



Clinical trial results:

A Phase 2/3, Randomized, Observer-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of mRNA-1345, an mRNA Vaccine Targeting Respiratory Syncytial Virus (RSV), in Adults 60 Years of Age Summary

EudraCT number	2021-005026-20
Trial protocol	DE FI BE ES PL
Global end of trial date	28 July 2025

Results information

Result version number	v1 (current)
This version publication date	14 August 2026
First version publication date	14 August 2026

Trial information

Trial identification

Sponsor protocol code	mRNA-1345-P301
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05127434
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	ModernaTX, Inc.
Sponsor organisation address	325 Binney Street, 325 Binney Street, United States, 02142
Public contact	Moderna WeCare Team, ModernaTX, Inc., +1 866-663-3762, WeCareClinicalTrials@modernatx.com
Scientific contact	Moderna WeCare Team, ModernaTX, Inc., +1 866-663-3762, WeCareClinicalTrials@modernatx.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	28 July 2025
Is this the analysis of the primary completion data?	Yes
Primary completion date	28 July 2025
Global end of trial reached?	Yes
Global end of trial date	28 July 2025
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main purpose of Part A of this study is to evaluate the safety and tolerability of mRNA-1345 vaccine and to demonstrate the efficacy of a single dose of mRNA-1345 vaccine in the prevention of a first episode of RSV-associated lower respiratory tract disease (RSV-LRTD) as compared with placebo from 14 days postinjection through 12 months. The main purpose of Part B of this study is to evaluate the safety, tolerability and immunogenicity of a booster dose (BD) of mRNA-1345 administered 24 months after the primary dose.

Protection of trial subjects:

This study was conducted in accordance with the protocol and consensus ethical principles derived from international guidelines including the Declaration of Helsinki, Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines, applicable International Council for Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines, and other applicable laws and regulations.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	17 November 2021
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Argentina: 3589
Country: Number of subjects enrolled	Australia: 256
Country: Number of subjects enrolled	Bangladesh: 2421
Country: Number of subjects enrolled	Belgium: 413
Country: Number of subjects enrolled	Canada: 706
Country: Number of subjects enrolled	Chile: 679
Country: Number of subjects enrolled	Colombia: 2625
Country: Number of subjects enrolled	Costa Rica: 208
Country: Number of subjects enrolled	Finland: 96
Country: Number of subjects enrolled	Germany: 471
Country: Number of subjects enrolled	Japan: 822
Country: Number of subjects enrolled	Mexico: 733
Country: Number of subjects enrolled	New Zealand: 299
Country: Number of subjects enrolled	Panama: 1551
Country: Number of subjects enrolled	Poland: 346
Country: Number of subjects enrolled	Singapore: 8
Country: Number of subjects enrolled	South Africa: 982

Country: Number of subjects enrolled	Korea, Republic of: 301
Country: Number of subjects enrolled	Spain: 220
Country: Number of subjects enrolled	Taiwan: 84
Country: Number of subjects enrolled	United Kingdom: 450
Country: Number of subjects enrolled	United States: 19554
Worldwide total number of subjects	36814
EEA total number of subjects	1546

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)	12451
From 65 to 84 years	23598
85 years and over	765

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 36814 participants were randomized in Part A (18427 participants in the mRNA-1345 group and 18387 participants in the placebo group). A total of 1510 participants from Part A mRNA-1345 group were randomized into Part B substudy (1005 participants in the mRNA-1345 group and 505 in the placebo group).

Period 1

Period 1 title	Part A
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Part A: Placebo

Arm description:

Participants received a single intramuscular (IM) injection of placebo on Day 1 in Part A.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Placebo matched to mRNA-1345 was administered per schedule specified in the arm description.

Arm title	Part A: mRNA-1345
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Arm description:

Participants received a single IM injection of mRNA-1345 on Day 1 in Part A.

Arm type	Experimental
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

mRNA-1345 was administered per schedule specified in the arm description.

Number of subjects in period 1	Part A: Placebo	Part A: mRNA-1345
Started	18387	18427
Safety Set	18316	18369
Solicited Safety Set	18102	18174
Per-protocol Efficacy (PPE) Set	18120	18164
Completed	15605	15726
Not completed	2782	2701
Physician decision	98	81
Consent withdrawn by subject	922	859
Other Than Specified	530	537
Non-Compliance with Study Drug	2	1
Adverse event, non-fatal	29	20
Death	305	300
Lost to follow-up	849	871
Protocol deviation	47	32

Period 2

Period 2 title	Part B
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Part B: Placebo

Arm description:

Participants who received mRNA-1345 in Part A, received a single IM injection of booster dose (BD) of placebo on BD Day 1 in Part B.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Placebo matched to mRNA-1345 was administered per schedule specified in the arm description.

Arm title	Part B: mRNA-1345
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Arm description:

Participants who received mRNA-1345 in Part A, continued to receive a single IM injection of BD of mRNA-1345 on BD Day 1 in Part B.

Arm type	Experimental
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Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

mRNA-1345 was administered per schedule specified in the arm description.

Number of subjects in period 2^[1]	Part B: Placebo	Part B: mRNA-1345
Started	505	1005
Received Revaccination (BD) Injection	504	998
Safety Set	504	998
Solicited Safety Set	503	995
Per-protocol (PP) Set	489	956
Completed	480	954
Not completed	25	51
Consent withdrawn by subject	3	9
Other Than Specified	15	30
Death	1	-
Lost to follow-up	6	12

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: Not all participants from Part A were randomized into Part B.

Baseline characteristics

Reporting groups

Reporting group title	Part A: Placebo
Reporting group description:	
Participants received a single intramuscular (IM) injection of placebo on Day 1 in Part A.	
Reporting group title	Part A: mRNA-1345
Reporting group description:	
Participants received a single IM injection of mRNA-1345 on Day 1 in Part A.	

Reporting group values	Part A: Placebo	Part A: mRNA-1345	Total
Number of subjects	18387	18427	36814
Age Categorical			
Units: participants			

Age Continuous			
Units: years			
arithmetic mean	68.5	68.5	
standard deviation	± 6.61	± 6.59	-
Gender Categorical			
Units: participants			
Female	9057	9017	18074
Male	9330	9410	18740
Race			
Units: Subjects			
White	11290	11311	22601
Black or African American	2173	2204	4377
Asian	2138	2151	4289
American Indian or Alaska Native	896	906	1802
Native Hawaiian or Other Pacific Islander	19	28	47
Other	1013	996	2009
Multiple	752	762	1514
Unknown	20	10	30
Not Reported	86	59	145
Ethnicity			
Units: Subjects			
Hispanic or Latino	6168	6117	12285
Not Hispanic or Latino	12010	12124	24134
Unknown	22	27	49
Not Reported	187	159	346

End points

End points reporting groups

Reporting group title	Part A: Placebo
Reporting group description: Participants received a single intramuscular (IM) injection of placebo on Day 1 in Part A.	
Reporting group title	Part A: mRNA-1345
Reporting group description: Participants received a single IM injection of mRNA-1345 on Day 1 in Part A.	
Reporting group title	Part B: Placebo
Reporting group description: Participants who received mRNA-1345 in Part A, received a single IM injection of booster dose (BD) of placebo on BD Day 1 in Part B.	
Reporting group title	Part B: mRNA-1345
Reporting group description: Participants who received mRNA-1345 in Part A, continued to receive a single IM injection of BD of mRNA-1345 on BD Day 1 in Part B.	
Subject analysis set title	mRNA-1345 Primary Vaccination
Subject analysis set type	Per protocol
Subject analysis set description: Participants received a single IM injection of mRNA-1345 (primary vaccination) on Day 1 in Part A.	
Subject analysis set title	mRNA-1345 Revaccination
Subject analysis set type	Per protocol
Subject analysis set description: Participants received a single IM injection of BD (revaccination) of mRNA-1345 on BD Day 1 in Part B.	

Primary: Part A: Number of Participants with Solicited Adverse Reactions (ARs) (Solicited Local and/or Systemic ARs)

End point title	Part A: Number of Participants with Solicited Adverse Reactions (ARs) (Solicited Local and/or Systemic ARs) ^[1]
End point description: Solicited ARs were collected in an electronic diary (eDiary). Local ARs: injection site pain, erythema (redness), swelling/induration (hardness); and axillary (underarm) swelling or tenderness ipsilateral to the side of injection. Systemic ARs: fever, headache, fatigue, myalgia, arthralgia, nausea/vomiting, and chills. Note, not all solicited ARs were considered adverse events (AEs). Investigator reviewed whether the solicited AR was also to be recorded as an AE. A summary of serious AEs (SAEs) and nonserious AEs ("Other"), regardless of causality, is located in the "Reported Adverse Events" section. Part A Solicited Safety Set included all randomized participants who received the study intervention and who contributed any solicited AR data. Participants were included in the treatment group corresponding to the study vaccination that they actually received.	
End point type	Primary
End point timeframe: Up to 7 days postinjection	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The endpoint is descriptive in nature.

End point values	Part A: Placebo	Part A: mRNA-1345		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18102	18174		
Units: participants	6975	12383		

Statistical analyses

No statistical analyses for this end point

Primary: Part B: Number of Participants with Solicited Local and Systemic ARs

End point title	Part B: Number of Participants with Solicited Local and Systemic ARs ^[2]
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End point description:

Solicited ARs were recorded daily using electronic diaries (eDiaries). Local ARs: injection site pain, erythema (redness), swelling/induration (hardness); and axillary (underarm) swelling or tenderness ipsilateral to the side of injection. Systemic ARs: fever, headache, fatigue, myalgia, arthralgia, nausea/vomiting, and chills. Note, not all solicited ARs were considered adverse events (AEs). Investigator reviewed whether the solicited AR was also to be recorded as an AE. A summary of all Serious Adverse Events (SAEs) and Other Adverse Events (nonserious) regardless of causality is located in the 'Reported Adverse Events' Section. Part B Solicited Safety Set included all Part B randomized participants who received any study intervention and contributed any solicited AR data. Participants were included in the treatment group corresponding to the study vaccination that they actually received.

End point type	Primary
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End point timeframe:

Up to 7 days post-BD injection

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The endpoint is descriptive in nature.

End point values	Part B: Placebo	Part B: mRNA-1345		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	503	995		
Units: participants	194	748		

Statistical analyses

No statistical analyses for this end point

Primary: Part A: Number of Participants with Unsolicited Adverse Events (AEs)

End point title	Part A: Number of Participants with Unsolicited Adverse Events (AEs) ^[3]
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End point description:

An unsolicited AE was defined as any AE reported by the participant that was not specified as a solicited AR in the protocol. An AE was defined as any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related. A summary of all SAEs and Other Adverse Events (nonserious) regardless of causality is located in the 'Reported Adverse Events' Section. Part A Safety Set included all randomized participants who received any study intervention. Participants were included in the treatment group corresponding to the study vaccination that they actually received.

End point type	Primary
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End point timeframe:

Up to 28 days postinjection

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The endpoint is descriptive in nature.

End point values	Part A: Placebo	Part A: mRNA-1345		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18316	18369		
Units: participants	3472	3841		

Statistical analyses

No statistical analyses for this end point

Primary: Part B: Number of Participants With MAAEs, AESIs, SAEs, and AEs Leading to Study Discontinuation

End point title	Part B: Number of Participants With MAAEs, AESIs, SAEs, and AEs Leading to Study Discontinuation ^[4]
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End point description:

MAAEs were AEs that led to an unscheduled visit to a healthcare provider. AESIs were AEs (serious or nonserious) of scientific and medical concern specific to the Sponsor's product or program for which ongoing monitoring and immediate notification by the investigator to the Sponsor was required. SAEs were AEs that resulted in death, were life threatening, required inpatient hospitalization or prolongation of existing hospitalization, resulted in persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, a congenital anomaly or birth defect, or was a medically important event. A summary of all SAEs and Other Adverse Events (nonserious) regardless of causality is located in the 'Reported Adverse Events' Section. Part B Safety Set included all Part B randomized participants who received any study intervention. Participants were included in the treatment group corresponding to the study vaccination that they actually received.

End point type	Primary
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End point timeframe:

Up to BD Day 181

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The endpoint is descriptive in nature.

End point values	Part B: Placebo	Part B: mRNA-1345		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	504	998		
Units: participants				
MAAEs	131	226		
AESIs	3	2		
SAEs	26	29		
AEs Leading to Study Discontinuation	1	0		

Statistical analyses

No statistical analyses for this end point

Primary: Part B: Number of Participants with Unsolicited AEs

End point title	Part B: Number of Participants with Unsolicited AEs ^[5]
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End point description:

An unsolicited AE was defined as any AE reported by the participant that was not specified as a solicited AR in the protocol. An AE was defined as any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related. A summary of all SAEs and Other Adverse Events (nonserious) regardless of causality is located in the 'Reported Adverse Events' Section. Part B Safety Set included all Part B randomized participants who received any study intervention. Participants were included in the treatment group corresponding to the study vaccination that they actually received.

End point type	Primary
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End point timeframe:

Up to 28 days post-BD injection

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The endpoint is descriptive in nature.

End point values	Part B: Placebo	Part B: mRNA-1345		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	504	998		
Units: participants	75	123		

Statistical analyses

No statistical analyses for this end point

Primary: Part A: Number of Participants With Medically Attended AEs (MAAEs), Adverse Events of Special Interest (AESIs), Serious Adverse Events (SAEs), and AEs Leading to Study Discontinuation

End point title	Part A: Number of Participants With Medically Attended AEs (MAAEs), Adverse Events of Special Interest (AESIs), Serious Adverse Events (SAEs), and AEs Leading to Study Discontinuation ^[6]
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End point description:

MAAEs were AEs that led to an unscheduled visit to a healthcare provider. AESIs were AEs (serious or nonserious) of scientific and medical concern specific to the Sponsor's product or program for which ongoing monitoring and immediate notification by the investigator to the Sponsor was required. SAEs were AEs that resulted in death, were life threatening, required inpatient hospitalization or prolongation of existing hospitalization, resulted in persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, a congenital anomaly or birth defect, or was a medically important event. A summary of all SAEs and Other Adverse Events (nonserious) regardless of causality is located in the 'Reported Adverse Events' Section. Part A Safety Set included all randomized participants who received any study intervention. Participants were included in the treatment group corresponding to the study vaccination that they actually received.

End point type	Primary
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End point timeframe:

Up to 24 months postinjection

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The endpoint is descriptive in nature.

End point values	Part A: Placebo	Part A: mRNA-1345		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18316	18369		
Units: participants				
MAAEs	10995	11313		
AESIs	154	158		
SAEs	2745	2773		
AEs Leading to Study Discontinuation	335	319		

Statistical analyses

No statistical analyses for this end point

Primary: Part A: Number of Participants With Respiratory Syncytial Virus-Associated Lower Respiratory Tract Disease (RSV-LRTD) With 2 or More Symptoms From 14 Days Postinjection up to 12 Months Postinjection

End point title	Part A: Number of Participants With Respiratory Syncytial Virus-Associated Lower Respiratory Tract Disease (RSV-LRTD) With 2 or More Symptoms From 14 Days Postinjection up to 12 Months Postinjection
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End point description:

RSV-LRTD: Reverse transcriptase polymerase chain reaction (RT PCR) confirmed RSV infection PLUS new or worsening of ≥ 2 of the following symptoms: shortness of breath, cough and/or fever (≥ 37.8 degrees Celsius [$^{\circ}\text{C}$]), wheezing and/or rales and/or rhonchi, sputum production, tachypnea (≥ 20 breaths/minute or increase of ≥ 2 breaths/minute from baseline measurement in those who had baseline tachypnea), hypoxemia (new oxygen saturation $\leq 93\%$ or new or increasing use of supplemental oxygen), pleuritic chest pain for ≥ 24 hours. Part A PPE Set: all randomized participants who received assigned study intervention according to protocol, completed ≥ 1 visit or surveillance contact 14 days after study intervention administration, and had no major protocol deviations affecting the efficacy outcomes as determined prior to database lock and unblinding. Participants were analyzed according to vaccination group to which they were randomized. 'Number analyzed' = participants evaluable for this endpoint.

End point type	Primary
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End point timeframe:

From 14 days postinjection up to 12 months postinjection

End point values	Part A: Placebo	Part A: mRNA-1345		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17516	17572		
Units: participants	55	9		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description: Vaccine efficacy (VE) of mRNA-1345 to prevent a first episode of RSV-LRTD with 2 or more symptoms within the period of 14 days postinjection up to 12 months post-injection was the primary endpoint. VE was defined as $100\% * (1 - \text{hazard ratio [mRNA-1345 vs placebo]})$.	
Comparison groups	Part A: Placebo v Part A: mRNA-1345
Number of subjects included in analysis	35088
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.0001
Method	Stratified Cox proportional hazard model
Parameter estimate	VE (%)
Point estimate	83.7
Confidence interval	
level	95.88 %
sides	2-sided
lower limit	66
upper limit	92.2

Primary: Part A: Number of Participants With RSV-LRTD With 3 or More Symptoms From 14 Days Postinjection up to 12 Months Postinjection

End point title	Part A: Number of Participants With RSV-LRTD With 3 or More Symptoms From 14 Days Postinjection up to 12 Months Postinjection
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End point description:

RSV-LRTD: RT PCR confirmed RSV infection PLUS new or worsening of ≥ 3 of the following symptoms: shortness of breath, cough and/or fever ($\geq 37.8^{\circ}\text{C}$), wheezing and/or rales and/or rhonchi, sputum production, tachypnea (≥ 20 breaths/minute or increase of ≥ 2 breaths/minute from baseline measurement in those who had baseline tachypnea), hypoxemia (new oxygen saturation $\leq 93\%$ or new or increasing use of supplemental oxygen), pleuritic chest pain for ≥ 24 hours. Part A PPE Set included all randomized participants who received assigned study intervention dose according to protocol, completed ≥ 1 visit or surveillance contact 14 days after study intervention administration, and had no major protocol deviations affecting the efficacy outcomes as determined prior to database lock and unblinding. Participants were analyzed according to the vaccination group to which they were randomized. 'Number analyzed' = participants evaluable for this endpoint.

End point type	Primary
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End point timeframe:

From 14 days postinjection up to 12 months postinjection

End point values	Part A: Placebo	Part A: mRNA-1345		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17516	17572		
Units: participants	17	3		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description:	
VE of mRNA-1345 to prevent a first episode of RSV-LRTD with 3 or more symptoms within the period of 14 days postinjection up to 12 months post-injection was the primary endpoint. VE was defined as $100\% * (1 - \text{hazard ratio [mRNA-1345 vs placebo]})$.	
Comparison groups	Part A: Placebo v Part A: mRNA-1345
Number of subjects included in analysis	35088
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0078
Method	Stratified Cox proportional hazard model
Parameter estimate	VE (%)
Point estimate	82.4
Confidence interval	
level	Other: 96.36 %
sides	2-sided
lower limit	34.8
upper limit	95.3

Primary: Part B: Geometric Mean Titer (GMT) of Serum Respiratory Syncytial Virus Subtype A (RSV-A) and Respiratory Syncytial Virus Subtype B (RSV-B) Neutralizing Antibodies (nAb) at BD Day 29 Compared to Primary Dose Day 29

End point title	Part B: Geometric Mean Titer (GMT) of Serum Respiratory Syncytial Virus Subtype A (RSV-A) and Respiratory Syncytial Virus Subtype B (RSV-B) Neutralizing Antibodies (nAb) at BD Day 29 Compared to Primary Dose Day 29
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End point description:

Antibody values reported as below lower limit of quantification (LLOQ) replaced by $0.5 * \text{LLOQ}$. Values greater than upper limit of quantification (ULOQ) replaced by ULOQ. LLOQ = 13 international units (IU)/milliliter (mL), ULOQ = 259061 IU/mL for RSV-A nAb. LLOQ = 10, ULOQ = 112476 for RSV-B nAb. Part B Per-protocol (PP) Set: all Part B randomized participants who received both Parts A and B assigned study intervention doses, had RSV immunogenicity titer results at pre-Primary Dose (baseline), had RSV immunogenicity titer results at Primary Dose Day 29, had at least 1 valid result at Revaccination Day 29, and had no major protocol deviations affecting the primary immunogenicity outcomes as determined prior to database lock and unblinding. Participants were analyzed according to the study intervention group to which they were randomized. 'Number analyzed' = participants evaluable for this endpoint. 'n' = participants evaluable for specified category.

End point type	Primary
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End point timeframe:

Primary Dose Day 29 and BD Day 29

End point values	mRNA-1345 Primary Vaccination	mRNA-1345 Revaccination		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	955	955		
Units: IU/mL				
geometric mean (confidence interval 95%)				
RSV-A (n=955,955)	17157.48 (16004.77 to 18393.22)	12339.87 (11538.56 to 13196.82)		

RSV-B (n=951,953)	5665.14 (5294.89 to 6061.28)	4005.79 (3771.68 to 4254.43)		
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Statistical analyses

Statistical analysis title	Statistical Analysis 2
Statistical analysis description: GMR of RSV-B nAb GMT at revaccination Day 29 over RSV-B nAb GMT at Primary Dose Day 29 was the primary endpoint.	
Comparison groups	mRNA-1345 Primary Vaccination v mRNA-1345 Revaccination
Number of subjects included in analysis	1910
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[7]
Parameter estimate	GMR
Point estimate	0.705
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.6671
upper limit	0.7444

Notes:

[7] - Number of participants in the analysis = 948 (Number of participants with non-missing antibody data at Baseline [primary dose Day 1], primary dose Day 29 and BD Day 29). Noninferiority margin = lower bound of 95% CI for GMR >0.667 (1/1.5).

Statistical analysis title	Statistical Analysis 1
Statistical analysis description: Geometric Mean Ratio (GMR) of RSV-A nAb GMT at revaccination Day 29 over RSV-A nAb GMT at Primary Dose Day 29 was the primary endpoint.	
Comparison groups	mRNA-1345 Primary Vaccination v mRNA-1345 Revaccination
Number of subjects included in analysis	1910
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[8]
Parameter estimate	GMR
Point estimate	0.719
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.676
upper limit	0.764

Notes:

[8] - Number of participants in the analysis = 954 (Number of participants with non-missing antibody data at Baseline [primary dose Day 1], primary dose Day 29 and BD Day 29). Noninferiority margin = lower bound of 95% CI for GMR >0.667 (1/1.5).

