / 1449 (0.48%)	7 / 1489 (0.47%)	
occurrences (all)	7	7	
Hip fracture			
subjects affected / exposed	1 / 1449 (0.07%)	3 / 1489 (0.20%)	
occurrences (all)	1	3	
Humerus fracture			
subjects affected / exposed	6 / 1449 (0.41%)	1 / 1489 (0.07%)	
occurrences (all)	6	1	
Joint dislocation			
subjects affected / exposed	5 / 1449 (0.35%)	6 / 1489 (0.40%)	
occurrences (all)	5	6	
Lower limb fracture			
subjects affected / exposed	3 / 1449 (0.21%)	4 / 1489 (0.27%)	
occurrences (all)	3	4	
Meniscus injury			

subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Meniscus lesion			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Multiple fractures			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
Patella fracture			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Pelvic fracture			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Radius fracture			
subjects affected / exposed	6 / 1449 (0.41%)	2 / 1489 (0.13%)	
occurrences (all)	6	2	
Rib fracture			
subjects affected / exposed	7 / 1449 (0.48%)	6 / 1489 (0.40%)	
occurrences (all)	7	6	
Skull fracture			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Spinal fracture			
subjects affected / exposed	5 / 1449 (0.35%)	7 / 1489 (0.47%)	
occurrences (all)	5	7	
Traumatic fracture			
subjects affected / exposed	2 / 1449 (0.14%)	2 / 1489 (0.13%)	
occurrences (all)	2	2	
Ulna fracture			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences (all)	2	0	
Upper limb fracture			
subjects affected / exposed	18 / 1449 (1.24%)	7 / 1489 (0.47%)	
occurrences (all)	18	7	
Wrist fracture			

subjects affected / exposed	30 / 1449 (2.07%)	15 / 1489 (1.01%)	
occurrences (all)	30	15	
Food poisoning			
subjects affected / exposed	6 / 1449 (0.41%)	7 / 1489 (0.47%)	
occurrences (all)	6	7	
Animal bite			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Corneal abrasion			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences (all)	0	2	
Excoriation			
subjects affected / exposed	10 / 1449 (0.69%)	9 / 1489 (0.60%)	
occurrences (all)	10	9	
Fall			
subjects affected / exposed	19 / 1449 (1.31%)	16 / 1489 (1.07%)	
occurrences (all)	19	16	
Injury			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences (all)	0	2	
Ligament injury			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Ligament rupture			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Mouth injury			
subjects affected / exposed	2 / 1449 (0.14%)	2 / 1489 (0.13%)	
occurrences (all)	2	2	
Muscle rupture			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Perineal laceration			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Retinal detachment			

subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Road traffic accident			
subjects affected / exposed	3 / 1449 (0.21%)	1 / 1489 (0.07%)	
occurrences (all)	3	1	
Soft tissue injury			
subjects affected / exposed	10 / 1449 (0.69%)	13 / 1489 (0.87%)	
occurrences (all)	10	13	
Superficial injury of eye			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Tendon rupture			
subjects affected / exposed	4 / 1449 (0.28%)	1 / 1489 (0.07%)	
occurrences (all)	4	1	
Tooth injury			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
Vascular injury			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
Vena cava injury			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Vitreous detachment			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Deep vein thrombosis postoperative			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Device intolerance			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Implant tissue necrosis			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Post procedural complication			

subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Post procedural haemorrhage			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
Postoperative thrombosis			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Postoperative wound complication			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Procedural pain			
subjects affected / exposed	3 / 1449 (0.21%)	11 / 1489 (0.74%)	
occurrences (all)	3	11	
Seroma			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
Vascular graft occlusion			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Congenital, familial and genetic disorders			
Gastrointestinal angiodysplasia			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Heart disease congenital			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Cataract congenital			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Haemangioma of retina			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Osteoporosis			

subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Congenital cystic kidney disease			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences (all)	2	0	
Basal cell naevus syndrome			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Keratosis follicular			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	5 / 1449 (0.35%)	7 / 1489 (0.47%)	
occurrences (all)	5	7	
Atrial fibrillation			
subjects affected / exposed	5 / 1449 (0.35%)	7 / 1489 (0.47%)	
occurrences (all)	5	7	
Atrial flutter			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Atrial tachycardia			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Bradyarrhythmia			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Tachycardia			
subjects affected / exposed	9 / 1449 (0.62%)	9 / 1489 (0.60%)	
occurrences (all)	9	9	
Cardiac discomfort			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Cardiac disorder			
subjects affected / exposed	2 / 1449 (0.14%)	1 / 1489 (0.07%)	
occurrences (all)	2	1	

Cardiovascular disorder			
subjects affected / exposed	2 / 1449 (0.14%)	1 / 1489 (0.07%)	
occurrences (all)	2	1	
Dizziness			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Dyspnoea			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences (all)	0	2	
Palpitations			
subjects affected / exposed	19 / 1449 (1.31%)	18 / 1489 (1.21%)	
occurrences (all)	19	18	
Aortic valve incompetence			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Aortic valve stenosis			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Mitral valve incompetence			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Mitral valve prolapse			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Angina pectoris			
subjects affected / exposed	6 / 1449 (0.41%)	0 / 1489 (0.00%)	
occurrences (all)	6	0	
Angina unstable			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences (all)	2	0	
Chest pain			
subjects affected / exposed	14 / 1449 (0.97%)	15 / 1489 (1.01%)	
occurrences (all)	14	15	
Coronary artery disease			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	

Coronary artery stenosis			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Myocardial infarction			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Myocardial ischaemia			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
Endocarditis			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Cardiac failure			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Cardiac failure chronic			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Left ventricular failure			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Cardiomegaly			
subjects affected / exposed	2 / 1449 (0.14%)	6 / 1489 (0.40%)	
occurrences (all)	2	6	
Cardiomyopathy			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences (all)	2	0	
Ventricular dysfunction			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Dressler's syndrome			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Pericardial effusion			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	

Nervous system disorders			
Carotid artery stenosis			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Cerebral vasoconstriction			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Cerebrovascular accident			
subjects affected / exposed	2 / 1449 (0.14%)	1 / 1489 (0.07%)	
occurrences (all)	2	1	
Haemorrhagic stroke			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Ischaemic stroke			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences (all)	0	2	
Temporal arteritis			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences (all)	0	2	
Transient ischaemic attack			
subjects affected / exposed	3 / 1449 (0.21%)	1 / 1489 (0.07%)	
occurrences (all)	3	1	
Anosmia			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences (all)	2	0	
Cranial nerve paralysis			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Facial palsy			
subjects affected / exposed	1 / 1449 (0.07%)	3 / 1489 (0.20%)	
occurrences (all)	1	3	
Facial spasm			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Neuritis cranial			

subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Optic neuritis			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
VIth nerve paralysis			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Multiple sclerosis			
subjects affected / exposed	1 / 1449 (0.07%)	4 / 1489 (0.27%)	
occurrences (all)	1	4	
Headache			
subjects affected / exposed	82 / 1449 (5.66%)	61 / 1489 (4.10%)	
occurrences (all)	82	61	
Migraine			
subjects affected / exposed	10 / 1449 (0.69%)	10 / 1489 (0.67%)	
occurrences (all)	10	10	
Migraine with aura			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Tension headache			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Amnesia			
subjects affected / exposed	27 / 1449 (1.86%)	28 / 1489 (1.88%)	
occurrences (all)	27	28	
Cognitive disorder			
subjects affected / exposed	3 / 1449 (0.21%)	0 / 1489 (0.00%)	
occurrences (all)	3	0	
Dementia Alzheimer's type			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Dementia of the Alzheimer's type, with depressed mood			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	

