

**Clinical trial results:****A Phase III Randomized, Placebo-Controlled, Clinical Trial to Study the Safety and Efficacy of V212 in Adult Patients with Solid Tumor or Hematologic Malignancy****Summary**

EudraCT number	2010-023156-89
Trial protocol	ES DE CZ GB SK AT BE EE LT GR BG IT
Global end of trial date	11 April 2017

**Results information**

Result version number	v1 (current)
This version publication date	13 April 2018
First version publication date	13 April 2018

**Trial information****Trial identification**

Sponsor protocol code	V212-011
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**Additional study identifiers**

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01254630
WHO universal trial number (UTN)	-

Notes:

**Sponsors**

Sponsor organisation name	Merck Sharp & Dohme Corp.
Sponsor organisation address	2000 Galloping Hill Road, Kenilworth, NJ, United States, 07033
Public contact	Clinical Trials Disclosure, Merck Sharp & Dohme Corp., ClinicalTrialsDisclosure@merck.com
Scientific contact	Clinical Trials Disclosure, Merck Sharp & Dohme Corp., ClinicalTrialsDisclosure@merck.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	11 April 2017
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	11 April 2017
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

This is a randomized, double-blind, placebo-controlled study to assess the safety and tolerability of V212 when administered to adults with solid tumor malignancy (STM) receiving chemotherapy and to assess the impact of V212 on the development of herpes zoster (HZ) in adults with STM receiving chemotherapy. The primary hypothesis is that vaccination with V212 will reduce the incidence of HZ compared with placebo in adults with STM (lower bound of the 97.5% {one-sided  $\alpha=0.0125$ } confidence interval [CI] for the estimated vaccine efficacy in adults with STM be >25%).

Participants with hematologic malignancy (HM) were also enrolled and were to be originally included in the primary and secondary objectives and analyses. After an interim analysis demonstrated clear evidence of futility of V212 in the HM population, enrollment of this population was stopped and all HM-related objectives and analyses were made exploratory and are not reported in this record.

Protection of trial subjects:

This study was conducted in conformance with Good Clinical Practice standards and applicable country and/or local statutes and regulations regarding ethical committee review, informed consent, and the protection of human subjects participating in biomedical research.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	24 June 2011
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: 35
Country: Number of subjects enrolled	Australia: 47
Country: Number of subjects enrolled	Austria: 55
Country: Number of subjects enrolled	Belgium: 28
Country: Number of subjects enrolled	Brazil: 119
Country: Number of subjects enrolled	Bulgaria: 75
Country: Number of subjects enrolled	Canada: 207
Country: Number of subjects enrolled	Chile: 152
Country: Number of subjects enrolled	Colombia: 261
Country: Number of subjects enrolled	Croatia: 41
Country: Number of subjects enrolled	Czech Republic: 22
Country: Number of subjects enrolled	Ecuador: 16
Country: Number of subjects enrolled	Estonia: 13
Country: Number of subjects enrolled	France: 90

Country: Number of subjects enrolled	Germany: 108
Country: Number of subjects enrolled	Greece: 115
Country: Number of subjects enrolled	Honduras: 142
Country: Number of subjects enrolled	Hong Kong: 30
Country: Number of subjects enrolled	Italy: 48
Country: Number of subjects enrolled	Jordan: 12
Country: Number of subjects enrolled	Korea, Republic of: 16
Country: Number of subjects enrolled	Lebanon: 89
Country: Number of subjects enrolled	Lithuania: 9
Country: Number of subjects enrolled	Mexico: 67
Country: Number of subjects enrolled	New Zealand: 13
Country: Number of subjects enrolled	Panama: 9
Country: Number of subjects enrolled	Peru: 183
Country: Number of subjects enrolled	Philippines: 22
Country: Number of subjects enrolled	Romania: 132
Country: Number of subjects enrolled	Russian Federation: 132
Country: Number of subjects enrolled	Saudi Arabia: 12
Country: Number of subjects enrolled	Singapore: 12
Country: Number of subjects enrolled	Slovakia: 18
Country: Number of subjects enrolled	South Africa: 9
Country: Number of subjects enrolled	Spain: 86
Country: Number of subjects enrolled	Taiwan: 109
Country: Number of subjects enrolled	Thailand: 88
Country: Number of subjects enrolled	Turkey: 68
Country: Number of subjects enrolled	United Kingdom: 21
Country: Number of subjects enrolled	United States: 2594
Worldwide total number of subjects	5305
EEA total number of subjects	861

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)	3335
From 65 to 84 years	1913
85 years and over	57

## Subject disposition

### Recruitment

Recruitment details:

Adult participants with a diagnosis of solid tumor malignancy (STM) or hematologic malignancy (HM) were enrolled from 328 sites.

### Pre-assignment

Screening details:

Out of 5507 screened participants, 5305 were randomized. Twenty randomized participants were not included in analyses: 19 participants from a single site identified to have major Good Clinical Practice compliance issues and 1 participant that was not vaccinated. Thus, a total of 5285 were included in analyses.

### Period 1

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

### Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	V212-STM

Arm description:

Participants with STM receiving chemotherapy randomized to receive V212 vaccine given as a 4-dose regimen administered approximately 30 days apart.

Arm type	Experimental
Investigational medicinal product name	V212
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solution for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

V212 viral antigen for HZ, 0.5 mL subcutaneous (SC) injection per dose, in a four dose regimen, approximately 30 days apart.

<b>Arm title</b>	V212-HM
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Arm description:

Participants with HM randomized to receive V212 vaccine given as a 4-dose regimen administered approximately 30 days apart.

Arm type	Experimental
Investigational medicinal product name	V212
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solution for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

V212 viral antigen for HZ, 0.5 mL SC injection per dose, in a four dose regimen, approximately 30 days apart.

<b>Arm title</b>	Placebo-STM
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Arm description:

Participants with STM receiving chemotherapy randomized to receive placebo to V212 vaccine given as a 4-dose regimen administered approximately 30 days apart.

Arm type	Placebo
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Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solution for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Vaccine stabilizer for V212 with no virus antigen, 0.5 mL SC injection per dose, in a four dose regimen, approximately 30 days apart.

<b>Arm title</b>	Placebo-HM
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Arm description:

Participants with HM randomized to receive placebo to V212 vaccine given as a 4-dose regimen administered approximately 30 days apart.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solution for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Vaccine stabilizer for V212 with no virus antigen, 0.5 mL SC injection per dose, in a four dose regimen, approximately 30 days apart.

<b>Number of subjects in period 1<sup>[1]</sup></b>	V212-STM	V212-HM	Placebo-STM
Started	1348	1288	1364
Received Vaccination 1	1328	1277	1350
Received Vaccination 2	1255	1217	1286
Received Vaccination 3	1198	1178	1247
Received Vaccination 4	1155	1145	1212
Completed	546	0	552
Not completed	802	1288	812
Adverse event, serious fatal	461	151	478
Physician decision	24	8	16
Consent withdrawn by subject	201	94	188
Adverse event, non-fatal	36	15	40
Status not recorded	-	-	1
Study terminated by sponsor	-	994	-
Lost to follow-up	80	26	89

<b>Number of subjects in period 1<sup>[1]</sup></b>	Placebo-HM
Started	1285
Received Vaccination 1	1275
Received Vaccination 2	1226

Received Vaccination 3	1194
Received Vaccination 4	1160
Completed	0
Not completed	1285
Adverse event, serious fatal	139
Physician decision	7
Consent withdrawn by subject	89
Adverse event, non-fatal	8
Status not recorded	-
Study terminated by sponsor	1010
Lost to follow-up	32

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Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: The number of participants in the baseline period (N=5285) does not match the Worldwide Number enrolled in the trial (N=5305) because 20 randomized participants were excluded from all analyses due to compliance issues (N=19) and not receiving vaccine (N=1).

## Baseline characteristics

### Reporting groups

Reporting group title	V212-STM
Reporting group description: Participants with STM receiving chemotherapy randomized to receive V212 vaccine given as a 4-dose regimen administered approximately 30 days apart.	
Reporting group title	V212-HM
Reporting group description: Participants with HM randomized to receive V212 vaccine given as a 4-dose regimen administered approximately 30 days apart.	
Reporting group title	Placebo-STM
Reporting group description: Participants with STM receiving chemotherapy randomized to receive placebo to V212 vaccine given as a 4-dose regimen administered approximately 30 days apart.	
Reporting group title	Placebo-HM
Reporting group description: Participants with HM randomized to receive placebo to V212 vaccine given as a 4-dose regimen administered approximately 30 days apart.	

Reporting group values	V212-STM	V212-HM	Placebo-STM
Number of subjects	1348	1288	1364
Age, Customized			
Units: Subjects			
Adults (between 18 and 64 years)	965	705	981
From 65 to 84 years	379	558	378
85 years and over	4	25	5
Age Continuous			
Units: years			
arithmetic mean	57.6	61.0	57.7
standard deviation	± 11.5	± 14.9	± 11.5
Sex: Female, Male			
Units: Subjects			
Female	867	528	892
Male	481	760	472
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	17	2	14
Asian	55	110	64
Native Hawaiian or Other Pacific Islander	2	2	3
Black or African American	86	41	92
White	1044	976	1031
More than one race	144	157	159
Unknown or Not Reported	0	0	1
Age, Customized			
Units: Subjects			
<50 years	299	235	320
≥50 years	1049	1053	1044

<b>Reporting group values</b>	Placebo-HM	Total	
Number of subjects	1285	5285	
Age, Customized Units: Subjects			
Adults (between 18 and 64 years)	673	3324	
From 65 to 84 years	589	1904	
85 years and over	23	57	
Age Continuous Units: years			
arithmetic mean	61.4	-	
standard deviation	± 14.5		
Sex: Female, Male Units: Subjects			
Female	523	2810	
Male	762	2475	
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	2	35	
Asian	94	323	
Native Hawaiian or Other Pacific Islander	2	9	
Black or African American	57	276	
White	986	4037	
More than one race	141	601	
Unknown or Not Reported	3	4	
Age, Customized Units: Subjects			
<50 years	223	1077	
≥50 years	1062	4208	

## End points

### End points reporting groups

Reporting group title	V212-STM
Reporting group description: Participants with STM receiving chemotherapy randomized to receive V212 vaccine given as a 4-dose regimen administered approximately 30 days apart.	
Reporting group title	V212-HM
Reporting group description: Participants with HM randomized to receive V212 vaccine given as a 4-dose regimen administered approximately 30 days apart.	
Reporting group title	Placebo-STM
Reporting group description: Participants with STM receiving chemotherapy randomized to receive placebo to V212 vaccine given as a 4-dose regimen administered approximately 30 days apart.	
Reporting group title	Placebo-HM
Reporting group description: Participants with HM randomized to receive placebo to V212 vaccine given as a 4-dose regimen administered approximately 30 days apart.	

### Primary: Incidence of Confirmed Herpes-Zoster

End point title	Incidence of Confirmed Herpes-Zoster <sup>[1]</sup>
End point description: Clinical criteria for suspected HZ cases were the development of a papular or vesicular rash with a dermatomal or generalized distribution, or in the absence of a rash, clinical suspicion of VZV infection with or without the detection of VZV in diagnostic specimens from blood, cerebrospinal fluid, lung, liver, or other organ. All suspected cases of HZ were subjected to adjudication by the Clinical Adjudication Committee (CAC). Case confirmation was based on skin lesion polymerase chain reaction, if available, or by adjudication of the clinical case description by the CAC, conducted according to the CAC Standard Operations Procedure.  This analysis was based on the Modified Intent-to-Treat (MITT) population. The MITT population for this outcome measure included all randomized participants in the STM population who received at least one dose of vaccination. This endpoint was exploratory for the HM population, therefore that group was not included in this analysis.	
End point type	Primary
End point timeframe: Up to approximately 5 years	

#### Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: This endpoint does not report data for all arms in the baseline period because it was considered exploratory for the V212-HM and Placebo-HM arms.

End point values	V212-STM	Placebo-STM		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1328	1350		
Units: Number of cases per 1000 person years				
number (confidence interval 95%)	6.737 (4.222 to 10.200)	18.457 (14.118 to 23.709)		

## Statistical analyses

<b>Statistical analysis title</b>	Vaccine Efficacy: Incidence of Confirmed HZ
Statistical analysis description: Vaccine efficacy was calculated as 1 minus the hazard ratio of HZ in the V212 group versus the placebo group. The success criterion for vaccine efficacy required that the lower bound of the 97.5% Confidence Interval (CI) be >0.25.	
Comparison groups	V212-STM v Placebo-STM
Number of subjects included in analysis	2678
Analysis specification	Pre-specified
Analysis type	superiority <sup>[2]</sup>
Parameter estimate	Vaccine Efficacy
Point estimate	0.636
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	0.364
upper limit	0.791

Notes:

[2] - Point estimate and 97.5% CI of vaccine efficacy (primary endpoint) were obtained from a Cox proportional hazards regression model, adjusting for age (<50 versus ≥50 years of age).

## Primary: Percentage of Participants with One or More Serious Adverse Events

End point title	Percentage of Participants with One or More Serious Adverse Events <sup>[3]</sup>
End point description: An adverse event (AE) is defined as any unfavorable and unintended change in the structure, function, or chemistry of the body temporally associated with the use of the sponsor's product, whether or not considered related to the use of the product. A serious adverse event (SAE) is an AE that results in death, is life threatening, results in a persistent or significant disability or incapacity, results in or prolongs an existing hospitalization, is a congenital anomaly or birth defect, is a cancer, is an overdose, or is another important medical event.  The analysis population included all participants who received ≥1 dose of vaccination or placebo and had safety follow-up. Three participants in the STM population were cross-treated, these participants were excluded from the safety analyses. This endpoint was exploratory for the HM population, therefore that group was not included in this analysis.	
End point type	Primary

End point timeframe:

Up to 28 days after vaccination 4 (up to approximately 118 days)

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: This endpoint does not report data for all arms in the baseline period because it was considered exploratory for the V212-HM and Placebo-HM arms.

<b>End point values</b>	V212-STM	Placebo-STM		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1322	1346		
Units: percentage of participants				
number (confidence interval 95%)	22.5 (20.3 to 24.9)	21.0 (18.9 to 23.3)		

## Statistical analyses

<b>Statistical analysis title</b>	SAE Risk Difference
Comparison groups	V212-STM v Placebo-STM
Number of subjects included in analysis	2668
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Risk difference (RD)
Point estimate	1.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.8
upper limit	4.5

## Secondary: Incidence of Moderate to Severe Herpes-Zoster-Associated Pain

End point title	Incidence of Moderate to Severe Herpes-Zoster-Associated
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End point description:

Moderate to severe HZ-associated pain was defined as 2 or more occurrences of a score of 3 or greater (0-to-10 scale, where 0 is no pain and 10 is pain as bad as you can imagine) on the Zoster Brief Pain Inventory (ZBPI) at any time from HZ onset through the end of the 6 month HZ-follow-up period.

This analysis was based on the MITT population. The MITT population for this outcome measure included all randomized participants in the STM population who received at least one dose of vaccination. This endpoint was exploratory for the HM population, therefore that group was not included in this analysis.

End point type	Secondary
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End point timeframe:

Up to 6 months after onset of HZ (up to approximately 5 years)

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: This endpoint does not report data for all arms in the baseline period because it was considered exploratory for the V212-HM and Placebo-HM arms.

<b>End point values</b>	V212-STM	Placebo-STM		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1328	1350		
Units: Number of cases per 1000 person years				
number (confidence interval 95%)	2.144 (0.862 to 4.417)	9.380 (6.373 to 13.314)		

## Statistical analyses

<b>Statistical analysis title</b>	Vaccine Efficacy: Incidence of HZ-associated Pain
Statistical analysis description:	
Vaccine efficacy was calculated as 1 minus the hazard ratio of HZ in the V212 group versus the placebo group. The success criterion for vaccine efficacy required that the lower bound of the 95% CI be >0.25.	
Comparison groups	V212-STM v Placebo-STM
Number of subjects included in analysis	2678
Analysis specification	Pre-specified
Analysis type	other <sup>[5]</sup>
Parameter estimate	Vaccine Efficacy
Point estimate	0.771
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.48
upper limit	0.899

Notes:

[5] - Point estimate and 95% CI of vaccine efficacy were obtained from a Cox proportional hazards regression model, adjusting for age (<50 versus ≥50 years of age).

## Secondary: Incidence of Herpes Zoster Complications

End point title	Incidence of Herpes Zoster Complications <sup>[6]</sup>
End point description:	
The composite efficacy endpoint of the incidence of HZ complications was defined as the occurrence of any of the following during the study: hospitalization or prolongation of hospitalization due to HZ, disseminated HZ (including disseminated HZ rash or VZV viremia), visceral HZ, ophthalmic HZ, neurological impairment due to HZ, or administration of intravenous acyclovir therapy for treatment of HZ.	
This analysis was based on the MITT population. The MITT population for this outcome measure included all randomized participants in the STM population who received at least one dose of vaccination. This endpoint was exploratory for the HM population, therefore that group was not included in this analysis.	