Secondary: Part A: Number of Participants With RSV-Associated Acute Respiratory Disease (RSV-ARD) From 14 Days Postinjection up to 12 Months Postinjection

End point title	Part A: Number of Participants With RSV-Associated Acute Respiratory Disease (RSV-ARD) From 14 Days Postinjection up to 12 Months Postinjection
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End point description:

RSV-ARD: RT-PCR-confirmed RSV infection and an acute symptomatic respiratory disease manifesting as new or worsening of 1 or more of cough, stuffy nose, runny nose, sore throat, fever ($\geq 37.8^{\circ}\text{C}$), shortness of breath, observed tachypnea (≥ 20 breaths/minute or increase of ≥ 2 breaths/minute from baseline in those who had baseline tachypnea), hypoxemia (new oxygen saturation $\leq 93\%$, or new or increasing use of supplemental oxygen), wheezing, sputum production, hoarseness, sinus pain, chills, pleuritic chest pain for at least 24 hours. Part A PPE Set: all randomized participants who received assigned study intervention dose, completed ≥ 1 visit or surveillance contact 14 days after study intervention administration, and had no major protocol deviations affecting efficacy outcomes as determined prior to database lock and unblinding. Participants were analyzed according to vaccination group to which they were randomized. 'Number analyzed' = participants evaluable for this endpoint.

End point type	Secondary
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End point timeframe:

From 14 days postinjection up to 12 months postinjection

End point values	Part A: Placebo	Part A: mRNA-1345		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17516	17572		
Units: participants	82	26		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
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Statistical analysis description:

VE of mRNA-1345 to prevent a first episode of RSV-ARD within the period of 14 days post-injection up to 12 months post-injection was the secondary endpoint. VE was defined as $100\% * (1 - \text{hazard ratio [mRNA-1345 vs placebo]})$.

Comparison groups	Part A: Placebo v Part A: mRNA-1345
Number of subjects included in analysis	35088
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	VE (%)
Point estimate	68.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	50.9
upper limit	79.7

Secondary: Part A: Number of Participants With All-Cause Hospitalizations From 14 Days Postinjection up to 12 Months Postinjection

End point title	Part A: Number of Participants With All-Cause Hospitalizations From 14 Days Postinjection up to 12 Months Postinjection
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End point description:

An all-cause hospitalization was defined as any reported hospitalization which was collected as inpatient or prolongation of existing hospitalization in the electronic case report form (eCRF) AE form. Part A PPE Set: all randomized participants who received assigned study intervention dose according to protocol, completed ≥ 1 visit or surveillance contact 14 days after study intervention administration, and had no

major protocol deviations affecting the efficacy outcomes as determined prior to database lock and unblinding. Participants were analyzed according to the vaccination group to which they were randomized.

End point type	Secondary
End point timeframe:	
From 14 days postinjection up to 12 months postinjection	

End point values	Part A: Placebo	Part A: mRNA-1345		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18120	18164		
Units: participants	1564	1580		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description:	
VE of mRNA-1345 to prevent all-cause hospitalizations within the period of 14 days post-injection up to 12 months post-injection was the secondary endpoint. VE was defined as $100\% * (1 - \text{ratio of model estimated hospitalization rates (mRNA-1345 vs. placebo)})$.	
Comparison groups	Part A: Placebo v Part A: mRNA-1345
Number of subjects included in analysis	36284
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	VE (%)
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8
upper limit	8.5

Secondary: Part A: Number of Participants With Hospitalization Associated with Protocol-defined RSV-ARD or RSV-LRTD From 14 Days Postinjection up to 12 Months Postinjection

End point title	Part A: Number of Participants With Hospitalization Associated with Protocol-defined RSV-ARD or RSV-LRTD From 14 Days Postinjection up to 12 Months Postinjection
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End point description:

A case of first hospitalization associated with protocol-defined RSV-ARD or RSV-LRTD was defined if: (a) The investigator assessed that an event was a confirmed diagnosis of RSV-LRTD or RSV-ARD and that required inpatient or prolongation of existing hospitalization; (b) a protocol-defined RSV-LRTD/RSV-ARD occurred; (c) date of protocol-defined RSV-LRTD/RSV-ARD was within 14 days prior or during hospitalization. RSV-ARD defined in Endpoint #10 and RSV-LRTD defined in Endpoint #7 above. Part A PPE Set: all randomized participants who received assigned study intervention dose according to protocol, completed ≥ 1 visit or surveillance contact 14 days after study intervention administration, and had no major protocol deviations affecting the efficacy outcomes as determined prior to database lock and unblinding. Participants were analyzed according to the vaccination group to which they were randomized. 'Number analyzed' = participants evaluable for this endpoint.

End point type	Secondary
End point timeframe:	
From 14 days postinjection up to 12 months postinjection	

End point values	Part A: Placebo	Part A: mRNA-1345		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18045	18112		
Units: participants	2	0		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description:	
VE of mRNA-1345 to prevent first hospitalization associated with RSV-ARD or RSV-LRTD within the period of 14 days post-injection up to 12 months post-injection was the secondary endpoint. VE was defined as $100\% * (1 - \text{hazard ratio [mRNA-1345 vs placebo]})$.	
Comparison groups	Part A: Placebo v Part A: mRNA-1345
Number of subjects included in analysis	36157
Analysis specification	Pre-specified
Analysis type	other ^[9]
Parameter estimate	VE (%)
Point estimate	100
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	100

Notes:

[9] - Lower limit of 95% CI reported as 0 signifies data could not be calculated due to smaller number of participants with an event.

Secondary: Part A: Number of Participants With RSV-LRTD With 2 or More Symptoms From 14 Days Postinjection up to 24 Months Postinjection

End point title	Part A: Number of Participants With RSV-LRTD With 2 or More Symptoms From 14 Days Postinjection up to 24 Months Postinjection
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End point description:

RSV-LRTD: RT PCR confirmed RSV infection PLUS new or worsening of ≥ 2 of the following symptoms: shortness of breath, cough and/or fever ($\geq 37.8^{\circ}\text{C}$), wheezing and/or rales and/or rhonchi, sputum production, tachypnea (≥ 20 breaths/minute or increase of ≥ 2 breaths/minute from baseline measurement in those who had baseline tachypnea), hypoxemia (new oxygen saturation $\leq 93\%$ or new or increasing use of supplemental oxygen), pleuritic chest pain for ≥ 24 hours. Part A PPE Set: all randomized participants who received assigned study intervention dose according to protocol, completed ≥ 1 visit or surveillance contact 14 days after study intervention administration, and had no major protocol deviations affecting the efficacy outcomes as determined prior to database lock and unblinding. Participants were analyzed according to the vaccination group to which they were randomized.

End point type	Secondary
End point timeframe:	
From 14 days postinjection up to 24 months postinjection	

End point values	Part A: Placebo	Part A: mRNA-1345		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18120	18164		
Units: participants	286	161		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description:	
VE of mRNA-1345 to prevent a first episode of RSV-LRTD with 2 or more symptoms within the period of 14 days post-injection up to 24 months post-injection was the secondary endpoint. VE was defined as $100\% * (1 - \text{hazard ratio [mRNA-1345 vs placebo]})$.	
Comparison groups	Part A: Placebo v Part A: mRNA-1345
Number of subjects included in analysis	36284
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	VE (%)
Point estimate	44.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	32.4
upper limit	54.1

Secondary: Part A: Number of Participants With RSV-LRTD With 3 or More Symptoms From 14 Days Postinjection up to 24 Months Postinjection

End point title	Part A: Number of Participants With RSV-LRTD With 3 or More Symptoms From 14 Days Postinjection up to 24 Months Postinjection
End point description:	
RSV-LRTD: RT PCR confirmed RSV infection PLUS new or worsening of ≥ 3 of the following symptoms: shortness of breath, cough and/or fever ($\geq 37.8^{\circ}\text{C}$), wheezing and/or rales and/or rhonchi, sputum production, tachypnea (≥ 20 breaths/minute or increase of ≥ 2 breaths/minute from baseline measurement in those who had baseline tachypnea), hypoxemia (new oxygen saturation $\leq 93\%$ or new or increasing use of supplemental oxygen), pleuritic chest pain for ≥ 24 hours. Part A PPE Set included all randomized participants who received assigned study intervention dose according to protocol, completed ≥ 1 visit or surveillance contact 14 days after study intervention administration, and had no major protocol deviations affecting the efficacy outcomes as determined prior to database lock and unblinding. Participants were analyzed according to the vaccination group to which they were randomized.	
End point type	Secondary
End point timeframe:	
From 14 days postinjection up to 24 months postinjection	

End point values	Part A: Placebo	Part A: mRNA-1345		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18120	18164		
Units: participants	123	61		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description:	
VE of mRNA-1345 to prevent a first episode of RSV-LRTD with 3 or more symptoms within the period of 14 days post-injection up to 24 months post-injection was the secondary endpoint. VE was defined as $100\% * (1 - \text{hazard ratio [mRNA-1345 vs placebo]})$.	
Comparison groups	Part A: Placebo v Part A: mRNA-1345
Number of subjects included in analysis	36284
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	VE (%)
Point estimate	50.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	33.2
upper limit	63.8

Secondary: Part A: Number of Participants With All-Cause LRTD From 14 Days Postinjection up to 12 Months Postinjection

End point title	Part A: Number of Participants With All-Cause LRTD From 14 Days Postinjection up to 12 Months Postinjection
End point description:	
All-cause LRTD: New or worsening of ≥ 2 of following symptoms: shortness of breath, cough and/or fever ($\geq 37.8^\circ\text{C}$), wheezing and/or rales and/or rhonchi, sputum production, tachypnea (≥ 20 breaths/minute or increase of ≥ 2 breaths/minute from baseline measurement in those who had baseline tachypnea), hypoxemia (new oxygen saturation $\leq 93\%$ or new or increasing use of supplemental oxygen), pleuritic chest pain for ≥ 24 hours with any or no RT-PCR result. All-cause LRTD was derived based on eligible LRTD symptoms onset within a respiratory illness episode. Part A PPE Set: all randomized participants who received assigned study intervention dose according to protocol, completed ≥ 1 visit or surveillance contact 14 days after study intervention administration, and had no major protocol deviations affecting the efficacy outcomes as determined prior to database lock and unblinding. Participants were analyzed according to the vaccination group to which they were randomized.	
End point type	Secondary
End point timeframe:	
From 14 days postinjection up to 12 months postinjection	

End point values	Part A: Placebo	Part A: mRNA-1345		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18120	18164		
Units: participants	5806	5762		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description:	
VE of mRNA-1345 to prevent all-cause LRTD within the period of 14 days post-injection up to 12 months post-injection was the secondary endpoint. VE was defined as $100\% * (1 - \text{ratio of model estimated LRTD rates (mRNA-1345 vs. placebo)})$.	
Comparison groups	Part A: Placebo v Part A: mRNA-1345
Number of subjects included in analysis	36284
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	VE (%)
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.1
upper limit	5.2

Secondary: Part A: Number of Participants With RSV-LRTD With 3 or More Symptoms by RSV Subtype A and RSV Subtype B From 14 Days Postinjection up to 12 Months Postinjection

End point title	Part A: Number of Participants With RSV-LRTD With 3 or More Symptoms by RSV Subtype A and RSV Subtype B From 14 Days Postinjection up to 12 Months Postinjection
End point description:	
RSV-LRTD: RT PCR confirmed RSV infection PLUS new or worsening of ≥ 3 of the following symptoms: shortness of breath, cough and/or fever ($\geq 37.8^{\circ}\text{C}$), wheezing and/or rales and/or rhonchi, sputum production, tachypnea (≥ 20 breaths/minute or increase of ≥ 2 breaths/minute from baseline measurement in those who had baseline tachypnea), hypoxemia (new oxygen saturation $\leq 93\%$ or new or increasing use of supplemental oxygen), pleuritic chest pain for ≥ 24 hours. Part A PPE Set included all randomized participants who received assigned study intervention dose according to protocol, completed ≥ 1 visit or surveillance contact 14 days after study intervention administration, and had no major protocol deviations affecting the efficacy outcomes as determined prior to database lock and unblinding. Participants were analyzed according to the vaccination group to which they were randomized. 'Number analyzed' = participants evaluable for this endpoint.	
End point type	Secondary
End point timeframe:	
From 14 days postinjection up to 12 months postinjection	

End point values	Part A: Placebo	Part A: mRNA-1345		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17516	17572		
Units: participants				
RSV-A	10	1		
RSV-B	7	2		

Statistical analyses

Statistical analysis title	Statistical Analysis 2
Statistical analysis description:	
For RSV-B: VE of mRNA-1345 to prevent a first episode of RSV-LRTD with 3 or more symptoms within the period of 14 days post-injection up to 12 months post-injection was the secondary endpoint. VE was defined as $100\% * (1 - \text{hazard ratio [mRNA-1345 vs placebo]})$.	
Comparison groups	Part A: Placebo v Part A: mRNA-1345
Number of subjects included in analysis	35088
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	VE (%)
Point estimate	71.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-37
upper limit	94.1

Statistical analysis title	Statistical Analysis 1
Statistical analysis description:	
For RSV-A: VE of mRNA-1345 to prevent a first episode of RSV-LRTD with 3 or more symptoms within the period of 14 days post-injection up to 12 months post-injection was the secondary endpoint. VE was defined as $100\% * (1 - \text{hazard ratio [mRNA-1345 vs placebo]})$.	
Comparison groups	Part A: Placebo v Part A: mRNA-1345
Number of subjects included in analysis	35088
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	VE (%)
Point estimate	90
Confidence interval	
level	95 %
sides	2-sided
lower limit	22
upper limit	98.7

Secondary: Part A: Number of Participants With RSV-LRTD With 2 or More Symptoms by RSV Subtype A and RSV Subtype B From 14 Days Postinjection up to

12 Months Postinjection

End point title	Part A: Number of Participants With RSV-LRTD With 2 or More Symptoms by RSV Subtype A and RSV Subtype B From 14 Days Postinjection up to 12 Months Postinjection
End point description: RSV-LRTD: RT PCR confirmed RSV infection PLUS new or worsening of ≥ 2 of the following symptoms: shortness of breath, cough and/or fever ($\geq 37.8^{\circ}\text{C}$), wheezing and/or rales and/or rhonchi, sputum production, tachypnea (≥ 20 breaths/minute or increase of ≥ 2 breaths/minute from baseline measurement in those who had baseline tachypnea), hypoxemia (new oxygen saturation $\leq 93\%$ or new or increasing use of supplemental oxygen), pleuritic chest pain for ≥ 24 hours. Part A PPE Set: all randomized participants who received assigned study intervention dose according to protocol, completed ≥ 1 visit or surveillance contact 14 days after study intervention administration, and had no major protocol deviations affecting the efficacy outcomes as determined prior to database lock and unblinding. Participants were analyzed according to the vaccination group to which they were randomized. 'Number analyzed' = participants evaluable for this endpoint.	
End point type	Secondary
End point timeframe: From 14 days postinjection up to 12 months postinjection	

End point values	Part A: Placebo	Part A: mRNA-1345		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17516	17572		
Units: participants				
RSV-A	36	3		
RSV-B	19	6		

Statistical analyses

Statistical analysis title	Statistical Analysis 2
Statistical analysis description: For RSV-B: VE of mRNA-1345 to prevent a first episode of RSV-LRTD with 2 or more symptoms within the period of 14 days post-injection up to 12 months post-injection was the secondary endpoint. VE was defined as $100\% * (1 - \text{hazard ratio [mRNA-1345 vs placebo]})$.	
Comparison groups	Part A: Placebo v Part A: mRNA-1345
Number of subjects included in analysis	35088
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	VE (%)
Point estimate	68.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	21.1
upper limit	87.4

Statistical analysis title	Statistical Analysis 1
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Statistical analysis description:

For RSV-A: VE of mRNA-1345 to prevent a first episode of RSV-LRTD with 2 or more symptoms within the period of 14 days post-injection up to 12 months post-injection was the secondary endpoint. VE was defined as $100\% * (1 - \text{hazard ratio [mRNA-1345 vs placebo]})$.

Comparison groups	Part A: Placebo v Part A: mRNA-1345
Number of subjects included in analysis	35088
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	VE (%)
Point estimate	91.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	73
upper limit	97.4

Secondary: Part A: Number of Participants with First Hospitalization Associated with Protocol-defined RSV-ARD or RSV-LRTD From 14 Days Postinjection up to 24 Months Postinjection

End point title	Part A: Number of Participants with First Hospitalization Associated with Protocol-defined RSV-ARD or RSV-LRTD From 14 Days Postinjection up to 24 Months Postinjection
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End point description:

A case of first hospitalization associated with protocol-defined RSV-ARD or RSV-LRTD was defined as: (a) The investigator assessed that an event was a confirmed diagnosis of RSV-LRTD or RSV-ARD and that required inpatient or prolongation of existing hospitalization; (b) a protocol-defined RSV-LRTD/RSV-ARD occurred; (c) date of protocol-defined RSV-LRTD/RSV-ARD was within 14 days prior or during hospitalization. RSV-ARD defined in Endpoint #10 and RSV-LRTD defined in Endpoint #7 above. Part A PPE Set: all randomized participants who received assigned study intervention dose according to protocol, completed ≥ 1 visit or surveillance contact 14 days after study intervention administration, and had no major protocol deviations affecting the efficacy outcomes as determined prior to database lock and unblinding. Participants were analyzed according to the vaccination group to which they were randomized.

End point type	Secondary
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End point timeframe:

From 14 days postinjection up to 24 months postinjection

End point values	Part A: Placebo	Part A: mRNA-1345		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18120	18164		
Units: participants	2	1		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
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Statistical analysis description:

VE of mRNA-1345 to prevent first hospitalization associated with RSV-ARD or RSV-LRTD within the

period of 14 days post-injection up to 24 months post-injection was the secondary endpoint. VE was defined as $100\% * (1 - \text{hazard ratio [mRNA-1345 vs placebo]})$.

Comparison groups	Part A: Placebo v Part A: mRNA-1345
Number of subjects included in analysis	36284
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	VE (%)
Point estimate	50.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-447.1
upper limit	95.5

Secondary: Part A: GMT of Serum RSV nAb

End point title	Part A: GMT of Serum RSV nAb
End point description:	
Antibody values reported as below LLOQ replaced by $0.5 * \text{LLOQ}$. Values greater than ULOQ replaced by ULOQ. LLOQ = 13 IU/mL, ULOQ = 259061 IU/mL for RSV-A nAb. LLOQ = 10, ULOQ = 112476 for RSV-B nAb. Part A Per-protocol Immunogenicity (PPI) Set: a randomly selected subset of participants who: a) received the assigned study drug, b) had RSV immunogenicity titer results at baseline (prior to study drug administration) and at least 1 valid result after the study drug administration at timepoint of interest, and c) had no major protocol deviation affecting the primary immunogenicity outcomes as determined prior to database lock and unblinding. Participants were analyzed according to the vaccination group to which they were randomized. 'Number analyzed' = participants evaluable for this endpoint. 'n' = participants evaluable for specified category.	
End point type	Secondary
End point timeframe:	
Baseline (Day 1), Days 29, 181, 365, and 730	

End point values	Part A: Placebo	Part A: mRNA-1345		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	341	1534		
Units: IU/mL				
geometric mean (confidence interval 95%)				
RSV-A: Day 1 (n=341,1533)	2403.59 (2137.23 to 2703.15)	2559.03 (2421.48 to 2704.39)		
RSV-A: Day 29 (n=332,1513)	2411.91 (2151.25 to 2704.16)	21258.26 (20083.91 to 22501.27)		
RSV-A: Day 181 (n=316,1421)	2114.80 (1874.89 to 2385.41)	7094.40 (6688.56 to 7524.87)		
RSV-A: Day 365 (n=306,1362)	2011.85 (1766.83 to 2290.85)	4646.43 (4375.17 to 4934.51)		
RSV-A: Day 730 (n=274,1200)	2259.10 (1922.61 to 2654.49)	3920.00 (3680.66 to 4174.90)		

RSV-B: Day 1 (n=340,1534)	1367.88 (1219.40 to 1534.43)	1425.73 (1354.03 to 1501.22)		
RSV-B: Day 29 (n=332,1512)	1308.32 (1163.27 to 1471.45)	7224.01 (6845.63 to 7623.30)		
RSV-B: Day 181 (n=316,1421)	1123.06 (1001.78 to 1259.02)	2797.20 (2653.08 to 2949.16)		
RSV-B: Day 365 (n=306,1362)	1087.30 (955.94 to 1236.71)	1993.79 (1891.72 to 2101.37)		
RSV-B: Day 730 (n=274,1204)	1174.89 (1022.03 to 1350.61)	1816.21 (1713.20 to 1925.41)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Change in Total Frailty Score From Baseline to 12 Months and 24 Months Postinjection, Using the Edmonton Frail Scale (EFS)

End point title	Part A: Change in Total Frailty Score From Baseline to 12 Months and 24 Months Postinjection, Using the Edmonton Frail Scale (EFS)
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End point description:

The total frail score is the sum of individual scores from the 11 questions representing 9 domains included in EFS, which is a multidimensional frail assessment scale that assesses domains related to frailty including cognition, general health status, functional independence, social support, medication use, nutrition, mood, continence, and functional performance. The total frail score ranges between 0 and 17. Higher scores suggest more frailty, and the total frail score can be interpreted as: 0-3=fit, 4-5=vulnerable, 6-7=mild frail, 8-9=moderate frail, 10 or more=severe frail. Part A PPE Set as defined in previous endpoint. 'Number analyzed' = participants evaluable for this endpoint. 'n' = participants evaluable at specified timepoint.