Disturbance in attention			
subjects affected / exposed	2 / 1449 (0.14%)	4 / 1489 (0.27%)	
occurrences (all)	2	4	
Memory impairment			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
Essential tremor			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Parkinsonism			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Parkinson's disease			
subjects affected / exposed	2 / 1449 (0.14%)	1 / 1489 (0.07%)	
occurrences (all)	2	1	
Spastic paralysis			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Torticollis			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Tremor			
subjects affected / exposed	2 / 1449 (0.14%)	10 / 1489 (0.67%)	
occurrences (all)	2	10	
Ageusia			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Analgesia			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Aphonia			
subjects affected / exposed	2 / 1449 (0.14%)	6 / 1489 (0.40%)	
occurrences (all)	2	6	
Balance disorder			
subjects affected / exposed	35 / 1449 (2.42%)	35 / 1489 (2.35%)	
occurrences (all)	35	35	

Confusional state			
subjects affected / exposed	4 / 1449 (0.28%)	2 / 1489 (0.13%)	
occurrences (all)	4	2	
Coordination abnormal			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Dizziness			
subjects affected / exposed	7 / 1449 (0.48%)	8 / 1489 (0.54%)	
occurrences (all)	7	8	
Dizziness postural			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Dysaesthesia			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Dysgeusia			
subjects affected / exposed	11 / 1449 (0.76%)	3 / 1489 (0.20%)	
occurrences (all)	11	3	
Hypoaesthesia			
subjects affected / exposed	10 / 1449 (0.69%)	10 / 1489 (0.67%)	
occurrences (all)	10	10	
Lethargy			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Loss of consciousness			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Neuralgia			
subjects affected / exposed	5 / 1449 (0.35%)	4 / 1489 (0.27%)	
occurrences (all)	5	4	
Neurological symptom			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Paraesthesia			
subjects affected / exposed	43 / 1449 (2.97%)	23 / 1489 (1.54%)	
occurrences (all)	43	23	

Presyncope			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
Restless legs syndrome			
subjects affected / exposed	2 / 1449 (0.14%)	3 / 1489 (0.20%)	
occurrences (all)	2	3	
Sensory disturbance			
subjects affected / exposed	8 / 1449 (0.55%)	1 / 1489 (0.07%)	
occurrences (all)	8	1	
Somnolence			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Syncope			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Vertigo			
subjects affected / exposed	15 / 1449 (1.04%)	17 / 1489 (1.14%)	
occurrences (all)	15	17	
Muscle rigidity			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Carpal tunnel syndrome			
subjects affected / exposed	35 / 1449 (2.42%)	13 / 1489 (0.87%)	
occurrences (all)	35	13	
Guillain-Barre syndrome			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Nerve compression			
subjects affected / exposed	4 / 1449 (0.28%)	2 / 1489 (0.13%)	
occurrences (all)	4	2	
Neuropathy peripheral			
subjects affected / exposed	17 / 1449 (1.17%)	14 / 1489 (0.94%)	
occurrences (all)	17	14	
Convulsion			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	

Epilepsy			
subjects affected / exposed	3 / 1449 (0.21%)	0 / 1489 (0.00%)	
occurrences (all)	3	0	
Insomnia			
subjects affected / exposed	3 / 1449 (0.21%)	0 / 1489 (0.00%)	
occurrences (all)	3	0	
Narcolepsy			
subjects affected / exposed	0 / 1449 (0.00%)	3 / 1489 (0.20%)	
occurrences (all)	0	3	
Radiculopathy			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Sciatica			
subjects affected / exposed	10 / 1449 (0.69%)	11 / 1489 (0.74%)	
occurrences (all)	10	11	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 1449 (0.21%)	3 / 1489 (0.20%)	
occurrences (all)	3	3	
Anaemia macrocytic			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Iron deficiency anaemia			
subjects affected / exposed	1 / 1449 (0.07%)	2 / 1489 (0.13%)	
occurrences (all)	1	2	
Coagulopathy			
subjects affected / exposed	1 / 1449 (0.07%)	2 / 1489 (0.13%)	
occurrences (all)	1	2	
Increased tendency to bruise			
subjects affected / exposed	0 / 1449 (0.00%)	4 / 1489 (0.27%)	
occurrences (all)	0	4	
Blood disorder			
subjects affected / exposed	3 / 1449 (0.21%)	2 / 1489 (0.13%)	
occurrences (all)	3	2	
Haemolytic anaemia			

subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Chronic lymphocytic leukaemia			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Non-Hodgkin's lymphoma			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Gammopathy			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences (all)	2	0	
Multiple myeloma			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Thrombocytopenia			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences (all)	0	2	
Lymphadenopathy			
subjects affected / exposed	1 / 1449 (0.07%)	2 / 1489 (0.13%)	
occurrences (all)	1	2	
Lymphoedema			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Leukocytosis			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Leukopenia			
subjects affected / exposed	4 / 1449 (0.28%)	4 / 1489 (0.27%)	
occurrences (all)	4	4	
Neutropenia			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Ear and labyrinth disorders			
Cholesteatoma			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	

Ear pain			
subjects affected / exposed	2 / 1449 (0.14%)	3 / 1489 (0.20%)	
occurrences (all)	2	3	
Deafness			
subjects affected / exposed	6 / 1449 (0.41%)	5 / 1489 (0.34%)	
occurrences (all)	6	5	
Hearing impaired			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Meniere's disease			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Tinnitus			
subjects affected / exposed	7 / 1449 (0.48%)	4 / 1489 (0.27%)	
occurrences (all)	7	4	
Vertigo			
subjects affected / exposed	3 / 1449 (0.21%)	1 / 1489 (0.07%)	
occurrences (all)	3	1	
Mastoid disorder			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Mastoiditis			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Middle ear adhesions			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Tympanic membrane perforation			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
Eye disorders			
Cataract			
subjects affected / exposed	77 / 1449 (5.31%)	64 / 1489 (4.30%)	
occurrences (all)	77	64	
Cataract congenital			

subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Cataract diabetic			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Cataract nuclear			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Entropion			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Corneal disorder			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Dry eye			
subjects affected / exposed	35 / 1449 (2.42%)	49 / 1489 (3.29%)	
occurrences (all)	35	49	
Eye disorder			
subjects affected / exposed	38 / 1449 (2.62%)	35 / 1489 (2.35%)	
occurrences (all)	38	35	
Eye pain			
subjects affected / exposed	8 / 1449 (0.55%)	5 / 1489 (0.34%)	
occurrences (all)	8	5	
Eyelid disorder			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Lacrimation increased			
subjects affected / exposed	12 / 1449 (0.83%)	7 / 1489 (0.47%)	
occurrences (all)	12	7	
Vitreous disorder			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Borderline glaucoma			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Glaucoma			

subjects affected / exposed	21 / 1449 (1.45%)	15 / 1489 (1.01%)	
occurrences (all)	21	15	
Ocular hypertension			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Conjunctival haemorrhage			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
Eye haemorrhage			
subjects affected / exposed	1 / 1449 (0.07%)	2 / 1489 (0.13%)	
occurrences (all)	1	2	
Blepharitis			
subjects affected / exposed	7 / 1449 (0.48%)	3 / 1489 (0.20%)	
occurrences (all)	7	3	
Conjunctivitis			
subjects affected / exposed	5 / 1449 (0.35%)	6 / 1489 (0.40%)	
occurrences (all)	5	6	
Episcleritis			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Eye irritation			
subjects affected / exposed	9 / 1449 (0.62%)	8 / 1489 (0.54%)	
occurrences (all)	9	8	
Ocular hyperaemia			
subjects affected / exposed	2 / 1449 (0.14%)	3 / 1489 (0.20%)	
occurrences (all)	2	3	
Haemangioma of retina			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Blepharospasm			
subjects affected / exposed	0 / 1449 (0.00%)	3 / 1489 (0.20%)	
occurrences (all)	0	3	
Macular degeneration			
subjects affected / exposed	8 / 1449 (0.55%)	5 / 1489 (0.34%)	
occurrences (all)	8	5	
Macular hole			

subjects affected / exposed	2 / 1449 (0.14%)	1 / 1489 (0.07%)	
occurrences (all)	2	1	
Retinal detachment			
subjects affected / exposed	4 / 1449 (0.28%)	4 / 1489 (0.27%)	
occurrences (all)	4	4	
Retinal tear			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Vitreous detachment			
subjects affected / exposed	6 / 1449 (0.41%)	4 / 1489 (0.27%)	
occurrences (all)	6	4	
Diabetic retinopathy			
subjects affected / exposed	3 / 1449 (0.21%)	0 / 1489 (0.00%)	
occurrences (all)	3	0	
Retinal artery occlusion			
subjects affected / exposed	3 / 1449 (0.21%)	0 / 1489 (0.00%)	
occurrences (all)	3	0	
Retinal vein occlusion			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
Retinal vein thrombosis			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Blindness			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Diplopia			
subjects affected / exposed	1 / 1449 (0.07%)	2 / 1489 (0.13%)	
occurrences (all)	1	2	
Myopia			
subjects affected / exposed	3 / 1449 (0.21%)	1 / 1489 (0.07%)	
occurrences (all)	3	1	
Vision blurred			
subjects affected / exposed	12 / 1449 (0.83%)	18 / 1489 (1.21%)	
occurrences (all)	12	18	
Visual acuity reduced			

subjects affected / exposed	40 / 1449 (2.76%)	42 / 1489 (2.82%)	
occurrences (all)	40	42	
Visual impairment			
subjects affected / exposed	11 / 1449 (0.76%)	14 / 1489 (0.94%)	
occurrences (all)	11	14	
Gastrointestinal disorders			
Abdominal hernia			
subjects affected / exposed	0 / 1449 (0.00%)	4 / 1489 (0.27%)	
occurrences (all)	0	4	
Femoral hernia			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Hiatus hernia			
subjects affected / exposed	6 / 1449 (0.41%)	5 / 1489 (0.34%)	
occurrences (all)	6	5	
Inguinal hernia			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Lumbar hernia			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Anal fissure			
subjects affected / exposed	2 / 1449 (0.14%)	3 / 1489 (0.20%)	
occurrences (all)	2	3	
Anal pruritus			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Anorectal disorder			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Anorectal squamous cell metaplasia			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Rectal prolapse			
subjects affected / exposed	3 / 1449 (0.21%)	1 / 1489 (0.07%)	
occurrences (all)	3	1	

Anal polyp			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Colonic polyp			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Gastric polyps			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences (all)	2	0	
Intestinal polyp			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Rectal polyp			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Gingival disorder			
subjects affected / exposed	8 / 1449 (0.55%)	5 / 1489 (0.34%)	
occurrences (all)	8	5	
Gingivitis			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Poor dental condition			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Tooth fracture			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Toothache			
subjects affected / exposed	1 / 1449 (0.07%)	2 / 1489 (0.13%)	
occurrences (all)	1	2	
Diverticulitis			
subjects affected / exposed	7 / 1449 (0.48%)	9 / 1489 (0.60%)	
occurrences (all)	7	9	
Diverticulitis intestinal haemorrhagic			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	

Diverticulum			
subjects affected / exposed	2 / 1449 (0.14%)	1 / 1489 (0.07%)	
occurrences (all)	2	1	
Barrett's oesophagus			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Food poisoning			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Gastric disorder			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Gastric mucosal hypertrophy			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal disorder			
subjects affected / exposed	4 / 1449 (0.28%)	12 / 1489 (0.81%)	
occurrences (all)	4	12	
Oesophageal disorder			
subjects affected / exposed	1 / 1449 (0.07%)	2 / 1489 (0.13%)	
occurrences (all)	1	2	
Haematemesis			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Haematochezia			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Rectal haemorrhage			
subjects affected / exposed	2 / 1449 (0.14%)	9 / 1489 (0.60%)	
occurrences (all)	2	9	
Small intestinal haemorrhage			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Colitis			
subjects affected / exposed	1 / 1449 (0.07%)	3 / 1489 (0.20%)	
occurrences (all)	1	3	

Colitis ischaemic			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
Colitis ulcerative			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Gastritis			
subjects affected / exposed	12 / 1449 (0.83%)	13 / 1489 (0.87%)	
occurrences (all)	12	13	
Gastrointestinal inflammation			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Inflammatory bowel disease			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences (all)	0	2	
Oesophagitis			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Proctocolitis			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences (all)	0	2	
Reflux oesophagitis			
subjects affected / exposed	17 / 1449 (1.17%)	18 / 1489 (1.21%)	
occurrences (all)	17	18	
Change of bowel habit			
subjects affected / exposed	5 / 1449 (0.35%)	2 / 1489 (0.13%)	
occurrences (all)	5	2	
Constipation			
subjects affected / exposed	24 / 1449 (1.66%)	42 / 1489 (2.82%)	
occurrences (all)	24	42	
Diarrhoea			
subjects affected / exposed	20 / 1449 (1.38%)	18 / 1489 (1.21%)	
occurrences (all)	20	18	
Duodenogastric reflux			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	

Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 1449 (0.07%)	2 / 1489 (0.13%)	
occurrences (all)	1	2	
Irritable bowel syndrome			
subjects affected / exposed	5 / 1449 (0.35%)	3 / 1489 (0.20%)	
occurrences (all)	5	3	
Abdominal discomfort			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Abdominal distension			
subjects affected / exposed	15 / 1449 (1.04%)	11 / 1489 (0.74%)	
occurrences (all)	15	11	
Abdominal mass			
subjects affected / exposed	1 / 1449 (0.07%)	2 / 1489 (0.13%)	
occurrences (all)	1	2	
Abdominal pain			
subjects affected / exposed	33 / 1449 (2.28%)	48 / 1489 (3.22%)	
occurrences (all)	33	48	
Dyspepsia			
subjects affected / exposed	25 / 1449 (1.73%)	24 / 1489 (1.61%)	
occurrences (all)	25	24	
Dysphagia			
subjects affected / exposed	3 / 1449 (0.21%)	1 / 1489 (0.07%)	
occurrences (all)	3	1	
Epigastric discomfort			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Flatulence			
subjects affected / exposed	9 / 1449 (0.62%)	10 / 1489 (0.67%)	
occurrences (all)	9	10	
Gastrointestinal pain			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Nausea			
subjects affected / exposed	57 / 1449 (3.93%)	51 / 1489 (3.43%)	
occurrences (all)	57	51	

Pelvic pain			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Vomiting			
subjects affected / exposed	9 / 1449 (0.62%)	7 / 1489 (0.47%)	
occurrences (all)	9	7	
Gallstone ileus			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Intestinal obstruction			
subjects affected / exposed	2 / 1449 (0.14%)	1 / 1489 (0.07%)	
occurrences (all)	2	1	
Gastric ulcer			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Large intestine perforation			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Haemorrhoids			
subjects affected / exposed	6 / 1449 (0.41%)	7 / 1489 (0.47%)	
occurrences (all)	6	7	
Coeliac disease			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences (all)	2	0	
Anal cancer			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Rectal cancer			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Mouth ulceration			
subjects affected / exposed	3 / 1449 (0.21%)	7 / 1489 (0.47%)	
occurrences (all)	3	7	
Oral pain			
subjects affected / exposed	2 / 1449 (0.14%)	1 / 1489 (0.07%)	
occurrences (all)	2	1	

Stomatitis			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences (all)	2	0	
Abdominal adhesions			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Dry mouth			
subjects affected / exposed	25 / 1449 (1.73%)	16 / 1489 (1.07%)	
occurrences (all)	25	16	
Dry throat			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Lip dry			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Salivary gland cyst			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Salivary gland disorder			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Ageusia			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Glossitis			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences (all)	0	2	
Tongue disorder			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 1449 (0.00%)	4 / 1489 (0.27%)	
occurrences (all)	0	4	
Actinic keratosis			

subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
Alopecia			
subjects affected / exposed	80 / 1449 (5.52%)	93 / 1489 (6.25%)	
occurrences (all)	80	93	
Alopecia areata			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Basal cell carcinoma			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences (all)	0	2	
Basal cell naevus syndrome			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Blister			
subjects affected / exposed	2 / 1449 (0.14%)	2 / 1489 (0.13%)	
occurrences (all)	2	2	
Bowen's disease			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Cellulitis			
subjects affected / exposed	2 / 1449 (0.14%)	4 / 1489 (0.27%)	
occurrences (all)	2	4	
Dermal cyst			
subjects affected / exposed	6 / 1449 (0.41%)	5 / 1489 (0.34%)	
occurrences (all)	6	5	
Dermatomyositis			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Dry skin			
subjects affected / exposed	27 / 1449 (1.86%)	28 / 1489 (1.88%)	
occurrences (all)	27	28	
Eczema			
subjects affected / exposed	6 / 1449 (0.41%)	18 / 1489 (1.21%)	
occurrences (all)	6	18	
Erythema			

subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Erythema multiforme			
subjects affected / exposed	5 / 1449 (0.35%)	3 / 1489 (0.20%)	
occurrences (all)	5	3	
Erythema nodosum			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Hair colour changes			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Hair disorder			
subjects affected / exposed	5 / 1449 (0.35%)	11 / 1489 (0.74%)	
occurrences (all)	5	11	
Hirsutism			
subjects affected / exposed	6 / 1449 (0.41%)	12 / 1489 (0.81%)	
occurrences (all)	6	12	
Hyperhidrosis			
subjects affected / exposed	25 / 1449 (1.73%)	18 / 1489 (1.21%)	
occurrences (all)	25	18	
Lichen planus			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Lichen sclerosus			
subjects affected / exposed	1 / 1449 (0.07%)	3 / 1489 (0.20%)	
occurrences (all)	1	3	
Morphoea			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Nail disorder			
subjects affected / exposed	6 / 1449 (0.41%)	13 / 1489 (0.87%)	
occurrences (all)	6	13	
Night sweats			
subjects affected / exposed	310 / 1449 (21.39%)	341 / 1489 (22.90%)	
occurrences (all)	310	341	

Onychoclasis			
subjects affected / exposed	6 / 1449 (0.41%)	16 / 1489 (1.07%)	
occurrences (all)	6	16	
Periorbital oedema			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences (all)	2	0	
Photosensitivity reaction			
subjects affected / exposed	2 / 1449 (0.14%)	2 / 1489 (0.13%)	
occurrences (all)	2	2	
Pigmentation disorder			
subjects affected / exposed	2 / 1449 (0.14%)	3 / 1489 (0.20%)	
occurrences (all)	2	3	
Pruritus			
subjects affected / exposed	22 / 1449 (1.52%)	38 / 1489 (2.55%)	
occurrences (all)	22	38	
Pruritus generalised			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Psoriasis			
subjects affected / exposed	6 / 1449 (0.41%)	3 / 1489 (0.20%)	
occurrences (all)	6	3	
Rash			
subjects affected / exposed	26 / 1449 (1.79%)	37 / 1489 (2.48%)	
occurrences (all)	26	37	
Rash erythematous			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Rash pruritic			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Rash scarlatiniform			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Rosacea			
subjects affected / exposed	1 / 1449 (0.07%)	6 / 1489 (0.40%)	
occurrences (all)	1	6	