End point type	Secondary
End point timeframe:	
Up to 6 months after onset of HZ (up to approximately 5 years)	

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: This endpoint does not report data for all arms in the baseline period because it was considered exploratory for the V212-HM and Placebo-HM arms.

End point values	V212-STM	Placebo-STM		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1328	1350		
Units: Number of cases per 1000 person years				
number (confidence interval 95%)	0.306 (0.008 to 1.706)	2.421 (1.045 to 4.770)		

## Statistical analyses

<b>Statistical analysis title</b>	Vaccine Efficacy: Incidence of HZ Complications
Statistical analysis description:	
Vaccine efficacy was calculated as 1 minus the hazard ratio of HZ in the V212 group versus the placebo group. The success criterion for vaccine efficacy required that the lower bound of the 95% CI be >0.25.	
Comparison groups	V212-STM v Placebo-STM
Number of subjects included in analysis	2678
Analysis specification	Pre-specified
Analysis type	other <sup>[7]</sup>
Parameter estimate	Vaccine Efficacy
Point estimate	0.874
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.005
upper limit	0.984

Notes:

[7] - Point estimate and 95% CI of vaccine efficacy were obtained from a Cox proportional hazards regression model, adjusting for age (<50 versus ≥50 years of age).

## Secondary: Incidence of Postherpetic Neuralgia

<b>End point title</b>	Incidence of Postherpetic Neuralgia <sup>[8]</sup>
End point description:	
Postherpetic Neuralgia (PHN) was defined as pain in the area of the HZ rash with pain in the last 24 hours scored as 3 or greater (on a 0 to 10 scale, where 0 is no pain and 10 is pain as bad as you can imagine) on the ZBPI that persists or appears greater than or equal to 90 days after HZ rash onset.	
This analysis was based on the MITT population. The MITT population for this outcome measure included all randomized participants in the STM population who received at least one dose of vaccination. This endpoint was exploratory for the HM population, therefore that group was not included in this analysis.	
<b>End point type</b>	Secondary

End point timeframe:

Up to 6 months after onset of HZ (up to approximately 5 years)

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: This endpoint does not report data for all arms in the baseline period because it was considered exploratory for the V212-HM and Placebo-HM arms.

<b>End point values</b>	V212-STM	Placebo-STM		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1328	1350		
Units: Number of cases per 1000 person years				
number (confidence interval 95%)	0.306 (0.008 to 1.706)	1.210 (0.330 to 3.099)		

## Statistical analyses

<b>Statistical analysis title</b>	Vaccine Efficacy: Incidence of PHN
Statistical analysis description:	
Vaccine efficacy was calculated as 1 minus the hazard ratio of HZ in the V212 group versus the placebo group. The success criterion for vaccine efficacy required that the lower bound of the 95% CI be >0.25.	
Comparison groups	V212-STM v Placebo-STM
Number of subjects included in analysis	2678
Analysis specification	Pre-specified
Analysis type	other <sup>[9]</sup>
Parameter estimate	Vaccine Efficacy
Point estimate	0.746
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.275
upper limit	0.972

Notes:

[9] - Point estimate and 95% CI of vaccine efficacy were obtained from a Cox proportional hazards regression model, adjusting for age (<50 versus ≥50 years of age).

## Other pre-specified: Percentage of Participants with Study Medication Withdrawn due to an Adverse Event

End point title	Percentage of Participants with Study Medication Withdrawn due to an Adverse Event <sup>[10]</sup>
End point description:	
An adverse event (AE) is defined as any unfavorable and unintended change in the structure, function, or chemistry of the body temporally associated with the use of the sponsor's product, whether or not considered related to the use of the product. A serious adverse event (SAE) is an AE that results in death, is life threatening, results in a persistent or significant disability or incapacity, results in or prolongs an existing hospitalization, is a congenital anomaly or birth defect, is a cancer, is an overdose, or is another important medical event.	
End point type	Other pre-specified

End point timeframe:

Up to 28 days after vaccination 4 (up to approximately 118 days)

Notes:

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint does not report data for all arms in the baseline period because it was considered exploratory for the V212-HM and Placebo-HM arms.

End point values	V212-STM	Placebo-STM		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1322	1346		
Units: percentage of participants				
number (not applicable)	2.2	1.7		

## Statistical analyses

<b>Statistical analysis title</b>	Discontinuation AEs Risk Difference
Comparison groups	V212-STM v Placebo-STM
Number of subjects included in analysis	2668
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Risk difference (RD)
Point estimate	0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.6
upper limit	1.6

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Adverse events were collected up to approximately 5 years after vaccination 1.

Adverse event reporting additional description:

The All Subjects as Treated population included all participants who received  $\geq 1$  dose of vaccination or placebo and had safety follow-up. Three participants in the STM population were cross-treated, these participants were excluded from the safety analyses.

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	19.1
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### Reporting groups

Reporting group title	V212-STM
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Reporting group description:

Participants with STM receiving chemotherapy randomized to receive V212 vaccine given as a 4-dose regimen administered approximately 30 days apart.

Reporting group title	V212-HM
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Reporting group description:

Participants with HM randomized to receive V212 vaccine given as a 4-dose regimen administered approximately 30 days apart.

Reporting group title	Placebo-STM
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Reporting group description:

Participants with STM receiving chemotherapy randomized to receive placebo to V212 vaccine given as a 4-dose regimen administered approximately 30 days apart.

Reporting group title	Placebo-HM
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Reporting group description:

Participants with HM randomized to receive placebo to V212 vaccine given as a 4-dose regimen administered approximately 30 days apart.

<b>Serious adverse events</b>	V212-STM	V212-HM	Placebo-STM
Total subjects affected by serious adverse events			
subjects affected / exposed	794 / 1322 (60.06%)	500 / 1274 (39.25%)	808 / 1346 (60.03%)
number of deaths (all causes)	472	159	488
number of deaths resulting from adverse events	0	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute leukaemia			
subjects affected / exposed	0 / 1322 (0.00%)	2 / 1274 (0.16%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Acute lymphocytic leukaemia			

subjects affected / exposed	0 / 1322 (0.00%)	4 / 1274 (0.31%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 3	0 / 0
Acute lymphocytic leukaemia recurrent			
subjects affected / exposed	0 / 1322 (0.00%)	2 / 1274 (0.16%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Acute monocytic leukaemia			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myeloid leukaemia			
subjects affected / exposed	0 / 1322 (0.00%)	5 / 1274 (0.39%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Acute myeloid leukaemia recurrent			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute promyelocytic leukaemia			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Adenocarcinoma			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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	5 / 1322 (0.38%)	1 / 1274 (0.08%)	3 / 1346 (0.22%)
occurrences causally related to treatment / all	0 / 5	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 3
Adenocarcinoma of appendix			

subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (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
Adenocarcinoma of colon			
subjects affected / exposed	9 / 1322 (0.68%)	0 / 1274 (0.00%)	10 / 1346 (0.74%)
occurrences causally related to treatment / all	0 / 9	0 / 0	0 / 11
deaths causally related to treatment / all	0 / 5	0 / 0	0 / 5
Adenocarcinoma of salivary gland			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Adenocarcinoma pancreas			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Anal cancer			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Anal cancer recurrent			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	0 / 1346 (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 cancer stage IV			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Anaplastic large cell lymphoma T- and null-cell types			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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 oligodendroglioma			

subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angiocentric lymphoma recurrent			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Appendix cancer			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	3 / 1346 (0.22%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
B precursor type acute leukaemia			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
B-cell lymphoma			
subjects affected / exposed	0 / 1322 (0.00%)	9 / 1274 (0.71%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	2 / 9	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
B-cell lymphoma recurrent			
subjects affected / exposed	0 / 1322 (0.00%)	3 / 1274 (0.24%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
B-cell lymphoma refractory			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
B-cell small lymphocytic lymphoma			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
B-cell unclassifiable lymphoma low grade			

subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Basal cell carcinoma</b>			
subjects affected / exposed	9 / 1322 (0.68%)	7 / 1274 (0.55%)	9 / 1346 (0.67%)
occurrences causally related to treatment / all	0 / 12	0 / 7	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Basosquamous carcinoma</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Benign renal neoplasm</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Bile duct cancer</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
<b>Bladder cancer</b>			
subjects affected / exposed	5 / 1322 (0.38%)	0 / 1274 (0.00%)	3 / 1346 (0.22%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 1
<b>Bladder neoplasm</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Bladder transitional cell carcinoma</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Bowen's disease</b>			

subjects affected / exposed	1 / 1322 (0.08%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Brain cancer metastatic</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
<b>Brain neoplasm benign</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Brain neoplasm malignant</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Breast cancer</b>			
subjects affected / exposed	94 / 1322 (7.11%)	2 / 1274 (0.16%)	86 / 1346 (6.39%)
occurrences causally related to treatment / all	0 / 98	0 / 2	0 / 89
deaths causally related to treatment / all	0 / 47	0 / 0	0 / 52
<b>Breast cancer metastatic</b>			
subjects affected / exposed	27 / 1322 (2.04%)	0 / 1274 (0.00%)	40 / 1346 (2.97%)
occurrences causally related to treatment / all	0 / 27	0 / 0	0 / 40
deaths causally related to treatment / all	0 / 12	0 / 0	0 / 26
<b>Breast cancer recurrent</b>			
subjects affected / exposed	3 / 1322 (0.23%)	0 / 1274 (0.00%)	12 / 1346 (0.89%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 12
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 2
<b>Breast cancer stage IV</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (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
<b>Breast neoplasm</b>			

subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial carcinoma			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Bronchioloalveolar carcinoma			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cancer pain			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervix cancer metastatic			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervix carcinoma			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	8 / 1346 (0.59%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 8
Cholangiocarcinoma			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	3 / 1346 (0.22%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 1
Cholesteatoma			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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	0 / 1322 (0.00%)	54 / 1274 (4.24%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	2 / 56	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 5	0 / 0
Chronic lymphocytic leukaemia recurrent			
subjects affected / exposed	0 / 1322 (0.00%)	2 / 1274 (0.16%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic lymphocytic leukaemia transformation			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Chronic myeloid leukaemia			
subjects affected / exposed	0 / 1322 (0.00%)	5 / 1274 (0.39%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Chronic myelomonocytic leukaemia			
subjects affected / exposed	0 / 1322 (0.00%)	2 / 1274 (0.16%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clear cell renal cell carcinoma			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clear cell sarcoma of soft tissue			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Colon adenoma			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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			

subjects affected / exposed	55 / 1322 (4.16%)	0 / 1274 (0.00%)	63 / 1346 (4.68%)
occurrences causally related to treatment / all	0 / 61	0 / 0	0 / 71
deaths causally related to treatment / all	0 / 38	0 / 0	0 / 43
Colon cancer metastatic			
subjects affected / exposed	33 / 1322 (2.50%)	0 / 1274 (0.00%)	24 / 1346 (1.78%)
occurrences causally related to treatment / all	0 / 35	0 / 0	0 / 27
deaths causally related to treatment / all	0 / 25	0 / 0	0 / 12
Colon cancer recurrent			
subjects affected / exposed	3 / 1322 (0.23%)	0 / 1274 (0.00%)	0 / 1346 (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
Colon cancer stage II			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon cancer stage IV			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (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
Colon neoplasm			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colorectal adenocarcinoma			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colorectal cancer			
subjects affected / exposed	10 / 1322 (0.76%)	0 / 1274 (0.00%)	8 / 1346 (0.59%)
occurrences causally related to treatment / all	0 / 10	0 / 0	0 / 8
deaths causally related to treatment / all	0 / 5	0 / 0	0 / 7
Colorectal cancer metastatic			

subjects affected / exposed	5 / 1322 (0.38%)	0 / 1274 (0.00%)	5 / 1346 (0.37%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 5	0 / 0	0 / 4
Diffuse large B-cell lymphoma			
subjects affected / exposed	0 / 1322 (0.00%)	6 / 1274 (0.47%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Diffuse large B-cell lymphoma recurrent			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Diffuse large B-cell lymphoma refractory			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Ductal adenocarcinoma of pancreas			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Duodenal neoplasm			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial adenocarcinoma			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 1
Endometrial cancer			
subjects affected / exposed	5 / 1322 (0.38%)	0 / 1274 (0.00%)	7 / 1346 (0.52%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 7
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 5
Endometrial cancer metastatic			

subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (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
Endometrial cancer stage IV			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ependymoma malignant			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epiglottic carcinoma			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (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
Essential thrombocythaemia			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (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
Ewing's sarcoma			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Ewing's sarcoma metastatic			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extranodal marginal zone B-cell lymphoma (MALT type)			
subjects affected / exposed	0 / 1322 (0.00%)	2 / 1274 (0.16%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extranodal marginal zone B-cell lymphoma (MALT type) recurrent			

subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Fallopian tube cancer			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibrous histiocytoma			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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 / 1322 (0.00%)	0 / 1274 (0.00%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Gallbladder cancer			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 1
Gastric cancer			
subjects affected / exposed	12 / 1322 (0.91%)	0 / 1274 (0.00%)	11 / 1346 (0.82%)
occurrences causally related to treatment / all	0 / 13	0 / 0	0 / 11
deaths causally related to treatment / all	0 / 9	0 / 0	0 / 9
Gastric cancer recurrent			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	0 / 1346 (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
Gastrointestinal cancer metastatic			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Gastrointestinal carcinoma			

subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Gastrointestinal melanoma			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Gastrointestinal stromal tumour			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal cancer			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	0 / 1346 (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
Glioblastoma			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Glioblastoma multiforme			
subjects affected / exposed	5 / 1322 (0.38%)	0 / 1274 (0.00%)	8 / 1346 (0.59%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 8
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 8
Hairy cell leukaemia			
subjects affected / exposed	0 / 1322 (0.00%)	2 / 1274 (0.16%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head and neck cancer			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (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
Hepatic cancer			

subjects affected / exposed	3 / 1322 (0.23%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 0
Hepatocellular carcinoma			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Hodgkin's disease			
subjects affected / exposed	0 / 1322 (0.00%)	11 / 1274 (0.86%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 12	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 4	0 / 0
Hodgkin's disease lymphocyte depletion type stage unspecified			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Hodgkin's disease mixed cellularity recurrent			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Hodgkin's disease nodular sclerosis			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Hodgkin's disease nodular sclerosis recurrent			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hodgkin's disease recurrent			
subjects affected / exposed	0 / 1322 (0.00%)	3 / 1274 (0.24%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Intestinal adenocarcinoma			

subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 1
<b>Intraductal proliferative breast lesion</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Invasive breast carcinoma</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (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
<b>Invasive ductal breast carcinoma</b>			
subjects affected / exposed	6 / 1322 (0.45%)	1 / 1274 (0.08%)	9 / 1346 (0.67%)
occurrences causally related to treatment / all	0 / 6	0 / 1	0 / 10
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 3
<b>Invasive lobular breast carcinoma</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
<b>Keratinising squamous cell carcinoma of nasopharynx</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (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
<b>Keratoacanthoma</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Large granular lymphocytosis</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Laryngeal cancer</b>			

subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	3 / 1346 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Laryngeal cancer metastatic			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Leiomyosarcoma			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	0 / 1346 (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
Leiomyosarcoma metastatic			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	0 / 1346 (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
Lentigo maligna			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukaemia			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Light chain disease			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liposarcoma			

subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	0 / 1346 (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
Liposarcoma recurrent			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (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
Lung adenocarcinoma			
subjects affected / exposed	6 / 1322 (0.45%)	1 / 1274 (0.08%)	5 / 1346 (0.37%)
occurrences causally related to treatment / all	0 / 6	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 5	0 / 0	0 / 1
Lung adenocarcinoma metastatic			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 2
Lung adenocarcinoma recurrent			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Lung cancer metastatic			
subjects affected / exposed	6 / 1322 (0.45%)	1 / 1274 (0.08%)	5 / 1346 (0.37%)
occurrences causally related to treatment / all	0 / 6	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 4	0 / 0	0 / 5
Lung neoplasm			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Lung neoplasm malignant			
subjects affected / exposed	52 / 1322 (3.93%)	3 / 1274 (0.24%)	47 / 1346 (3.49%)
occurrences causally related to treatment / all	0 / 52	0 / 3	0 / 51
deaths causally related to treatment / all	0 / 38	0 / 1	0 / 32
Lung squamous cell carcinoma recurrent			

subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung squamous cell carcinoma stage III			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (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
Lymphocytic lymphoma			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Lymphoma			
subjects affected / exposed	0 / 1322 (0.00%)	4 / 1274 (0.31%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Lymphoma transformation			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Lymphoplasmacytoid lymphoma/immunocytoma			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Lymphoplasmacytoid lymphoma/immunocytoma recurrent			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Malignant ascites			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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 histiocytosis			

subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
<b>Malignant melanoma</b>			
subjects affected / exposed	3 / 1322 (0.23%)	1 / 1274 (0.08%)	6 / 1346 (0.45%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 3
<b>Malignant melanoma in situ</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Malignant neoplasm of ampulla of Vater</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	4 / 1346 (0.30%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 3
<b>Malignant neoplasm of unknown primary site</b>			
subjects affected / exposed	3 / 1322 (0.23%)	0 / 1274 (0.00%)	4 / 1346 (0.30%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 3
<b>Malignant peritoneal neoplasm</b>			
subjects affected / exposed	3 / 1322 (0.23%)	0 / 1274 (0.00%)	0 / 1346 (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
<b>Malignant pleural effusion</b>			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	4 / 1346 (0.30%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
<b>Mantle cell lymphoma</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Mantle cell lymphoma recurrent</b>			

subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medullary carcinoma of breast			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (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
Meningioma			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningioma malignant			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mesothelioma			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (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
Mesothelioma malignant			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to bone			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to central nervous system			
subjects affected / exposed	1 / 1322 (0.08%)	1 / 1274 (0.08%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Metastases to liver			

subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Metastases to lung</b>			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Metastases to lymph nodes</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Metastases to meninges</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
<b>Metastases to ovary</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Metastases to rectum</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Metastatic carcinoma of the bladder</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
<b>Metastatic gastric cancer</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	3 / 1346 (0.22%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 2
<b>Metastatic malignant melanoma</b>			

subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
<b>Metastatic neoplasm</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
<b>Metastatic renal cell carcinoma</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	3 / 1346 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
<b>Metastatic squamous cell carcinoma</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Mucinous adenocarcinoma of appendix</b>			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	0 / 1346 (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
<b>Mycosis fungoides</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
<b>Mycosis fungoides recurrent</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Myelodysplastic syndrome</b>			
subjects affected / exposed	1 / 1322 (0.08%)	12 / 1274 (0.94%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 14	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 3	0 / 0
<b>Myelodysplastic syndrome transformation</b>			

subjects affected / exposed	0 / 1322 (0.00%)	3 / 1274 (0.24%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 3	0 / 0
<b>Myelofibrosis</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Myeloid leukaemia</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
<b>Myeloproliferative neoplasm</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Nasopharyngeal cancer</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
<b>Nasopharyngeal cancer recurrent</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Neuroendocrine carcinoma</b>			
subjects affected / exposed	1 / 1322 (0.08%)	1 / 1274 (0.08%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
<b>Neuroendocrine carcinoma metastatic</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	4 / 1346 (0.30%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
<b>Neuroendocrine carcinoma of the skin</b>			

subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Neuroendocrine tumour			
subjects affected / exposed	1 / 1322 (0.08%)	1 / 1274 (0.08%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Non-Hodgkin's lymphoma			
subjects affected / exposed	0 / 1322 (0.00%)	17 / 1274 (1.33%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 17	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 7	0 / 0
Non-Hodgkin's lymphoma metastatic			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-Hodgkin's lymphoma recurrent			
subjects affected / exposed	0 / 1322 (0.00%)	2 / 1274 (0.16%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Non-Hodgkin's lymphoma unspecified histology aggressive			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Non-small cell lung cancer			
subjects affected / exposed	22 / 1322 (1.66%)	1 / 1274 (0.08%)	18 / 1346 (1.34%)
occurrences causally related to treatment / all	0 / 23	0 / 1	0 / 23
deaths causally related to treatment / all	0 / 16	0 / 0	0 / 16
Non-small cell lung cancer metastatic			
subjects affected / exposed	3 / 1322 (0.23%)	0 / 1274 (0.00%)	4 / 1346 (0.30%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 2
Non-small cell lung cancer recurrent			

subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-small cell lung cancer stage IIIB			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (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
Oesophageal adenocarcinoma			
subjects affected / exposed	1 / 1322 (0.08%)	1 / 1274 (0.08%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 2
Oesophageal adenocarcinoma metastatic			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal cancer metastatic			
subjects affected / exposed	3 / 1322 (0.23%)	0 / 1274 (0.00%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 2
Oesophageal carcinoma			
subjects affected / exposed	5 / 1322 (0.38%)	0 / 1274 (0.00%)	15 / 1346 (1.11%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 15
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 12
Oesophageal squamous cell carcinoma			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (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
Oropharyngeal cancer			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteosarcoma metastatic			

subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (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
Osteosarcoma recurrent			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (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
Ovarian cancer			
subjects affected / exposed	27 / 1322 (2.04%)	0 / 1274 (0.00%)	29 / 1346 (2.15%)
occurrences causally related to treatment / all	0 / 30	0 / 0	0 / 32
deaths causally related to treatment / all	0 / 15	0 / 0	0 / 20
Ovarian cancer metastatic			
subjects affected / exposed	6 / 1322 (0.45%)	0 / 1274 (0.00%)	3 / 1346 (0.22%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 3
Ovarian cancer recurrent			
subjects affected / exposed	6 / 1322 (0.45%)	0 / 1274 (0.00%)	3 / 1346 (0.22%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 2
Ovarian epithelial cancer			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 2
Ovarian epithelial cancer recurrent			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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	13 / 1322 (0.98%)	2 / 1274 (0.16%)	17 / 1346 (1.26%)
occurrences causally related to treatment / all	0 / 13	0 / 2	0 / 18
deaths causally related to treatment / all	0 / 11	0 / 2	0 / 14
Pancreatic carcinoma metastatic			

subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	5 / 1346 (0.37%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 5
Pancreatic carcinoma recurrent			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pancreatic neoplasm			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic neuroendocrine tumour			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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 neuroendocrine tumour metastatic			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Papillary thyroid cancer			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (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
Parathyroid tumour			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral T-cell lymphoma unspecified			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Peripheral T-cell lymphoma unspecified recurrent			

subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Peritoneal carcinoma metastatic			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Peritoneal neoplasm			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pituitary tumour benign			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Plasma cell myeloma			
subjects affected / exposed	0 / 1322 (0.00%)	54 / 1274 (4.24%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 54	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 25	0 / 0
Plasma cell myeloma recurrent			
subjects affected / exposed	0 / 1322 (0.00%)	8 / 1274 (0.63%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 8	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Plasmablastic lymphoma			
subjects affected / exposed	0 / 1322 (0.00%)	2 / 1274 (0.16%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Plasmacytoma			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Precursor T-lymphoblastic lymphoma/leukaemia			

subjects affected / exposed	0 / 1322 (0.00%)	3 / 1274 (0.24%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Precursor T-lymphoblastic lymphoma/leukaemia recurrent			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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	15 / 1322 (1.13%)	5 / 1274 (0.39%)	10 / 1346 (0.74%)
occurrences causally related to treatment / all	0 / 17	0 / 5	0 / 14
deaths causally related to treatment / all	0 / 7	0 / 1	0 / 8
Prostate cancer metastatic			
subjects affected / exposed	4 / 1322 (0.30%)	0 / 1274 (0.00%)	6 / 1346 (0.45%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 2
Rectal adenocarcinoma			
subjects affected / exposed	2 / 1322 (0.15%)	1 / 1274 (0.08%)	5 / 1346 (0.37%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 5
Rectal cancer			
subjects affected / exposed	25 / 1322 (1.89%)	0 / 1274 (0.00%)	17 / 1346 (1.26%)
occurrences causally related to treatment / all	0 / 34	0 / 0	0 / 18
deaths causally related to treatment / all	0 / 16	0 / 0	0 / 8
Rectal cancer metastatic			
subjects affected / exposed	9 / 1322 (0.68%)	0 / 1274 (0.00%)	7 / 1346 (0.52%)
occurrences causally related to treatment / all	0 / 9	0 / 0	0 / 7
deaths causally related to treatment / all	0 / 4	0 / 0	0 / 5
Rectal cancer recurrent			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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 neoplasm			

subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Rectosigmoid cancer			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Refractory anaemia with an excess of blasts			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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 / 1322 (0.23%)	1 / 1274 (0.08%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 1
Renal cancer metastatic			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Renal cancer recurrent			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cell carcinoma			
subjects affected / exposed	1 / 1322 (0.08%)	3 / 1274 (0.24%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Sarcoma			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (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
Sarcoma metastatic			

subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Sarcoma of skin			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Schwannoma			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Signet-ring cell carcinoma			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Skin cancer			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Skin cancer metastatic			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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 carcinoma			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Small cell lung cancer			
subjects affected / exposed	7 / 1322 (0.53%)	0 / 1274 (0.00%)	6 / 1346 (0.45%)
occurrences causally related to treatment / all	0 / 8	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 4	0 / 0	0 / 5
Small cell lung cancer extensive stage			

subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (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
Small cell lung cancer metastatic			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 1
Small intestine adenocarcinoma			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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 / 1322 (0.00%)	0 / 1274 (0.00%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Splenic marginal zone lymphoma			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Squamous cell carcinoma			
subjects affected / exposed	3 / 1322 (0.23%)	6 / 1274 (0.47%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Squamous cell carcinoma of head and neck			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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 lung			
subjects affected / exposed	4 / 1322 (0.30%)	0 / 1274 (0.00%)	4 / 1346 (0.30%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 2
Squamous cell carcinoma of skin			

subjects affected / exposed	1 / 1322 (0.08%)	6 / 1274 (0.47%)	4 / 1346 (0.30%)
occurrences causally related to treatment / all	0 / 1	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Squamous cell carcinoma of the hypopharynx			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (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
Squamous cell carcinoma of the oral cavity			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	3 / 1346 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of the tongue			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
T-cell lymphoma			
subjects affected / exposed	0 / 1322 (0.00%)	5 / 1274 (0.39%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
T-cell lymphoma recurrent			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
T-cell type acute leukaemia			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thymoma			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroid cancer			

subjects affected / exposed	1 / 1322 (0.08%)	1 / 1274 (0.08%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroid cancer metastatic			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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	0 / 1322 (0.00%)	0 / 1274 (0.00%)	3 / 1346 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Tonsil cancer			
subjects affected / exposed	3 / 1322 (0.23%)	0 / 1274 (0.00%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Tonsillar neoplasm			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Transitional cell carcinoma			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	3 / 1346 (0.22%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 3
Tumour flare			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureteric cancer			

subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (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
<b>Urethral cancer</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (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
<b>Uterine cancer</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	4 / 1346 (0.30%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 3
<b>Uterine leiomyosarcoma</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (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
<b>Vaginal cancer</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
<b>Vulval cancer</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
<b>Waldenstrom's macroglobulinaemia</b>			
subjects affected / exposed	0 / 1322 (0.00%)	2 / 1274 (0.16%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Vascular disorders</b>			
<b>Accelerated hypertension</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Aortic aneurysm</b>			

subjects affected / exposed	1 / 1322 (0.08%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Aortic dissection</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
<b>Aortic stenosis</b>			
subjects affected / exposed	2 / 1322 (0.15%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Arterial thrombosis</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Circulatory collapse</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Deep vein thrombosis</b>			
subjects affected / exposed	14 / 1322 (1.06%)	6 / 1274 (0.47%)	12 / 1346 (0.89%)
occurrences causally related to treatment / all	0 / 14	0 / 6	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Embolism</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
<b>Haematoma</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Haemorrhage</b>			

subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Hypertension			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive crisis			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (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 emergency			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	1 / 1322 (0.08%)	1 / 1274 (0.08%)	4 / 1346 (0.30%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemic shock			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Lymphoedema			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	3 / 1346 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic hypotension			
subjects affected / exposed	0 / 1322 (0.00%)	2 / 1274 (0.16%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic venous thrombosis			

subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral arterial occlusive disease			
subjects affected / exposed	0 / 1322 (0.00%)	2 / 1274 (0.16%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery occlusion			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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 embolism			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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 ischaemia			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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 venous disease			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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 / 1322 (0.00%)	0 / 1274 (0.00%)	3 / 1346 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior vena cava syndrome			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombosis			

subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous thrombosis limb			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Adverse drug reaction			
subjects affected / exposed	3 / 1322 (0.23%)	0 / 1274 (0.00%)	0 / 1346 (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
Asthenia			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	4 / 1346 (0.30%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest discomfort			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	6 / 1322 (0.45%)	4 / 1274 (0.31%)	12 / 1346 (0.89%)
occurrences causally related to treatment / all	0 / 6	0 / 4	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chills			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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

Complication associated with device			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	31 / 1322 (2.34%)	13 / 1274 (1.02%)	17 / 1346 (1.26%)
occurrences causally related to treatment / all	0 / 31	0 / 13	0 / 17
deaths causally related to treatment / all	0 / 31	0 / 13	0 / 17
Drug withdrawal syndrome			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	0 / 1346 (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	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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 physical health deterioration			
subjects affected / exposed	5 / 1322 (0.38%)	1 / 1274 (0.08%)	3 / 1346 (0.22%)
occurrences causally related to treatment / all	0 / 5	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Generalised oedema			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Granuloma			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired healing			

subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Incarcerated hernia</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	3 / 1346 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Malaise</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Medical device pain</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Mucosal haemorrhage</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Mucosal inflammation</b>			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	3 / 1346 (0.22%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Multiple organ dysfunction syndrome</b>			
subjects affected / exposed	0 / 1322 (0.00%)	2 / 1274 (0.16%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 1
<b>Nodule</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Non-cardiac chest pain</b>			

subjects affected / exposed	1 / 1322 (0.08%)	1 / 1274 (0.08%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Oedema peripheral</b>			
subjects affected / exposed	3 / 1322 (0.23%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Organ failure</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Pain</b>			
subjects affected / exposed	3 / 1322 (0.23%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Polyserositis</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Pyrexia</b>			
subjects affected / exposed	11 / 1322 (0.83%)	5 / 1274 (0.39%)	15 / 1346 (1.11%)
occurrences causally related to treatment / all	0 / 11	0 / 5	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Sudden death</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (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
<b>Systemic inflammatory response syndrome</b>			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	0 / 1346 (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
<b>Ulcer haemorrhage</b>			

subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Vascular stent thrombosis</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Visceral pain</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Immune system disorders</b>			
<b>Anaphylactic reaction</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Drug hypersensitivity</b>			
subjects affected / exposed	4 / 1322 (0.30%)	1 / 1274 (0.08%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Graft versus host disease</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hypersensitivity</b>			
subjects affected / exposed	2 / 1322 (0.15%)	1 / 1274 (0.08%)	3 / 1346 (0.22%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hypogammaglobulinaemia</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Sarcoidosis</b>			

subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Reproductive system and breast disorders</b>			
<b>Adnexa uteri mass</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Benign prostatic hyperplasia</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Cervical dysplasia</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Colpocele</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Dysfunctional uterine bleeding</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Endometrial hyperplasia</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Genital erosion</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Genital lesion</b>			

subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic ovarian cyst			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metrorrhagia			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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 / 1322 (0.15%)	1 / 1274 (0.08%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian disorder			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian mass			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Postmenopausal haemorrhage			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Prostatic disorder			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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 dysplasia			

subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Testicular pain			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Vaginal disorder			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal haemorrhage			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Respiratory, thoracic and mediastinal disorders			
Acute interstitial pneumonitis			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute pulmonary oedema			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 1322 (0.00%)	2 / 1274 (0.16%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Acute respiratory failure			
subjects affected / exposed	9 / 1322 (0.68%)	0 / 1274 (0.00%)	3 / 1346 (0.22%)
occurrences causally related to treatment / all	0 / 9	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 5	0 / 0	0 / 1
Alveolitis allergic			

subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Apnoea</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
<b>Aspiration</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Asthma</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	4 / 1346 (0.30%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Atelectasis</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Bronchial hyperreactivity</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Chronic obstructive pulmonary disease</b>			
subjects affected / exposed	10 / 1322 (0.76%)	8 / 1274 (0.63%)	10 / 1346 (0.74%)
occurrences causally related to treatment / all	0 / 14	0 / 19	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
<b>Chronic respiratory failure</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
<b>Chylothorax</b>			

subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Cough</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Dyspnoea</b>			
subjects affected / exposed	5 / 1322 (0.38%)	1 / 1274 (0.08%)	6 / 1346 (0.45%)
occurrences causally related to treatment / all	0 / 5	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
<b>Dyspnoea exertional</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Emphysema</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
<b>Epistaxis</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
<b>Haemoptysis</b>			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	3 / 1346 (0.22%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Haemothorax</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hypoxia</b>			