End point type	Secondary
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End point timeframe:

Baseline, 12 months and 24 months postinjection

End point values	Part A: Placebo	Part A: mRNA-1345		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15703	15807		
Units: score on a scale				
arithmetic mean (standard deviation)				
Change at Month 12 (n=15703,15807)	0.2 (± 1.79)	0.2 (± 1.78)		
Change at Month 24 (n=14577,14680)	0.3 (± 1.91)	0.3 (± 1.89)		

Statistical analyses

Secondary: Part A: Geometric Mean Concentration (GMC) of Serum RSV Binding Antibodies

End point title	Part A: Geometric Mean Concentration (GMC) of Serum RSV Binding Antibodies
End point description:	
Antibody values reported as below LLOQ replaced by 0.5 * LLOQ. Values greater than ULOQ replaced by ULOQ. LLOQ = 35 arbitrary unit (AU)/mL, ULOQ = 580553 AU/mL for RSV Pre-F immunoglobulin G (IgG) antibody (Ab). LLOQ = 57, ULOQ = 847551 for RSV Post-F IgG Ab. Part A PPI Set: a randomly selected subset of participants who: a) received the assigned study drug, b) had RSV immunogenicity titer results at baseline (prior to study drug administration) and at least 1 valid result after the study drug administration at timepoint of interest, and c) had no major protocol deviation affecting the primary immunogenicity outcomes as determined prior to database lock and unblinding. Participants were analyzed according to the vaccination group to which they were randomized. 'Number analyzed' = participants evaluable for this endpoint. 'n' = participants evaluable for specified category.	
End point type	Secondary
End point timeframe:	
Baseline (Day 1), Days 29, 181, 365, and 730	

End point values	Part A: Placebo	Part A: mRNA-1345		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	341	1535		
Units: AU/mL				
geometric mean (confidence interval 95%)				
RSV Pre-F IgG: Day 1 (n=341,1535)	10197.91 (9390.41 to 11074.85)	10719.10 (10305.60 to 11149.19)		
RSV Pre-F IgG: Day 29 (n=333,1513)	10068.44 (9267.14 to 10939.01)	81897.81 (78658.16 to 85270.89)		
RSV Pre-F IgG: Day 181 (n=316,1423)	11559.45 (10640.29 to 12558.00)	36208.22 (34870.87 to 37596.87)		
RSV Pre-F IgG: Day 365 (n=306,1362)	11986.87 (10920.62 to 13157.22)	26033.56 (25079.43 to 27023.99)		
RSV Pre-F IgG: Day 730 (n=274,1204)	12673.59 (11359.94 to 14139.14)	22428.74 (21513.33 to 23383.10)		
RSV Post-F IgG: Day 1 (n=341,1535)	14188.99 (12866.04 to 15647.97)	14405.86 (13767.81 to 15073.48)		
RSV Post-F IgG: Day 29 (n=333,1513)	14054.35 (12744.65 to 15498.65)	84081.63 (80191.52 to 88160.45)		
RSV Post-F IgG: Day 181 (n=316,1423)	14335.77 (12948.78 to 15871.34)	36078.03 (34477.82 to 37752.51)		
RSV Post-F IgG: Day 365 (n=306,1362)	14957.00 (13401.73 to 16692.77)	26977.85 (25796.45 to 28213.36)		
RSV Post-F IgG: Day 730 (n=274,1204)	15681.64 (13810.96 to 17805.70)	24413.11 (23258.27 to 25625.30)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Percentage of Participants With Seroresponse in RSV nAb

End point title	Part A: Percentage of Participants With Seroresponse in RSV nAb
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End point description:

Seroresponse was defined as a change from below the LLOQ to equal or above 4 * LLOQ, or at least a 4-fold increase if baseline was equal to or above the LLOQ. Part A PPI Set: a randomly selected subset of participants who: a) received the assigned study drug, b) had RSV immunogenicity titer results at baseline (prior to study drug administration) and at least 1 valid result after the study drug administration at timepoint of interest, and c) had no major protocol deviation affecting the primary immunogenicity outcomes as determined prior to database lock and unblinding. Participants were analyzed according to the vaccination group to which they were randomized. 'Number analyzed' = participants evaluable for this endpoint. 'n' = participants evaluable for specified category.

End point type	Secondary
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End point timeframe:

Days 29, 181, 365, and 730

End point values	Part A: Placebo	Part A: mRNA-1345		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	332	1510		
Units: percentage of participants				
number (confidence interval 95%)				
RSV-A: Day 29 (n=332,1510)	0.6 (0.1 to 2.2)	74.0 (71.7 to 76.2)		
RSV-A: Day 181 (n=316,1418)	3.2 (1.5 to 5.7)	32.9 (30.4 to 35.4)		
RSV-A: Day 365 (n=306,1359)	5.2 (3.0 to 8.4)	19.3 (17.2 to 21.5)		
RSV-A: Day 730 (n=274,1197)	7.7 (4.8 to 11.5)	15.7 (13.7 to 17.9)		
RSV-B: Day 29 (n=332,1510)	1.5 (0.5 to 3.5)	56.6 (54.0 to 59.1)		
RSV-B: Day 181 (n=315,1419)	3.2 (1.5 to 5.8)	19.9 (17.8 to 22.0)		
RSV-B: Day 365 (n=305,1360)	4.9 (2.8 to 8.0)	10.5 (8.9 to 12.3)		
RSV-B: Day 730 (n=274,1202)	6.9 (4.2 to 10.6)	9.2 (7.6 to 10.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Geometric Mean Fold-Rise (GMFR) of Postbaseline/Baseline Antibody Titers

End point title	Part A: Geometric Mean Fold-Rise (GMFR) of Postbaseline/Baseline Antibody Titers
End point description: Antibody values reported as below LLOQ replaced by 0.5 * LLOQ. Values greater than ULOQ replaced by ULOQ. LLOQ = 13 IU/mL, ULOQ = 259061 IU/mL for RSV-A nAb. LLOQ = 10, ULOQ = 112476 for RSV-B nAb. Part A PPI Set: a randomly selected subset of participants who: a) received the assigned study drug, b) had RSV immunogenicity titer results at baseline (prior to study drug administration) and at least 1 valid result after the study drug administration at timepoint of interest, and c) had no major protocol deviation affecting the primary immunogenicity outcomes as determined prior to database lock and unblinding. Participants were analyzed according to the vaccination group to which they were randomized. 'Number analyzed' = participants evaluable for this endpoint. 'n' = participants evaluable for specified category.	
End point type	Secondary
End point timeframe: Days 29, 181, 365, and 730	

End point values	Part A: Placebo	Part A: mRNA-1345		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	332	1510		
Units: ratio				
geometric mean (confidence interval 95%)				
RSV-A: Day 29 (n=332,1510)	1.00 (0.95 to 1.06)	8.33 (7.88 to 8.80)		
RSV-A: Day 181 (n=316,1418)	0.88 (0.81 to 0.94)	2.80 (2.65 to 2.96)		
RSV-A: Day 365 (n=306,1359)	0.84 (0.77 to 0.92)	1.82 (1.73 to 1.92)		
RSV-A: Day 730 (n=274,1197)	0.94 (0.84 to 1.04)	1.60 (1.51 to 1.69)		
RSV-B: Day 29 (n=332,1510)	0.96 (0.91 to 1.03)	5.10 (4.86 to 5.36)		
RSV-B: Day 181 (n=315,1419)	0.83 (0.77 to 0.89)	1.98 (1.89 to 2.08)		
RSV-B: Day 365 (n=305,1360)	0.80 (0.73 to 0.88)	1.41 (1.35 to 1.48)		
RSV-B: Day 730 (n=274,1202)	0.86 (0.76 to 0.97)	1.32 (1.26 to 1.39)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Percentage of Participants with ≥ 2 -fold Increases in Antibody Titers from Baseline

End point title	Part A: Percentage of Participants with ≥ 2 -fold Increases in Antibody Titers from Baseline
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End point description:

A ≥ 2 -fold increase from baseline was defined as a change from below the LLOQ to equal or above 2 * LLOQ, or at least a 2-fold increase if baseline was equal to or above the LLOQ. Part A PPI Set: a randomly selected subset of participants who: a) received the assigned study drug, b) had RSV immunogenicity titer results at baseline (prior to study drug administration) and at least 1 valid result after the study drug administration at timepoint of interest, and c) had no major protocol deviation affecting the primary immunogenicity outcomes as determined prior to database lock and unblinding. Participants were analyzed according to the vaccination group to which they were randomized. 'Number analyzed' = participants evaluable for this endpoint. 'n' = participants evaluable for specified category.

End point type	Secondary
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End point timeframe:

Days 29, 181, 365, and 730

End point values	Part A: Placebo	Part A: mRNA-1345		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	332	1510		
Units: percentage of participants				
number (confidence interval 95%)				
RSV-A: Day 29 (n=332,1510)	4.5 (2.6 to 7.3)	91.1 (89.6 to 92.5)		
RSV-A: Day 181 (n=316,1418)	7.9 (5.2 to 11.5)	60.9 (58.3 to 63.4)		
RSV-A: Day 365 (n=306,1359)	10.5 (7.3 to 14.4)	42.7 (40.0 to 45.4)		
RSV-A: Day 730 (n=274,1197)	13.5 (9.7 to 18.1)	35.2 (32.5 to 38.0)		
RSV-B: Day 29 (n=332,1510)	5.4 (3.2 to 8.4)	84.2 (82.2 to 86.0)		
RSV-B: Day 181 (n=315,1419)	8.9 (6.0 to 12.6)	46.7 (44.0 to 49.3)		
RSV-B: Day 365 (n=305,1360)	9.2 (6.2 to 13.0)	29.6 (27.1 to 32.1)		
RSV-B: Day 730 (n=274,1202)	15.7 (11.6 to 20.6)	27.6 (25.1 to 30.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: GMT of Serum RSV-A and RSV-B nAb at BD Day 1 and BD Day 181

End point title	Part B: GMT of Serum RSV-A and RSV-B nAb at BD Day 1 and BD Day 181
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End point description:

Antibody values reported as below LLOQ replaced by 0.5 * LLOQ. Values greater than ULOQ replaced by ULOQ. LLOQ = 13 IU/mL, ULOQ = 259061 IU/mL for RSV-A nAb. LLOQ = 10, ULOQ = 112476 for RSV-B nAb. Part B PP Set: all Part B randomized participants who received both Parts A and B assigned study intervention doses, had RSV immunogenicity titer results at pre-Primary Dose (baseline), had RSV immunogenicity titer results at Primary Dose Day 29, had at least 1 valid result at Revaccination Day 29, and had no major protocol deviations affecting the primary immunogenicity outcomes as determined prior to database lock and unblinding. Participants were analyzed according to the study intervention group to which they were randomized. 'Number analyzed' = participants evaluable for this endpoint. 'n' = participants evaluable for specified category.

End point type	Secondary
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End point timeframe:

BD Day 1 and BD Day 181

End point values	Part B: Placebo	Part B: mRNA-1345		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	489	954		
Units: IU/mL				
geometric mean (confidence interval 95%)				
RSV-A: BD Day 1 (n=489,954)	3533.60 (3212.07 to 3887.31)	4186.08 (3899.52 to 4493.69)		
RSV-A: BD Day 181 (n=465,902)	3156.10 (2846.53 to 3499.35)	6256.67 (5818.27 to 6728.10)		
RSV-B: BD Day 1 (n=489,954)	1636.66 (1504.60 to 1780.31)	1626.56 (1529.35 to 1729.95)		
RSV-B: BD Day 181 (n=465,902)	1495.45 (1366.74 to 1636.27)	2269.18 (2133.63 to 2413.34)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Percentage of Participants With Seroresponse of Serum RSV-A and RSV-B nAb at BD Day 29 Compared to Primary Dose Day 29

End point title	Part B: Percentage of Participants With Seroresponse of Serum RSV-A and RSV-B nAb at BD Day 29 Compared to Primary Dose Day 29
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End point description:

Seroresponse was defined as a post-primary dose or post-revaccination titer $\geq 4 \times$ LLOQ if Baseline was $< \text{LLOQ}$ or a ≥ 4 -fold increase from baseline if baseline was $\geq \text{LLOQ}$. Part B PP Set: all Part B randomized participants who received both Parts A and B assigned study intervention doses, had RSV immunogenicity titer results at pre-Primary Dose (baseline), had RSV immunogenicity titer results at Primary Dose Day 29, had at least 1 valid result at Revaccination Day 29, and had no major protocol deviations affecting the primary immunogenicity outcomes as determined prior to database lock and unblinding. Participants were analyzed according to the study intervention group to which they were randomized. 'Number analyzed' = participants evaluable for this endpoint. 'n' = participants evaluable for specified category.

End point type	Secondary
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End point timeframe:

Primary Dose Day 29 and BD Day 29

End point values	mRNA-1345 Primary Vaccination	mRNA-1345 Revaccination		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	955	955		
Units: percentage of participants				
number (confidence interval 95%)				
RSV-A (n=955,955)	73.3 (70.4 to 76.1)	66.0 (62.9 to 69.0)		
RSV-B (n=951,953)	57.9 (54.7 to 61.1)	46.0 (42.8 to 49.2)		

Statistical analyses

Statistical analysis title	Statistical Analysis 2
Statistical analysis description: SRR difference of RSV-B nAb SRR at revaccination Day 29 over RSV-A nAb SRR at Primary Dose Day 29 was the secondary endpoint.	
Comparison groups	mRNA-1345 Primary Vaccination v mRNA-1345 Revaccination
Number of subjects included in analysis	1910
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[10]
Parameter estimate	SRR Difference
Point estimate	-12.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15.4
upper limit	-8.9

Notes:

[10] - Number of participants in the analysis = 948 (Number of participants with non-missing antibody data at Baseline [primary dose Day 1], primary dose Day 29 and BD Day 29). Noninferiority margin = lower bound of 95% CI for SRR >10%.

Statistical analysis title	Statistical Analysis 1
Statistical analysis description: Seroresponse Rate (SRR) difference of RSV-A nAb SRR at revaccination Day 29 over RSV-A nAb SRR at Primary Dose Day 29 was the secondary endpoint.	
Comparison groups	mRNA-1345 Primary Vaccination v mRNA-1345 Revaccination
Number of subjects included in analysis	1910
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[11]
Parameter estimate	SRR Difference
Point estimate	-7.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.4
upper limit	-4.3

Notes:

[11] - Number of participants in the analysis = 954 (Number of participants with non-missing antibody data at Baseline [primary dose Day 1], primary dose Day 29 and BD Day 29). Noninferiority margin = lower bound of 95% CI for SRR >10%.

Secondary: Part B: GMFR of Serum RSV-A and RSV-B NAb from Pre-primary Dose (Baseline)

End point title	Part B: GMFR of Serum RSV-A and RSV-B NAb from Pre-primary Dose (Baseline)
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End point description:

Antibody values reported as below LLOQ replaced by $0.5 * \text{LLOQ}$. Values greater than ULOQ replaced by ULOQ. LLOQ = 13 IU/mL, ULOQ = 259061 IU/mL for RSV-A nAb. LLOQ = 10, ULOQ = 112476 for RSV-B nAb. Part B PP Set: all Part B randomized participants who received both Parts A and B assigned study intervention doses, had RSV immunogenicity titer results at pre-Primary Dose (baseline), had RSV immunogenicity titer results at Primary Dose Day 29, had at least 1 valid result at Revaccination Day 29, and had no major protocol deviations affecting the primary immunogenicity outcomes as determined prior to database lock and unblinding. Participants were analyzed according to the study intervention group to which they were randomized. 'Number analyzed' = participants evaluable for this endpoint. 'n' = participants evaluable for specified category.

End point type	Secondary
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End point timeframe:

BD Day 1, BD Day 29, and BD Day 181

End point values	Part B: Placebo	Part B: mRNA-1345		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	489	955		
Units: ratio				
geometric mean (confidence interval 95%)				
RSV-A: BD Day 1 (n=489,954)	1.73 (1.58 to 1.88)	2.04 (1.91 to 2.18)		
RSV-A: BD Day 29 (n=488,955)	1.74 (1.59 to 1.91)	6.01 (5.57 to 6.50)		
RSV-A: BD Day 181 (n=465,902)	1.58 (1.44 to 1.73)	3.05 (2.84 to 3.27)		
RSV-B: BD Day 1 (n=489,954)	1.31 (1.22 to 1.41)	1.46 (1.38 to 1.54)		
RSV-B: BD Day 29 (n=489,953)	1.24 (1.16 to 1.33)	3.59 (3.36 to 3.84)		
RSV-B: BD Day 181 (n=465,902)	1.22 (1.13 to 1.31)	2.02 (1.90 to 2.15)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Percentage of Participants With Seroresponse of Serum RSV-A and RSV-B Neutralizing Antibodies from Pre-primary Dose (Baseline)

End point title	Part B: Percentage of Participants With Seroresponse of Serum RSV-A and RSV-B Neutralizing Antibodies from Pre-primary Dose (Baseline)
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End point description:

Seroresponse was defined as a post-primary dose or post-revaccination titer $\geq 4 * \text{LLOQ}$ if Baseline was

<LLOQ or a ≥ 4 -fold increase from baseline if baseline was $\geq$ LLOQ. Part B PP Set: all Part B randomized participants who received both Parts A and B assigned study intervention doses, had RSV immunogenicity titer results at pre-Primary Dose (baseline), had RSV immunogenicity titer results at Primary Dose Day 29, had at least 1 valid result at Revaccination Day 29, and had no major protocol deviations affecting the primary immunogenicity outcomes as determined prior to database lock and unblinding. Participants were analyzed according to the study intervention group to which they were randomized. 'Number analyzed' = participants evaluable for this endpoint. 'n' = participants evaluable for specified category.

End point type	Secondary
End point timeframe:	
BD Day 1, BD Day 29, and BD Day 181	

End point values	Part B: Placebo	Part B: mRNA-1345		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	489	955		
Units: percentage of participants				
number (confidence interval 95%)				
RSV-A: BD Day 1 (n=489,954)	18.8 (15.5 to 22.6)	22.6 (20.0 to 25.4)		
RSV-A: BD Day 29 (n=488,955)	18.2 (14.9 to 22.0)	66.0 (62.9 to 69.0)		
RSV-A: BD Day 181 (n=468,902)	15.7 (12.5 to 19.3)	39.4 (36.2 to 42.6)		
RSV-B: BD Day 1 (n=489,954)	6.7 (4.7 to 9.4)	9.6 (7.8 to 11.7)		
RSV-B: BD Day 29 (n=489,953)	6.7 (4.7 to 9.4)	46.0 (42.8 to 49.2)		
RSV-B: BD Day 181 (n=465,902)	7.5 (5.3 to 10.3)	20.3 (17.7 to 23.1)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Deaths, SAEs, AESIs, MAAEs, and AEs led to study discontinuation: up to Month 24 (Part A) and up to BD Day 181 (Part B). Non-serious AEs: up to 28 days after study injection, unless they met criteria for AESIs, MAAEs, or AEs led to study discontinuation.

Adverse event reporting additional description:

Part A Safety Set: randomized participants who received any study drug. Part B Safety Set: Part B randomized participants who received any study drug. Participants included in study arms corresponding to study drug actually received. 'Deaths' as reason for study discontinuation reported in subject disposition; 'all deaths' reported in AE section.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	25.0
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Reporting groups

Reporting group title	Part A: Placebo
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Reporting group description:

Participants received a single IM injection of placebo on Day 1 in Part A

Reporting group title	Part B: mRNA-1345
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Reporting group description:

Participants received a single IM injection of BD (revaccination) of mRNA-1345 on BD Day 1 in Part B.

Reporting group title	Part B: Placebo
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Reporting group description:

Participants received a single IM injection of BD of placebo on BD Day 1 in Part B.

Reporting group title	Part A: mRNA-1345
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Reporting group description:

Participants received a single IM injection of mRNA-1345 (primary vaccination) on Day 1 in Part A.

Serious adverse events	Part A: Placebo	Part B: mRNA-1345	Part B: Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	2745 / 18316 (14.99%)	29 / 998 (2.91%)	26 / 504 (5.16%)
number of deaths (all causes)	307	0	1
number of deaths resulting from adverse events	307	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute myeloid leukaemia			
subjects affected / exposed	6 / 18316 (0.03%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 0
Adenocarcinoma			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenocarcinoma gastric			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenocarcinoma metastatic			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenocarcinoma of colon			
subjects affected / exposed	8 / 18316 (0.04%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 8	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Adenocarcinoma pancreas			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
B-cell small lymphocytic lymphoma			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal cancer			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal squamous cell carcinoma			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaplastic thyroid cancer			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
B-cell lymphoma			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
B-cell lymphoma stage IV			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	1 / 504 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adrenocortical carcinoma			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal cell carcinoma			
subjects affected / exposed	14 / 18316 (0.08%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 15	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basosquamous carcinoma of skin			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign bone neoplasm			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign gastrointestinal neoplasm			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign lung neoplasm			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign renal neoplasm			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign neoplasm of ampulla of Vater			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign neoplasm of bladder			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign ovarian tumour			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign pericardium neoplasm			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign mediastinal neoplasm			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile duct cancer			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder cancer			

subjects affected / exposed	9 / 18316 (0.05%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 9	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder cancer recurrent			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder cancer stage IV			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder neoplasm			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain neoplasm benign			
subjects affected / exposed	0 / 18316 (0.00%)	1 / 998 (0.10%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder transitional cell carcinoma			
subjects affected / exposed	9 / 18316 (0.05%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 10	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone cancer			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bowen's disease			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain cancer metastatic			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Brain neoplasm			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder squamous cell carcinoma stage unspecified			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain neoplasm malignant			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer			
subjects affected / exposed	13 / 18316 (0.07%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 13	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer in situ			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer metastatic			
subjects affected / exposed	6 / 18316 (0.03%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer stage I			
subjects affected / exposed	4 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac neoplasm unspecified			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial neoplasm			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cancer pain			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carcinoid tumour of the stomach			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carcinoid tumour pulmonary			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carcinoma in situ of skin			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial carcinoma			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Central nervous system lymphoma			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervix carcinoma			

subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervix carcinoma stage II			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangiocarcinoma			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholesteatoma			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon cancer stage III			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clear cell renal cell carcinoma			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Colon cancer			
subjects affected / exposed	8 / 18316 (0.04%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 8	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon cancer metastatic			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon cancer stage 0			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon cancer stage II			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic lymphocytic leukaemia			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cutaneous T-cell lymphoma			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diffuse large B-cell lymphoma			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ductal adenocarcinoma of pancreas			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Elastofibroma			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial adenocarcinoma			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colorectal cancer stage I			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epithelioid mesothelioma			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon neoplasm			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colorectal adenocarcinoma			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colorectal adenoma			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colorectal cancer			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial sarcoma			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extranodal marginal zone B-cell lymphoma (MALT type)			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fallopian tube cancer stage III			

subjects affected / exposed	0 / 18316 (0.00%)	1 / 998 (0.10%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Follicular lymphoma			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder adenocarcinoma			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder cancer			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glioblastoma			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric cancer			
subjects affected / exposed	5 / 18316 (0.03%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Gastric cancer stage 0			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal lymphoma			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal stromal tumour			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Genitourinary tract neoplasm			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder neoplasm			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glioblastoma multiforme			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Haemangioma of bone			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemangioma of liver			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic cancer			
subjects affected / exposed	5 / 18316 (0.03%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic cancer metastatic			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatocellular carcinoma			