Scar			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Scar pain			
subjects affected / exposed	1 / 1449 (0.07%)	4 / 1489 (0.27%)	
occurrences (all)	1	4	
Skin atrophy			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Skin cancer			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Skin disorder			
subjects affected / exposed	12 / 1449 (0.83%)	12 / 1489 (0.81%)	
occurrences (all)	12	12	
Skin lesion			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Skin mass			
subjects affected / exposed	3 / 1449 (0.21%)	2 / 1489 (0.13%)	
occurrences (all)	3	2	
Skin swelling			
subjects affected / exposed	2 / 1449 (0.14%)	6 / 1489 (0.40%)	
occurrences (all)	2	6	
Skin ulcer			
subjects affected / exposed	3 / 1449 (0.21%)	1 / 1489 (0.07%)	
occurrences (all)	3	1	
Skin warm			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Superficial spreading melanoma stage unspecified			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Swelling face			

subjects affected / exposed	1 / 1449 (0.07%)	2 / 1489 (0.13%)	
occurrences (all)	1	2	
Telangiectasia			
subjects affected / exposed	0 / 1449 (0.00%)	3 / 1489 (0.20%)	
occurrences (all)	0	3	
Urticaria			
subjects affected / exposed	6 / 1449 (0.41%)	11 / 1489 (0.74%)	
occurrences (all)	6	11	
Varicella			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Vitiligo			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences (all)	2	0	
Renal and urinary disorders			
Bladder disorder			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Bladder prolapse			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Calculus bladder			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences (all)	0	2	
Chromaturia			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Cystitis			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
Dysuria			
subjects affected / exposed	2 / 1449 (0.14%)	6 / 1489 (0.40%)	
occurrences (all)	2	6	
Haematuria			
subjects affected / exposed	2 / 1449 (0.14%)	1 / 1489 (0.07%)	
occurrences (all)	2	1	

Haemorrhage urinary tract			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Micturition disorder			
subjects affected / exposed	7 / 1449 (0.48%)	16 / 1489 (1.07%)	
occurrences (all)	7	16	
Micturition urgency			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences (all)	2	0	
Nephrolithiasis			
subjects affected / exposed	3 / 1449 (0.21%)	0 / 1489 (0.00%)	
occurrences (all)	3	0	
Nocturia			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
Pollakiuria			
subjects affected / exposed	6 / 1449 (0.41%)	10 / 1489 (0.67%)	
occurrences (all)	6	10	
Polyuria			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Renal colic			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences (all)	0	2	
Renal cyst			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Renal disorder			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Renal failure chronic			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Renal tubular acidosis			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	

Stress urinary incontinence			
subjects affected / exposed	1 / 1449 (0.07%)	3 / 1489 (0.20%)	
occurrences (all)	1	3	
Urethral stenosis			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
Urinary incontinence			
subjects affected / exposed	6 / 1449 (0.41%)	15 / 1489 (1.01%)	
occurrences (all)	6	15	
Urinary tract infection			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Endocrine disorders			
Adrenal adenoma			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Adrenal carcinoma			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Adrenal disorder			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Adrenal mass			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Diabetes mellitus			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences (all)	2	0	
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 1449 (0.00%)	4 / 1489 (0.27%)	
occurrences (all)	0	4	
Hypoparathyroidism			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Parathyroid disorder			

subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Goitre			
subjects affected / exposed	6 / 1449 (0.41%)	5 / 1489 (0.34%)	
occurrences (all)	6	5	
Hyperthyroidism			
subjects affected / exposed	3 / 1449 (0.21%)	0 / 1489 (0.00%)	
occurrences (all)	3	0	
Hypothyroidism			
subjects affected / exposed	12 / 1449 (0.83%)	16 / 1489 (1.07%)	
occurrences (all)	12	16	
Thyroid cyst			
subjects affected / exposed	2 / 1449 (0.14%)	2 / 1489 (0.13%)	
occurrences (all)	2	2	
Thyroid disorder			
subjects affected / exposed	2 / 1449 (0.14%)	2 / 1489 (0.13%)	
occurrences (all)	2	2	
Musculoskeletal and connective tissue disorders			
Bone erosion			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Exostosis			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
Jaw disorder			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Osteitis deformans			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences (all)	0	2	
Osteonecrosis			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Osteopenia			

subjects affected / exposed	11 / 1449 (0.76%)	4 / 1489 (0.27%)	
occurrences (all)	11	4	
Osteoporosis			
subjects affected / exposed	106 / 1449 (7.32%)	71 / 1489 (4.77%)	
occurrences (all)	106	71	
Osteoporosis postmenopausal			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Pain in jaw			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Spinal disorder			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
CREST syndrome			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Morphoea			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Polymyalgia rheumatica			
subjects affected / exposed	5 / 1449 (0.35%)	2 / 1489 (0.13%)	
occurrences (all)	5	2	
Scleroderma			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Sjogren's syndrome			
subjects affected / exposed	2 / 1449 (0.14%)	1 / 1489 (0.07%)	
occurrences (all)	2	1	
Ankle fracture			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences (all)	0	2	
Clavicle fracture			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences (all)	0	2	
Fibula fracture			

subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Foot fracture			
subjects affected / exposed	2 / 1449 (0.14%)	2 / 1489 (0.13%)	
occurrences (all)	2	2	
Forearm fracture			
subjects affected / exposed	3 / 1449 (0.21%)	0 / 1489 (0.00%)	
occurrences (all)	3	0	
Fractured coccyx			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Hand fracture			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences (all)	0	2	
Hip fracture			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Humerus fracture			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Lower limb fracture			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
Osteoporotic fracture			
subjects affected / exposed	3 / 1449 (0.21%)	1 / 1489 (0.07%)	
occurrences (all)	3	1	
Pathological fracture			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
Radius fracture			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Rib fracture			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Spinal fracture			

subjects affected / exposed	2 / 1449 (0.14%)	2 / 1489 (0.13%)	
occurrences (all)	2	2	
Thoracic vertebral fracture			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Upper limb fracture			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences (all)	2	0	
Wrist fracture			
subjects affected / exposed	3 / 1449 (0.21%)	1 / 1489 (0.07%)	
occurrences (all)	3	1	
Ankylosing spondylitis			
subjects affected / exposed	2 / 1449 (0.14%)	2 / 1489 (0.13%)	
occurrences (all)	2	2	
Arthralgia			
subjects affected / exposed	842 / 1449 (58.11%)	748 / 1489 (50.24%)	
occurrences (all)	842	748	
Arthritis			
subjects affected / exposed	52 / 1449 (3.59%)	50 / 1489 (3.36%)	
occurrences (all)	52	50	
Arthritis bacterial			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
Arthritis infective			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Arthritis reactive			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Arthropathy			
subjects affected / exposed	11 / 1449 (0.76%)	9 / 1489 (0.60%)	
occurrences (all)	11	9	
Floating patella			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	