subjects affected / exposed	2 / 1322 (0.15%)	2 / 1274 (0.16%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Idiopathic pulmonary fibrosis</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
<b>Interstitial lung disease</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (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
<b>Lung disorder</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Lung infiltration</b>			
subjects affected / exposed	0 / 1322 (0.00%)	2 / 1274 (0.16%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Nasal septum deviation</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Obstructive airways disorder</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Organising pneumonia</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Paranasal sinus mucosal hypertrophy</b>			

subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	11 / 1322 (0.83%)	5 / 1274 (0.39%)	12 / 1346 (0.89%)
occurrences causally related to treatment / all	0 / 12	0 / 5	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pneumonia aspiration			
subjects affected / exposed	3 / 1322 (0.23%)	1 / 1274 (0.08%)	4 / 1346 (0.30%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 8
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Pneumonia lipoid			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Pneumonitis			
subjects affected / exposed	4 / 1322 (0.30%)	1 / 1274 (0.08%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pneumothorax			
subjects affected / exposed	3 / 1322 (0.23%)	1 / 1274 (0.08%)	5 / 1346 (0.37%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pulmonary embolism			
subjects affected / exposed	28 / 1322 (2.12%)	7 / 1274 (0.55%)	19 / 1346 (1.41%)
occurrences causally related to treatment / all	0 / 28	0 / 7	0 / 20
deaths causally related to treatment / all	0 / 2	0 / 2	0 / 1
Pulmonary fibrosis			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pulmonary hypertension			

subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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 infarction			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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	0 / 1322 (0.00%)	0 / 1274 (0.00%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	1 / 1322 (0.08%)	1 / 1274 (0.08%)	0 / 1346 (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
Pulmonary toxicity			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reactive airways dysfunction syndrome			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiration abnormal			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory acidosis			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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 disorder			

subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Respiratory distress</b>			
subjects affected / exposed	3 / 1322 (0.23%)	0 / 1274 (0.00%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 2
<b>Respiratory failure</b>			
subjects affected / exposed	6 / 1322 (0.45%)	2 / 1274 (0.16%)	8 / 1346 (0.59%)
occurrences causally related to treatment / all	0 / 6	0 / 2	0 / 8
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 6
<b>Sleep apnoea syndrome</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Tracheal stenosis</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Vocal cord thickening</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Psychiatric disorders</b>			
<b>Adjustment disorder</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Anxiety</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Confusional state</b>			

subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Delirium</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Depression</b>			
subjects affected / exposed	1 / 1322 (0.08%)	1 / 1274 (0.08%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Major depression</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Mania</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Mental disorder</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Mental status changes</b>			
subjects affected / exposed	5 / 1322 (0.38%)	0 / 1274 (0.00%)	4 / 1346 (0.30%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Mood altered</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Somatic symptom disorder</b>			

subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide attempt			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	0 / 1346 (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
Product issues			
Device dislocation			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	3 / 1346 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device failure			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device leakage			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device malfunction			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device occlusion			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	3 / 1346 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stent malfunction			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombosis in device			

subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Hepatobiliary disorders</b>			
Acute hepatic failure			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Bile duct obstruction			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	3 / 1346 (0.22%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile duct stone			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary colic			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biloma			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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	4 / 1322 (0.30%)	0 / 1274 (0.00%)	7 / 1346 (0.52%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis acute			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			

subjects affected / exposed	0 / 1322 (0.00%)	2 / 1274 (0.16%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Cholecystitis acute</b>			
subjects affected / exposed	3 / 1322 (0.23%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Cholecystitis chronic</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Cholelithiasis</b>			
subjects affected / exposed	1 / 1322 (0.08%)	2 / 1274 (0.16%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Cholestasis</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Drug-induced liver injury</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Gallbladder disorder</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Haemobilia</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Hepatic cirrhosis</b>			

subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Hepatic failure			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Hepatic function abnormal			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Hepatic haemorrhage			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis cholestatic			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Hepatorenal syndrome			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (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
Hepatotoxicity			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Jaundice cholestatic			

subjects affected / exposed	1 / 1322 (0.08%)	1 / 1274 (0.08%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver injury			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal vein thrombosis			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
CSF test abnormal			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oxygen saturation decreased			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prothrombin time abnormal			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin increased			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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 wound dehiscence			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Accidental overdose			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anastomotic stenosis			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle fracture			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	4 / 1346 (0.30%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical vertebral fracture			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chemical peritonitis			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Compression fracture			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contusion			

subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Craniocerebral injury</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Cystitis radiation</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Eschar</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Eye contusion</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Fall</b>			
subjects affected / exposed	3 / 1322 (0.23%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Femoral neck fracture</b>			
subjects affected / exposed	1 / 1322 (0.08%)	1 / 1274 (0.08%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Femur fracture</b>			
subjects affected / exposed	2 / 1322 (0.15%)	3 / 1274 (0.24%)	5 / 1346 (0.37%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Fibula fracture</b>			

subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot fracture			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis radiation			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal stoma complication			
subjects affected / exposed	2 / 1322 (0.15%)	1 / 1274 (0.08%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heat exhaustion			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	5 / 1322 (0.38%)	1 / 1274 (0.08%)	3 / 1346 (0.22%)
occurrences causally related to treatment / all	0 / 5	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incarcerated incisional hernia			

subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Incisional hernia</b>			
subjects affected / exposed	3 / 1322 (0.23%)	0 / 1274 (0.00%)	0 / 1346 (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
<b>Infusion related reaction</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Intentional overdose</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Joint dislocation</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Joint injury</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Laceration</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Ligament rupture</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Lower limb fracture</b>			

subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Lumbar vertebral fracture</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Muscle rupture</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Osteoradionecrosis</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Overdose</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pelvic fracture</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Periorbital haematoma</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Post procedural bile leak</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Post procedural discharge</b>			

subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural fistula			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haematoma			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haematuria			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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	2 / 1322 (0.15%)	3 / 1274 (0.24%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative fever			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative ileus			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative respiratory distress			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural hypotension			

subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Procedural pneumothorax</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	3 / 1346 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Radiation necrosis</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (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
<b>Radiation oesophagitis</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Radiation pericarditis</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Radiation pneumonitis</b>			
subjects affected / exposed	2 / 1322 (0.15%)	1 / 1274 (0.08%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Radius fracture</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Rib fracture</b>			
subjects affected / exposed	0 / 1322 (0.00%)	2 / 1274 (0.16%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Road traffic accident</b>			

subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
<b>Seroma</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Skin wound</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Spinal column injury</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Spinal compression fracture</b>			
subjects affected / exposed	3 / 1322 (0.23%)	2 / 1274 (0.16%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Spinal fracture</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Sternal fracture</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Stoma site haemorrhage</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Stomal hernia</b>			

subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Stress fracture</b>			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	0 / 1346 (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
<b>Subarachnoid haemorrhage</b>			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Subcutaneous haematoma</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Subdural haematoma</b>			
subjects affected / exposed	1 / 1322 (0.08%)	2 / 1274 (0.16%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Subdural haemorrhage</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Thermal burn</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Thoracic vertebral fracture</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Tibia fracture</b>			

subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxicity to various agents			
subjects affected / exposed	2 / 1322 (0.15%)	3 / 1274 (0.24%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Transplant dysfunction			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic haematoma			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Traumatic haemothorax			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention postoperative			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urostomy complication			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Wound dehiscence</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Wrist fracture</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Congenital, familial and genetic disorders</b>			
<b>Dysplastic naevus syndrome</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (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
<b>Tracheo-oesophageal fistula</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Cardiac disorders</b>			
<b>Acute coronary syndrome</b>			
subjects affected / exposed	1 / 1322 (0.08%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Acute myocardial infarction</b>			
subjects affected / exposed	2 / 1322 (0.15%)	6 / 1274 (0.47%)	6 / 1346 (0.45%)
occurrences causally related to treatment / all	0 / 2	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Angina pectoris</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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

Angina unstable			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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 valve sclerosis			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Aortic valve stenosis			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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	0 / 1322 (0.00%)	1 / 1274 (0.08%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Atrial fibrillation			
subjects affected / exposed	7 / 1322 (0.53%)	9 / 1274 (0.71%)	11 / 1346 (0.82%)
occurrences causally related to treatment / all	0 / 8	0 / 12	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	0 / 1322 (0.00%)	3 / 1274 (0.24%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block second degree			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Cardiac arrest			
subjects affected / exposed	8 / 1322 (0.61%)	4 / 1274 (0.31%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 8	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 8	0 / 3	0 / 0
Cardiac failure			

subjects affected / exposed	6 / 1322 (0.45%)	3 / 1274 (0.24%)	4 / 1346 (0.30%)
occurrences causally related to treatment / all	0 / 6	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
<b>Cardiac failure acute</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Cardiac failure chronic</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Cardiac failure congestive</b>			
subjects affected / exposed	9 / 1322 (0.68%)	11 / 1274 (0.86%)	6 / 1346 (0.45%)
occurrences causally related to treatment / all	0 / 11	0 / 12	0 / 7
deaths causally related to treatment / all	0 / 1	0 / 2	0 / 0
<b>Cardiac tamponade</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Cardiac valve disease</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Cardiac ventricular thrombosis</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Cardio-respiratory arrest</b>			
subjects affected / exposed	2 / 1322 (0.15%)	1 / 1274 (0.08%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 2
<b>Cardiomyopathy</b>			

subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Cardiomyopathy acute</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Cardiopulmonary failure</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Cardiorenal syndrome</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Congestive cardiomyopathy</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Coronary artery disease</b>			
subjects affected / exposed	3 / 1322 (0.23%)	3 / 1274 (0.24%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
<b>Coronary artery insufficiency</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (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
<b>Ischaemic cardiomyopathy</b>			
subjects affected / exposed	0 / 1322 (0.00%)	2 / 1274 (0.16%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
<b>Mitral valve incompetence</b>			

subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Myocardial infarction</b>			
subjects affected / exposed	3 / 1322 (0.23%)	4 / 1274 (0.31%)	4 / 1346 (0.30%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 2	0 / 2	0 / 0
<b>Myocardial ischaemia</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
<b>Palpitations</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pericardial effusion</b>			
subjects affected / exposed	2 / 1322 (0.15%)	1 / 1274 (0.08%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pericardial haemorrhage</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pericarditis</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
<b>Pulseless electrical activity</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (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
<b>Sinus node dysfunction</b>			

subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus tachycardia			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress cardiomyopathy			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 1322 (0.00%)	2 / 1274 (0.16%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular dyssynchrony			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Ventricular extrasystoles			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Nervous system disorders</b>			
<b>Aphasia</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Autonomic nervous system imbalance</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Brain oedema</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Carotid artery aneurysm</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Carotid artery stenosis</b>			
subjects affected / exposed	1 / 1322 (0.08%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Cerebellar infarction</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Cerebral haematoma</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Cerebral haemorrhage</b>			

subjects affected / exposed	1 / 1322 (0.08%)	1 / 1274 (0.08%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
<b>Cerebral infarction</b>			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	0 / 1346 (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
<b>Cerebral microangiopathy</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Cerebrovascular accident</b>			
subjects affected / exposed	8 / 1322 (0.61%)	4 / 1274 (0.31%)	5 / 1346 (0.37%)
occurrences causally related to treatment / all	0 / 8	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 3	0 / 1	0 / 0
<b>Cervical cord compression</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Cognitive disorder</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Cubital tunnel syndrome</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Dementia</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Dementia Alzheimer's type</b>			

subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depressed level of consciousness			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Diabetic coma			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolic stroke			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	3 / 1346 (0.22%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	3 / 1346 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Guillain-Barre syndrome			

subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Haemorrhage intracranial</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Headache</b>			
subjects affected / exposed	1 / 1322 (0.08%)	3 / 1274 (0.24%)	5 / 1346 (0.37%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hemiparesis</b>			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	0 / 1346 (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
<b>Hepatic encephalopathy</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hypoglycaemic coma</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hypoxic-ischaemic encephalopathy</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
<b>Intensive care unit acquired weakness</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Intracranial haematoma</b>			

subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Intraventricular haemorrhage			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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 stroke			
subjects affected / exposed	1 / 1322 (0.08%)	2 / 1274 (0.16%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Lumbar radiculopathy			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningeal disorder			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelitis transverse			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Nervous system disorder			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuralgia			

subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Neuropathy peripheral</b>			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Parkinson's disease</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Polyneuropathy</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Post herpetic neuralgia</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Posterior reversible encephalopathy syndrome</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Presyncope</b>			
subjects affected / exposed	1 / 1322 (0.08%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Sciatica</b>			
subjects affected / exposed	1 / 1322 (0.08%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Seizure</b>			

subjects affected / exposed	6 / 1322 (0.45%)	2 / 1274 (0.16%)	5 / 1346 (0.37%)
occurrences causally related to treatment / all	0 / 6	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Senile dementia</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Serotonin syndrome</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Simple partial seizures</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Spinal cord compression</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Syncope</b>			
subjects affected / exposed	5 / 1322 (0.38%)	1 / 1274 (0.08%)	3 / 1346 (0.22%)
occurrences causally related to treatment / all	0 / 5	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Toxic encephalopathy</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	3 / 1346 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Transient ischaemic attack</b>			
subjects affected / exposed	2 / 1322 (0.15%)	5 / 1274 (0.39%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Vasogenic cerebral oedema</b>			

subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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 paralysis			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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 and lymphatic system disorders			
Anaemia			
subjects affected / exposed	9 / 1322 (0.68%)	16 / 1274 (1.26%)	24 / 1346 (1.78%)
occurrences causally related to treatment / all	0 / 9	0 / 19	0 / 25
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Anaemia of chronic disease			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	3 / 1346 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia of malignant disease			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune haemolytic anaemia			
subjects affected / exposed	0 / 1322 (0.00%)	2 / 1274 (0.16%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone marrow failure			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Coagulopathy			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			

subjects affected / exposed	21 / 1322 (1.59%)	44 / 1274 (3.45%)	35 / 1346 (2.60%)
occurrences causally related to treatment / all	0 / 23	0 / 64	0 / 37
deaths causally related to treatment / all	0 / 1	0 / 4	0 / 2
<b>Haematotoxicity</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
<b>Haemolysis</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Haemolytic anaemia</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Haemorrhagic anaemia</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hypoprothrombinaemia</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Iron deficiency anaemia</b>			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	0 / 1346 (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
<b>Leukocytosis</b>			
subjects affected / exposed	2 / 1322 (0.15%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Leukopenia</b>			

subjects affected / exposed	1 / 1322 (0.08%)	1 / 1274 (0.08%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymph node pain			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenitis			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Lymphadenopathy			
subjects affected / exposed	1 / 1322 (0.08%)	1 / 1274 (0.08%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	4 / 1322 (0.30%)	4 / 1274 (0.31%)	5 / 1346 (0.37%)
occurrences causally related to treatment / all	0 / 4	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	7 / 1322 (0.53%)	5 / 1274 (0.39%)	9 / 1346 (0.67%)
occurrences causally related to treatment / all	0 / 8	0 / 5	0 / 12
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Splénomegaly			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Thrombocytopenia			
subjects affected / exposed	5 / 1322 (0.38%)	4 / 1274 (0.31%)	5 / 1346 (0.37%)
occurrences causally related to treatment / all	1 / 6	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Inner ear disorder			

subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Neurosensory hypoacusis			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Vertigo			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Vertigo positional			
subjects affected / exposed	1 / 1322 (0.08%)	1 / 1274 (0.08%)	0 / 1346 (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
Eye disorders			
Blindness transient			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cataract			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Cortical visual impairment			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myopia			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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 retinitis			

subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Retinal detachment</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Ulcerative keratitis</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Gastrointestinal disorders</b>			
<b>Abdominal hernia</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Abdominal hernia obstructive</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Abdominal pain</b>			
subjects affected / exposed	9 / 1322 (0.68%)	3 / 1274 (0.24%)	7 / 1346 (0.52%)
occurrences causally related to treatment / all	0 / 10	0 / 3	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Abdominal pain lower</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Abdominal pain upper</b>			
subjects affected / exposed	2 / 1322 (0.15%)	1 / 1274 (0.08%)	4 / 1346 (0.30%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Abdominal wall haematoma</b>			

subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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 fissure			
subjects affected / exposed	1 / 1322 (0.08%)	1 / 1274 (0.08%)	0 / 1346 (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
Anal fistula			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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	1 / 1322 (0.08%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 1322 (0.00%)	2 / 1274 (0.16%)	3 / 1346 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ischaemic			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	7 / 1322 (0.53%)	1 / 1274 (0.08%)	8 / 1346 (0.59%)
occurrences causally related to treatment / all	0 / 8	0 / 1	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Crohn's disease			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cyclic vomiting syndrome			

subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	17 / 1322 (1.29%)	1 / 1274 (0.08%)	13 / 1346 (0.97%)
occurrences causally related to treatment / all	0 / 20	0 / 1	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticular perforation			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum intestinal			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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 obstruction			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer haemorrhage			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenitis			

subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Dyspepsia</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Dysphagia</b>			
subjects affected / exposed	3 / 1322 (0.23%)	0 / 1274 (0.00%)	5 / 1346 (0.37%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Enteritis</b>			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Enterocutaneous fistula</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Eosinophilic colitis</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Erosive oesophagitis</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Faecaloma</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Gastric ulcer haemorrhage</b>			

subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Gastritis</b>			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Gastritis erosive</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Gastrointestinal disorder</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Gastrointestinal haemorrhage</b>			
subjects affected / exposed	7 / 1322 (0.53%)	6 / 1274 (0.47%)	13 / 1346 (0.97%)
occurrences causally related to treatment / all	0 / 8	0 / 6	0 / 13
deaths causally related to treatment / all	0 / 4	0 / 1	0 / 4
<b>Gastrointestinal hypomotility</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Gastrointestinal obstruction</b>			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	0 / 1346 (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
<b>Gastrointestinal pain</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Gastrointestinal perforation</b>			

subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Haematemesis</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Haematochezia</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Haemorrhoidal haemorrhage</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Haemorrhoids</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Hiatus hernia</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Ileus</b>			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	4 / 1346 (0.30%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Impaired gastric emptying</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Incarcerated inguinal hernia</b>			

subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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			
subjects affected / exposed	1 / 1322 (0.08%)	1 / 1274 (0.08%)	0 / 1346 (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
Inguinal hernia strangulated			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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 fibrosis			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Intestinal ischaemia			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (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
Intestinal obstruction			
subjects affected / exposed	12 / 1322 (0.91%)	3 / 1274 (0.24%)	10 / 1346 (0.74%)
occurrences causally related to treatment / all	0 / 16	0 / 4	0 / 12
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Intestinal perforation			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (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
Intestinal prolapse			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			

subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	3 / 1322 (0.23%)	1 / 1274 (0.08%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine polyp			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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 gastrointestinal haemorrhage			
subjects affected / exposed	0 / 1322 (0.00%)	2 / 1274 (0.16%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mallory-Weiss syndrome			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mouth ulceration			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	4 / 1322 (0.30%)	1 / 1274 (0.08%)	5 / 1346 (0.37%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic colitis			
subjects affected / exposed	0 / 1322 (0.00%)	3 / 1274 (0.24%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstruction gastric			

subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Odynophagia</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Oesophageal perforation</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Oesophageal rupture</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Oesophageal spasm</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Oesophageal ulcer haemorrhage</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Oesophageal varices haemorrhage</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Oesophagitis</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pancreatic cyst</b>			

subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pancreatic insufficiency</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pancreatic mass</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pancreatitis</b>			
subjects affected / exposed	4 / 1322 (0.30%)	1 / 1274 (0.08%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 5	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pancreatitis acute</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	3 / 1346 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pancreatitis chronic</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Proctalgia</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Proctitis</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Rectal haemorrhage</b>			

subjects affected / exposed	0 / 1322 (0.00%)	3 / 1274 (0.24%)	3 / 1346 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal ulcer			
subjects affected / exposed	1 / 1322 (0.08%)	1 / 1274 (0.08%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retroperitoneal haemorrhage			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Salivary gland calculus			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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 intestinal obstruction			
subjects affected / exposed	21 / 1322 (1.59%)	4 / 1274 (0.31%)	12 / 1346 (0.89%)
occurrences causally related to treatment / all	0 / 43	0 / 4	0 / 17
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 1
Small intestinal perforation			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Stomatitis			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	4 / 1346 (0.30%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			

subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	1 / 1322 (0.08%)	3 / 1274 (0.24%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Volvulus			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Vomiting			
subjects affected / exposed	11 / 1322 (0.83%)	2 / 1274 (0.16%)	13 / 1346 (0.97%)
occurrences causally related to treatment / all	0 / 11	0 / 4	0 / 16
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	0 / 1346 (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
Brow ptosis			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Decubitus ulcer			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug reaction with eosinophilia and systemic symptoms			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Eczema nummular			

subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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 erythema			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Pruritus			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Pyoderma gangrenosum			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Rash maculo-papular			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Rash vesicular			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin exfoliation			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin necrosis			

subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Skin reaction</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Skin ulcer</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Stasis dermatitis</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Stevens-Johnson syndrome</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Swelling face</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Toxic epidermal necrolysis</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Urticaria</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Renal and urinary disorders</b>			
Acute kidney injury			

subjects affected / exposed	12 / 1322 (0.91%)	10 / 1274 (0.78%)	18 / 1346 (1.34%)
occurrences causally related to treatment / all	0 / 12	0 / 11	0 / 20
deaths causally related to treatment / all	0 / 3	0 / 1	0 / 0
<b>Chronic kidney disease</b>			
subjects affected / exposed	0 / 1322 (0.00%)	3 / 1274 (0.24%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
<b>End stage renal disease</b>			
subjects affected / exposed	1 / 1322 (0.08%)	2 / 1274 (0.16%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
<b>Haematuria</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	3 / 1346 (0.22%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hydronephrosis</b>			
subjects affected / exposed	4 / 1322 (0.30%)	0 / 1274 (0.00%)	4 / 1346 (0.30%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hypercalcaemic nephropathy</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (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
<b>Incontinence</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Micturition disorder</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Nephrolithiasis</b>			

subjects affected / exposed	0 / 1322 (0.00%)	2 / 1274 (0.16%)	3 / 1346 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Obstructive uropathy</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Renal failure</b>			
subjects affected / exposed	5 / 1322 (0.38%)	2 / 1274 (0.16%)	6 / 1346 (0.45%)
occurrences causally related to treatment / all	0 / 5	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
<b>Renal impairment</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Stag horn calculus</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Ureteric obstruction</b>			
subjects affected / exposed	1 / 1322 (0.08%)	1 / 1274 (0.08%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Ureterolithiasis</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Urinary bladder haemorrhage</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Urinary retention</b>			

subjects affected / exposed	2 / 1322 (0.15%)	1 / 1274 (0.08%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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 disorders			
Adrenal insufficiency			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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 syndrome			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cushing's syndrome			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Goitre			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia of malignancy			
subjects affected / exposed	1 / 1322 (0.08%)	2 / 1274 (0.16%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthyroidism			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypothyroidism			

subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroid mass			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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			
Ankylosing spondylitis			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthralgia			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthropathy			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Back pain			
subjects affected / exposed	4 / 1322 (0.30%)	1 / 1274 (0.08%)	3 / 1346 (0.22%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone cyst			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fistula			

subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fracture delayed union			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemarthrosis			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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 disorder			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Lumbar spinal stenosis			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle haemorrhage			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle spasms			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			

subjects affected / exposed	1 / 1322 (0.08%)	1 / 1274 (0.08%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Musculoskeletal chest pain</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Musculoskeletal pain</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Myopathy</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Neck pain</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Osteoarthritis</b>			
subjects affected / exposed	3 / 1322 (0.23%)	0 / 1274 (0.00%)	5 / 1346 (0.37%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Osteolysis</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Osteonecrosis</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pain in extremity</b>			

subjects affected / exposed	2 / 1322 (0.15%)	2 / 1274 (0.16%)	3 / 1346 (0.22%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pathological fracture</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Polyarthritis</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Rhabdomyolysis</b>			
subjects affected / exposed	1 / 1322 (0.08%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Rheumatoid arthritis</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Rotator cuff syndrome</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Sacroiliitis</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Soft tissue mass</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Spinal osteoarthritis</b>			

subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Spondylolisthesis</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Synovial cyst</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Vertebral foraminal stenosis</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Infections and infestations</b>			
<b>Abdominal abscess</b>			
subjects affected / exposed	3 / 1322 (0.23%)	0 / 1274 (0.00%)	0 / 1346 (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
<b>Abdominal infection</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Abdominal sepsis</b>			
subjects affected / exposed	1 / 1322 (0.08%)	1 / 1274 (0.08%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Abdominal wall abscess</b>			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	0 / 1346 (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
<b>Abscess</b>			

subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Abscess jaw</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Abscess limb</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Abscess soft tissue</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Anal abscess</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Appendicitis</b>			
subjects affected / exposed	1 / 1322 (0.08%)	2 / 1274 (0.16%)	6 / 1346 (0.45%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Appendicitis perforated</b>			
subjects affected / exposed	1 / 1322 (0.08%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Arthritis bacterial</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Arthritis infective</b>			

subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Atypical pneumonia</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Bacillus bacteraemia</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Bacteraemia</b>			
subjects affected / exposed	1 / 1322 (0.08%)	1 / 1274 (0.08%)	6 / 1346 (0.45%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Bacterial sepsis</b>			
subjects affected / exposed	2 / 1322 (0.15%)	3 / 1274 (0.24%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
<b>Bacterial tracheitis</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Biliary sepsis</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Breast abscess</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Breast cellulitis</b>			

subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Bronchiolitis</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Bronchitis</b>			
subjects affected / exposed	2 / 1322 (0.15%)	10 / 1274 (0.78%)	6 / 1346 (0.45%)
occurrences causally related to treatment / all	0 / 2	0 / 10	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Bronchopulmonary aspergillosis</b>			
subjects affected / exposed	0 / 1322 (0.00%)	3 / 1274 (0.24%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
<b>Campylobacter gastroenteritis</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Cellulitis</b>			
subjects affected / exposed	12 / 1322 (0.91%)	13 / 1274 (1.02%)	19 / 1346 (1.41%)
occurrences causally related to treatment / all	0 / 19	0 / 18	0 / 21
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
<b>Cellulitis staphylococcal</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Cerebral aspergillosis</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Chronic sinusitis</b>			

subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Citrobacter sepsis			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridial infection			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Clostridial sepsis			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Clostridium difficile colitis			
subjects affected / exposed	9 / 1322 (0.68%)	2 / 1274 (0.16%)	5 / 1346 (0.37%)
occurrences causally related to treatment / all	0 / 9	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	2 / 1322 (0.15%)	1 / 1274 (0.08%)	4 / 1346 (0.30%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dengue fever			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Device related infection			

subjects affected / exposed	7 / 1322 (0.53%)	4 / 1274 (0.31%)	10 / 1346 (0.74%)
occurrences causally related to treatment / all	0 / 7	0 / 5	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related sepsis			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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 infectious			
subjects affected / exposed	0 / 1322 (0.00%)	3 / 1274 (0.24%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated cryptococcosis			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	4 / 1346 (0.30%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Empyema			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Endocarditis			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endophthalmitis			

subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis infectious			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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	0 / 1322 (0.00%)	2 / 1274 (0.16%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epididymitis			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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	0 / 1322 (0.00%)	0 / 1274 (0.00%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia bacteraemia			
subjects affected / exposed	1 / 1322 (0.08%)	1 / 1274 (0.08%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia infection			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia sepsis			
subjects affected / exposed	4 / 1322 (0.30%)	2 / 1274 (0.16%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection			

subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Extradural abscess</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Febrile infection</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Fungaemia</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (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
<b>Fungal oesophagitis</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Gastroenteritis</b>			
subjects affected / exposed	6 / 1322 (0.45%)	5 / 1274 (0.39%)	5 / 1346 (0.37%)
occurrences causally related to treatment / all	0 / 6	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Gastroenteritis rotavirus</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Gastroenteritis salmonella</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Gastroenteritis viral</b>			

subjects affected / exposed	1 / 1322 (0.08%)	1 / 1274 (0.08%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Gastrointestinal infection</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Genital herpes</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Groin abscess</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>H1N1 influenza</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Haematoma infection</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Haemophilus bacteraemia</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Hepatitis B</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hepatitis C</b>			

subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatosplenic candidiasis			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes virus infection			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Herpes zoster			
subjects affected / exposed	1 / 1322 (0.08%)	4 / 1274 (0.31%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 1	2 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster disseminated			
subjects affected / exposed	0 / 1322 (0.00%)	2 / 1274 (0.16%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster oticus			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Implant site infection			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Infected bite			
subjects affected / exposed	0 / 1322 (0.00%)	2 / 1274 (0.16%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected fistula			

subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected seroma			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Infectious colitis			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infectious pleural effusion			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	3 / 1322 (0.23%)	4 / 1274 (0.31%)	3 / 1346 (0.22%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Intestinal fistula infection			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint abscess			

subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Kidney infection</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Klebsiella bacteraemia</b>			
subjects affected / exposed	1 / 1322 (0.08%)	1 / 1274 (0.08%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
<b>Klebsiella sepsis</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
<b>Labyrinthitis</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Listeria sepsis</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Lower respiratory tract infection</b>			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	0 / 1346 (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
<b>Lower respiratory tract infection bacterial</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Lower respiratory tract infection fungal</b>			

subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Lung abscess			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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 infection			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Lung infection pseudomonal			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (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
Meningitis aseptic			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Meningitis cryptococcal			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Meningoencephalitis herpetic			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Metapneumovirus infection			

subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Muscle abscess</b>			
subjects affected / exposed	0 / 1322 (0.00%)	2 / 1274 (0.16%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Nasopharyngitis</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Necrotising fasciitis</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	3 / 1346 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
<b>Neutropenic sepsis</b>			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	0 / 1346 (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
<b>Ophthalmic herpes zoster</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Orchitis</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Osteomyelitis</b>			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	0 / 1346 (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
<b>Otitis media</b>			

subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Paraspinal abscess</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Pelvic abscess</b>			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	4 / 1346 (0.30%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
<b>Pelvic inflammatory disease</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Periodontitis</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Periorbital cellulitis</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Perirectal abscess</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Peritonitis</b>			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	0 / 1346 (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
<b>Peritonitis bacterial</b>			

subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonsillar abscess			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Pharyngitis streptococcal			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Pilonidal cyst			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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 viral			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 1322 (0.00%)	2 / 1274 (0.16%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	49 / 1322 (3.71%)	72 / 1274 (5.65%)	49 / 1346 (3.64%)
occurrences causally related to treatment / all	0 / 57	1 / 83	0 / 53
deaths causally related to treatment / all	0 / 5	0 / 14	0 / 9
Pneumonia bacterial			
subjects affected / exposed	0 / 1322 (0.00%)	2 / 1274 (0.16%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pneumonia cytomegaloviral			

subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Pneumonia fungal			
subjects affected / exposed	0 / 1322 (0.00%)	2 / 1274 (0.16%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia influenzal			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia klebsiella			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia moraxella			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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 / 1322 (0.08%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia necrotising			
subjects affected / exposed	0 / 1322 (0.00%)	2 / 1274 (0.16%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia pneumococcal			
subjects affected / exposed	1 / 1322 (0.08%)	1 / 1274 (0.08%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Pneumonia pseudomonal			

subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	0 / 1346 (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
Pneumonia streptococcal			
subjects affected / exposed	1 / 1322 (0.08%)	2 / 1274 (0.16%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural cellulitis			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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	2 / 1322 (0.15%)	0 / 1274 (0.00%)	0 / 1346 (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 sepsis			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative wound infection			
subjects affected / exposed	3 / 1322 (0.23%)	0 / 1274 (0.00%)	3 / 1346 (0.22%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Progressive multifocal leukoencephalopathy			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Pseudomembranous colitis			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonal bacteraemia			

subjects affected / exposed	1 / 1322 (0.08%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Pseudomonal sepsis</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Psoas abscess</b>			
subjects affected / exposed	1 / 1322 (0.08%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Pulmonary sepsis</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pyelonephritis</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pyelonephritis acute</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pyomyositis</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Rectal abscess</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Renal abscess</b>			

subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Respiratory moniliasis</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Respiratory syncytial virus infection</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Respiratory tract infection</b>			
subjects affected / exposed	2 / 1322 (0.15%)	1 / 1274 (0.08%)	3 / 1346 (0.22%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Respiratory tract infection bacterial</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Rhinovirus infection</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Scrotal infection</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Sepsis</b>			
subjects affected / exposed	28 / 1322 (2.12%)	17 / 1274 (1.33%)	21 / 1346 (1.56%)
occurrences causally related to treatment / all	0 / 32	1 / 18	0 / 23
deaths causally related to treatment / all	0 / 8	0 / 4	0 / 4
<b>Sepsis syndrome</b>			

subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	0 / 1346 (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
<b>Septic shock</b>			
subjects affected / exposed	6 / 1322 (0.45%)	7 / 1274 (0.55%)	7 / 1346 (0.52%)
occurrences causally related to treatment / all	0 / 6	0 / 7	0 / 7
deaths causally related to treatment / all	0 / 5	0 / 2	0 / 3
<b>Serratia bacteraemia</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Serratia sepsis</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Sinusitis</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Skin infection</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Soft tissue infection</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Splenic abscess</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Staphylococcal abscess</b>			

subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal infection			
subjects affected / exposed	0 / 1322 (0.00%)	2 / 1274 (0.16%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal sepsis			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal skin infection			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stenotrophomonas sepsis			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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 abscess			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis bacterial			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Tooth abscess			

subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Tuberculosis			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Upper respiratory tract infection			
subjects affected / exposed	0 / 1322 (0.00%)	2 / 1274 (0.16%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	19 / 1322 (1.44%)	11 / 1274 (0.86%)	24 / 1346 (1.78%)
occurrences causally related to treatment / all	0 / 20	0 / 11	0 / 24
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection bacterial			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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 tract infection fungal			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Urinary tract infection staphylococcal			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	3 / 1322 (0.23%)	2 / 1274 (0.16%)	6 / 1346 (0.45%)
occurrences causally related to treatment / all	0 / 3	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicella			

subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicella zoster pneumonia			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Viraemia			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Viral infection			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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 upper respiratory tract infection			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Vulval abscess			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
West Nile viral infection			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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 abscess			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
Wound infection			

subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Metabolism and nutrition disorders</b>			
<b>Decreased appetite</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Dehydration</b>			
subjects affected / exposed	16 / 1322 (1.21%)	2 / 1274 (0.16%)	17 / 1346 (1.26%)
occurrences causally related to treatment / all	0 / 16	0 / 2	0 / 18
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Diabetes mellitus inadequate control</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Diabetic ketoacidosis</b>			
subjects affected / exposed	3 / 1322 (0.23%)	0 / 1274 (0.00%)	3 / 1346 (0.22%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
<b>Electrolyte imbalance</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Failure to thrive</b>			
subjects affected / exposed	3 / 1322 (0.23%)	1 / 1274 (0.08%)	3 / 1346 (0.22%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Fluid overload</b>			
subjects affected / exposed	0 / 1322 (0.00%)	2 / 1274 (0.16%)	0 / 1346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Food intolerance</b>			

subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	0 / 1346 (0.00%)
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>Gout</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hypercalcaemia</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	3 / 1346 (0.22%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hyperglycaemia</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hyperkalaemia</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hypocalcaemia</b>			
subjects affected / exposed	3 / 1322 (0.23%)	0 / 1274 (0.00%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hypoglycaemia</b>			
subjects affected / exposed	3 / 1322 (0.23%)	1 / 1274 (0.08%)	3 / 1346 (0.22%)
occurrences causally related to treatment / all	0 / 5	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hypokalaemia</b>			
subjects affected / exposed	1 / 1322 (0.08%)	7 / 1274 (0.55%)	6 / 1346 (0.45%)
occurrences causally related to treatment / all	0 / 1	0 / 9	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hypomagnesaemia</b>			

subjects affected / exposed	2 / 1322 (0.15%)	0 / 1274 (0.00%)	0 / 1346 (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
<b>Hyponatraemia</b>			
subjects affected / exposed	2 / 1322 (0.15%)	2 / 1274 (0.16%)	2 / 1346 (0.15%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hypovolaemia</b>			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1274 (0.00%)	1 / 1346 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Malnutrition</b>			
subjects affected / exposed	0 / 1322 (0.00%)	0 / 1274 (0.00%)	3 / 1346 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Metabolic alkalosis</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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
<b>Tumour lysis syndrome</b>			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1274 (0.08%)	0 / 1346 (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

<b>Serious adverse events</b>	Placebo-HM		
<b>Total subjects affected by serious adverse events</b>			
subjects affected / exposed	507 / 1274 (39.80%)		
number of deaths (all causes)	146		
number of deaths resulting from adverse events	0		
<b>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</b>			
<b>Acute leukaemia</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Acute lymphocytic leukaemia				
subjects affected / exposed	1 / 1274 (0.08%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Acute lymphocytic leukaemia recurrent				
subjects affected / exposed	1 / 1274 (0.08%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Acute monocytic leukaemia				
subjects affected / exposed	0 / 1274 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Acute myeloid leukaemia				
subjects affected / exposed	5 / 1274 (0.39%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 2			
Acute myeloid leukaemia recurrent				
subjects affected / exposed	4 / 1274 (0.31%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 2			
Acute promyelocytic leukaemia				
subjects affected / exposed	1 / 1274 (0.08%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Adenocarcinoma				
subjects affected / exposed	0 / 1274 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Adenocarcinoma gastric				
subjects affected / exposed	1 / 1274 (0.08%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Adenocarcinoma of appendix				

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Adenocarcinoma of colon			
subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Adenocarcinoma of salivary gland			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Adenocarcinoma pancreas			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Anal cancer			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anal cancer recurrent			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anal cancer stage IV			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anaplastic large cell lymphoma T- and null-cell types			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Anaplastic oligodendroglioma			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Angiocentric lymphoma recurrent			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Appendix cancer			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
B precursor type acute leukaemia			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
B-cell lymphoma			
subjects affected / exposed	20 / 1274 (1.57%)		
occurrences causally related to treatment / all	0 / 20		
deaths causally related to treatment / all	0 / 3		
B-cell lymphoma recurrent			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
B-cell lymphoma refractory			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
B-cell small lymphocytic lymphoma			
subjects affected / exposed	3 / 1274 (0.24%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 1		
B-cell unclassifiable lymphoma low grade			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Basal cell carcinoma</b>			
subjects affected / exposed	11 / 1274 (0.86%)		
occurrences causally related to treatment / all	0 / 11		
deaths causally related to treatment / all	0 / 0		
<b>Basosquamous carcinoma</b>			
subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
<b>Benign renal neoplasm</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Bile duct cancer</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Bladder cancer</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Bladder neoplasm</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Bladder transitional cell carcinoma</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Bowen's disease</b>			

subjects affected / exposed	4 / 1274 (0.31%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
<b>Brain cancer metastatic</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Brain neoplasm benign</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Brain neoplasm malignant</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Breast cancer</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Breast cancer metastatic</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Breast cancer recurrent</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Breast cancer stage IV</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Breast neoplasm</b>			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Bronchial carcinoma</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Bronchioloalveolar carcinoma</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Cancer pain</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Cervix cancer metastatic</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Cervix carcinoma</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Cholangiocarcinoma</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Cholesteatoma</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Chronic lymphocytic leukaemia</b>			

subjects affected / exposed	62 / 1274 (4.87%)		
occurrences causally related to treatment / all	0 / 67		
deaths causally related to treatment / all	0 / 5		
Chronic lymphocytic leukaemia recurrent			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chronic lymphocytic leukaemia transformation			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chronic myeloid leukaemia			
subjects affected / exposed	7 / 1274 (0.55%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 4		
Chronic myelomonocytic leukaemia			
subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 2		
Clear cell renal cell carcinoma			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Clear cell sarcoma of soft tissue			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Colon adenoma			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Colon cancer			

subjects affected / exposed	3 / 1274 (0.24%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 1		
Colon cancer metastatic			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Colon cancer recurrent			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Colon cancer stage II			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Colon cancer stage IV			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Colon neoplasm			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Colorectal adenocarcinoma			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Colorectal cancer			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Colorectal cancer metastatic			

subjects affected / exposed	0 / 1274 (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	4 / 1274 (0.31%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 1		
Diffuse large B-cell lymphoma recurrent			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diffuse large B-cell lymphoma refractory			
subjects affected / exposed	0 / 1274 (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 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Duodenal neoplasm			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Endometrial adenocarcinoma			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Endometrial cancer			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Endometrial cancer metastatic			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Endometrial cancer stage IV			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ependymoma malignant			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Epiglottic carcinoma			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Essential thrombocythaemia			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ewing's sarcoma			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ewing's sarcoma metastatic			
subjects affected / exposed	0 / 1274 (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	4 / 1274 (0.31%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 1		
Extranodal marginal zone B-cell lymphoma (MALT type) recurrent			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Fallopian tube cancer			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Fibrous histiocytoma			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gallbladder adenocarcinoma			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gallbladder cancer			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastric cancer			
subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Gastric cancer recurrent			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal cancer metastatic			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal carcinoma			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal melanoma			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal stromal tumour			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrooesophageal cancer			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Glioblastoma			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Glioblastoma multiforme			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hairy cell leukaemia			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Head and neck cancer			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatic cancer			

subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatocellular carcinoma			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hodgkin's disease			
subjects affected / exposed	7 / 1274 (0.55%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 0		
Hodgkin's disease lymphocyte depletion type stage unspecified			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hodgkin's disease mixed cellularity recurrent			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hodgkin's disease nodular sclerosis			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hodgkin's disease nodular sclerosis recurrent			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hodgkin's disease recurrent			
subjects affected / exposed	3 / 1274 (0.24%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Intestinal adenocarcinoma			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intraductal proliferative breast lesion			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Invasive breast carcinoma			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Invasive ductal breast carcinoma			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Invasive lobular breast carcinoma			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Keratinising squamous cell carcinoma of nasopharynx			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Keratoacanthoma			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Large granular lymphocytosis			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Laryngeal cancer			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Laryngeal cancer metastatic			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Leiomyosarcoma			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Leiomyosarcoma metastatic			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lentigo maligna			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Leukaemia			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Light chain disease			
subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 2		
Lip and/or oral cavity cancer			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Liposarcoma			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Liposarcoma recurrent			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lung adenocarcinoma			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lung adenocarcinoma metastatic			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lung adenocarcinoma recurrent			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lung cancer metastatic			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lung neoplasm			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lung neoplasm malignant			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lung squamous cell carcinoma recurrent			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lung squamous cell carcinoma stage III			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lymphocytic lymphoma			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lymphoma			
subjects affected / exposed	6 / 1274 (0.47%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Lymphoma transformation			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lymphoplasmacytoid lymphoma/immunocytoma			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lymphoplasmacytoid lymphoma/immunocytoma recurrent			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Malignant ascites			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Malignant histiocytosis			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Malignant melanoma</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Malignant melanoma in situ</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Malignant neoplasm of ampulla of Vater</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Malignant neoplasm of unknown primary site</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Malignant peritoneal neoplasm</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Malignant pleural effusion</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Mantle cell lymphoma</b>			
subjects affected / exposed	5 / 1274 (0.39%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 2		
<b>Mantle cell lymphoma recurrent</b>			

subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Medullary carcinoma of breast			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Meningioma			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Meningioma malignant			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mesothelioma			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mesothelioma malignant			
subjects affected / exposed	0 / 1274 (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 / 1274 (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 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metastases to liver			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metastases to lung			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metastases to lymph nodes			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metastases to meninges			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metastases to ovary			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metastases to rectum			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metastatic carcinoma of the bladder			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metastatic gastric cancer			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metastatic malignant melanoma			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Metastatic neoplasm</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Metastatic renal cell carcinoma</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Metastatic squamous cell carcinoma</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Mucinous adenocarcinoma of appendix</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Mycosis fungoides</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Mycosis fungoides recurrent</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Myelodysplastic syndrome</b>			
subjects affected / exposed	7 / 1274 (0.55%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 4		
<b>Myelodysplastic syndrome transformation</b>			

subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 2		
<b>Myelofibrosis</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
<b>Myeloid leukaemia</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
<b>Myeloproliferative neoplasm</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
<b>Nasopharyngeal cancer</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Nasopharyngeal cancer recurrent</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Neuroendocrine carcinoma</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Neuroendocrine carcinoma metastatic</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Neuroendocrine carcinoma of the skin</b>			

subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Neuroendocrine tumour			
subjects affected / exposed	0 / 1274 (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	10 / 1274 (0.78%)		
occurrences causally related to treatment / all	0 / 10		
deaths causally related to treatment / all	0 / 6		
Non-Hodgkin's lymphoma metastatic			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Non-Hodgkin's lymphoma recurrent			
subjects affected / exposed	3 / 1274 (0.24%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 1		
Non-Hodgkin's lymphoma unspecified histology aggressive			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Non-small cell lung cancer			
subjects affected / exposed	1 / 1274 (0.08%)		
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	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Non-small cell lung cancer recurrent			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Non-small cell lung cancer stage IIIB			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oesophageal adenocarcinoma			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Oesophageal adenocarcinoma metastatic			
subjects affected / exposed	0 / 1274 (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 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oesophageal carcinoma			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oesophageal squamous cell carcinoma			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oropharyngeal cancer			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Osteosarcoma metastatic			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Osteosarcoma recurrent			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ovarian cancer			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ovarian cancer metastatic			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ovarian cancer recurrent			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ovarian epithelial cancer			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ovarian epithelial cancer recurrent			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancreatic carcinoma			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancreatic carcinoma metastatic			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancreatic carcinoma recurrent			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancreatic neoplasm			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancreatic neuroendocrine tumour			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pancreatic neuroendocrine tumour metastatic			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Papillary thyroid cancer			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Parathyroid tumour			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peripheral T-cell lymphoma unspecified			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peripheral T-cell lymphoma unspecified recurrent			

subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peritoneal carcinoma metastatic			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peritoneal neoplasm			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pituitary tumour benign			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Plasma cell myeloma			
subjects affected / exposed	54 / 1274 (4.24%)		
occurrences causally related to treatment / all	0 / 57		
deaths causally related to treatment / all	0 / 21		
Plasma cell myeloma recurrent			
subjects affected / exposed	5 / 1274 (0.39%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 1		
Plasmablastic lymphoma			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Plasmacytoma			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Precursor T-lymphoblastic lymphoma/leukaemia			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Precursor T-lymphoblastic lymphoma/leukaemia recurrent			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Prostate cancer			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Prostate cancer metastatic			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rectal adenocarcinoma			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rectal cancer			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Rectal cancer metastatic			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rectal cancer recurrent			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rectal neoplasm			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rectosigmoid cancer			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Refractory anaemia with an excess of blasts			
subjects affected / exposed	3 / 1274 (0.24%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 2		
Renal cancer			
subjects affected / exposed	0 / 1274 (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 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal cancer recurrent			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal cell carcinoma			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sarcoma			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sarcoma metastatic			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sarcoma of skin			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Schwannoma			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Signet-ring cell carcinoma			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin cancer			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin cancer metastatic			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Small cell carcinoma			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Small cell lung cancer			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Small cell lung cancer extensive stage			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Small cell lung cancer metastatic			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Small intestine adenocarcinoma			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Small intestine carcinoma			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Splenic marginal zone lymphoma			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Squamous cell carcinoma			
subjects affected / exposed	5 / 1274 (0.39%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Squamous cell carcinoma of head and neck			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Squamous cell carcinoma of lung			
subjects affected / exposed	0 / 1274 (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	10 / 1274 (0.78%)		
occurrences causally related to treatment / all	0 / 10		
deaths causally related to treatment / all	0 / 0		
Squamous cell carcinoma of the hypopharynx			
subjects affected / exposed	0 / 1274 (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	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Squamous cell carcinoma of the tongue			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
T-cell lymphoma			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
T-cell lymphoma recurrent			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
T-cell type acute leukaemia			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Thymoma			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thyroid cancer			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thyroid cancer metastatic			
subjects affected / exposed	0 / 1274 (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	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tonsil cancer			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tonsillar neoplasm			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Transitional cell carcinoma			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tumour flare			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tumour haemorrhage			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ureteric cancer			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urethral cancer			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Uterine cancer			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Uterine leiomyosarcoma			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vaginal cancer			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vulval cancer			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Waldenstrom's macroglobulinaemia			
subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Vascular disorders			
Accelerated hypertension			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Aortic aneurysm			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Aortic dissection</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Aortic stenosis</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Arterial thrombosis</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Circulatory collapse</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Deep vein thrombosis</b>			
subjects affected / exposed	7 / 1274 (0.55%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
<b>Embolism</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Haematoma</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Haemorrhage</b>			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypertension			
subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Hypertensive crisis			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypertensive emergency			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypotension			
subjects affected / exposed	4 / 1274 (0.31%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Hypovolaemic shock			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lymphoedema			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Orthostatic hypotension			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pelvic venous thrombosis			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peripheral arterial occlusive disease			
subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Peripheral artery occlusion			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peripheral embolism			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peripheral ischaemia			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peripheral venous disease			
subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Subclavian vein thrombosis			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Superior vena cava syndrome			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thrombosis			

subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Venous thrombosis limb			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Adverse drug reaction			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Asthenia			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chest discomfort			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chest pain			
subjects affected / exposed	8 / 1274 (0.63%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 0		
Chills			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Complication associated with device				
subjects affected / exposed	0 / 1274 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Death				
subjects affected / exposed	7 / 1274 (0.55%)			
occurrences causally related to treatment / all	0 / 7			
deaths causally related to treatment / all	0 / 7			
Drug withdrawal syndrome				
subjects affected / exposed	0 / 1274 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fatigue				
subjects affected / exposed	2 / 1274 (0.16%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Gait disturbance				
subjects affected / exposed	1 / 1274 (0.08%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
General physical health deterioration				
subjects affected / exposed	0 / 1274 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Generalised oedema				
subjects affected / exposed	0 / 1274 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Granuloma				
subjects affected / exposed	0 / 1274 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Impaired healing				