subjects affected / exposed	4 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Hodgkin's disease			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hormone receptor positive HER2 negative breast cancer			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected neoplasm			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal adenocarcinoma			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Intraductal papillary breast neoplasm			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraductal papillary mucinous neoplasm			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraductal proliferative breast lesion			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Invasive breast carcinoma			

subjects affected / exposed	5 / 18316 (0.03%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Invasive ductal breast carcinoma			
subjects affected / exposed	5 / 18316 (0.03%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Invasive lobular breast carcinoma			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngeal squamous cell carcinoma			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Kaposi's sarcoma			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Keratoacanthoma			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine benign neoplasm			
subjects affected / exposed	1 / 18316 (0.01%)	1 / 998 (0.10%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngeal cancer			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngeal neoplasm			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Invasive papillary breast carcinoma			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukaemia			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Linitis plastica			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lip and/or oral cavity cancer			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipoma			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liposarcoma			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung carcinoma cell type unspecified stage I			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung adenocarcinoma			

subjects affected / exposed	4 / 18316 (0.02%)	0 / 998 (0.00%)	1 / 504 (0.20%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung adenocarcinoma stage IV			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung cancer metastatic			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Lung carcinoma cell type unspecified recurrent			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lobular breast carcinoma in situ			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm of unknown primary site			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Lung carcinoma cell type unspecified stage IV			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung neoplasm			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung neoplasm malignant			

subjects affected / exposed	10 / 18316 (0.05%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 10	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Lymphocytic leukaemia			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant melanoma stage I			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant ascites			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant genitourinary tract neoplasm			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant glioma			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant melanoma			
subjects affected / exposed	7 / 18316 (0.04%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant melanoma in situ			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphoma			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant peritoneal neoplasm			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant pleural effusion			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mantle cell lymphoma			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Mediastinum neoplasm			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melanocytic naevus			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to lung			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metaplastic breast carcinoma			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to abdominal cavity			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Metastases to bone			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to central nervous system			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to liver			
subjects affected / exposed	4 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Meningioma			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to lymph nodes			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to peritoneum			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastasis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Metastatic carcinoma of the bladder			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic malignant melanoma			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myeloproliferative neoplasm			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic squamous cell carcinoma			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucoepidermoid carcinoma of salivary gland			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelodysplastic syndrome			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelofibrosis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	1 / 504 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic renal cell carcinoma			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal sinus cancer			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm malignant			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Neuroblastoma			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuroendocrine carcinoma metastatic			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal cancer metastatic			
subjects affected / exposed	4 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-Hodgkin's lymphoma			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-small cell lung cancer			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Non-small cell lung cancer metastatic			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal adenocarcinoma			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal adenocarcinoma stage IV			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nodular melanoma			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal carcinoma			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal squamous cell carcinoma			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral haemangioma			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oropharyngeal cancer			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oropharyngeal squamous cell carcinoma			

subjects affected / exposed	3 / 18316 (0.02%)	1 / 998 (0.10%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic carcinoma metastatic			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Ovarian cancer			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cancer metastatic			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cancer recurrent			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian germ cell teratoma benign			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic carcinoma			
subjects affected / exposed	6 / 18316 (0.03%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian adenoma			
subjects affected / exposed	4 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic carcinoma stage IV			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic neoplasm			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papillary renal cell carcinoma			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papillary thyroid cancer			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parathyroid tumour benign			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer metastatic			
subjects affected / exposed	5 / 18316 (0.03%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Plasma cell myeloma			
subjects affected / exposed	4 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Plasma cell myeloma in remission			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleomorphic adenoma			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polycythaemia vera			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	56 / 18316 (0.31%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 56	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pituitary tumour benign			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatic adenoma			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal adenocarcinoma			
subjects affected / exposed	4 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal cancer			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Rectal neoplasm			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cancer			

subjects affected / exposed	3 / 18316 (0.02%)	1 / 998 (0.10%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer stage IV			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cancer stage IV			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer recurrent			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer stage I			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer stage II			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cancer metastatic			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Renal cell carcinoma			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	1 / 504 (0.20%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Renal neoplasm			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal oncocytoma			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract neoplasm			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salivary gland cancer			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestine carcinoma			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sarcoma			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin cancer			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small cell carcinoma			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small cell lung cancer			

subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Small cell lung cancer metastatic			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salivary gland neoplasm			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestine neuroendocrine tumour			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of lung			
subjects affected / exposed	7 / 18316 (0.04%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Squamous cell carcinoma of pharynx			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of skin			
subjects affected / exposed	9 / 18316 (0.05%)	0 / 998 (0.00%)	1 / 504 (0.20%)
occurrences causally related to treatment / all	0 / 9	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroid neoplasm			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of the oral cavity			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of the parotid gland			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of the tongue			
subjects affected / exposed	1 / 18316 (0.01%)	1 / 998 (0.10%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
T-cell lymphoma stage IV			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Testicular seminoma (pure)			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of the cervix			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tongue neoplasm malignant stage unspecified			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0

Tonsil cancer			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Transitional cell carcinoma			
subjects affected / exposed	5 / 18316 (0.03%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine cancer			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine leiomyoma			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Waldenstrom's macroglobulinaemia			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal neoplasm			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Aneurysm thrombosis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic aneurysm			
subjects affected / exposed	14 / 18316 (0.08%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 14	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic thrombosis			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic arteriosclerosis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic dissection			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Aortic intramural haematoma			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic occlusion			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic stenosis			
subjects affected / exposed	12 / 18316 (0.07%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 12	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic aneurysm rupture			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial disorder			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial occlusive disease			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Giant cell arteritis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral artery embolism			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extremity necrosis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Essential hypertension			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Distributive shock			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	10 / 18316 (0.05%)	0 / 998 (0.00%)	1 / 504 (0.20%)
occurrences causally related to treatment / all	0 / 10	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Circulatory collapse			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriovenous fistula			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriosclerosis			
subjects affected / exposed	7 / 18316 (0.04%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 0
Arterial rupture			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematoma			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jugular vein thrombosis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Internal haemorrhage			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intermittent claudication			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemic shock			
subjects affected / exposed	4 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Lymphoedema			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive urgency			
subjects affected / exposed	7 / 18316 (0.04%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive end-organ damage			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive emergency			
subjects affected / exposed	6 / 18316 (0.03%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive crisis			
subjects affected / exposed	19 / 18316 (0.10%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 20	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	29 / 18316 (0.16%)	1 / 998 (0.10%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 29	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	14 / 18316 (0.08%)	1 / 998 (0.10%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 14	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant hypertension			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral venous disease			

subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral vascular disorder			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral ischaemia			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery thrombosis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery occlusion			
subjects affected / exposed	4 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery aneurysm			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral arterial occlusive disease			
subjects affected / exposed	11 / 18316 (0.06%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 12	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic hypotension			
subjects affected / exposed	6 / 18316 (0.03%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurogenic shock			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Phlebitis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subclavian vein thrombosis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superficial vein thrombosis			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock haemorrhagic			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Subclavian artery stenosis			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subclavian steal syndrome			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vasculitis			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicose vein			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicose ulceration			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombosis			
subjects affected / exposed	4 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombophlebitis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vein rupture			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Adverse event			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adverse drug reaction			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthenia			

subjects affected / exposed	4 / 18316 (0.02%)	1 / 998 (0.10%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Cardiac complication associated with device			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	37 / 18316 (0.20%)	0 / 998 (0.00%)	1 / 504 (0.20%)
occurrences causally related to treatment / all	0 / 37	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 37	0 / 0	0 / 1
Dehiscence			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac death			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Chest discomfort			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	13 / 18316 (0.07%)	1 / 998 (0.10%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 13	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chills			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Complication associated with device			

subjects affected / exposed	6 / 18316 (0.03%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gait inability			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised oedema			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gait disturbance			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body reaction			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye complication associated with device			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug intolerance			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Granuloma			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthermia			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza like illness			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incarcerated hernia			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	6 / 18316 (0.03%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Pain			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Organ failure			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	6 / 18316 (0.03%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	9 / 18316 (0.05%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 10	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral swelling			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	1 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden death			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden cardiac death			
subjects affected / exposed	7 / 18316 (0.04%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 7	0 / 0	0 / 0
Strangulated hernia			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stent-graft endoleak			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical failure			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular stent thrombosis			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular stent stenosis			

subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular stent occlusion			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Unevaluable event			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ulcer haemorrhage			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Swelling face			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Withdrawal syndrome			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic shock			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaphylactic reaction			
subjects affected / exposed	4 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Allergy to arthropod sting			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaphylactoid reaction			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anti-neutrophil cytoplasmic antibody positive vasculitis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Secondary immunodeficiency			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug hypersensitivity			
subjects affected / exposed	4 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contrast media allergy			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Social circumstances			
Organ donor			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			

Acquired phimosis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adnexa uteri mass			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Balanoposthitis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign prostatic hyperplasia			
subjects affected / exposed	32 / 18316 (0.17%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 32	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast disorder			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Genital haemorrhage			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast mass			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical dysplasia			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystocele			

subjects affected / exposed	4 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial hyperplasia			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast enlargement			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Genital prolapse			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gynaecomastia			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cyst			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic organ prolapse			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic pain			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Testicular mass			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatic obstruction			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatitis			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatomegaly			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectocele			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postmenopausal haemorrhage			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urogenital prolapse			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine adhesions			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine prolapse			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterovaginal prolapse			
subjects affected / exposed	5 / 18316 (0.03%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal prolapse			
subjects affected / exposed	4 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	5 / 18316 (0.03%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory distress syndrome			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Acute respiratory failure			
subjects affected / exposed	44 / 18316 (0.24%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 49	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 6	0 / 0	0 / 0
Aspiration			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	15 / 18316 (0.08%)	0 / 998 (0.00%)	1 / 504 (0.20%)
occurrences causally related to treatment / all	0 / 17	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma-chronic obstructive pulmonary disease overlap syndrome			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthmatic crisis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atelectasis			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiectasis			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis chronic			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchospasm			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chylothorax			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			

subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	21 / 18316 (0.11%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 22	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Emphysema			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	5 / 18316 (0.03%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	94 / 18316 (0.51%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 117	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 0
Organising pneumonia			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	6 / 18316 (0.03%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Idiopathic pulmonary fibrosis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial lung disease			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung consolidation			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstructive sleep apnoea syndrome			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infiltration			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mediastinal mass			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal polyps			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstructive airways disorder			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung disorder			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngeal haemorrhage			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngeal swelling			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	8 / 18316 (0.04%)	1 / 998 (0.10%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 8	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural fibrosis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleurisy			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	31 / 18316 (0.17%)	0 / 998 (0.00%)	1 / 504 (0.20%)
occurrences causally related to treatment / all	0 / 33	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pneumomediastinum			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis aspiration			

subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	10 / 18316 (0.05%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 11	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pneumothorax spontaneous			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleuritic pain			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary fibrosis			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary haemorrhage			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary hypertension			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary mass			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary sarcoidosis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary thrombosis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory arrest			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Respiratory disorder			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	7 / 18316 (0.04%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	19 / 18316 (0.10%)	1 / 998 (0.10%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 20	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 5	0 / 0	0 / 0
Respiratory symptom			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus polyp			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sleep apnoea syndrome			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stridor			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vocal cord atrophy			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Acute psychosis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute stress disorder			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcohol abuse			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bipolar I disorder			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcohol withdrawal syndrome			

subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcoholism			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bipolar disorder			
subjects affected / exposed	5 / 18316 (0.03%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcohol use disorder			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Completed suicide			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Compulsive sexual behaviour			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Confusional state			
subjects affected / exposed	4 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			

subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delusion			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Major depression			
subjects affected / exposed	7 / 18316 (0.04%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression suicidal			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug abuse			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised anxiety disorder			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Homicidal ideation			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intentional self-injury			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			

subjects affected / exposed	11 / 18316 (0.06%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 12	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mania			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental disorder			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	11 / 18316 (0.06%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 12	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post-traumatic stress disorder			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychotic disorder			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Schizophrenia			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Substance-induced psychotic disorder			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Substance abuse			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Substance use disorder			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Schizoaffective disorder depressive type			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide attempt			
subjects affected / exposed	4 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device loosening			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device dislocation			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device extrusion			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device failure			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device capturing issue			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device occlusion			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device power source issue			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	6 / 18316 (0.03%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary dilatation			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary colic			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile duct stone			
subjects affected / exposed	8 / 18316 (0.04%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 8	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile duct stenosis			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune hepatitis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcoholic liver disease			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic hepatic failure			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	30 / 18316 (0.16%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 30	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis chronic			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	18 / 18316 (0.10%)	1 / 998 (0.10%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 19	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	20 / 18316 (0.11%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 20	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis sclerosing			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congestive hepatopathy			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug-induced liver injury			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder polyp			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder rupture			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic calcification			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic cirrhosis			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Hepatic cyst			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic fibrosis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic function abnormal			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic haematoma			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic lesion			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic mass			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic steatosis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Primary biliary cholangitis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perforation bile duct			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver disorder			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Anticoagulation drug level above therapeutic			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine abnormal			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood potassium abnormal			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enzyme level abnormal			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood pressure increased			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug level decreased			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood potassium decreased			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibrin D dimer increased			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal stoma output increased			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoglobin decreased			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oxygen saturation decreased			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic enzyme increased			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test increased			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Occult blood			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heart rate irregular			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin increased			
subjects affected / exposed	4 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urine output decreased			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight decreased			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
White blood cell count decreased			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Abdominal injury			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Accident			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Accidental overdose			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acetabulum fracture			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcohol poisoning			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle fracture			
subjects affected / exposed	12 / 18316 (0.07%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 12	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anastomotic leak			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Animal bite			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia postoperative			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial injury			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriovenous fistula maturation failure			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthropod bite			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain contusion			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back injury			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bite			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone contusion			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Avulsion fracture			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Burns second degree			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Burns third degree			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carbon monoxide poisoning			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral hyperperfusion syndrome			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cataract operation complication			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Central cord syndrome			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac procedure complication			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical vertebral fracture			

subjects affected / exposed	5 / 18316 (0.03%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest injury			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clavicle fracture			
subjects affected / exposed	4 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Costal cartilage fracture			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Complications of bone marrow transplant			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contusion			
subjects affected / exposed	4 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Complicated fracture			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Craniocerebral injury			

subjects affected / exposed	11 / 18316 (0.06%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 11	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear injury			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exposure to extreme temperature			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Face injury			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye contusion			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye injury			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extradural haematoma			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial bones fracture			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			

subjects affected / exposed	16 / 18316 (0.09%)	1 / 998 (0.10%)	1 / 504 (0.20%)
occurrences causally related to treatment / all	0 / 16	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral neck fracture			
subjects affected / exposed	10 / 18316 (0.05%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 10	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot fracture			
subjects affected / exposed	6 / 18316 (0.03%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibula fracture			
subjects affected / exposed	3 / 18316 (0.02%)	1 / 998 (0.10%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flail chest			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	28 / 18316 (0.15%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 29	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Forearm fracture			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body in gastrointestinal tract			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body ingestion			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gun shot wound			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fractured coccyx			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fractured sacrum			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal anastomotic leak			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fracture displacement			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hand fracture			
subjects affected / exposed	11 / 18316 (0.06%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 12	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	9 / 18316 (0.05%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 9	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Heat exhaustion			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incarcerated incisional hernia			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	28 / 18316 (0.15%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 29	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			
subjects affected / exposed	15 / 18316 (0.08%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 15	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heat stroke			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incision site haematoma			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incision site impaired healing			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incisional hernia			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intentional overdose			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	1 / 18316 (0.01%)	1 / 998 (0.10%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incomplete spinal fusion			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint dislocation			
subjects affected / exposed	6 / 18316 (0.03%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint injury			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament injury			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			
subjects affected / exposed	10 / 18316 (0.05%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 10	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament sprain			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb crushing injury			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb injury			
subjects affected / exposed	8 / 18316 (0.04%)	0 / 998 (0.00%)	1 / 504 (0.20%)
occurrences causally related to treatment / all	0 / 8	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament rupture			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar vertebral fracture			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscus injury			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple fractures			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Open fracture			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle strain			

subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neck injury			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple injuries			
subjects affected / exposed	8 / 18316 (0.04%)	0 / 998 (0.00%)	1 / 504 (0.20%)
occurrences causally related to treatment / all	0 / 8	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Petroleum distillate poisoning			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteophyte fracture			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Patella fracture			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed	8 / 18316 (0.04%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 8	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perineal injury			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital haematoma			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periprosthetic fracture			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post concussion syndrome			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post-traumatic pain			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax traumatic			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	1 / 504 (0.20%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngeal injury			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post laminectomy syndrome			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural complication			

subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Post procedural fever			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haematoma			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haematuria			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haemorrhage			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural hypotension			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural stroke			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative ileus			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative wound complication			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary contusion			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pneumothorax			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pain			
subjects affected / exposed	10 / 18316 (0.05%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 11	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural haemorrhage			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radiation oesophagitis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	16 / 18316 (0.09%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 16	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory fume inhalation disorder			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius fracture			

subjects affected / exposed	10 / 18316 (0.05%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 10	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	7 / 18316 (0.04%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 0
Sciatic nerve injury			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal column injury			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skull fracture			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin laceration			
subjects affected / exposed	5 / 18316 (0.03%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin injury			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin abrasion			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seroma			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	6 / 18316 (0.03%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sternal fracture			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress fracture			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	11 / 18316 (0.06%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 11	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stab wound			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic rupture			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal fracture			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haemorrhage			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon injury			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon rupture			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thermal burn			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic fracture			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia fracture			
subjects affected / exposed	4 / 18316 (0.02%)	1 / 998 (0.10%)	1 / 504 (0.20%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxicity to various agents			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thoracic vertebral fracture			
subjects affected / exposed	4 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic haematoma			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic haemothorax			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic lung injury			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention postoperative			
subjects affected / exposed	2 / 18316 (0.01%)	1 / 998 (0.10%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			
subjects affected / exposed	7 / 18316 (0.04%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral injury			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ulna fracture			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular pseudoaneurysm			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vulvovaginal injury			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound evisceration			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound haemorrhage			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrist fracture			
subjects affected / exposed	7 / 18316 (0.04%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound dehiscence			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Atrial septal defect			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bicuspid aortic valve			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertrophic cardiomyopathy			

subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Corneal dystrophy			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermoid cyst			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fabry's disease			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocele			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital cystic kidney disease			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myotonic dystrophy			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Phimosis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute coronary syndrome			

subjects affected / exposed	14 / 18316 (0.08%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 16	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Acute left ventricular failure			
subjects affected / exposed	8 / 18316 (0.04%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 8	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 0
Acute myocardial infarction			
subjects affected / exposed	73 / 18316 (0.40%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 75	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 8	0 / 0	0 / 0
Angina pectoris			
subjects affected / exposed	20 / 18316 (0.11%)	1 / 998 (0.10%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 21	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	83 / 18316 (0.45%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 92	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriosclerosis coronary artery			
subjects affected / exposed	4 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia supraventricular			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia			
subjects affected / exposed	7 / 18316 (0.04%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 8	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 0
Aortic valve stenosis			

subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic valve incompetence			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic valve disease			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic valve calcification			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina unstable			
subjects affected / exposed	23 / 18316 (0.13%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 25	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	10 / 18316 (0.05%)	1 / 998 (0.10%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 10	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	66 / 18316 (0.36%)	1 / 998 (0.10%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 69	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 64	0 / 0	0 / 0
Bundle branch block right			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bundle branch block left			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradycardia			
subjects affected / exposed	12 / 18316 (0.07%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 12	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorder			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block second degree			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block complete			
subjects affected / exposed	14 / 18316 (0.08%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 14	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial tachycardia			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular dissociation			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac perfusion defect			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac tamponade			
subjects affected / exposed	4 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Cardiac valve disease			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac ventricular thrombosis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardio-respiratory arrest			
subjects affected / exposed	17 / 18316 (0.09%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 17	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 14	0 / 0	0 / 0
Cardiogenic shock			
subjects affected / exposed	9 / 18316 (0.05%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 9	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Cardiomyopathy			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiopulmonary failure			
subjects affected / exposed	8 / 18316 (0.04%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 8	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 8	0 / 0	0 / 0
Cardiac failure			

subjects affected / exposed	26 / 18316 (0.14%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 32	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure acute			
subjects affected / exposed	11 / 18316 (0.06%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 11	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Cardiac failure chronic			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	48 / 18316 (0.26%)	1 / 998 (0.10%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 52	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Cardiovascular disorder			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic left ventricular failure			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congestive cardiomyopathy			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cor pulmonale			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			

subjects affected / exposed	62 / 18316 (0.34%)	1 / 998 (0.10%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 67	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Hypertensive cardiomyopathy			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery occlusion			
subjects affected / exposed	1 / 18316 (0.01%)	1 / 998 (0.10%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery stenosis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Degenerative aortic valve disease			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extrasystoles			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery dissection			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracardiac thrombus			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic cardiomyopathy			

subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Left ventricular failure			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mitral valve disease			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mitral valve incompetence			
subjects affected / exposed	5 / 18316 (0.03%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nodal arrhythmia			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mitral valve stenosis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	52 / 18316 (0.28%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 54	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 18	0 / 0	0 / 0
Myocardial ischaemia			
subjects affected / exposed	17 / 18316 (0.09%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 17	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Myocarditis			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mitral valve prolapse			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nodal rhythm			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Palpitations			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis constrictive			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus arrhythmia			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rheumatic heart disease			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Right ventricular failure			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Silent myocardial infarction			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus arrest			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prinzmetal angina			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus bradycardia			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus node dysfunction			
subjects affected / exposed	8 / 18316 (0.04%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 8	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress cardiomyopathy			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular extrasystoles			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	7 / 18316 (0.04%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 9	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular extrasystoles			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia paroxysmal			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tricuspid valve incompetence			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Trifascicular block			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular arrhythmia			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Tachyarrhythmia			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular fibrillation			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular tachyarrhythmia			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular tachycardia			
subjects affected / exposed	8 / 18316 (0.04%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 8	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Aphasia			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcoholic seizure			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Altered state of consciousness			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amnesia			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amyotrophic lateral sclerosis			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arachnoiditis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basilar artery aneurysm			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bell's palsy			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain injury			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 0
Brain oedema			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery stenosis			
subjects affected / exposed	11 / 18316 (0.06%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 11	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain stem infarction			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid arteriosclerosis			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery aneurysm			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery occlusion			
subjects affected / exposed	4 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain stem haemorrhage			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carpal tunnel syndrome			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cauda equina syndrome			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Central nervous system lesion			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Cerebellar infarction			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebellar stroke			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	50 / 18316 (0.27%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 51	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 10	0 / 0	0 / 0
Cerebral haemorrhage			
subjects affected / exposed	5 / 18316 (0.03%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	9 / 18316 (0.05%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 9	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral ischaemia			
subjects affected / exposed	8 / 18316 (0.04%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 9	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 0
Cerebral small vessel ischaemic disease			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrospinal fluid leakage			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haematoma			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cognitive disorder			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dementia			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dementia Alzheimer's type			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Diabetic coma			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic neuropathy			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic inflammatory demyelinating polyradiculoneuropathy			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysarthria			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular disorder			
subjects affected / exposed	6 / 18316 (0.03%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular insufficiency			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical cord compression			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical radiculopathy			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	5 / 18316 (0.03%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embololic stroke			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	4 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Essential tremor			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial paresis			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	5 / 18316 (0.03%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Haemorrhagic cerebral infarction			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic stroke			
subjects affected / exposed	7 / 18316 (0.04%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 4	0 / 0	0 / 0
Headache			
subjects affected / exposed	4 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised tonic-clonic seizure			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiplegia			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocephalus			

subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive encephalopathy			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoaesthesia			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxic-ischaemic encephalopathy			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic cerebral infarction			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune effector cell-associated neurotoxicity syndrome			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial aneurysm			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial haematoma			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Intracranial mass			

subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Intraventricular haemorrhage			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
IIIrd nerve paralysis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	52 / 18316 (0.28%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 52	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
IVth nerve paralysis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lacunar infarction			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lacunar stroke			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of consciousness			
subjects affected / exposed	7 / 18316 (0.04%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Lumbar radiculopathy			

subjects affected / exposed	4 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meralgia paraesthetica			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic encephalopathy			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Monoparesis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Morton's neuralgia			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Motor dysfunction			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Motor neurone disease			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple system atrophy			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle spasticity			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myasthenia gravis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelopathy			
subjects affected / exposed	4 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorder			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuropathy peripheral			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Normal pressure hydrocephalus			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Optic neuritis			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nerve compression			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Primary progressive aphasia			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paralysis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraplegia			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parkinson's disease			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parkinsonism			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral sensorimotor neuropathy			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peroneal nerve palsy			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Petit mal epilepsy			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Posterior reversible encephalopathy syndrome			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral motor neuropathy			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudostroke			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychogenic seizure			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			

subjects affected / exposed	4 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Simple partial seizures			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Speech disorder			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal claudication			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	9 / 18316 (0.05%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	1 / 9	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord infarction			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal meningeal cyst			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal stroke			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status epilepticus			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thalamus haemorrhage			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	52 / 18316 (0.28%)	0 / 998 (0.00%)	1 / 504 (0.20%)
occurrences causally related to treatment / all	0 / 56	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Temporal lobe epilepsy			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thalamic infarction			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subarachnoid haemorrhage			
subjects affected / exposed	6 / 18316 (0.03%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thoracic radiculopathy			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxic encephalopathy			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient global amnesia			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vasogenic cerebral oedema			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Unresponsive to stimuli			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular dementia			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	24 / 18316 (0.13%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	1 / 24	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertebral artery dissection			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertebrobasilar insufficiency			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertebrobasilar stroke			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vocal cord paralysis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial paralysis	Additional description: One event of facial paralysis assessed related to study drug by investigator; assessed not related by Sponsor due to participant's medical history and later developments suggesting another explanation for event.		
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Guillain-Barre syndrome	Additional description: Incidence of Guillain-Barre syndrome was balanced between groups, none of the events occurred <500 days following study injection and none were assessed as related to the study vaccine.		
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia vitamin B12 deficiency			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			
subjects affected / exposed	25 / 18316 (0.14%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 26	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia macrocytic			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune haemolytic anaemia			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Blood loss anaemia			
subjects affected / exposed	4 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Methaemoglobinaemia			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukopenia			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenopathy mediastinal			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune thrombocytopenia			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coagulopathy			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heparin-induced thrombocytopenia			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron deficiency anaemia			
subjects affected / exposed	5 / 18316 (0.03%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	9 / 18316 (0.05%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 10	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spontaneous haematoma			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenomegaly			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic infarction			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic haemorrhage			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	4 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Normocytic anaemia			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Normochromic anaemia			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Microcytic anaemia			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Tympanic membrane perforation			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertigo			
subjects affected / exposed	11 / 18316 (0.06%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 11	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertigo positional			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Cataract			
subjects affected / exposed	4 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cataract nuclear			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Conjunctival cyst			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Corneal leukoma			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blindness unilateral			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amaurosis fugax			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angle closure glaucoma			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Corneal thinning			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diplopia			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ectropion			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine ophthalmopathy			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epiretinal membrane			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Macular degeneration			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eyelid ptosis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glaucoma			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Keratoconus			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lens dislocation			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye haemorrhage			
subjects affected / exposed	0 / 18316 (0.00%)	1 / 998 (0.10%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Macular hole			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metamorphopsia			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neovascular age-related macular degeneration			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ocular vascular disorder			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Open angle glaucoma			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal detachment			
subjects affected / exposed	3 / 18316 (0.02%)	1 / 998 (0.10%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Optic neuropathy			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pterygium			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal artery occlusion			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal degeneration			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Optic atrophy			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal tear			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal vein occlusion			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinopathy hypertensive			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vision blurred			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Visual acuity reduced			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vitreous haemorrhage			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Visual impairment			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal hernia obstructive			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal adhesions			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal fat apron			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal hernia			
subjects affected / exposed	7 / 18316 (0.04%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal hernia perforation			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal incarcerated hernia			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal mass			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	10 / 18316 (0.05%)	0 / 998 (0.00%)	1 / 504 (0.20%)
occurrences causally related to treatment / all	0 / 10	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal rigidity			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acid peptic disease			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute abdomen			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcoholic pancreatitis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal fissure			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal fistula			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	5 / 18316 (0.03%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Barrett's oesophagus			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cannabinoid hyperemesis syndrome			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic gastritis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic gastrointestinal bleeding			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coeliac disease			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ischaemic			

subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis microscopic			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ulcerative			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon dysplasia			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	11 / 18316 (0.06%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 12	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticular perforation			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum intestinal			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum intestinal haemorrhagic			

subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal obstruction			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	9 / 18316 (0.05%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 9	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer haemorrhage			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Crohn's disease			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diaphragmatic hernia			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diaphragmatic hernia, obstructive			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer			
subjects affected / exposed	4 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer perforation			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenitis			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysbiosis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspepsia			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Food poisoning			
subjects affected / exposed	4 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Faeces discoloured			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral hernia strangulated			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flatulence			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric disorder			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric perforation			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric polyps			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric stenosis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer			
subjects affected / exposed	5 / 18316 (0.03%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal ulcer haemorrhage			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer perforation			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric volvulus			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal fistula			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	8 / 18316 (0.04%)	1 / 998 (0.10%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 8	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer haemorrhage			
subjects affected / exposed	4 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
subjects affected / exposed	4 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gingival bleeding			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glossitis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematochezia			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoperitoneum			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic erosive gastritis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoids			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hiatus hernia			

subjects affected / exposed	11 / 18316 (0.06%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 11	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileal perforation			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incarcerated inguinal hernia			
subjects affected / exposed	0 / 18316 (0.00%)	1 / 998 (0.10%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus paralytic			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired gastric emptying			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	4 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incarcerated umbilical hernia			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	24 / 18316 (0.13%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 25	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia perforation			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal fistula			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia, obstructive			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal cyst			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia strangulated			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal pseudo-obstruction			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal perforation			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	21 / 18316 (0.11%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 24	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Intestinal ischaemia			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal haemorrhage			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal haematoma			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intra-abdominal fluid collection			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intra-abdominal haematoma			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar hernia			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Large intestine polyp			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Large intestinal ulcer			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mallory-Weiss syndrome			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstruction gastric			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstructive pancreatitis			
subjects affected / exposed	4 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Odynophagia			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal achalasia			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal food impaction			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal perforation			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal stenosis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal ulcer			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal varices haemorrhage			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis haemorrhagic			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic cyst			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic disorder			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peptic ulcer haemorrhage			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peptic ulcer			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatolithiasis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis necrotising			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	6 / 18316 (0.03%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			

subjects affected / exposed	8 / 18316 (0.04%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 8	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic mass			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Proctitis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritoneal adhesions			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peptic ulcer perforation			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal prolapse			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retroperitoneal haemorrhage			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salivary gland cyst			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Strangulated umbilical hernia			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal perforation			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	12 / 18316 (0.07%)	1 / 998 (0.10%)	1 / 504 (0.20%)
occurrences causally related to treatment / all	0 / 13	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	13 / 18316 (0.07%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 15	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			
subjects affected / exposed	8 / 18316 (0.04%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 8	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombosis mesenteric vessel			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Terminal ileitis			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varices oesophageal			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Volvulus			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	5 / 18316 (0.03%)	1 / 998 (0.10%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Diabetic foot			
subjects affected / exposed	8 / 18316 (0.04%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 10	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute generalised exanthematous pustulosis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angioedema			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blister			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Decubitus ulcer			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic wound			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug eruption			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug reaction with eosinophilia and systemic symptoms			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Excessive skin			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hidradenitis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stevens-Johnson syndrome			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Panniculitis			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Petechiae			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pruritus			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin ulcer			
subjects affected / exposed	5 / 18316 (0.03%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intertrigo			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous emphysema			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urticaria			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	56 / 18316 (0.31%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 59	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anuria			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder perforation			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder prolapse			
subjects affected / exposed	4 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	12 / 18316 (0.07%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 12	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus urinary			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic kidney disease			
subjects affected / exposed	17 / 18316 (0.09%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 19	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis haemorrhagic			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
End stage renal disease			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glomerulonephritis rapidly progressive			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus bladder			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	4 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertonic bladder			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	26 / 18316 (0.14%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 28	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephropathy			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal colic			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postrenal failure			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal artery stenosis			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal artery thrombosis			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oliguria			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cortical necrosis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cyst haemorrhage			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cyst ruptured			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal infarct			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	5 / 18316 (0.03%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal haematoma			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal impairment			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal disorder			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal mass			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal tubular necrosis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal vascular thrombosis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stag horn calculus			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureteric stenosis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcapsular renal haematoma			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureteric fistula			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureteric obstruction			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress urinary incontinence			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral obstruction			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral stenosis			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urge incontinence			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary bladder haemorrhage			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary bladder polyp			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral meatus stenosis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary incontinence			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	10 / 18316 (0.05%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 10	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureterolithiasis			
subjects affected / exposed	7 / 18316 (0.04%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 8	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral cyst			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary hesitation			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Hyperparathyroidism primary			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adrenal mass			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basedow's disease			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Goitre			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperparathyroidism			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adrenal haemorrhage			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoparathyroidism secondary			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Primary hyperaldosteronism			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyrotoxic crisis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypothyroidism			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Articular calcification			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthralgia			
subjects affected / exposed	7 / 18316 (0.04%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthropathy			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	1 / 504 (0.20%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	24 / 18316 (0.13%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 26	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone cyst			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bursitis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical spinal stenosis			
subjects affected / exposed	9 / 18316 (0.05%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 10	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chondropathy			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Compartment syndrome			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Costochondritis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dupuytren's contracture			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exostosis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibromyalgia			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot deformity			
subjects affected / exposed	5 / 18316 (0.03%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematoma muscle			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemarthrosis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Greater trochanteric pain syndrome			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fracture pain			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fracture nonunion			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligamentum flavum hypertrophy			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Kyphoscoliosis			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mobility decreased			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Lumbar spinal stenosis			
subjects affected / exposed	9 / 18316 (0.05%)	0 / 998 (0.00%)	1 / 504 (0.20%)
occurrences causally related to treatment / all	0 / 9	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint instability			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint effusion			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
subjects affected / exposed	15 / 18316 (0.08%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 17	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc disorder			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc degeneration			
subjects affected / exposed	5 / 18316 (0.03%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc compression			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neck pain			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	108 / 18316 (0.59%)	2 / 998 (0.20%)	4 / 504 (0.79%)
occurrences causally related to treatment / all	0 / 109	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteochondrosis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoporosis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myalgia			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myositis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myopathy			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal chest pain			
subjects affected / exposed	7 / 18316 (0.04%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal pain			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neck mass			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seronegative arthritis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator cuff syndrome			
subjects affected / exposed	8 / 18316 (0.04%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 8	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator cuff tear arthropathy			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scoliosis			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhabdomyolysis			
subjects affected / exposed	4 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polymyalgia rheumatica			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periarthritis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pathological fracture			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Patellofemoral pain syndrome			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoporotic fracture			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal retrolisthesis			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal osteoarthritis			
subjects affected / exposed	8 / 18316 (0.04%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 8	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal deformity			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sjogren's syndrome			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal stenosis			
subjects affected / exposed	7 / 18316 (0.04%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Synovial cyst			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendonitis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tenosynovitis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Torticollis			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertebral foraminal stenosis			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spondylolisthesis			
subjects affected / exposed	5 / 18316 (0.03%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal sepsis			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal abscess			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal wall abscess			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess intestinal			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess jaw			
subjects affected / exposed	0 / 18316 (0.00%)	1 / 998 (0.10%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendiceal abscess			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal abscess			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenovirus infection			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute sinusitis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute hepatitis C			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess limb			
subjects affected / exposed	7 / 18316 (0.04%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asymptomatic COVID-19			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asymptomatic bacteriuria			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis infective			

subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis perforated			
subjects affected / exposed	5 / 18316 (0.03%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	22 / 18316 (0.12%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 22	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atypical mycobacterial infection			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atypical pneumonia			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	7 / 18316 (0.04%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cellulitis			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain abscess			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial sepsis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial prostatitis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial food poisoning			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Campylobacter gastroenteritis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bursitis infective			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			

subjects affected / exposed	43 / 18316 (0.23%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 45	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis orbital			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis staphylococcal			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis infective			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholera			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Complicated appendicitis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	5 / 18316 (0.03%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronavirus infection			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dacryocystitis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	8 / 18316 (0.04%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 8	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	24 / 18316 (0.13%)	0 / 998 (0.00%)	1 / 504 (0.20%)
occurrences causally related to treatment / all	0 / 25	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysentery			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	24 / 18316 (0.13%)	1 / 998 (0.10%)	1 / 504 (0.20%)
occurrences causally related to treatment / all	0 / 27	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Ear infection			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dengue fever			

subjects affected / exposed	9 / 18316 (0.05%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 9	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dengue haemorrhagic fever			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Echinococcosis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocarditis			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocarditis bacterial			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Enterobacter sepsis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterococcal bacteraemia			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterococcal sepsis			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Emphysematous cystitis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Empyema			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Epididymitis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia bacteraemia			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia sepsis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extradural abscess			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Focal peritonitis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Furuncle			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fracture infection			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fournier's gangrene			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder abscess			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	16 / 18316 (0.09%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 17	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Gastric infection			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gangrene			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder empyema			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis bacterial			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	4 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Groin abscess			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gingivitis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Giardiasis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal infection			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
H1N1 influenza			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemophilus infection			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematoma infection			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
H3N2 influenza			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HCoV-OC43 infection			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HIV infection			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes oesophagitis			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic cyst infection			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected cyst			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected bite			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocele male infected			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected skin ulcer			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infectious pleural effusion			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective exacerbation of bronchiectasis			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	19 / 18316 (0.10%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 19	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective spondylitis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral discitis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella bacteraemia			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Kidney infection			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	1 / 504 (0.20%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint abscess			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal tuberculosis			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella infection			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella sepsis			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine infection			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Latent syphilis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leptospirosis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver abscess			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised infection			
subjects affected / exposed	4 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis bacterial			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	7 / 18316 (0.04%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 8	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung abscess			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mastoiditis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mediastinitis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medical device site infection			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mycobacterial infection			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Murine typhus			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucormycosis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metapneumovirus pneumonia			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metapneumovirus infection			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis viral			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mycobacterium avium complex infection			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis borrelia			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis acute			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			

subjects affected / exposed	12 / 18316 (0.07%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 13	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orchitis			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ophthalmic herpes zoster			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic sepsis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Necrotising fasciitis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis chronic			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paronychia			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	4 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis externa			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pasteurella infection			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	1 / 504 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perihepatic abscess			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital cellulitis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumococcal sepsis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Plasmodium vivax infection			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pilonidal disease			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			

subjects affected / exposed	147 / 18316 (0.80%)	3 / 998 (0.30%)	2 / 504 (0.40%)
occurrences causally related to treatment / all	0 / 163	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 6	0 / 0	0 / 0
Pneumonia influenzal			
subjects affected / exposed	6 / 18316 (0.03%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia haemophilus			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	8 / 18316 (0.04%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 8	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	11 / 18316 (0.06%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 11	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia klebsiella			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia legionella			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia pneumococcal			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia parainfluenzae viral			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia necrotising			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia mycoplasmal			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia pseudomonal			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative abscess			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative wound infection			
subjects affected / exposed	9 / 18316 (0.05%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 11	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prosthetic valve endocarditis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia staphylococcal			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia streptococcal			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia viral			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural infection			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonal bacteraemia			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonas infection			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psoas abscess			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary sepsis			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary tuberculosis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Puncture site infection			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	10 / 18316 (0.05%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 10	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal abscess			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal abscess			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	9 / 18316 (0.05%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 9	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection fungal			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotavirus infection			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salmonellosis			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sialoadenitis			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shigella infection			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	22 / 18316 (0.12%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 22	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 6	0 / 0	0 / 0
Septic encephalopathy			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	44 / 18316 (0.24%)	2 / 998 (0.20%)	1 / 504 (0.20%)
occurrences causally related to treatment / all	0 / 44	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 4	0 / 0	0 / 0
Scrotal infection			
subjects affected / exposed	0 / 18316 (0.00%)	1 / 998 (0.10%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scrotal cellulitis			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal abscess			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord abscess			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin infection			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal infection			
subjects affected / exposed	4 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal osteomyelitis			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal sepsis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Strongyloidiasis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal sepsis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal bacteraemia			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stoma site cellulitis			
subjects affected / exposed	0 / 18316 (0.00%)	1 / 998 (0.10%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal skin infection			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombophlebitis septic			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tetanus			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superinfection			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Submandibular abscess			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous abscess			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tinea capitis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tinea pedis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tuberculosis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheobronchitis bacterial			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxic shock syndrome streptococcal			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth abscess			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Typhoid fever			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract candidiasis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection staphylococcal			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection pseudomonal			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection enterococcal			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection bacterial			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	76 / 18316 (0.41%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 81	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Vascular device infection			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	13 / 18316 (0.07%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 13	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Vestibular neuronitis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral sepsis			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection bacterial			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection staphylococcal			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound sepsis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	25 / 18316 (0.14%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 25	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cachexia			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Decreased appetite			

subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus			
subjects affected / exposed	5 / 18316 (0.03%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus inadequate control			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			
subjects affected / exposed	4 / 18316 (0.02%)	1 / 998 (0.10%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Fluid retention			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyslipidaemia			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrolyte imbalance			
subjects affected / exposed	4 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic metabolic decompensation			

subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Food intolerance			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glucose tolerance impaired			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gout			
subjects affected / exposed	4 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	4 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	3 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemic hyperosmolar nonketotic syndrome			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			

subjects affected / exposed	7 / 18316 (0.04%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 8	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	6 / 18316 (0.03%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypomagnesaemia			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			
subjects affected / exposed	4 / 18316 (0.02%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperuricaemia			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypervolaemia			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoalbuminaemia			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypernatraemia			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			

subjects affected / exposed	7 / 18316 (0.04%)	0 / 998 (0.00%)	2 / 504 (0.40%)
occurrences causally related to treatment / all	0 / 7	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemia			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron deficiency			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic alkalosis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malnutrition			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Metabolic acidosis			
subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lactic acidosis			
subjects affected / exposed	2 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obesity			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock hypoglycaemic			

subjects affected / exposed	1 / 18316 (0.01%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 2 diabetes mellitus			
subjects affected / exposed	9 / 18316 (0.05%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 9	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uraemic acidosis			
subjects affected / exposed	0 / 18316 (0.00%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part A: mRNA-1345		
Total subjects affected by serious adverse events			
subjects affected / exposed	2773 / 18369 (15.10%)		
number of deaths (all causes)	301		
number of deaths resulting from adverse events	301		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute myeloid leukaemia			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Adenocarcinoma			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Adenocarcinoma gastric			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Adenocarcinoma metastatic			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Adenocarcinoma of colon				
subjects affected / exposed	10 / 18369 (0.05%)			
occurrences causally related to treatment / all	0 / 12			
deaths causally related to treatment / all	0 / 0			
Adenocarcinoma pancreas				
subjects affected / exposed	2 / 18369 (0.01%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 1			
B-cell small lymphocytic lymphoma				
subjects affected / exposed	1 / 18369 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Anal cancer				
subjects affected / exposed	1 / 18369 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Anal squamous cell carcinoma				
subjects affected / exposed	1 / 18369 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Anaplastic thyroid cancer				
subjects affected / exposed	0 / 18369 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
B-cell lymphoma				
subjects affected / exposed	2 / 18369 (0.01%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
B-cell lymphoma stage IV				
subjects affected / exposed	0 / 18369 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Adrenocortical carcinoma				