Haemarthrosis			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Joint dislocation			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Joint effusion			
subjects affected / exposed	2 / 1449 (0.14%)	1 / 1489 (0.07%)	
occurrences (all)	2	1	
Joint stiffness			
subjects affected / exposed	74 / 1449 (5.11%)	37 / 1489 (2.48%)	
occurrences (all)	74	37	
Joint swelling			
subjects affected / exposed	18 / 1449 (1.24%)	17 / 1489 (1.14%)	
occurrences (all)	18	17	
Neuropathic arthropathy			
subjects affected / exposed	3 / 1449 (0.21%)	0 / 1489 (0.00%)	
occurrences (all)	3	0	
Osteoarthritis			
subjects affected / exposed	67 / 1449 (4.62%)	53 / 1489 (3.56%)	
occurrences (all)	67	53	
Palindromic rheumatism			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Periarthritis			
subjects affected / exposed	9 / 1449 (0.62%)	4 / 1489 (0.27%)	
occurrences (all)	9	4	
Rheumatoid arthritis			
subjects affected / exposed	15 / 1449 (1.04%)	12 / 1489 (0.81%)	
occurrences (all)	15	12	
Rotator cuff syndrome			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Senile ankylosing vertebral hyperostosis			

subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Spinal osteoarthritis			
subjects affected / exposed	4 / 1449 (0.28%)	6 / 1489 (0.40%)	
occurrences (all)	4	6	
Spondylitis			
subjects affected / exposed	2 / 1449 (0.14%)	3 / 1489 (0.20%)	
occurrences (all)	2	3	
Temporomandibular joint syndrome			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Fibromyalgia			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Muscle atrophy			
subjects affected / exposed	2 / 1449 (0.14%)	1 / 1489 (0.07%)	
occurrences (all)	2	1	
Muscle spasms			
subjects affected / exposed	26 / 1449 (1.79%)	108 / 1489 (7.25%)	
occurrences (all)	26	108	
Myalgia			
subjects affected / exposed	124 / 1449 (8.56%)	106 / 1489 (7.12%)	
occurrences (all)	124	106	
Periodic limb movement disorder			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Torticollis			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
Trismus			
subjects affected / exposed	3 / 1449 (0.21%)	1 / 1489 (0.07%)	
occurrences (all)	3	1	
Cervical spinal stenosis			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Foot deformity			

subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
Intervertebral disc compression			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Intervertebral disc disorder			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Intervertebral disc protrusion			
subjects affected / exposed	6 / 1449 (0.41%)	7 / 1489 (0.47%)	
occurrences (all)	6	7	
Lumbar spine flattening			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Sciatica			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Scoliosis			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Axillary mass			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Back disorder			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
Back pain			
subjects affected / exposed	82 / 1449 (5.66%)	101 / 1489 (6.78%)	
occurrences (all)	82	101	
Dupuytren's contracture			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences (all)	2	0	
Limb discomfort			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences (all)	0	2	
Musculoskeletal chest pain			

subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Musculoskeletal pain			
subjects affected / exposed	100 / 1449 (6.90%)	95 / 1489 (6.38%)	
occurrences (all)	100	95	
Musculoskeletal stiffness			
subjects affected / exposed	19 / 1449 (1.31%)	18 / 1489 (1.21%)	
occurrences (all)	19	18	
Neck mass			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Neck pain			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences (all)	0	2	
Pain in extremity			
subjects affected / exposed	101 / 1449 (6.97%)	80 / 1489 (5.37%)	
occurrences (all)	101	80	
Plantar fasciitis			
subjects affected / exposed	4 / 1449 (0.28%)	5 / 1489 (0.34%)	
occurrences (all)	4	5	
Bunion			
subjects affected / exposed	1 / 1449 (0.07%)	3 / 1489 (0.20%)	
occurrences (all)	1	3	
Bursitis			
subjects affected / exposed	2 / 1449 (0.14%)	11 / 1489 (0.74%)	
occurrences (all)	2	11	
Synovial cyst			
subjects affected / exposed	1 / 1449 (0.07%)	2 / 1489 (0.13%)	
occurrences (all)	1	2	
Cartilage injury			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Costochondritis			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Tendonitis			

subjects affected / exposed	18 / 1449 (1.24%)	8 / 1489 (0.54%)	
occurrences (all)	18	8	
Tenosynovitis			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Trigger finger			
subjects affected / exposed	10 / 1449 (0.69%)	4 / 1489 (0.27%)	
occurrences (all)	10	4	
Breast cancer			
subjects affected / exposed	3 / 1449 (0.21%)	6 / 1489 (0.40%)	
occurrences (all)	3	6	
Infections and infestations			
Subacute sclerosing panencephalitis			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Bacterial infection			
subjects affected / exposed	5 / 1449 (0.35%)	2 / 1489 (0.13%)	
occurrences (all)	5	2	
Breast cellulitis			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Cellulitis			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences (all)	0	2	
Folliculitis			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Helicobacter gastritis			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Helicobacter infection			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences (all)	2	0	
Lyme disease			
subjects affected / exposed	0 / 1449 (0.00%)	3 / 1489 (0.20%)	
occurrences (all)	0	3	

Staphylococcal infection			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Fungal infection			
subjects affected / exposed	3 / 1449 (0.21%)	3 / 1489 (0.20%)	
occurrences (all)	3	3	
Oral candidiasis			
subjects affected / exposed	0 / 1449 (0.00%)	3 / 1489 (0.20%)	
occurrences (all)	0	3	
Pneumonia cryptococcal			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Vulvovaginal candidiasis			
subjects affected / exposed	9 / 1449 (0.62%)	42 / 1489 (2.82%)	
occurrences (all)	9	42	
Acute sinusitis			
subjects affected / exposed	1 / 1449 (0.07%)	3 / 1489 (0.20%)	
occurrences (all)	1	3	
Arthritis infective			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
Breast abscess			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Bronchiectasis			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences (all)	0	2	
Chronic sinusitis			
subjects affected / exposed	3 / 1449 (0.21%)	3 / 1489 (0.20%)	
occurrences (all)	3	3	
Cystitis			
subjects affected / exposed	14 / 1449 (0.97%)	14 / 1489 (0.94%)	
occurrences (all)	14	14	
Diverticulitis			
subjects affected / exposed	4 / 1449 (0.28%)	5 / 1489 (0.34%)	
occurrences (all)	4	5	

Eye infection			
subjects affected / exposed	1 / 1449 (0.07%)	2 / 1489 (0.13%)	
occurrences (all)	1	2	
Furuncle			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Gastroenteritis			
subjects affected / exposed	1 / 1449 (0.07%)	2 / 1489 (0.13%)	
occurrences (all)	1	2	
Hordeolum			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Incision site infection			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Labyrinthitis			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Liver abscess			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Localised infection			
subjects affected / exposed	1 / 1449 (0.07%)	2 / 1489 (0.13%)	
occurrences (all)	1	2	
Lower respiratory tract infection			
subjects affected / exposed	5 / 1449 (0.35%)	14 / 1489 (0.94%)	
occurrences (all)	5	14	
Lung infection			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Mastitis			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences (all)	2	0	
Otitis externa			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	