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Incarcerated hernia</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Malaise</b>			
subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
<b>Medical device pain</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Mucosal haemorrhage</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Mucosal inflammation</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Multiple organ dysfunction syndrome</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
<b>Nodule</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Non-cardiac chest pain</b>			

subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Oedema peripheral</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Organ failure</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Pain</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Polyserositis</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Pyrexia</b>			
subjects affected / exposed	13 / 1274 (1.02%)		
occurrences causally related to treatment / all	0 / 14		
deaths causally related to treatment / all	0 / 0		
<b>Sudden death</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Systemic inflammatory response syndrome</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Ulcer haemorrhage</b>			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Vascular stent thrombosis</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Visceral pain</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Immune system disorders</b>			
<b>Anaphylactic reaction</b>			
subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
<b>Drug hypersensitivity</b>			
subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
<b>Graft versus host disease</b>			
subjects affected / exposed	3 / 1274 (0.24%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
<b>Hypersensitivity</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Hypogammaglobulinaemia</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Sarcoidosis</b>			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Reproductive system and breast disorders</b>			
Adnexa uteri mass			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Benign prostatic hyperplasia			
subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Cervical dysplasia			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Colpocele			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Dysfunctional uterine bleeding			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Endometrial hyperplasia			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Genital erosion			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Genital lesion			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemorrhagic ovarian cyst			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metrorrhagia			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ovarian cyst			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ovarian disorder			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ovarian mass			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Postmenopausal haemorrhage			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Prostatic disorder			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Prostatic dysplasia			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Testicular pain			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vaginal disorder			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vaginal haemorrhage			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Acute interstitial pneumonitis			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acute pulmonary oedema			
subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acute respiratory failure			
subjects affected / exposed	4 / 1274 (0.31%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Alveolitis allergic			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Apnoea			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Aspiration			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Asthma			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Atelectasis			
subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Bronchial hyperreactivity			
subjects affected / exposed	0 / 1274 (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	7 / 1274 (0.55%)		
occurrences causally related to treatment / all	0 / 10		
deaths causally related to treatment / all	0 / 1		
Chronic respiratory failure			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Chylothorax			

subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Cough</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Dyspnoea</b>			
subjects affected / exposed	4 / 1274 (0.31%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
<b>Dyspnoea exertional</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Emphysema</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
<b>Epistaxis</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Haemoptysis</b>			
subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
<b>Haemothorax</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Hypoxia</b>			

subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Idiopathic pulmonary fibrosis</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Interstitial lung disease</b>			
subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
<b>Lung disorder</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Lung infiltration</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Nasal septum deviation</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Obstructive airways disorder</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Organising pneumonia</b>			
subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
<b>Paranasal sinus mucosal hypertrophy</b>			

subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Pleural effusion</b>			
subjects affected / exposed	10 / 1274 (0.78%)		
occurrences causally related to treatment / all	0 / 10		
deaths causally related to treatment / all	0 / 1		
<b>Pneumonia aspiration</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
<b>Pneumonia lipoid</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Pneumonitis</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Pneumothorax</b>			
subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
<b>Pulmonary embolism</b>			
subjects affected / exposed	5 / 1274 (0.39%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 1		
<b>Pulmonary fibrosis</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
<b>Pulmonary hypertension</b>			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Pulmonary infarction</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Pulmonary mass</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Pulmonary oedema</b>			
subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
<b>Pulmonary toxicity</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
<b>Reactive airways dysfunction syndrome</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Respiration abnormal</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Respiratory acidosis</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Respiratory disorder</b>			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Respiratory distress</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Respiratory failure</b>			
subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
<b>Sleep apnoea syndrome</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Tracheal stenosis</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Vocal cord thickening</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Psychiatric disorders</b>			
<b>Adjustment disorder</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Anxiety</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Confusional state</b>			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Delirium</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Depression</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
<b>Major depression</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Mania</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Mental disorder</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Mental status changes</b>			
subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
<b>Mood altered</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Somatic symptom disorder</b>			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Suicide attempt			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Product issues			
Device dislocation			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Device failure			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Device leakage			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Device malfunction			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Device occlusion			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Stent malfunction			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thrombosis in device			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Hepatobiliary disorders</b>			
Acute hepatic failure			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bile duct obstruction			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bile duct stone			
subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Biliary colic			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Biloma			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholangitis			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholangitis acute			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholecystitis			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Cholecystitis acute</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Cholecystitis chronic</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Cholelithiasis</b>			
subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
<b>Cholestasis</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Drug-induced liver injury</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Gallbladder disorder</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Haemobilia</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Hepatic cirrhosis</b>			

subjects affected / exposed	3 / 1274 (0.24%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 2		
<b>Hepatic failure</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Hepatic function abnormal</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Hepatic haemorrhage</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Hepatitis cholestatic</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Hepatorenal syndrome</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Hepatotoxicity</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
<b>Hyperbilirubinaemia</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Jaundice cholestatic</b>			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Liver injury			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Portal vein thrombosis			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Investigations			
CSF test abnormal			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Oxygen saturation decreased			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Prothrombin time abnormal			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Troponin increased			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Abdominal wound dehiscence			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Accidental overdose				
subjects affected / exposed	0 / 1274 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Acetabulum fracture				
subjects affected / exposed	0 / 1274 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anastomotic stenosis				
subjects affected / exposed	0 / 1274 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ankle fracture				
subjects affected / exposed	1 / 1274 (0.08%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cervical vertebral fracture				
subjects affected / exposed	0 / 1274 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chemical peritonitis				
subjects affected / exposed	0 / 1274 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Compression fracture				
subjects affected / exposed	0 / 1274 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Concussion				
subjects affected / exposed	0 / 1274 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Contusion				

subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Craniocerebral injury</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
<b>Cystitis radiation</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Eschar</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Eye contusion</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Fall</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Femoral neck fracture</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Femur fracture</b>			
subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
<b>Fibula fracture</b>			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Foot fracture			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis radiation			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal stoma complication			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Head injury			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Heat exhaustion			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hip fracture			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Humerus fracture			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Incarcerated incisional hernia			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Incisional hernia			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infusion related reaction			
subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Intentional overdose			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Joint dislocation			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Joint injury			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Laceration			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ligament rupture			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lower limb fracture			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Lumbar vertebral fracture</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Muscle rupture</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Osteoradionecrosis</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Overdose</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Pelvic fracture</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Periorbital haematoma</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Post procedural bile leak</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Post procedural discharge</b>			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Post procedural fistula			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Post procedural haematoma			
subjects affected / exposed	0 / 1274 (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 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Post procedural haemorrhage			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Postoperative fever			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Postoperative ileus			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Postoperative respiratory distress			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Procedural hypotension			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Procedural pneumothorax			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Radiation necrosis			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Radiation oesophagitis			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Radiation pericarditis			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Radiation pneumonitis			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Radius fracture			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Rib fracture			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Road traffic accident			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Seroma</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Skin wound</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Spinal column injury</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Spinal compression fracture</b>			
subjects affected / exposed	3 / 1274 (0.24%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
<b>Spinal fracture</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Sternal fracture</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Stoma site haemorrhage</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Stomal hernia</b>			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Stress fracture</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Subarachnoid haemorrhage</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Subcutaneous haematoma</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Subdural haematoma</b>			
subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
<b>Subdural haemorrhage</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Thermal burn</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Thoracic vertebral fracture</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Tibia fracture</b>			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Toxicity to various agents			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Transplant dysfunction			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Traumatic haematoma			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Traumatic haemothorax			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Upper limb fracture			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary retention postoperative			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urostomy complication			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Wound			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Wound dehiscence</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Wrist fracture</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Congenital, familial and genetic disorders</b>			
<b>Dysplastic naevus syndrome</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Tracheo-oesophageal fistula</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Cardiac disorders</b>			
<b>Acute coronary syndrome</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Acute myocardial infarction</b>			
subjects affected / exposed	5 / 1274 (0.39%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
<b>Angina pectoris</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Angina unstable				
subjects affected / exposed	1 / 1274 (0.08%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Aortic valve sclerosis				
subjects affected / exposed	0 / 1274 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Aortic valve stenosis				
subjects affected / exposed	0 / 1274 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Arrhythmia				
subjects affected / exposed	0 / 1274 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atrial fibrillation				
subjects affected / exposed	15 / 1274 (1.18%)			
occurrences causally related to treatment / all	0 / 15			
deaths causally related to treatment / all	0 / 0			
Atrial flutter				
subjects affected / exposed	1 / 1274 (0.08%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Atrioventricular block second degree				
subjects affected / exposed	0 / 1274 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac arrest				
subjects affected / exposed	0 / 1274 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac failure				

subjects affected / exposed	3 / 1274 (0.24%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Cardiac failure acute			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Cardiac failure chronic			
subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Cardiac failure congestive			
subjects affected / exposed	10 / 1274 (0.78%)		
occurrences causally related to treatment / all	0 / 15		
deaths causally related to treatment / all	0 / 2		
Cardiac tamponade			
subjects affected / exposed	0 / 1274 (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 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Cardiac ventricular thrombosis			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardio-respiratory arrest			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiomyopathy			

subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Cardiomyopathy acute</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Cardiopulmonary failure</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Cardiorenal syndrome</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Congestive cardiomyopathy</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Coronary artery disease</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
<b>Coronary artery insufficiency</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Ischaemic cardiomyopathy</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Mitral valve incompetence</b>			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Myocardial infarction</b>			
subjects affected / exposed	4 / 1274 (0.31%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 1		
<b>Myocardial ischaemia</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Palpitations</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Pericardial effusion</b>			
subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
<b>Pericardial haemorrhage</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Pericarditis</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Pulseless electrical activity</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Sinus node dysfunction</b>			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sinus tachycardia			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Stress cardiomyopathy			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Supraventricular tachycardia			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tachycardia			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ventricular dyssynchrony			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ventricular extrasystoles			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ventricular fibrillation			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ventricular tachycardia			

subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Nervous system disorders</b>			
<b>Aphasia</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Autonomic nervous system imbalance</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Brain oedema</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Carotid artery aneurysm</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Carotid artery stenosis</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Cerebellar infarction</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Cerebral haematoma</b>			
subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
<b>Cerebral haemorrhage</b>			

subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
<b>Cerebral infarction</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Cerebral microangiopathy</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Cerebrovascular accident</b>			
subjects affected / exposed	3 / 1274 (0.24%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
<b>Cervical cord compression</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Cognitive disorder</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Cubital tunnel syndrome</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Dementia</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Dementia Alzheimer's type</b>			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Depressed level of consciousness			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diabetic coma			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dizziness			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Embolic stroke			
subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Encephalopathy			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Epilepsy			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Facial paralysis			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Guillain-Barre syndrome			

subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Haemorrhage intracranial</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Headache</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Hemiparesis</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Hepatic encephalopathy</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Hypoglycaemic coma</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Hypoxic-ischaemic encephalopathy</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Intensive care unit acquired weakness</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Intracranial haematoma</b>			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Intraventricular haemorrhage</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
<b>Ischaemic stroke</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Lumbar radiculopathy</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Meningeal disorder</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Migraine</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Myelitis transverse</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Nervous system disorder</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Neuralgia</b>			

subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Neuropathy peripheral</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Parkinson's disease</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Polyneuropathy</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Post herpetic neuralgia</b>			
subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
<b>Posterior reversible encephalopathy syndrome</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Presyncope</b>			
subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
<b>Sciatica</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Seizure</b>			

subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Senile dementia			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Serotonin syndrome			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Simple partial seizures			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spinal cord compression			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Syncope			
subjects affected / exposed	5 / 1274 (0.39%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Toxic encephalopathy			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Transient ischaemic attack			
subjects affected / exposed	3 / 1274 (0.24%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Vasogenic cerebral oedema			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vocal cord paralysis			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	11 / 1274 (0.86%)		
occurrences causally related to treatment / all	0 / 11		
deaths causally related to treatment / all	0 / 0		
Anaemia of chronic disease			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Anaemia of malignant disease			
subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Autoimmune haemolytic anaemia			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bone marrow failure			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Coagulopathy			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Febrile neutropenia			

subjects affected / exposed	35 / 1274 (2.75%)		
occurrences causally related to treatment / all	1 / 43		
deaths causally related to treatment / all	0 / 1		
<b>Haematotoxicity</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Haemolysis</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Haemolytic anaemia</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Haemorrhagic anaemia</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Hypoprothrombinaemia</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Iron deficiency anaemia</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Leukocytosis</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Leukopenia</b>			

subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lymph node pain			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lymphadenitis			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lymphadenopathy			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Neutropenia			
subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Pancytopenia			
subjects affected / exposed	5 / 1274 (0.39%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Splenomegaly			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Thrombocytopenia			
subjects affected / exposed	4 / 1274 (0.31%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Ear and labyrinth disorders			
Inner ear disorder			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Neurosensory hypoacusis</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Vertigo</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Vertigo positional</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Eye disorders</b>			
<b>Blindness transient</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Cataract</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Cortical visual impairment</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Myopia</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Necrotising retinitis</b>			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Retinal detachment			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ulcerative keratitis			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal hernia			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abdominal hernia obstructive			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal pain			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abdominal pain lower			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal pain upper			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal wall haematoma			

subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Anal fissure			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anal fistula			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ascites			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Colitis			
subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Colitis ischaemic			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Constipation			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Crohn's disease			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cyclic vomiting syndrome			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diarrhoea			
subjects affected / exposed	3 / 1274 (0.24%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diverticular perforation			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diverticulum			
subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Diverticulum intestinal			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Duodenal obstruction			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Duodenal ulcer haemorrhage			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Duodenitis			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Dyspepsia</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Dysphagia</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Enteritis</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Enterocutaneous fistula</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Eosinophilic colitis</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Erosive oesophagitis</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Faecaloma</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Gastric ulcer haemorrhage</b>			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Gastritis</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Gastritis erosive</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Gastrointestinal disorder</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Gastrointestinal haemorrhage</b>			
subjects affected / exposed	5 / 1274 (0.39%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 1		
<b>Gastrointestinal hypomotility</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Gastrointestinal obstruction</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Gastrointestinal pain</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Gastrointestinal perforation</b>			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Haematemesis</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Haematochezia</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Haemorrhoidal haemorrhage</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Haemorrhoids</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Hiatus hernia</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Ileus</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Impaired gastric emptying</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Incarcerated inguinal hernia</b>			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Inguinal hernia			
subjects affected / exposed	0 / 1274 (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 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intestinal fibrosis			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intestinal ischaemia			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intestinal obstruction			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intestinal perforation			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intestinal prolapse			
subjects affected / exposed	0 / 1274 (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 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Large intestine perforation			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Large intestine polyp			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mallory-Weiss syndrome			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Mouth ulceration			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nausea			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Neutropenic colitis			
subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Obstruction gastric			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Odynophagia</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Oesophageal perforation</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Oesophageal rupture</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Oesophageal spasm</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Oesophageal ulcer haemorrhage</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
<b>Oesophageal varices haemorrhage</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Oesophagitis</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Pancreatic cyst</b>			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Pancreatic insufficiency</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Pancreatic mass</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Pancreatitis</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Pancreatitis acute</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Pancreatitis chronic</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Proctalgia</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Proctitis</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Rectal haemorrhage</b>			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Rectal ulcer</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Retroperitoneal haemorrhage</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Salivary gland calculus</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Small intestinal obstruction</b>			
subjects affected / exposed	5 / 1274 (0.39%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
<b>Small intestinal perforation</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Stomatitis</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Subileus</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Umbilical hernia</b>			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Upper gastrointestinal haemorrhage			
subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Volvulus			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vomiting			
subjects affected / exposed	3 / 1274 (0.24%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Brow ptosis			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Decubitus ulcer			
subjects affected / exposed	0 / 1274 (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	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eczema nummular			

subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Generalised erythema			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pruritus			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pyoderma gangrenosum			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Rash			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rash maculo-papular			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rash vesicular			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin exfoliation			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin necrosis			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin reaction			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin ulcer			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Stasis dermatitis			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Stevens-Johnson syndrome			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Swelling face			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Toxic epidermal necrolysis			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urticaria			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Acute kidney injury			

subjects affected / exposed	10 / 1274 (0.78%)		
occurrences causally related to treatment / all	0 / 10		
deaths causally related to treatment / all	0 / 1		
<b>Chronic kidney disease</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>End stage renal disease</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
<b>Haematuria</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Hydronephrosis</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Hypercalcaemic nephropathy</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Incontinence</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Micturition disorder</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Nephrolithiasis</b>			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Obstructive uropathy</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Renal failure</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Renal impairment</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Stag horn calculus</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Ureteric obstruction</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Ureterolithiasis</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Urinary bladder haemorrhage</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Urinary retention</b>			

subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urinary tract obstruction			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Carcinoid syndrome			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cushing's syndrome			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Goitre			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypercalcaemia of malignancy			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyperthyroidism			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypothyroidism			

subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thyroid mass			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Ankylosing spondylitis			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Arthralgia			
subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Arthropathy			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Back pain			
subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Bone cyst			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Fistula			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Fracture delayed union			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemarthrosis			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intervertebral disc disorder			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intervertebral disc protrusion			
subjects affected / exposed	3 / 1274 (0.24%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Lumbar spinal stenosis			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Muscle haemorrhage			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Muscle spasms			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Muscular weakness			

subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal chest pain			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal pain			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myopathy			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neck pain			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Osteoarthritis			
subjects affected / exposed	4 / 1274 (0.31%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Osteolysis			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Osteonecrosis			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pain in extremity			

subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Pathological fracture</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Polyarthritis</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Rhabdomyolysis</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Rheumatoid arthritis</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
<b>Rotator cuff syndrome</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Sacroiliitis</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Soft tissue mass</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Spinal osteoarthritis</b>			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Spondylolisthesis</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Synovial cyst</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Vertebral foraminal stenosis</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Infections and infestations</b>			
<b>Abdominal abscess</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Abdominal infection</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Abdominal sepsis</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Abdominal wall abscess</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Abscess</b>			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Abscess jaw</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Abscess limb</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Abscess soft tissue</b>			
subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
<b>Anal abscess</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Appendicitis</b>			
subjects affected / exposed	3 / 1274 (0.24%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
<b>Appendicitis perforated</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Arthritis bacterial</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Arthritis infective</b>			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Atypical pneumonia</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Bacillus bacteraemia</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Bacteraemia</b>			
subjects affected / exposed	3 / 1274 (0.24%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
<b>Bacterial sepsis</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Bacterial tracheitis</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Biliary sepsis</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Breast abscess</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Breast cellulitis</b>			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Bronchiolitis</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Bronchitis</b>			
subjects affected / exposed	6 / 1274 (0.47%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
<b>Bronchopulmonary aspergillosis</b>			
subjects affected / exposed	4 / 1274 (0.31%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
<b>Campylobacter gastroenteritis</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Cellulitis</b>			
subjects affected / exposed	13 / 1274 (1.02%)		
occurrences causally related to treatment / all	0 / 14		
deaths causally related to treatment / all	0 / 0		
<b>Cellulitis staphylococcal</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Cerebral aspergillosis</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
<b>Chronic sinusitis</b>			

subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Citrobacter sepsis			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Clostridial infection			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Clostridial sepsis			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Clostridium difficile colitis			
subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Clostridium difficile infection			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cystitis			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dengue fever			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Device related infection			

subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Device related sepsis			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diarrhoea infectious			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Disseminated cryptococcosis			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diverticulitis			
subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Empyema			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Encephalitis			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Endocarditis			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Endophthalmitis			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Enteritis infectious			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Enterococcal sepsis			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Epididymitis			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Erysipelas			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Escherichia bacteraemia			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Escherichia infection			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Escherichia sepsis			
subjects affected / exposed	4 / 1274 (0.31%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 1		
Escherichia urinary tract infection			

subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Extradural abscess			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Febrile infection			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Fungaemia			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Fungal oesophagitis			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis			
subjects affected / exposed	4 / 1274 (0.31%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis salmonella			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis viral			

subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
<b>Gastrointestinal infection</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Genital herpes</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Groin abscess</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>H1N1 influenza</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Haematoma infection</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Haemophilus bacteraemia</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Hepatitis B</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Hepatitis C</b>			

subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Hepatosplenic candidiasis			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Herpes virus infection			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Herpes zoster			
subjects affected / exposed	4 / 1274 (0.31%)		
occurrences causally related to treatment / all	1 / 4		
deaths causally related to treatment / all	0 / 0		
Herpes zoster disseminated			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Herpes zoster oticus			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Implant site infection			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infected bite			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infected fistula			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infected seroma			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infection			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infectious colitis			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infectious pleural effusion			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Influenza			
subjects affected / exposed	6 / 1274 (0.47%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Intestinal fistula infection			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Joint abscess			

subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Kidney infection			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Klebsiella bacteraemia			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Klebsiella sepsis			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Labyrinthitis			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Listeria sepsis			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lower respiratory tract infection			
subjects affected / exposed	3 / 1274 (0.24%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Lower respiratory tract infection bacterial			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lower respiratory tract infection fungal			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lung abscess			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lung infection			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lung infection pseudomonal			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Mediastinitis			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Meningitis aseptic			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Meningitis cryptococcal			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Meningoencephalitis herpetic			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metapneumovirus infection			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Muscle abscess</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Nasopharyngitis</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Necrotising fasciitis</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Neutropenic sepsis</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Ophthalmic herpes zoster</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Orchitis</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Osteomyelitis</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Otitis media</b>			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Paraspinal abscess</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Pelvic abscess</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Pelvic inflammatory disease</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Periodontitis</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Periorbital cellulitis</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Perirectal abscess</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Peritonitis</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Peritonitis bacterial</b>			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peritonsillar abscess			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pharyngitis streptococcal			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pilonidal cyst			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pleurisy viral			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	66 / 1274 (5.18%)		
occurrences causally related to treatment / all	0 / 87		
deaths causally related to treatment / all	0 / 9		
Pneumonia bacterial			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia cytomegaloviral			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia fungal			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia influenzal			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia klebsiella			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia moraxella			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia mycoplasmal			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia necrotising			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia pneumococcal			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Pneumonia pseudomonal			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia streptococcal			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Post procedural cellulitis			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Post procedural infection			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Post procedural sepsis			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Postoperative wound infection			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Progressive multifocal leukoencephalopathy			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Pseudomembranous colitis			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pseudomonal bacteraemia			

subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
<b>Pseudomonal sepsis</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Psoas abscess</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Pulmonary sepsis</b>			
subjects affected / exposed	4 / 1274 (0.31%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 2		
<b>Pyelonephritis</b>			
subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
<b>Pyelonephritis acute</b>			
subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
<b>Pyomyositis</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
<b>Rectal abscess</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Renal abscess</b>			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Respiratory moniliasis</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Respiratory syncytial virus infection</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Respiratory tract infection</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Respiratory tract infection bacterial</b>			
subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
<b>Rhinovirus infection</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Scrotal infection</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Sepsis</b>			
subjects affected / exposed	21 / 1274 (1.65%)		
occurrences causally related to treatment / all	0 / 22		
deaths causally related to treatment / all	0 / 9		
<b>Sepsis syndrome</b>			

subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Septic shock			
subjects affected / exposed	10 / 1274 (0.78%)		
occurrences causally related to treatment / all	0 / 10		
deaths causally related to treatment / all	0 / 7		
Serratia bacteraemia			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Serratia sepsis			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sinusitis			
subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Skin infection			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Soft tissue infection			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Splenic abscess			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Staphylococcal abscess			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Staphylococcal bacteraemia</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Staphylococcal infection</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Staphylococcal sepsis</b>			
subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
<b>Staphylococcal skin infection</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Stenotrophomonas sepsis</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Subcutaneous abscess</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Tonsillitis bacterial</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Tooth abscess</b>			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tuberculosis			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Upper respiratory tract infection			
subjects affected / exposed	4 / 1274 (0.31%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection			
subjects affected / exposed	11 / 1274 (0.86%)		
occurrences causally related to treatment / all	0 / 11		
deaths causally related to treatment / all	0 / 1		
Urinary tract infection bacterial			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection fungal			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection staphylococcal			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urosepsis			
subjects affected / exposed	4 / 1274 (0.31%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 1		
Varicella			

subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Varicella zoster pneumonia			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Viraemia			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Viral infection			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vulval abscess			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
West Nile viral infection			
subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Wound abscess			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Wound infection			

subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Metabolism and nutrition disorders</b>			
Decreased appetite			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dehydration			
subjects affected / exposed	2 / 1274 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Diabetes mellitus inadequate control			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diabetic ketoacidosis			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Electrolyte imbalance			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Failure to thrive			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Fluid overload			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Food intolerance			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Gout</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Hypercalcaemia</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Hyperglycaemia</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Hyperkalaemia</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Hypocalcaemia</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Hypoglycaemia</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Hypokalaemia</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Hypomagnesaemia</b>			

subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Hyponatraemia</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Hypovolaemia</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Malnutrition</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Metabolic alkalosis</b>			
subjects affected / exposed	0 / 1274 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Tumour lysis syndrome</b>			
subjects affected / exposed	1 / 1274 (0.08%)		
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 %

<b>Non-serious adverse events</b>	V212-STM	V212-HM	Placebo-STM
<b>Total subjects affected by non-serious adverse events</b>			
subjects affected / exposed	857 / 1322 (64.83%)	779 / 1274 (61.15%)	759 / 1346 (56.39%)
<b>Nervous system disorders</b>			
<b>Headache</b>			
subjects affected / exposed	94 / 1322 (7.11%)	107 / 1274 (8.40%)	114 / 1346 (8.47%)
occurrences (all)	137	172	192
<b>Neuropathy peripheral</b>			

subjects affected / exposed occurrences (all)	69 / 1322 (5.22%) 77	13 / 1274 (1.02%) 13	76 / 1346 (5.65%) 86
<b>Blood and lymphatic system disorders</b>			
<b>Anaemia</b>			
subjects affected / exposed occurrences (all)	108 / 1322 (8.17%) 127	51 / 1274 (4.00%) 61	114 / 1346 (8.47%) 140
<b>Neutropenia</b>			
subjects affected / exposed occurrences (all)	89 / 1322 (6.73%) 121	23 / 1274 (1.81%) 25	92 / 1346 (6.84%) 125
<b>Thrombocytopenia</b>			
subjects affected / exposed occurrences (all)	67 / 1322 (5.07%) 88	14 / 1274 (1.10%) 15	62 / 1346 (4.61%) 77
<b>General disorders and administration site conditions</b>			
<b>Fatigue</b>			
subjects affected / exposed occurrences (all)	136 / 1322 (10.29%) 159	71 / 1274 (5.57%) 74	156 / 1346 (11.59%) 179
<b>Injection site erythema</b>			
subjects affected / exposed occurrences (all)	371 / 1322 (28.06%) 865	389 / 1274 (30.53%) 875	32 / 1346 (2.38%) 40
<b>Injection site pain</b>			
subjects affected / exposed occurrences (all)	311 / 1322 (23.52%) 650	373 / 1274 (29.28%) 741	78 / 1346 (5.79%) 103
<b>Injection site pruritus</b>			
subjects affected / exposed occurrences (all)	68 / 1322 (5.14%) 106	94 / 1274 (7.38%) 153	3 / 1346 (0.22%) 5
<b>Injection site swelling</b>			
subjects affected / exposed occurrences (all)	291 / 1322 (22.01%) 663	329 / 1274 (25.82%) 715	25 / 1346 (1.86%) 32
<b>Pyrexia</b>			
subjects affected / exposed occurrences (all)	197 / 1322 (14.90%) 325	180 / 1274 (14.13%) 291	198 / 1346 (14.71%) 361
<b>Gastrointestinal disorders</b>			
<b>Constipation</b>			
subjects affected / exposed occurrences (all)	63 / 1322 (4.77%) 68	29 / 1274 (2.28%) 33	81 / 1346 (6.02%) 97

Diarrhoea			
subjects affected / exposed	126 / 1322 (9.53%)	70 / 1274 (5.49%)	137 / 1346 (10.18%)
occurrences (all)	160	83	181
Nausea			
subjects affected / exposed	163 / 1322 (12.33%)	83 / 1274 (6.51%)	168 / 1346 (12.48%)
occurrences (all)	222	125	215
Vomiting			
subjects affected / exposed	80 / 1322 (6.05%)	35 / 1274 (2.75%)	92 / 1346 (6.84%)
occurrences (all)	103	51	104
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	66 / 1322 (4.99%)	68 / 1274 (5.34%)	73 / 1346 (5.42%)
occurrences (all)	71	76	77
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	38 / 1322 (2.87%)	70 / 1274 (5.49%)	58 / 1346 (4.31%)
occurrences (all)	40	84	63

<b>Non-serious adverse events</b>	Placebo-HM		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	559 / 1274 (43.88%)		
Nervous system disorders			
Headache			
subjects affected / exposed	95 / 1274 (7.46%)		
occurrences (all)	172		
Neuropathy peripheral			
subjects affected / exposed	22 / 1274 (1.73%)		
occurrences (all)	22		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	35 / 1274 (2.75%)		
occurrences (all)	36		
Neutropenia			
subjects affected / exposed	28 / 1274 (2.20%)		
occurrences (all)	32		
Thrombocytopenia			

subjects affected / exposed occurrences (all)	24 / 1274 (1.88%) 28		
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	66 / 1274 (5.18%)		
occurrences (all)	72		
Injection site erythema			
subjects affected / exposed	68 / 1274 (5.34%)		
occurrences (all)	89		
Injection site pain			
subjects affected / exposed	107 / 1274 (8.40%)		
occurrences (all)	151		
Injection site pruritus			
subjects affected / exposed	7 / 1274 (0.55%)		
occurrences (all)	7		
Injection site swelling			
subjects affected / exposed	51 / 1274 (4.00%)		
occurrences (all)	63		
Pyrexia			
subjects affected / exposed	145 / 1274 (11.38%)		
occurrences (all)	247		
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	38 / 1274 (2.98%)		
occurrences (all)	42		
Diarrhoea			
subjects affected / exposed	69 / 1274 (5.42%)		
occurrences (all)	87		
Nausea			
subjects affected / exposed	79 / 1274 (6.20%)		
occurrences (all)	105		
Vomiting			
subjects affected / exposed	52 / 1274 (4.08%)		
occurrences (all)	65		
Respiratory, thoracic and mediastinal disorders			

Cough subjects affected / exposed occurrences (all)	65 / 1274 (5.10%) 71		
Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all)	71 / 1274 (5.57%) 88		

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
09 January 2012	Protocol Amendment (AM1) 1 modified the statistical criterion for success as related to the secondary clinical efficacy objective of the incidence of HZ in STM and HM populations, by increasing the lower bound of the 95% CI from >0% to >10%.
21 December 2012	Protocol AM3 allowed the inclusion of participants who were receiving or who were expected to require chemotherapy treatment containing an anti-Cellular Differentiation (CD)20 monoclonal antibody (beginning 3 months before enrollment through 28 days Post vaccination 4). The relevant sections in the protocol were modified accordingly to allow those participants to be qualified for enrollment.
15 July 2015	Protocol AM4 revised the trial hypothesis, endpoints, and methods for statistical analysis of the primary and secondary efficacy analyses to include only the STM population in response to the first planned interim analysis for futility. Enrollment in the HM arm was stopped and all objectives for the HM population were changed to exploratory. In addition, the target HZ case accrual was updated from 210 to 90 for the STM population, and the requirement for a second interim analysis was removed.

Notes:

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### Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
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22 September 2012	<p>The external Data Monitoring Committee (eDMC) Charter identified stopping rules for V212-011 which included a pause in enrollment and/or a pause in the administration of subsequent doses of vaccine and placebo in the event that 2 participants had disseminated Varicella-zoster virus (VZV) that was positive for VZV Oka/Merck vaccine strain. On 21-Sep-2012, the Sponsor received notification from its external testing laboratory that 2 participants in HM population had nonserious AEs of disseminated rash, and lesion specimens were borderline positive for VZV Oka/Merck (vaccine strain) by PCR testing. On 22-Sep-2012 the Sponsor informed trial sites of a temporary pause in enrollment and vaccine administration for V212-011 as a precautionary measure while further investigation of preliminary safety information occurred. On 02-Oct-2012, the eDMC met to review the results of the completed investigation of the laboratory findings. On the basis of the available evidence, the borderline positive Oka/Merck VZV PCR results were likely because of either contamination introduced during the PCR assay or spurious off-target amplification and were interpreted as false-positive PCR results and not true vaccine strain VZV-related outcomes. Thus, on the basis of this review, the eDMC recommended that the Sponsor resume enrollment and vaccine administration, and subsequent communication to the study sites occurred. Although the available evidence suggested that the PCR results were likely false positives for VZV Oka/Merck (vaccine strain), the Sponsor revised the informed consent's risk language and required submission to IRBs/ERCs and recommended that all newly enrolled participants, as well as those who had not yet completed the 4-dose regimen, be consented or re-consented before dosing.</p>	10 October 2012
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Notes:

### Limitations and caveats

None reported