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Basal cell carcinoma			
subjects affected / exposed	13 / 18369 (0.07%)		
occurrences causally related to treatment / all	0 / 15		
deaths causally related to treatment / all	0 / 0		
Basosquamous carcinoma of skin			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Benign bone neoplasm			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Benign gastrointestinal neoplasm			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Benign lung neoplasm			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Benign renal neoplasm			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Benign neoplasm of ampulla of Vater			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Benign neoplasm of bladder			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Benign ovarian tumour			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Benign pericardium neoplasm			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Benign mediastinal neoplasm			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bile duct cancer			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bladder cancer			
subjects affected / exposed	4 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Bladder cancer recurrent			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bladder cancer stage IV			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bladder neoplasm			

subjects affected / exposed	1 / 18369 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Brain neoplasm benign				
subjects affected / exposed	0 / 18369 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bladder transitional cell carcinoma				
subjects affected / exposed	2 / 18369 (0.01%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Bone cancer				
subjects affected / exposed	0 / 18369 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bowen's disease				
subjects affected / exposed	0 / 18369 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Brain cancer metastatic				
subjects affected / exposed	1 / 18369 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Brain neoplasm				
subjects affected / exposed	1 / 18369 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bladder squamous cell carcinoma stage unspecified				
subjects affected / exposed	1 / 18369 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Brain neoplasm malignant				

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Breast cancer			
subjects affected / exposed	9 / 18369 (0.05%)		
occurrences causally related to treatment / all	0 / 10		
deaths causally related to treatment / all	0 / 0		
Breast cancer in situ			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Breast cancer metastatic			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 2		
Breast cancer stage I			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac neoplasm unspecified			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bronchial neoplasm			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cancer pain			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Carcinoid tumour of the stomach			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Carcinoid tumour pulmonary			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Carcinoma in situ of skin			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bronchial carcinoma			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Central nervous system lymphoma			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cervix carcinoma			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cervix carcinoma stage II			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholangiocarcinoma			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Cholesteatoma			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Colon cancer stage III			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Clear cell renal cell carcinoma			
subjects affected / exposed	4 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Colon cancer			
subjects affected / exposed	11 / 18369 (0.06%)		
occurrences causally related to treatment / all	0 / 12		
deaths causally related to treatment / all	0 / 1		
Colon cancer metastatic			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Colon cancer stage 0			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Colon cancer stage II			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Chronic lymphocytic leukaemia			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Cutaneous T-cell lymphoma			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diffuse large B-cell lymphoma			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ductal adenocarcinoma of pancreas			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Elastofibroma			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Endometrial adenocarcinoma			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Colorectal cancer stage I			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Epithelioid mesothelioma			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Colon neoplasm			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Colorectal adenocarcinoma			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Colorectal adenoma			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Colorectal cancer			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Endometrial sarcoma			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Extranodal marginal zone B-cell lymphoma (MALT type)			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Fallopian tube cancer stage III			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Follicular lymphoma			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gallbladder adenocarcinoma			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Gallbladder cancer			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Glioblastoma			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastric cancer			
subjects affected / exposed	5 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 1		
Gastric cancer stage 0			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal lymphoma			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal stromal tumour			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Genitourinary tract neoplasm			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gallbladder neoplasm			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Glioblastoma multiforme			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemangioma of bone			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Haemangioma of liver			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatic cancer			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 2		
Hepatic cancer metastatic			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Hepatocellular carcinoma			
subjects affected / exposed	7 / 18369 (0.04%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 1		
Hodgkin's disease			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hormone receptor positive HER2 negative breast cancer			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infected neoplasm			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intestinal adenocarcinoma			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intraductal papillary breast neoplasm			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intraductal papillary mucinous neoplasm			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intraductal proliferative breast lesion			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Invasive breast carcinoma			
subjects affected / exposed	5 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Invasive ductal breast carcinoma			
subjects affected / exposed	14 / 18369 (0.08%)		
occurrences causally related to treatment / all	0 / 14		
deaths causally related to treatment / all	0 / 0		
Invasive lobular breast carcinoma			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Laryngeal squamous cell carcinoma			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Kaposi's sarcoma			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Keratoacanthoma			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Large intestine benign neoplasm			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Laryngeal cancer			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Laryngeal neoplasm			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Invasive papillary breast carcinoma			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Leukaemia			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Linitis plastica			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lip and/or oral cavity cancer			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lipoma			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Liposarcoma			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lung carcinoma cell type unspecified stage I			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lung adenocarcinoma			
subjects affected / exposed	10 / 18369 (0.05%)		
occurrences causally related to treatment / all	0 / 11		
deaths causally related to treatment / all	0 / 3		
Lung adenocarcinoma stage IV			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lung cancer metastatic			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Lung carcinoma cell type unspecified recurrent			

subjects affected / exposed	1 / 18369 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lobular breast carcinoma in situ				
subjects affected / exposed	0 / 18369 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Malignant neoplasm of unknown primary site				
subjects affected / exposed	0 / 18369 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung carcinoma cell type unspecified stage IV				
subjects affected / exposed	3 / 18369 (0.02%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 2			
Lung neoplasm				
subjects affected / exposed	1 / 18369 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lung neoplasm malignant				
subjects affected / exposed	12 / 18369 (0.07%)			
occurrences causally related to treatment / all	0 / 12			
deaths causally related to treatment / all	0 / 4			
Lymphocytic leukaemia				
subjects affected / exposed	1 / 18369 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Malignant melanoma stage I				
subjects affected / exposed	0 / 18369 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Malignant ascites				

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 1		
Malignant genitourinary tract neoplasm			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Malignant glioma			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Malignant melanoma			
subjects affected / exposed	4 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Malignant melanoma in situ			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lymphoma			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Malignant peritoneal neoplasm			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Malignant pleural effusion			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Mantle cell lymphoma			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mediastinum neoplasm			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Melanocytic naevus			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metastases to lung			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metaplastic breast carcinoma			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metastases to abdominal cavity			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metastases to bone			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metastases to central nervous system			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metastases to liver			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Meningioma			
subjects affected / exposed	4 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Metastases to lymph nodes			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metastases to peritoneum			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metastasis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metastatic carcinoma of the bladder			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Metastatic malignant melanoma			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myeloproliferative neoplasm			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metastatic squamous cell carcinoma			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Mucoepidermoid carcinoma of salivary gland			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myelodysplastic syndrome			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myelofibrosis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metastatic renal cell carcinoma			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nasal sinus cancer			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neoplasm			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Neoplasm malignant			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Neuroblastoma			

subjects affected / exposed	1 / 18369 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Neuroendocrine carcinoma metastatic				
subjects affected / exposed	0 / 18369 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oesophageal cancer metastatic				
subjects affected / exposed	0 / 18369 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Non-Hodgkin's lymphoma				
subjects affected / exposed	1 / 18369 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Non-small cell lung cancer				
subjects affected / exposed	1 / 18369 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Non-small cell lung cancer metastatic				
subjects affected / exposed	2 / 18369 (0.01%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Oesophageal adenocarcinoma				
subjects affected / exposed	2 / 18369 (0.01%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Oesophageal adenocarcinoma stage IV				
subjects affected / exposed	1 / 18369 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Nodular melanoma				

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oesophageal carcinoma			
subjects affected / exposed	4 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Oesophageal squamous cell carcinoma			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Oral haemangioma			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Oropharyngeal cancer			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oropharyngeal squamous cell carcinoma			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pancreatic carcinoma metastatic			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ovarian cancer			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Ovarian cancer metastatic			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ovarian cancer recurrent			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ovarian germ cell teratoma benign			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancreatic carcinoma			
subjects affected / exposed	9 / 18369 (0.05%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 3		
Ovarian adenoma			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancreatic carcinoma stage IV			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancreatic neoplasm			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Papillary renal cell carcinoma			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Papillary thyroid cancer			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Parathyroid tumour benign			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Prostate cancer metastatic			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Plasma cell myeloma			
subjects affected / exposed	4 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 1		
Plasma cell myeloma in remission			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pleomorphic adenoma			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Polycythaemia vera			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Prostate cancer			
subjects affected / exposed	52 / 18369 (0.28%)		
occurrences causally related to treatment / all	0 / 54		
deaths causally related to treatment / all	0 / 1		
Pituitary tumour benign			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Prostatic adenoma			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rectal adenocarcinoma			
subjects affected / exposed	5 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 1		
Rectal cancer			
subjects affected / exposed	4 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Rectal neoplasm			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal cancer			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Prostate cancer stage IV			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal cancer stage IV			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Prostate cancer recurrent			

subjects affected / exposed	5 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Prostate cancer stage I			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Prostate cancer stage II			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal cancer metastatic			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal cell carcinoma			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal neoplasm			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Renal oncocytoma			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory tract neoplasm			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Salivary gland cancer			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Small intestine carcinoma			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Sarcoma			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Skin cancer			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Small cell carcinoma			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Small cell lung cancer			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Small cell lung cancer metastatic			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Salivary gland neoplasm			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Small intestine neuroendocrine tumour			

subjects affected / exposed	1 / 18369 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Squamous cell carcinoma				
subjects affected / exposed	1 / 18369 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Squamous cell carcinoma of lung				
subjects affected / exposed	3 / 18369 (0.02%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Squamous cell carcinoma of pharynx				
subjects affected / exposed	0 / 18369 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Squamous cell carcinoma of skin				
subjects affected / exposed	3 / 18369 (0.02%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Thyroid neoplasm				
subjects affected / exposed	0 / 18369 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Squamous cell carcinoma of the oral cavity				
subjects affected / exposed	2 / 18369 (0.01%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Squamous cell carcinoma of the parotid gland				
subjects affected / exposed	1 / 18369 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Squamous cell carcinoma of the tongue				

subjects affected / exposed	2 / 18369 (0.01%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
T-cell lymphoma stage IV				
subjects affected / exposed	0 / 18369 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Testicular seminoma (pure)				
subjects affected / exposed	1 / 18369 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Squamous cell carcinoma of the cervix				
subjects affected / exposed	0 / 18369 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tongue neoplasm malignant stage unspecified				
subjects affected / exposed	2 / 18369 (0.01%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Tonsil cancer				
subjects affected / exposed	0 / 18369 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Transitional cell carcinoma				
subjects affected / exposed	4 / 18369 (0.02%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Uterine cancer				
subjects affected / exposed	5 / 18369 (0.03%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Uterine leiomyoma				

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Waldenstrom's macroglobulinaemia			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vaginal neoplasm			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Aneurysm thrombosis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Aortic aneurysm			
subjects affected / exposed	8 / 18369 (0.04%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 0		
Aortic thrombosis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Aortic arteriosclerosis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Aortic dissection			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Aortic intramural haematoma			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Aortic occlusion			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Aortic stenosis			
subjects affected / exposed	4 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Aortic aneurysm rupture			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Arterial disorder			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Arterial occlusive disease			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Giant cell arteritis			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Femoral artery embolism			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Extremity necrosis			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Essential hypertension			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Distributive shock			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Deep vein thrombosis			
subjects affected / exposed	23 / 18369 (0.13%)		
occurrences causally related to treatment / all	0 / 24		
deaths causally related to treatment / all	0 / 2		
Circulatory collapse			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Arteriovenous fistula			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Arteriosclerosis			
subjects affected / exposed	5 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 3		
Arterial rupture			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haematoma			

subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Jugular vein thrombosis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Internal haemorrhage			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intermittent claudication			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypovolaemic shock			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Lymphoedema			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypertensive urgency			
subjects affected / exposed	9 / 18369 (0.05%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 0		
Hypertensive end-organ damage			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypertensive emergency			

subjects affected / exposed	5 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Hypertensive crisis			
subjects affected / exposed	15 / 18369 (0.08%)		
occurrences causally related to treatment / all	0 / 15		
deaths causally related to treatment / all	0 / 0		
Hypertension			
subjects affected / exposed	44 / 18369 (0.24%)		
occurrences causally related to treatment / all	0 / 47		
deaths causally related to treatment / all	0 / 0		
Hypotension			
subjects affected / exposed	22 / 18369 (0.12%)		
occurrences causally related to treatment / all	0 / 24		
deaths causally related to treatment / all	0 / 0		
Malignant hypertension			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peripheral venous disease			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peripheral vascular disorder			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Peripheral ischaemia			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Peripheral artery thrombosis			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peripheral artery occlusion			
subjects affected / exposed	4 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Peripheral artery aneurysm			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peripheral arterial occlusive disease			
subjects affected / exposed	18 / 18369 (0.10%)		
occurrences causally related to treatment / all	0 / 20		
deaths causally related to treatment / all	0 / 0		
Orthostatic hypotension			
subjects affected / exposed	8 / 18369 (0.04%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 0		
Neurogenic shock			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Phlebitis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Shock			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Subclavian vein thrombosis			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Superficial vein thrombosis			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Shock haemorrhagic			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Subclavian artery stenosis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Subclavian steal syndrome			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vasculitis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Varicose vein			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Varicose ulceration			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Thrombosis			

subjects affected / exposed	4 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Thrombophlebitis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vein rupture			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Adverse event			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Adverse drug reaction			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Asthenia			
subjects affected / exposed	9 / 18369 (0.05%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 0		
Cardiac complication associated with device			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Death			
subjects affected / exposed	37 / 18369 (0.20%)		
occurrences causally related to treatment / all	0 / 37		
deaths causally related to treatment / all	0 / 37		
Dehiscence			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac death			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chest discomfort			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Chest pain			
subjects affected / exposed	16 / 18369 (0.09%)		
occurrences causally related to treatment / all	0 / 16		
deaths causally related to treatment / all	0 / 0		
Chills			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Complication associated with device			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gait inability			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Generalised oedema			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gait disturbance			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Foreign body reaction			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye complication associated with device			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Drug intolerance			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Granuloma			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hyperthermia			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Influenza like illness			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Incarcerated hernia			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Multiple organ dysfunction syndrome			

subjects affected / exposed	5 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 4		
Pain			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Organ failure			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Oedema peripheral			
subjects affected / exposed	5 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Non-cardiac chest pain			
subjects affected / exposed	11 / 18369 (0.06%)		
occurrences causally related to treatment / all	0 / 11		
deaths causally related to treatment / all	0 / 0		
Peripheral swelling			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Pyrexia			
subjects affected / exposed	4 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Sudden death			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 2		
Sudden cardiac death			

subjects affected / exposed	4 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 4		
Strangulated hernia			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Stent-graft endoleak			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Surgical failure			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular stent thrombosis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular stent stenosis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular stent occlusion			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Unevaluable event			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Ulcer haemorrhage			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Swelling face			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Withdrawal syndrome			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Anaphylactic shock			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Anaphylactic reaction			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Allergy to arthropod sting			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Anaphylactoid reaction			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anti-neutrophil cytoplasmic antibody positive vasculitis			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Secondary immunodeficiency			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypersensitivity			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Drug hypersensitivity			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Contrast media allergy			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Social circumstances			
Organ donor			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Acquired phimosis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Adnexa uteri mass			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Balanoposthitis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Benign prostatic hyperplasia				
subjects affected / exposed	29 / 18369 (0.16%)			
occurrences causally related to treatment / all	0 / 29			
deaths causally related to treatment / all	0 / 0			
Breast disorder				
subjects affected / exposed	0 / 18369 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Genital haemorrhage				
subjects affected / exposed	0 / 18369 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Breast mass				
subjects affected / exposed	3 / 18369 (0.02%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Cervical dysplasia				
subjects affected / exposed	2 / 18369 (0.01%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Cystocele				
subjects affected / exposed	4 / 18369 (0.02%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Endometrial hyperplasia				
subjects affected / exposed	1 / 18369 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Breast enlargement				
subjects affected / exposed	0 / 18369 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Genital prolapse				

subjects affected / exposed	4 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Gynaecomastia			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ovarian cyst			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pelvic organ prolapse			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Pelvic pain			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Testicular mass			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Prostatic obstruction			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Prostatitis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Prostatomegaly			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Rectocele			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Postmenopausal haemorrhage			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Urogenital prolapse			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Uterine adhesions			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Uterine prolapse			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Uterovaginal prolapse			
subjects affected / exposed	4 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Vaginal prolapse			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			

subjects affected / exposed	5 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Acute respiratory distress syndrome			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Acute respiratory failure			
subjects affected / exposed	35 / 18369 (0.19%)		
occurrences causally related to treatment / all	0 / 36		
deaths causally related to treatment / all	0 / 4		
Aspiration			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 1		
Asthma			
subjects affected / exposed	15 / 18369 (0.08%)		
occurrences causally related to treatment / all	0 / 15		
deaths causally related to treatment / all	0 / 0		
Asthma-chronic obstructive pulmonary disease overlap syndrome			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Asthmatic crisis			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Atelectasis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bronchiectasis			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchitis chronic			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Bronchospasm			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Haemoptysis			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Chylothorax			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cough			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dyspnoea			
subjects affected / exposed	10 / 18369 (0.05%)		
occurrences causally related to treatment / all	0 / 10		
deaths causally related to treatment / all	0 / 0		
Emphysema			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Epistaxis			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chronic obstructive pulmonary disease			
subjects affected / exposed	111 / 18369 (0.60%)		
occurrences causally related to treatment / all	0 / 142		
deaths causally related to treatment / all	0 / 6		
Organising pneumonia			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypoxia			
subjects affected / exposed	9 / 18369 (0.05%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 0		
Idiopathic pulmonary fibrosis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Interstitial lung disease			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Lung consolidation			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Obstructive sleep apnoea syndrome			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lung infiltration			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mediastinal mass			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nasal polyps			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Obstructive airways disorder			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lung disorder			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pharyngeal haemorrhage			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pharyngeal swelling			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pleural effusion			
subjects affected / exposed	17 / 18369 (0.09%)		
occurrences causally related to treatment / all	0 / 19		
deaths causally related to treatment / all	0 / 0		
Pleural fibrosis			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pleurisy			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary embolism			
subjects affected / exposed	33 / 18369 (0.18%)		
occurrences causally related to treatment / all	0 / 33		
deaths causally related to treatment / all	0 / 1		
Pneumomediastinum			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonitis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonitis aspiration			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumothorax			
subjects affected / exposed	11 / 18369 (0.06%)		
occurrences causally related to treatment / all	0 / 11		
deaths causally related to treatment / all	0 / 0		
Pneumothorax spontaneous			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pleuritic pain			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary fibrosis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pulmonary haemorrhage			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Pulmonary hypertension			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Pulmonary mass			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Respiratory distress			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Pulmonary sarcoidosis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pulmonary thrombosis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory arrest			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Respiratory disorder			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary oedema			
subjects affected / exposed	7 / 18369 (0.04%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 0		
Respiratory failure			
subjects affected / exposed	23 / 18369 (0.13%)		
occurrences causally related to treatment / all	0 / 24		
deaths causally related to treatment / all	0 / 7		
Respiratory symptom			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Sinus polyp			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sleep apnoea syndrome			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Stridor			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vocal cord atrophy			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Acute psychosis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acute stress disorder			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Alcohol abuse			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bipolar I disorder			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Alcohol withdrawal syndrome			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Alcoholism			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anxiety			
subjects affected / exposed	4 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Bipolar disorder			

subjects affected / exposed	4 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Alcohol use disorder			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Completed suicide			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Compulsive sexual behaviour			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Confusional state			
subjects affected / exposed	4 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Delirium			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Delusion			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Major depression			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Depression suicidal			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Drug abuse			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Generalised anxiety disorder			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Homicidal ideation			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intentional self-injury			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Depression			
subjects affected / exposed	10 / 18369 (0.05%)		
occurrences causally related to treatment / all	0 / 11		
deaths causally related to treatment / all	0 / 0		
Mania			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Mental disorder			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Mental status changes			

subjects affected / exposed	7 / 18369 (0.04%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Post-traumatic stress disorder			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Psychotic disorder			
subjects affected / exposed	4 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Suicidal ideation			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Schizophrenia			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Substance-induced psychotic disorder			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Substance abuse			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Substance use disorder			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Schizoaffective disorder depressive type			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Suicide attempt			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Product issues			
Device loosening			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Device dislocation			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Device extrusion			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Device failure			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Device capturing issue			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Device occlusion			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Device power source issue			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Biliary dilatation			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Biliary colic			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bile duct stone			
subjects affected / exposed	6 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Bile duct stenosis			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Autoimmune hepatitis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Alcoholic liver disease			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chronic hepatic failure			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholelithiasis			
subjects affected / exposed	32 / 18369 (0.17%)		
occurrences causally related to treatment / all	0 / 32		
deaths causally related to treatment / all	0 / 0		
Cholecystitis chronic			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Cholecystitis acute			
subjects affected / exposed	16 / 18369 (0.09%)		
occurrences causally related to treatment / all	0 / 16		
deaths causally related to treatment / all	0 / 0		
Cholecystitis			
subjects affected / exposed	16 / 18369 (0.09%)		
occurrences causally related to treatment / all	0 / 16		
deaths causally related to treatment / all	0 / 0		
Cholangitis sclerosing			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholangitis			
subjects affected / exposed	4 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Congestive hepatopathy			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Drug-induced liver injury			

subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Gallbladder polyp			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gallbladder rupture			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatic calcification			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatic cirrhosis			
subjects affected / exposed	5 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Hepatic cyst			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Hepatic fibrosis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatic function abnormal			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatic haematoma			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatic lesion			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatic mass			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Hepatic steatosis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyperbilirubinaemia			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Jaundice			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Primary biliary cholangitis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Perforation bile duct			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Liver disorder			

subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Investigations			
Anticoagulation drug level above therapeutic			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood creatinine abnormal			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood creatinine increased			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood potassium abnormal			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Enzyme level abnormal			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood pressure increased			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Drug level decreased			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood potassium decreased			

subjects affected / exposed	1 / 18369 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Fibrin D dimer increased				
subjects affected / exposed	1 / 18369 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal stoma output increased				
subjects affected / exposed	1 / 18369 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Haemoglobin decreased				
subjects affected / exposed	1 / 18369 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Oxygen saturation decreased				
subjects affected / exposed	0 / 18369 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatic enzyme increased				
subjects affected / exposed	1 / 18369 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Liver function test increased				
subjects affected / exposed	0 / 18369 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Occult blood				
subjects affected / exposed	1 / 18369 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Heart rate irregular				