Otitis media			
subjects affected / exposed	4 / 1449 (0.28%)	4 / 1489 (0.27%)	
occurrences (all)	4	4	
Paronychia			
subjects affected / exposed	0 / 1449 (0.00%)	3 / 1489 (0.20%)	
occurrences (all)	0	3	
Pharyngitis			
subjects affected / exposed	2 / 1449 (0.14%)	7 / 1489 (0.47%)	
occurrences (all)	2	7	
Pneumonia			
subjects affected / exposed	5 / 1449 (0.35%)	0 / 1489 (0.00%)	
occurrences (all)	5	0	
Post procedural infection			
subjects affected / exposed	3 / 1449 (0.21%)	3 / 1489 (0.20%)	
occurrences (all)	3	3	
Respiratory tract infection			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
Rhinitis			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences (all)	2	0	
Sepsis			
subjects affected / exposed	1 / 1449 (0.07%)	2 / 1489 (0.13%)	
occurrences (all)	1	2	
Sialoadenitis			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences (all)	0	2	
Sinusitis			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences (all)	2	0	
Skin infection			
subjects affected / exposed	1 / 1449 (0.07%)	4 / 1489 (0.27%)	
occurrences (all)	1	4	
Tonsillitis			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	

Tooth abscess			
subjects affected / exposed	5 / 1449 (0.35%)	7 / 1489 (0.47%)	
occurrences (all)	5	7	
Upper respiratory tract infection			
subjects affected / exposed	6 / 1449 (0.41%)	5 / 1489 (0.34%)	
occurrences (all)	6	5	
Urinary tract infection			
subjects affected / exposed	23 / 1449 (1.59%)	32 / 1489 (2.15%)	
occurrences (all)	23	32	
Wound infection			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
Mycobacterial infection			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Tuberculosis			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Toxoplasmosis			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Hepatitis viral			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Herpes simplex			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Herpes zoster			
subjects affected / exposed	11 / 1449 (0.76%)	13 / 1489 (0.87%)	
occurrences (all)	11	13	
Influenza			
subjects affected / exposed	2 / 1449 (0.14%)	14 / 1489 (0.94%)	
occurrences (all)	2	14	
Post viral fatigue syndrome			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences (all)	0	2	

Vestibular neuronitis			
subjects affected / exposed	1 / 1449 (0.07%)	2 / 1489 (0.13%)	
occurrences (all)	1	2	
Viral infection			
subjects affected / exposed	7 / 1449 (0.48%)	8 / 1489 (0.54%)	
occurrences (all)	7	8	
Metabolism and nutrition disorders			
Renal tubular acidosis			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Decreased appetite			
subjects affected / exposed	10 / 1449 (0.69%)	6 / 1489 (0.40%)	
occurrences (all)	10	6	
Increased appetite			
subjects affected / exposed	2 / 1449 (0.14%)	0 / 1489 (0.00%)	
occurrences (all)	2	0	
Weight fluctuation			
subjects affected / exposed	6 / 1449 (0.41%)	2 / 1489 (0.13%)	
occurrences (all)	6	2	
Bone metabolism disorder			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Osteopenia			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Osteoporosis			
subjects affected / exposed	4 / 1449 (0.28%)	2 / 1489 (0.13%)	
occurrences (all)	4	2	
Diabetic foot			
subjects affected / exposed	1 / 1449 (0.07%)	1 / 1489 (0.07%)	
occurrences (all)	1	1	
Fluid retention			
subjects affected / exposed	3 / 1449 (0.21%)	5 / 1489 (0.34%)	
occurrences (all)	3	5	
Hyperkalaemia			

subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Hypokalaemia			
subjects affected / exposed	2 / 1449 (0.14%)	1 / 1489 (0.07%)	
occurrences (all)	2	1	
Hyponatraemia			
subjects affected / exposed	3 / 1449 (0.21%)	0 / 1489 (0.00%)	
occurrences (all)	3	0	
Diabetes mellitus			
subjects affected / exposed	21 / 1449 (1.45%)	13 / 1489 (0.87%)	
occurrences (all)	21	13	
Diabetes mellitus inadequate control			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Hypoglycaemia			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Type 1 diabetes mellitus			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences (all)	0	2	
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 1449 (0.00%)	4 / 1489 (0.27%)	
occurrences (all)	0	4	
Haemochromatosis			
subjects affected / exposed	0 / 1449 (0.00%)	2 / 1489 (0.13%)	
occurrences (all)	0	2	
Iron deficiency anaemia			
subjects affected / exposed	2 / 1449 (0.14%)	3 / 1489 (0.20%)	
occurrences (all)	2	3	
Iron overload			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Hypercholesterolaemia			
subjects affected / exposed	47 / 1449 (3.24%)	11 / 1489 (0.74%)	
occurrences (all)	47	11	
Hyperlipidaemia			

subjects affected / exposed	3 / 1449 (0.21%)	8 / 1489 (0.54%)	
occurrences (all)	3	8	
Goitre			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Hypothyroidism			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Gout			
subjects affected / exposed	1 / 1449 (0.07%)	2 / 1489 (0.13%)	
occurrences (all)	1	2	
Folate deficiency			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Multi-vitamin deficiency			
subjects affected / exposed	1 / 1449 (0.07%)	0 / 1489 (0.00%)	
occurrences (all)	1	0	
Vitamin B12 deficiency			
subjects affected / exposed	0 / 1449 (0.00%)	1 / 1489 (0.07%)	
occurrences (all)	0	1	
Vitamin B6 deficiency			
subjects affected / exposed	1 / 1449 (0.07%)	2 / 1489 (0.13%)	
occurrences (all)	1	2	
Vitamin D deficiency			
subjects affected / exposed	1 / 1449 (0.07%)	2 / 1489 (0.13%)	
occurrences (all)	1	2	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
14 February 2005	Transfer from CTC to CTA
23 September 2005	- New steering committee members listed. - New GCP statement. - Clarification of roles of CR-UK and QM. - Addition of any previous breast cancer and history of gluten intolerance to exclusion criteria. - Clarification of acceptable management of menopausal symptoms. - Reference added to million women study. - Clarifications of lines of reporting for AEs and SAEs. - Clarification that the study nurse can consent patients in the study. - Clarification of requirements for blood samples and pathology specimens. - Development of new information flyer and poster on the DCIS arm of the trial.
29 September 2006	- Details of the new IBIS-II DCIS sites have been listed together with the names of the principal investigators. - A new joint patient information sheet (PIS) was developed for these patients who will be approached to enter the IBIS-II DCIS and/or BASO DCIS (DCIIS) trial. Each of these patients will now receive the IBIS-II DCIS PIS, the BASO DCIS PIS and the new joint IBIS-II/DCIS PIS. - Prof. Ian Weller has become chairman of the IBIS-II IDMC and Prof. Abdel Babiker has joined the IDMC.
31 January 2007	- The details of the new IBIS-II DCIS sites have been listed together with the names of the principal investigators. - The reference to 'bone pain' in section 10 of the IBIS-II DCIS PIS was clarified and changed to 'joint pain and stiffness' (I.e. Arthralgia). - The reference to CERES in section 2 was deleted. - Section 9 of IBIS-II DCIS PIS: 'What are the alternatives for diagnosis or treatment?' was reworded slightly: 'If you choose not to take part in the study, your treating clinician will advise whether you should take Tamoxifen or another appropriate treatment. Alternatively you may wish to have no additional treatment but rely on surgery and radiotherapy if recommended by your clinician.'
21 May 2007	- The details of the new IBIS-II DCIS sites have been listed together with the names of the principal investigators. - New eligibility criteria have been added to the protocol: 1) IBIS-I participants off trial therapy for at least 5 years; 2) Patients who have Paget's disease with underlying DCIS. - Carpal Tunnel Syndrome and ischaemic cardiovascular events have been added as a possible side effect of Anastrozole to the protocol and Carpal Tunnel Syndrome is now included in the PIS as a possible side effect. - Some of the members of the IDMC changed. These have been reflected in the protocol. - Notification of extension of recruitment to the end of 2010.
30 April 2008	- Creation of a questionnaire to follow up participants who are no longer on the trial. The questionnaire will only be sent out to participants who have agreed to be contacted by the IBIS-II CCO. It aims to record any medical conditions the women are experiencing and the severity of those conditions. It will also record any medication that the participants are taking.

04 August 2008	Women who have had a locally excised DCIS are only eligible if the Oestrogen Receptor and/or Progesterone Receptor (ER and/or PgR) status is known and is greater than or equal to 5% positive cells. The protocol previously stated that the ER and PgR status should be greater than 5% positive cells. Clarification of one of entry criteria. The protocol states that patients are eligible if they have had surgery to remove an ER or PgR +ve DCIS within the last six months. The protocol was previously unclear as to whether a patient was eligible for the trial six months from diagnosis or six months from surgery. Inclusion of a paragraph to say that where it is not possible for a patient to be randomized within this six month period between surgery for DCIS, due to unavailability of an appointment for baseline scans, the patient can join the trial provided that this is no longer than an additional three months. However, this must be authorised by the IBIS-II Central Coordinating Office (CCO). This has been added as we have found that many hospitals have long waiting lists for scans and the delays have had a knock-on effect in delaying randomization. Reference to the BASO DCIS II trial has been deleted as this trial is now closed. The protocol now states that two spinal x-rays in one lateral dimension are required to assess low trauma vertebral fractures. Due to a previous error the protocol had stated that only one x-ray was required. Clarified the issue of micro invasion; the protocol now states that patients with a multiple focus of micro invasion are eligible to join IBIS-II as long as each focus is less than 1mm in size. The protocol had previously stated that only a single focus of micro invasion was eligible for the trial. The protocol now states that the diagnosis of breast cancer is not an SAE as this is a study end point, included to comply with GCP. The end point of the trial has been defined as being the last participants' last visit.
13 March 2009	Changes to the age limits in the entry criteria for the DCIS trial in order to include more time to receive the test results for the trial. The age limits are currently 40-70 has been widened to +/-24 months of this range. However participants who are under 40 or over 70 can only enter on the agreement of the IBIS-II Steering Group co-chairmen. Also in order to include more time to receive the test results, an increase the time limit between scans and randomization. The entry criteria now states that: 1. If there is a delay in receiving the test results of a mammogram an extension of up to 6 months may be obtained with prior approval from one of the IBIS II Steering Group co-chairmen. 2. If there is a delay in receiving the test results of a DXA scan an extension of up to 6 months may be obtained with prior approval from one of the IBIS II Steering Group co-chairmen. 3. If there is a delay in receiving the test results of a spinal x-ray an extension of up to 12 months may be obtained with prior approval from one of the IBIS II Steering Group co-chairmen. Additional points added to the inclusion criteria: Patients who have had atypical hyperplasia or lobular carcinoma in-situ to be randomized into the DCIS trial plus 'In cases where the deep margin is less than 1mm, due to the proximity of the chest wall, the patient may be eligible if the clinicians involved in her care agree that the whole of the DCIS has been excised'. Removal of sentence from the exclusion criteria: If a participant is osteoporotic they can enter the trial as long as their T-score is more than minus four and they have no more than two low trauma vertebral fractures. In either case they must take bisphosphonate treatment and have regular DXA scans. The protocol had previously said 'The results of the scans must be provided to the trial, as for women in the IBIS-II Prevention bone sub-protocol.' Clarification to the entry criteria for the Quick score and H-score measures of ER/PR positivity.
30 June 2009	- Clarifications to the entry criteria of the DCIS protocol; osteoporotic women with T-scores greater than or equal to -4 (T-score≥ -4) are eligible for the DCIS trial. - Letter and reminder letter to accompany the IBIS-II annual questionnaire. - The IBIS-II CCO has been in contact with AstraZeneca regarding the distribution of updates of the Investigator Brochure (IB) to the IBIS-II sites. It has been agreed that instead of distributing hardcopy updates of the IB the IBIS-II team will now send electronic copies of the Summary of Product Characteristics (SmPC) instead.
10 December 2009	- New secondary labelling and distribution company

11 January 2011	- Addition of any history of lactose intolerance as an exclusion criterion. - Extension to the reporting of SAEs to cover the entire duration of the trial as requested by AZ. - Revision of the participant information sheet and consent forms specifically on frequency of mammogram and procedures for sending films, clarification that data may be obtained via NHS registries, and time to end of recruitment. - Revision of the post-treatment follow-up annual questionnaire. - Numerous non-substantial amendments to both the DCIS protocol and related study documents.
28 February 2012	- Notification to MHRA that Penn Pharmaceuticals will manufacture Tamoxifen placebo (replacing AZ)
26 June 2014	• Information on reporting of SAEs via data received from NHS registries, • Clarification of cancers that should not be reported as SAEs (but AEs), • A new common side effect which has been listed in the SmPC for Arimidex • A change of a Steering Committee member.
30 June 2017	Change in contact person for sponsor Protocol changes to reflect end of active treatment period (reduced sample size and supporting power calculation to meet primary objective, streamlined participant data collection questionnaires to focus on primary and unmet secondary objectives and simplified safety reporting procedures). Central storage of UK consent forms at trial coordinating office to support information requests for events identified by national registries (HES, ONS). Clarification of RSI control. Newsletter for IBIS-II participants with study updates. Update in trial oversight committee structures. Change in codebreak procedure to allow patient-requested codebreaks now active treatment period is complete.
05 December 2019	- Change of Trial Steering Committee members: - Closure of all UK sites - As part of a streamlining initiative started with amendment 52, to transfer follow up to NHS digital registries only - Reduced Safety reporting - Early closure of study in Italy - Clarification of consent process for collection and storage of patient identifiable information - Section added to revised protocol giving specific reference to ongoing section 251 CAG support

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

This CTIMP trial which recruited between 03 Mar 2003 and 08 Feb 2012 formally ended 6 months early on 31 May 2021 (early termination).
Primary outcome analysis took place in 2016 (see publications). Data entry closed 31st May 2021.

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/26686313