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Troponin increased			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Urine output decreased			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Weight decreased			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
White blood cell count decreased			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Abdominal injury			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Accident			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Accidental overdose			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acetabulum fracture			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Alcohol poisoning			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Ankle fracture			
subjects affected / exposed	17 / 18369 (0.09%)		
occurrences causally related to treatment / all	0 / 17		
deaths causally related to treatment / all	0 / 0		
Anastomotic leak			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Animal bite			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Anaemia postoperative			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Arterial injury			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Arteriovenous fistula maturation failure			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Arthropod bite			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Brain contusion			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Back injury			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bite			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bone contusion			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Avulsion fracture			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Burns second degree			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Burns third degree			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Carbon monoxide poisoning			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cerebral hyperperfusion syndrome			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cataract operation complication			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Central cord syndrome			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac procedure complication			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Cervical vertebral fracture			
subjects affected / exposed	8 / 18369 (0.04%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 0		
Chest injury			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Clavicle fracture			
subjects affected / exposed	5 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Costal cartilage fracture			

subjects affected / exposed	1 / 18369 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Complications of bone marrow transplant				
subjects affected / exposed	0 / 18369 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Concussion				
subjects affected / exposed	2 / 18369 (0.01%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Contusion				
subjects affected / exposed	2 / 18369 (0.01%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Complicated fracture				
subjects affected / exposed	0 / 18369 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Craniocerebral injury				
subjects affected / exposed	16 / 18369 (0.09%)			
occurrences causally related to treatment / all	0 / 16			
deaths causally related to treatment / all	0 / 1			
Ear injury				
subjects affected / exposed	0 / 18369 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Exposure to extreme temperature				
subjects affected / exposed	1 / 18369 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Face injury				

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Eye contusion			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Eye injury			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Extradural haematoma			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Facial bones fracture			
subjects affected / exposed	6 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Fall			
subjects affected / exposed	25 / 18369 (0.14%)		
occurrences causally related to treatment / all	0 / 25		
deaths causally related to treatment / all	0 / 0		
Femoral neck fracture			
subjects affected / exposed	7 / 18369 (0.04%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Foot fracture			
subjects affected / exposed	7 / 18369 (0.04%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Fibula fracture			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Flail chest			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Femur fracture			
subjects affected / exposed	27 / 18369 (0.15%)		
occurrences causally related to treatment / all	0 / 27		
deaths causally related to treatment / all	0 / 0		
Forearm fracture			
subjects affected / exposed	4 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Foreign body in gastrointestinal tract			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Foreign body ingestion			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gun shot wound			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 1		
Fractured coccyx			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Fractured sacrum			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal anastomotic leak			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Fracture displacement			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Hand fracture			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Head injury			
subjects affected / exposed	8 / 18369 (0.04%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 0		
Heat exhaustion			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Incarcerated incisional hernia			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hip fracture			
subjects affected / exposed	24 / 18369 (0.13%)		
occurrences causally related to treatment / all	0 / 25		
deaths causally related to treatment / all	0 / 0		
Humerus fracture			

subjects affected / exposed	11 / 18369 (0.06%)		
occurrences causally related to treatment / all	0 / 11		
deaths causally related to treatment / all	0 / 1		
Heat stroke			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Incision site haematoma			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Incision site impaired healing			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Incisional hernia			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intentional overdose			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infusion related reaction			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 1		
Incomplete spinal fusion			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Joint dislocation			
subjects affected / exposed	5 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Joint injury			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ligament injury			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lower limb fracture			
subjects affected / exposed	6 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Ligament sprain			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Limb crushing injury			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Limb injury			
subjects affected / exposed	6 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Ligament rupture			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lumbar vertebral fracture			
subjects affected / exposed	4 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Meniscus injury			
subjects affected / exposed	5 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Multiple fractures			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Open fracture			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Muscle strain			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neck injury			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Multiple injuries			
subjects affected / exposed	10 / 18369 (0.05%)		
occurrences causally related to treatment / all	0 / 10		
deaths causally related to treatment / all	0 / 0		
Petroleum distillate poisoning			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Osteophyte fracture			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Overdose			
subjects affected / exposed	5 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 2		
Patella fracture			
subjects affected / exposed	7 / 18369 (0.04%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Pelvic fracture			
subjects affected / exposed	8 / 18369 (0.04%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 0		
Perineal injury			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Periorbital haematoma			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Periprosthetic fracture			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Post concussion syndrome			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Post-traumatic pain			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumothorax traumatic			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pharyngeal injury			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Post laminectomy syndrome			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Post procedural complication			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Post procedural fever			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Post procedural haematoma			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Post procedural haematuria			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Post procedural haemorrhage			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Post procedural hypotension			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Post procedural stroke			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Postoperative ileus			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Postoperative wound complication			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary contusion			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Procedural pneumothorax			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Procedural pain			

subjects affected / exposed	9 / 18369 (0.05%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 0		
Procedural haemorrhage			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Radiation oesophagitis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Rib fracture			
subjects affected / exposed	14 / 18369 (0.08%)		
occurrences causally related to treatment / all	0 / 15		
deaths causally related to treatment / all	0 / 0		
Respiratory fume inhalation disorder			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Radius fracture			
subjects affected / exposed	8 / 18369 (0.04%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 0		
Road traffic accident			
subjects affected / exposed	7 / 18369 (0.04%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 2		
Sciatic nerve injury			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spinal column injury			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skull fracture			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Skin laceration			
subjects affected / exposed	5 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Skin injury			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Skin abrasion			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Seroma			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Spinal compression fracture			
subjects affected / exposed	11 / 18369 (0.06%)		
occurrences causally related to treatment / all	0 / 11		
deaths causally related to treatment / all	0 / 0		
Sternal fracture			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Stress fracture			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Subdural haematoma			
subjects affected / exposed	13 / 18369 (0.07%)		
occurrences causally related to treatment / all	0 / 13		
deaths causally related to treatment / all	0 / 0		
Stab wound			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Splenic rupture			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spinal fracture			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Subdural haemorrhage			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tendon injury			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Tendon rupture			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Thermal burn			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Traumatic fracture			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tibia fracture			
subjects affected / exposed	6 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Toxicity to various agents			
subjects affected / exposed	5 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Thoracic vertebral fracture			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Traumatic haematoma			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Traumatic haemothorax			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Traumatic lung injury			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urinary retention postoperative			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Upper limb fracture			
subjects affected / exposed	11 / 18369 (0.06%)		
occurrences causally related to treatment / all	0 / 11		
deaths causally related to treatment / all	0 / 0		
Urethral injury			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ulna fracture			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Vascular pseudoaneurysm			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vulvovaginal injury			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Wound			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Wound evisceration			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Wound haemorrhage			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Wrist fracture			
subjects affected / exposed	11 / 18369 (0.06%)		
occurrences causally related to treatment / all	0 / 11		
deaths causally related to treatment / all	0 / 0		
Wound dehiscence			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Congenital, familial and genetic disorders			
Atrial septal defect			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bicuspid aortic valve			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypertrophic cardiomyopathy			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Corneal dystrophy			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Dermoid cyst			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Fabry's disease			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hydrocele			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Congenital cystic kidney disease			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Myotonic dystrophy			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Phimosis			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	12 / 18369 (0.07%)		
occurrences causally related to treatment / all	0 / 12		
deaths causally related to treatment / all	0 / 2		
Acute left ventricular failure			
subjects affected / exposed	11 / 18369 (0.06%)		
occurrences causally related to treatment / all	0 / 11		
deaths causally related to treatment / all	0 / 0		
Acute myocardial infarction			
subjects affected / exposed	85 / 18369 (0.46%)		
occurrences causally related to treatment / all	0 / 93		
deaths causally related to treatment / all	0 / 11		
Angina pectoris			

subjects affected / exposed	30 / 18369 (0.16%)		
occurrences causally related to treatment / all	0 / 30		
deaths causally related to treatment / all	0 / 0		
Atrial fibrillation			
subjects affected / exposed	80 / 18369 (0.44%)		
occurrences causally related to treatment / all	0 / 87		
deaths causally related to treatment / all	0 / 0		
Arteriosclerosis coronary artery			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Arrhythmia supraventricular			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Arrhythmia			
subjects affected / exposed	11 / 18369 (0.06%)		
occurrences causally related to treatment / all	0 / 12		
deaths causally related to treatment / all	0 / 1		
Aortic valve stenosis			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Aortic valve incompetence			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Aortic valve disease			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Aortic valve calcification			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Angina unstable			
subjects affected / exposed	17 / 18369 (0.09%)		
occurrences causally related to treatment / all	0 / 17		
deaths causally related to treatment / all	0 / 0		
Atrial flutter			
subjects affected / exposed	12 / 18369 (0.07%)		
occurrences causally related to treatment / all	0 / 13		
deaths causally related to treatment / all	0 / 0		
Cardiac arrest			
subjects affected / exposed	58 / 18369 (0.32%)		
occurrences causally related to treatment / all	0 / 58		
deaths causally related to treatment / all	0 / 51		
Bundle branch block right			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bundle branch block left			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bradycardia			
subjects affected / exposed	13 / 18369 (0.07%)		
occurrences causally related to treatment / all	0 / 14		
deaths causally related to treatment / all	0 / 0		
Cardiac disorder			
subjects affected / exposed	5 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 2		
Atrioventricular block second degree			

subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Atrioventricular block complete			
subjects affected / exposed	6 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Atrioventricular block			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Atrial tachycardia			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Atrioventricular dissociation			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac perfusion defect			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac tamponade			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac valve disease			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac ventricular thrombosis			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardio-respiratory arrest			
subjects affected / exposed	9 / 18369 (0.05%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 9		
Cardiogenic shock			
subjects affected / exposed	6 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 2		
Cardiomyopathy			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Cardiopulmonary failure			
subjects affected / exposed	11 / 18369 (0.06%)		
occurrences causally related to treatment / all	0 / 11		
deaths causally related to treatment / all	0 / 11		
Cardiac failure			
subjects affected / exposed	34 / 18369 (0.19%)		
occurrences causally related to treatment / all	0 / 43		
deaths causally related to treatment / all	0 / 7		
Cardiac failure acute			
subjects affected / exposed	8 / 18369 (0.04%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 0		
Cardiac failure chronic			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac failure congestive			

subjects affected / exposed	34 / 18369 (0.19%)		
occurrences causally related to treatment / all	0 / 39		
deaths causally related to treatment / all	0 / 2		
Cardiovascular disorder			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Chronic left ventricular failure			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congestive cardiomyopathy			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Cor pulmonale			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Coronary artery disease			
subjects affected / exposed	60 / 18369 (0.33%)		
occurrences causally related to treatment / all	0 / 64		
deaths causally related to treatment / all	0 / 1		
Hypertensive cardiomyopathy			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Coronary artery occlusion			
subjects affected / exposed	5 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Coronary artery stenosis			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Degenerative aortic valve disease			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Extrasystoles			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Coronary artery dissection			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intracardiac thrombus			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ischaemic cardiomyopathy			
subjects affected / exposed	6 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Left ventricular failure			
subjects affected / exposed	4 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Mitral valve disease			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mitral valve incompetence			

subjects affected / exposed	4 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Nodal arrhythmia			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Mitral valve stenosis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myocardial infarction			
subjects affected / exposed	53 / 18369 (0.29%)		
occurrences causally related to treatment / all	0 / 53		
deaths causally related to treatment / all	0 / 14		
Myocardial ischaemia			
subjects affected / exposed	18 / 18369 (0.10%)		
occurrences causally related to treatment / all	0 / 20		
deaths causally related to treatment / all	0 / 1		
Myocarditis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mitral valve prolapse			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nodal rhythm			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Palpitations			

subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Pericardial effusion			
subjects affected / exposed	8 / 18369 (0.04%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 0		
Pericarditis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pericarditis constrictive			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sinus arrhythmia			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rheumatic heart disease			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Right ventricular failure			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Silent myocardial infarction			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sinus arrest			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Prinzmetal angina			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sinus bradycardia			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Sinus node dysfunction			
subjects affected / exposed	4 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Stress cardiomyopathy			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Supraventricular extrasystoles			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Supraventricular tachycardia			
subjects affected / exposed	4 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Ventricular extrasystoles			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Tachycardia			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tachycardia paroxysmal			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tricuspid valve incompetence			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Trifascicular block			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ventricular arrhythmia			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tachyarrhythmia			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ventricular fibrillation			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ventricular tachyarrhythmia			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ventricular tachycardia			

subjects affected / exposed	9 / 18369 (0.05%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Aphasia			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Alcoholic seizure			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Altered state of consciousness			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Amnesia			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Amyotrophic lateral sclerosis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Arachnoiditis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Basilar artery aneurysm			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bell's palsy			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Brain injury			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Brain oedema			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Carotid artery stenosis			
subjects affected / exposed	6 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Brain stem infarction			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Carotid arteriosclerosis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Carotid artery aneurysm			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Carotid artery occlusion			
subjects affected / exposed	4 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Brain stem haemorrhage			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Carpal tunnel syndrome			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Cauda equina syndrome			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Central nervous system lesion			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebellar infarction			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cerebellar stroke			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cerebrovascular accident			
subjects affected / exposed	39 / 18369 (0.21%)		
occurrences causally related to treatment / all	0 / 42		
deaths causally related to treatment / all	0 / 4		
Cerebral haemorrhage			
subjects affected / exposed	7 / 18369 (0.04%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 1		
Cerebral infarction			

subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Cerebral ischaemia			
subjects affected / exposed	14 / 18369 (0.08%)		
occurrences causally related to treatment / all	0 / 14		
deaths causally related to treatment / all	0 / 0		
Cerebral small vessel ischaemic disease			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cerebrospinal fluid leakage			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cerebral haematoma			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cognitive disorder			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Dementia			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Dementia Alzheimer's type			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diabetic coma			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diabetic neuropathy			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Chronic inflammatory demyelinating polyradiculoneuropathy			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Dysarthria			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebrovascular disorder			
subjects affected / exposed	6 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Cerebrovascular insufficiency			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cervical cord compression			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cervical radiculopathy			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Dizziness			

subjects affected / exposed	7 / 18369 (0.04%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Embolitic stroke			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Encephalopathy			
subjects affected / exposed	7 / 18369 (0.04%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Epilepsy			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Essential tremor			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Facial paresis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hemiparesis			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Haemorrhage intracranial			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Haemorrhagic cerebral infarction			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Haemorrhagic stroke			
subjects affected / exposed	7 / 18369 (0.04%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 2		
Headache			
subjects affected / exposed	5 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Generalised tonic-clonic seizure			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hemiplegia			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hydrocephalus			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypertensive encephalopathy			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypoaesthesia			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypoxic-ischaemic encephalopathy			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ischaemic cerebral infarction			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Immune effector cell-associated neurotoxicity syndrome			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intracranial aneurysm			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Intracranial haematoma			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intracranial mass			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 3		
Intraventricular haemorrhage			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
IIIrd nerve paralysis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ischaemic stroke			

subjects affected / exposed	46 / 18369 (0.25%)		
occurrences causally related to treatment / all	0 / 47		
deaths causally related to treatment / all	0 / 4		
IVth nerve paralysis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lacunar infarction			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lacunar stroke			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Loss of consciousness			
subjects affected / exposed	7 / 18369 (0.04%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Lumbar radiculopathy			
subjects affected / exposed	4 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Meralgia paraesthetica			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolic encephalopathy			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Migraine			

subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Monoparesis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Morton's neuralgia			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Motor dysfunction			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Motor neurone disease			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Multiple system atrophy			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Muscle spasticity			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Myasthenia gravis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myelopathy			

subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Paraesthesia			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Nervous system disorder			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neuropathy peripheral			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Normal pressure hydrocephalus			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Optic neuritis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nerve compression			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Primary progressive aphasia			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Paralysis			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Paraplegia			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Parkinson's disease			
subjects affected / exposed	4 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Parkinsonism			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Presyncope			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Peripheral sensorimotor neuropathy			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peroneal nerve palsy			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Petit mal epilepsy			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Posterior reversible encephalopathy syndrome			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peripheral motor neuropathy			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pseudostroke			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychogenic seizure			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sciatica			
subjects affected / exposed	6 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Spinal cord compression			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Simple partial seizures			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Speech disorder			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spinal claudication			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Seizure			
subjects affected / exposed	13 / 18369 (0.07%)		
occurrences causally related to treatment / all	0 / 14		
deaths causally related to treatment / all	0 / 0		
Spinal cord infarction			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Spinal meningeal cyst			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spinal stroke			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Status epilepticus			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thalamus haemorrhage			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Syncope			

subjects affected / exposed	43 / 18369 (0.23%)		
occurrences causally related to treatment / all	0 / 43		
deaths causally related to treatment / all	0 / 0		
Temporal lobe epilepsy			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thalamic infarction			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Subarachnoid haemorrhage			
subjects affected / exposed	9 / 18369 (0.05%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 1		
Thoracic radiculopathy			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Toxic encephalopathy			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Transient global amnesia			
subjects affected / exposed	4 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Vasogenic cerebral oedema			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Unresponsive to stimuli			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular dementia			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Transient ischaemic attack			
subjects affected / exposed	26 / 18369 (0.14%)		
occurrences causally related to treatment / all	0 / 26		
deaths causally related to treatment / all	0 / 0		
Vertebral artery dissection			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vertebrobasilar insufficiency			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vertebrobasilar stroke			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vocal cord paralysis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Facial paralysis	Additional description: One event of facial paralysis assessed related to study drug by investigator; assessed not related by Sponsor due to participant's medical history and later developments suggesting another explanation for event.		
subjects affected / exposed	4 / 18369 (0.02%)		
occurrences causally related to treatment / all	1 / 4		
deaths causally related to treatment / all	0 / 0		
Guillain-Barre syndrome	Additional description: Incidence of Guillain-Barre syndrome was balanced between groups, none of the events occurred <500 days following study injection and none were assessed as related to the study vaccine.		

subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Anaemia vitamin B12 deficiency			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Anaemia			
subjects affected / exposed	38 / 18369 (0.21%)		
occurrences causally related to treatment / all	0 / 40		
deaths causally related to treatment / all	0 / 0		
Anaemia macrocytic			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Autoimmune haemolytic anaemia			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood loss anaemia			
subjects affected / exposed	6 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Leukocytosis			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Methaemoglobinaemia			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Leukopenia			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lymphadenopathy mediastinal			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Immune thrombocytopenia			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Coagulopathy			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Febrile neutropenia			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Heparin-induced thrombocytopenia			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Iron deficiency anaemia			
subjects affected / exposed	8 / 18369 (0.04%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 0		
Thrombocytopenia			
subjects affected / exposed	12 / 18369 (0.07%)		
occurrences causally related to treatment / all	0 / 12		
deaths causally related to treatment / all	0 / 0		
Spontaneous haematoma			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Splenomegaly			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Splenic infarction			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Splenic haemorrhage			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancytopenia			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Normocytic anaemia			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Normochromic anaemia			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Microcytic anaemia			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Ear and labyrinth disorders			
Tympanic membrane perforation			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vertigo			
subjects affected / exposed	13 / 18369 (0.07%)		
occurrences causally related to treatment / all	0 / 14		
deaths causally related to treatment / all	0 / 0		
Vertigo positional			
subjects affected / exposed	7 / 18369 (0.04%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Cataract			
subjects affected / exposed	7 / 18369 (0.04%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 0		
Cataract nuclear			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Conjunctival cyst			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Corneal leukoma			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blindness unilateral			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Amaurosis fugax			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Angle closure glaucoma			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Corneal thinning			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diplopia			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ectropion			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Endocrine ophthalmopathy			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Epiretinal membrane			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Macular degeneration			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eyelid ptosis			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Glaucoma			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Keratoconus			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lens dislocation			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye haemorrhage			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Macular hole			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metamorphopsia			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neovascular age-related macular degeneration			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ocular vascular disorder			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Open angle glaucoma			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Retinal detachment			
subjects affected / exposed	6 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Optic neuropathy			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pterygium			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Retinal artery occlusion			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Retinal degeneration			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Optic atrophy			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Retinal tear			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Retinal vein occlusion			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Retinopathy hypertensive			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vision blurred			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Visual acuity reduced			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vitreous haemorrhage			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Visual impairment			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal hernia obstructive			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal adhesions			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abdominal fat apron			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abdominal hernia			
subjects affected / exposed	5 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Abdominal hernia perforation			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal incarcerated hernia			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abdominal mass			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abdominal pain			
subjects affected / exposed	9 / 18369 (0.05%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 0		
Abdominal pain upper			
subjects affected / exposed	5 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Abdominal rigidity			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Acid peptic disease			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acute abdomen			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Alcoholic pancreatitis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anal fissure			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Anal fistula			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ascites			
subjects affected / exposed	5 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Barrett's oesophagus			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cannabinoid hyperemesis syndrome			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chronic gastritis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Chronic gastrointestinal bleeding			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Coeliac disease			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Constipation			
subjects affected / exposed	6 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Colitis ischaemic			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Colitis microscopic			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Colitis ulcerative			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Colon dysplasia			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Colitis			
subjects affected / exposed	8 / 18369 (0.04%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 0		
Diverticular perforation			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Diverticulum			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Diverticulum intestinal			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Diverticulum intestinal haemorrhagic			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Duodenal obstruction			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diarrhoea			
subjects affected / exposed	9 / 18369 (0.05%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 0		
Duodenal ulcer haemorrhage			

subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Crohn's disease			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diaphragmatic hernia			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Diaphragmatic hernia, obstructive			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Duodenal ulcer			
subjects affected / exposed	4 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Duodenal ulcer perforation			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Duodenitis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dysbiosis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Dyspepsia			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Dysphagia			
subjects affected / exposed	6 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Food poisoning			
subjects affected / exposed	4 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Enterocolitis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Faeces discoloured			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Femoral hernia strangulated			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Flatulence			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Enteritis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastric disorder			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastric perforation			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastric polyps			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastric stenosis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastric ulcer			
subjects affected / exposed	6 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal ulcer haemorrhage			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastric ulcer perforation			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastric volvulus			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastritis			

subjects affected / exposed	5 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal fistula			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal haemorrhage			
subjects affected / exposed	12 / 18369 (0.07%)		
occurrences causally related to treatment / all	0 / 13		
deaths causally related to treatment / all	0 / 0		
Gastric ulcer haemorrhage			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Gastrooesophageal reflux disease			
subjects affected / exposed	5 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Gingival bleeding			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Glossitis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Haemorrhoidal haemorrhage			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Haematochezia			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Haemoperitoneum			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Haemorrhagic erosive gastritis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haematemesis			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Haemorrhoids			
subjects affected / exposed	6 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Hiatus hernia			
subjects affected / exposed	6 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Ileal perforation			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Incarcerated inguinal hernia			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ileus paralytic			

subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Impaired gastric emptying			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ileus			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Incarcerated umbilical hernia			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Inguinal hernia			
subjects affected / exposed	23 / 18369 (0.13%)		
occurrences causally related to treatment / all	0 / 23		
deaths causally related to treatment / all	0 / 0		
Inguinal hernia perforation			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intestinal fistula			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Inguinal hernia, obstructive			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Intestinal cyst			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Inguinal hernia strangulated			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intestinal pseudo-obstruction			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intestinal perforation			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intestinal obstruction			
subjects affected / exposed	25 / 18369 (0.14%)		
occurrences causally related to treatment / all	0 / 27		
deaths causally related to treatment / all	0 / 1		
Intestinal ischaemia			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Intestinal haemorrhage			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intestinal haematoma			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intra-abdominal fluid collection			

subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Intra-abdominal haematoma			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lumbar hernia			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lower gastrointestinal haemorrhage			
subjects affected / exposed	6 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Large intestine polyp			
subjects affected / exposed	8 / 18369 (0.04%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 0		
Large intestine perforation			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Large intestinal ulcer			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Large intestinal obstruction			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Mallory-Weiss syndrome			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Melaena			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Nausea			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Obstruction gastric			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Obstructive pancreatitis			
subjects affected / exposed	4 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 1		
Odynophagia			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oesophageal achalasia			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Oesophageal food impaction			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Oesophageal perforation			

subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Oesophageal stenosis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Oesophageal ulcer			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Oesophageal varices haemorrhage			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Oesophagitis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Oesophagitis haemorrhagic			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pancreatic cyst			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pancreatic disorder			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peptic ulcer haemorrhage			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peptic ulcer			
subjects affected / exposed	6 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Pancreatolithiasis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Pancreatitis necrotising			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pancreatitis acute			
subjects affected / exposed	7 / 18369 (0.04%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 1		
Pancreatitis			
subjects affected / exposed	5 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Pancreatic mass			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Proctitis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peritoneal adhesions			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peptic ulcer perforation			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Rectal haemorrhage			
subjects affected / exposed	5 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Rectal prolapse			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Retroperitoneal haemorrhage			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Salivary gland cyst			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Strangulated umbilical hernia			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Small intestinal perforation			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Small intestinal obstruction			

subjects affected / exposed	19 / 18369 (0.10%)		
occurrences causally related to treatment / all	0 / 22		
deaths causally related to treatment / all	0 / 0		
Subileus			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Upper gastrointestinal haemorrhage			
subjects affected / exposed	10 / 18369 (0.05%)		
occurrences causally related to treatment / all	0 / 10		
deaths causally related to treatment / all	0 / 0		
Umbilical hernia			
subjects affected / exposed	5 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Thrombosis mesenteric vessel			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Terminal ileitis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Varices oesophageal			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Volvulus			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vomiting			

subjects affected / exposed	6 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Diabetic foot			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Acute generalised exanthematous pustulosis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Angioedema			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Blister			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Decubitus ulcer			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Dermatitis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Diabetic wound			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Drug eruption			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Drug reaction with eosinophilia and systemic symptoms			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Excessive skin			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hidradenitis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Stevens-Johnson syndrome			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Panniculitis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Petechiae			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pruritus			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin ulcer			

subjects affected / exposed	5 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Intertrigo			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Subcutaneous emphysema			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urticaria			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	35 / 18369 (0.19%)		
occurrences causally related to treatment / all	0 / 35		
deaths causally related to treatment / all	0 / 0		
Anuria			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Bladder perforation			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bladder prolapse			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Haematuria			

subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Calculus urinary			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Chronic kidney disease			
subjects affected / exposed	8 / 18369 (0.04%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 0		
Cystitis haemorrhagic			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
End stage renal disease			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Glomerulonephritis rapidly progressive			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Calculus bladder			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hydronephrosis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypertonic bladder			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nephrolithiasis			
subjects affected / exposed	28 / 18369 (0.15%)		
occurrences causally related to treatment / all	0 / 31		
deaths causally related to treatment / all	0 / 0		
Nephropathy			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal colic			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Postrenal failure			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal artery stenosis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal artery thrombosis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oliguria			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal cortical necrosis			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal cyst haemorrhage			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Renal cyst ruptured			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal infarct			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal failure			
subjects affected / exposed	9 / 18369 (0.05%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 2		
Renal haematoma			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal impairment			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Renal disorder			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal mass			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal tubular necrosis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal vascular thrombosis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Stag horn calculus			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ureteric stenosis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Subcapsular renal haematoma			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ureteric fistula			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ureteric obstruction			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Stress urinary incontinence			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urethral obstruction			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urethral stenosis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urge incontinence			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary bladder haemorrhage			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary bladder polyp			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Urethral meatus stenosis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urinary incontinence			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urinary retention			

subjects affected / exposed	15 / 18369 (0.08%)		
occurrences causally related to treatment / all	0 / 15		
deaths causally related to treatment / all	0 / 0		
Urinary tract obstruction			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 1		
Ureterolithiasis			
subjects affected / exposed	5 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Urethral cyst			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urinary hesitation			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Endocrine disorders			
Hyperparathyroidism primary			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Adrenal mass			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Basedow's disease			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Goitre			

subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Hyperparathyroidism			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Adrenal haemorrhage			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypoparathyroidism secondary			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Primary hyperaldosteronism			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thyrotoxic crisis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypothyroidism			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			

Articular calcification				
subjects affected / exposed	0 / 18369 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Arthralgia				
subjects affected / exposed	13 / 18369 (0.07%)			
occurrences causally related to treatment / all	0 / 14			
deaths causally related to treatment / all	0 / 0			
Arthritis				
subjects affected / exposed	1 / 18369 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Arthropathy				
subjects affected / exposed	1 / 18369 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Back pain				
subjects affected / exposed	26 / 18369 (0.14%)			
occurrences causally related to treatment / all	0 / 28			
deaths causally related to treatment / all	0 / 0			
Bone cyst				
subjects affected / exposed	0 / 18369 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bursitis				
subjects affected / exposed	0 / 18369 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cervical spinal stenosis				
subjects affected / exposed	3 / 18369 (0.02%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Chondropathy				

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Compartment syndrome			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Costochondritis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Dupuytren's contracture			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Exostosis			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Fibromyalgia			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Foot deformity			
subjects affected / exposed	5 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Haematoma muscle			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemarthrosis			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Greater trochanteric pain syndrome			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Fracture pain			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Fracture nonunion			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ligamentum flavum hypertrophy			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Kyphoscoliosis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Mobility decreased			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lumbar spinal stenosis			
subjects affected / exposed	14 / 18369 (0.08%)		
occurrences causally related to treatment / all	0 / 15		
deaths causally related to treatment / all	0 / 0		
Joint instability			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Joint effusion			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intervertebral disc protrusion			
subjects affected / exposed	9 / 18369 (0.05%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 0		
Intervertebral disc disorder			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Intervertebral disc degeneration			
subjects affected / exposed	9 / 18369 (0.05%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 0		
Intervertebral disc compression			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Neck pain			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Osteoarthritis			
subjects affected / exposed	114 / 18369 (0.62%)		
occurrences causally related to treatment / all	0 / 120		
deaths causally related to treatment / all	0 / 0		
Osteochondrosis			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Osteonecrosis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Osteoporosis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Myalgia			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myositis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Myopathy			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Muscular weakness			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal chest pain			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal pain			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neck mass			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Seronegative arthritis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Rotator cuff syndrome			
subjects affected / exposed	12 / 18369 (0.07%)		
occurrences causally related to treatment / all	0 / 12		
deaths causally related to treatment / all	0 / 0		
Rotator cuff tear arthropathy			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Scoliosis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rhabdomyolysis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Polymyalgia rheumatica			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Periarthritis			

subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Pathological fracture			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Patellofemoral pain syndrome			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pain in extremity			
subjects affected / exposed	4 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 1		
Osteoporotic fracture			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Spinal retrolisthesis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Spinal osteoarthritis			
subjects affected / exposed	11 / 18369 (0.06%)		
occurrences causally related to treatment / all	0 / 12		
deaths causally related to treatment / all	0 / 0		
Spinal deformity			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sjogren's syndrome			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spinal stenosis			
subjects affected / exposed	9 / 18369 (0.05%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 0		
Synovial cyst			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tendonitis			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Tenosynovitis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Torticollis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vertebral foraminal stenosis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Spondylolisthesis			
subjects affected / exposed	6 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Abdominal sepsis			

subjects affected / exposed	4 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 2		
Abdominal abscess			
subjects affected / exposed	5 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Abdominal wall abscess			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abscess intestinal			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abscess jaw			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Appendiceal abscess			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anal abscess			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Adenovirus infection			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acute sinusitis			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acute hepatitis C			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abscess limb			
subjects affected / exposed	4 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Asymptomatic COVID-19			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Asymptomatic bacteriuria			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Arthritis infective			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Arthritis bacterial			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Appendicitis perforated			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Appendicitis			

subjects affected / exposed	10 / 18369 (0.05%)		
occurrences causally related to treatment / all	0 / 10		
deaths causally related to treatment / all	0 / 0		
Atypical mycobacterial infection			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Atypical pneumonia			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Bronchitis			
subjects affected / exposed	11 / 18369 (0.06%)		
occurrences causally related to treatment / all	0 / 11		
deaths causally related to treatment / all	0 / 0		
Breast cellulitis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Brain abscess			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bacterial sepsis			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Bacterial prostatitis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bacterial food poisoning			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bacteraemia			
subjects affected / exposed	4 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Campylobacter gastroenteritis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bursitis infective			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchopulmonary aspergillosis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cellulitis			
subjects affected / exposed	25 / 18369 (0.14%)		
occurrences causally related to treatment / all	0 / 27		
deaths causally related to treatment / all	0 / 1		
Cellulitis orbital			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cellulitis staphylococcal			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cholecystitis infective			

subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Cholera			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Complicated appendicitis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Clostridium difficile infection			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Clostridium difficile colitis			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Coronavirus infection			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Dacryocystitis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cystitis			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
COVID-19 pneumonia			

subjects affected / exposed	6 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
COVID-19			
subjects affected / exposed	26 / 18369 (0.14%)		
occurrences causally related to treatment / all	0 / 26		
deaths causally related to treatment / all	0 / 1		
Dysentery			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Diverticulitis			
subjects affected / exposed	24 / 18369 (0.13%)		
occurrences causally related to treatment / all	0 / 26		
deaths causally related to treatment / all	0 / 0		
Ear infection			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dengue fever			
subjects affected / exposed	11 / 18369 (0.06%)		
occurrences causally related to treatment / all	0 / 11		
deaths causally related to treatment / all	0 / 0		
Dengue haemorrhagic fever			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Device related infection			
subjects affected / exposed	4 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Echinococciasis			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Endocarditis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Endocarditis bacterial			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Enterobacter sepsis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Enterococcal bacteraemia			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Enterococcal sepsis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Emphysematous cystitis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Empyema			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Encephalitis			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Epididymitis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Erysipelas			
subjects affected / exposed	4 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Escherichia bacteraemia			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Escherichia sepsis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Escherichia urinary tract infection			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Extradural abscess			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Focal peritonitis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Furuncle			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Fracture infection			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Fournier's gangrene			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gallbladder abscess			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis			
subjects affected / exposed	25 / 18369 (0.14%)		
occurrences causally related to treatment / all	0 / 26		
deaths causally related to treatment / all	0 / 0		
Gastric infection			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gangrene			
subjects affected / exposed	5 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Gallbladder empyema			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis bacterial			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis viral			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Groin abscess			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gingivitis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Giardiasis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal infection			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
H1N1 influenza			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Haemophilus infection			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haematoma infection			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
H3N2 influenza			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
HCoV-OC43 infection			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
HIV infection			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Herpes zoster			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Herpes oesophagitis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatic cyst infection			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infected cyst			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infected bite			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hydrocele male infected			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infected skin ulcer			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infection			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infectious pleural effusion			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infective exacerbation of bronchiectasis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Influenza			
subjects affected / exposed	13 / 18369 (0.07%)		
occurrences causally related to treatment / all	0 / 13		
deaths causally related to treatment / all	0 / 0		
Infective spondylitis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infective exacerbation of chronic obstructive airways disease			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intervertebral discitis			
subjects affected / exposed	4 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Klebsiella bacteraemia			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Kidney infection			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Joint abscess			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intestinal tuberculosis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Klebsiella infection			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Klebsiella sepsis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Large intestine infection			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Latent syphilis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Leptospirosis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Liver abscess			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Localised infection			
subjects affected / exposed	4 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Meningitis bacterial			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lower respiratory tract infection			
subjects affected / exposed	8 / 18369 (0.04%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 1		
Lung abscess			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Mastoiditis			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Mediastinitis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Medical device site infection			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Meningitis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mycobacterial infection			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Murine typhus			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mucormycosis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metapneumovirus pneumonia			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metapneumovirus infection			

subjects affected / exposed	2 / 18369 (0.01%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Meningitis viral				
subjects affected / exposed	1 / 18369 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Mycobacterium avium complex infection				
subjects affected / exposed	1 / 18369 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Meningitis borrelia				
subjects affected / exposed	1 / 18369 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Osteomyelitis acute				
subjects affected / exposed	0 / 18369 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Osteomyelitis				
subjects affected / exposed	16 / 18369 (0.09%)			
occurrences causally related to treatment / all	0 / 17			
deaths causally related to treatment / all	0 / 0			
Orchitis				
subjects affected / exposed	2 / 18369 (0.01%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Ophthalmic herpes zoster				
subjects affected / exposed	0 / 18369 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neutropenic sepsis				

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Necrotising fasciitis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Osteomyelitis chronic			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Paronychia			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Parainfluenzae virus infection			
subjects affected / exposed	4 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Otitis externa			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pasteurella infection			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Perihepatic abscess			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Periorbital cellulitis			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peritonitis			
subjects affected / exposed	5 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Pneumococcal sepsis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Plasmodium vivax infection			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pilonidal disease			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	163 / 18369 (0.89%)		
occurrences causally related to treatment / all	0 / 182		
deaths causally related to treatment / all	0 / 9		
Pneumonia influenzal			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Pneumonia haemophilus			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia bacterial			

subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Pneumonia aspiration			
subjects affected / exposed	10 / 18369 (0.05%)		
occurrences causally related to treatment / all	0 / 10		
deaths causally related to treatment / all	0 / 1		
Pneumonia klebsiella			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia legionella			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia pneumococcal			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Pneumonia parainfluenzae viral			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia necrotising			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia mycoplasmal			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia pseudomonal			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Postoperative abscess			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Postoperative wound infection			
subjects affected / exposed	8 / 18369 (0.04%)		
occurrences causally related to treatment / all	0 / 10		
deaths causally related to treatment / all	0 / 1		
Prosthetic valve endocarditis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia staphylococcal			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia streptococcal			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia viral			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Post procedural infection			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pseudomonal bacteraemia			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pseudomonas infection			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Psoas abscess			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pulmonary sepsis			
subjects affected / exposed	5 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 1		
Pulmonary tuberculosis			
subjects affected / exposed	5 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Puncture site infection			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pyelonephritis			
subjects affected / exposed	12 / 18369 (0.07%)		
occurrences causally related to treatment / all	0 / 15		
deaths causally related to treatment / all	0 / 0		
Pyelonephritis acute			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Rectal abscess			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal abscess			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory tract infection			
subjects affected / exposed	10 / 18369 (0.05%)		
occurrences causally related to treatment / all	0 / 11		
deaths causally related to treatment / all	0 / 2		
Respiratory tract infection fungal			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rhinovirus infection			
subjects affected / exposed	8 / 18369 (0.04%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 0		
Rotavirus infection			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Salmonellosis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sialoadenitis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Shigella infection			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Septic shock			
subjects affected / exposed	21 / 18369 (0.11%)		
occurrences causally related to treatment / all	0 / 21		
deaths causally related to treatment / all	0 / 7		
Septic encephalopathy			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sepsis			
subjects affected / exposed	25 / 18369 (0.14%)		
occurrences causally related to treatment / all	0 / 26		
deaths causally related to treatment / all	0 / 3		
Scrotal infection			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Scrotal cellulitis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Staphylococcal abscess			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Spinal cord abscess			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Soft tissue infection			

subjects affected / exposed	4 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Skin infection			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Sinusitis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Staphylococcal bacteraemia			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Staphylococcal infection			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Staphylococcal osteomyelitis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Staphylococcal sepsis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Strongyloidiasis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Streptococcal sepsis			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Streptococcal bacteraemia			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Stoma site cellulitis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Staphylococcal skin infection			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Thrombophlebitis septic			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tetanus			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Superinfection			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Submandibular abscess			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Subcutaneous abscess			

subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Tinea capitis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tinea pedis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tuberculosis			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Tracheobronchitis bacterial			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Toxic shock syndrome streptococcal			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tooth abscess			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tonsillitis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Typhoid fever			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urinary tract candidiasis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Upper respiratory tract infection			
subjects affected / exposed	5 / 18369 (0.03%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection staphylococcal			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection pseudomonal			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection enterococcal			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection bacterial			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection			
subjects affected / exposed	66 / 18369 (0.36%)		
occurrences causally related to treatment / all	0 / 74		
deaths causally related to treatment / all	0 / 1		
Vascular device infection			

subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Urosepsis			
subjects affected / exposed	9 / 18369 (0.05%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 0		
Vestibular neuronitis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Viral infection			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Viral sepsis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Wound infection bacterial			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Wound infection staphylococcal			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Wound sepsis			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vulvovaginal mycotic infection			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Wound infection			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	28 / 18369 (0.15%)		
occurrences causally related to treatment / all	1 / 28		
deaths causally related to treatment / all	0 / 0		
Cachexia			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Decreased appetite			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Diabetes mellitus			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Diabetes mellitus inadequate control			
subjects affected / exposed	4 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Diabetic ketoacidosis			

subjects affected / exposed	8 / 18369 (0.04%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 1		
Fluid retention			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Dyslipidaemia			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Electrolyte imbalance			
subjects affected / exposed	4 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Failure to thrive			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Diabetic metabolic decompensation			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Food intolerance			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Glucose tolerance impaired			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gout			

subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Hyperkalaemia			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Hyperglycaemia			
subjects affected / exposed	9 / 18369 (0.05%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 1		
Hyperglycaemic hyperosmolar nonketotic syndrome			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypercalcaemia			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypoglycaemia			
subjects affected / exposed	7 / 18369 (0.04%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 1		
Hypokalaemia			
subjects affected / exposed	10 / 18369 (0.05%)		
occurrences causally related to treatment / all	0 / 10		
deaths causally related to treatment / all	0 / 0		
Hypomagnesaemia			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Hypocalcaemia			

subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Hyperuricaemia			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypervolaemia			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypoalbuminaemia			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypernatraemia			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyponatraemia			
subjects affected / exposed	16 / 18369 (0.09%)		
occurrences causally related to treatment / all	0 / 18		
deaths causally related to treatment / all	0 / 0		
Hypovolaemia			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Iron deficiency			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metabolic alkalosis			

subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Malnutrition			
subjects affected / exposed	2 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Metabolic acidosis			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Lactic acidosis			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Obesity			
subjects affected / exposed	3 / 18369 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Shock hypoglycaemic			
subjects affected / exposed	0 / 18369 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Type 2 diabetes mellitus			
subjects affected / exposed	11 / 18369 (0.06%)		
occurrences causally related to treatment / all	0 / 11		
deaths causally related to treatment / all	0 / 1		
Uraemic acidosis			
subjects affected / exposed	1 / 18369 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Part A: Placebo	Part B: mRNA-1345	Part B: Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6916 / 18316 (37.76%)	48 / 998 (4.81%)	29 / 504 (5.75%)
Vascular disorders			
Hypertension			
subjects affected / exposed	1225 / 18316 (6.69%)	8 / 998 (0.80%)	2 / 504 (0.40%)
occurrences (all)	1303	8	2
Infections and infestations			
COVID-19			
subjects affected / exposed	3302 / 18316 (18.03%)	22 / 998 (2.20%)	14 / 504 (2.78%)
occurrences (all)	3722	22	14
Upper respiratory tract infection			
subjects affected / exposed	2153 / 18316 (11.75%)	17 / 998 (1.70%)	13 / 504 (2.58%)
occurrences (all)	3215	18	15
Nasopharyngitis			
subjects affected / exposed	1384 / 18316 (7.56%)	0 / 998 (0.00%)	0 / 504 (0.00%)
occurrences (all)	2735	0	0
Rhinovirus infection			
subjects affected / exposed	1683 / 18316 (9.19%)	2 / 998 (0.20%)	3 / 504 (0.60%)
occurrences (all)	2091	2	3

Non-serious adverse events	Part A: mRNA-1345		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7080 / 18369 (38.54%)		
Vascular disorders			
Hypertension			
subjects affected / exposed	1244 / 18369 (6.77%)		
occurrences (all)	1351		
Infections and infestations			
COVID-19			
subjects affected / exposed	3404 / 18369 (18.53%)		
occurrences (all)	3830		
Upper respiratory tract infection			

subjects affected / exposed	2198 / 18369 (11.97%)		
occurrences (all)	3300		
Nasopharyngitis			
subjects affected / exposed	1430 / 18369 (7.78%)		
occurrences (all)	2893		
Rhinovirus infection			
subjects affected / exposed	1698 / 18369 (9.24%)		
occurrences (all)	2158		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
22 September 2022	The changes in this amendment included the following: • Update to primary efficacy endpoints: Added RSV-LRTD case definition requiring 3 or more symptoms of LRTD to be present. This endpoint (corresponding to the second case definition) was tested in a hierarchical fashion after RSV-LRTD with 2 or more LRTD symptoms. • Increase in planned study sample size to 37000 participants to provide adequate power for the RSV-LRTD with 3 or more symptoms endpoint. • Futility analysis removed because study enrollment would have been nearly complete when the data safety monitoring board (DSMB) reviewed the futility analysis results.
16 November 2022	This amendment was implemented to harmonize the prespecified efficacy statistical success criteria with the published criteria, through an updated interim analysis success criterion of a lower bound of the alpha-adjusted CI of VE >20%, using an updated alpha-spending approach of Lan-DeMets Pocock approximation function. In addition, the amendment clarified that visits due to surveillance for RSV (per-protocol illness visits) that would normally have not resulted in consultation of a healthcare professional (HCP) were not to be reported as MAAEs.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported