



## Clinical trial results:

### A Phase III Randomized, Double-blind, Placebo-controlled Multicenter Study in Adults to Determine the Safety, Efficacy, and Immunogenicity of AZD1222, a Non-replicating ChAdOx1 Vector Vaccine, for the Prevention of COVID-19

#### Summary

EudraCT number	2020-005226-28
Trial protocol	FR DE IT
Global end of trial date	21 March 2023

#### Results information

Result version number	v1 (current)
This version publication date	23 November 2023
First version publication date	23 November 2023

#### Trial information

##### Trial identification

Sponsor protocol code	D8110C00001
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##### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04516746
WHO universal trial number (UTN)	-

Notes:

#### Sponsors

Sponsor organisation name	AstraZeneca AB
Sponsor organisation address	Karlebyhusentren, B674 Astraallen, Södertälje, Sweden, SE-151 85
Public contact	Global Clinical Lead, AstraZeneca, +1 877-240-9479, information.center@astrazeneca.com
Scientific contact	Global Clinical Lead, AstraZeneca, +1 877-240-9479, information.center@astrazeneca.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	21 March 2023
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	21 March 2023
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

To estimate the efficacy and assess the safety, tolerability and reactogenicity (for substudy only) of 2 intramuscular (IM) doses of AZD1222 compared to saline placebo for the prevention of coronavirus disease-2019 (COVID-19).

Protection of trial subjects:

This study was performed in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with International Council for Harmonisation/Good Clinical Practice, applicable regulatory requirements, and the AstraZeneca policy on Bioethics.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	28 August 2020
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	2 Years
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

## Population of trial subjects

### Subjects enrolled per country

Country: Number of subjects enrolled	Chile: 2206
Country: Number of subjects enrolled	Peru: 1470
Country: Number of subjects enrolled	United States: 28774
Worldwide total number of subjects	32450
EEA total number of subjects	0

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)	25195
From 65 to 84 years	7136
85 years and over	119

## Subject disposition

### Recruitment

Recruitment details:

This Phase III randomized study was conducted in adult participants who were healthy or had medically stable chronic diseases and were at increased risk for severe acute respiratory syndrome-coronavirus-2 (SARS-CoV-2) acquisition and coronavirus disease-2019 (COVID-19). One participant was enrolled at 2 sites and excluded from all analysis sets.

### Pre-assignment

Screening details:

Study had a screening period (14 days), followed by a treatment and follow-up period (up to 760 days). A total of 32450 participants were randomized in a 2:1 ratio to receive AZD1222 or placebo. The first participants randomized in each age group in the United States of America participated in a substudy to assess immunogenicity and reactogenicity.

### 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, Monitor, Carer

### Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	AZD1222

Arm description:

Participants were randomized to receive 2 IM doses of  $5 \times 10^{10}$  viral particles (vp) (nominal,  $\pm 1.5 \times 10^{10}$  vp) AZD1222 on Days 1 and 29.

Arm type	Experimental
Investigational medicinal product name	AZD1222
Investigational medicinal product code	ChAdOx1 nCoV-19
Other name	Vaxzevria
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

AZD1222  $5 \times 10^{10}$  vp was administered on Days 1 and 29.

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

Participants were randomized to receive 2 IM doses of placebo matching with AZD1222 on Days 1 and 29.

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

Dosage and administration details:

Placebo matching with AZD1222 was administered on Days 1 and 29.

<b>Number of subjects in period 1</b>	AZD1222	Placebo
Started	21634	10816
Participants who received first dose	21583	10797
Participants who received second dose	20770	9954
Completed	16099	7213
Not completed	5535	3603
Consent withdrawn by subject	1946	1696
Physician decision	10	8
Adverse event, non-fatal	-	1
Death	62	32
Randomized but not Treated	51	19
Unspecified	35	16
Lost to follow-up	3431	1831

## Baseline characteristics

### Reporting groups

Reporting group title	AZD1222
Reporting group description:	Participants were randomized to receive 2 IM doses of $5 \times 10^{10}$ viral particles (vp) (nominal, $\pm 1.5 \times 10^{10}$ vp) AZD1222 on Days 1 and 29.
Reporting group title	Placebo
Reporting group description:	Participants were randomized to receive 2 IM doses of placebo matching with AZD1222 on Days 1 and 29.

Reporting group values	AZD1222	Placebo	Total
Number of subjects	21634	10816	32450
Age Categorical Units: Subjects			

Age Continuous Units: years arithmetic mean standard deviation	50.2 $\pm 15.92$	50.2 $\pm 15.86$	-
Gender Categorical Units: Subjects			
Female	9603	4797	14400
Male	12031	6019	18050
Ethnicity Units: Subjects			
Hispanic or Latino	4787	2456	7243
Not Hispanic or Latino	16506	8217	24723
Not reported	293	127	420
Unknown	48	16	64
Race Units: Subjects			
Multiple	513	258	771
White	17100	8534	25634
Black or African American	1798	899	2697
Asian	947	483	1430
American Indian or Alaska Native	855	430	1285
Native Hawaiian or Other Pacific Islander	60	21	81
Not reported	260	138	398
Unknown	101	53	154

## End points

### End points reporting groups

Reporting group title	AZD1222
Reporting group description:	Participants were randomized to receive 2 IM doses of $5 \times 10^{10}$ viral particles (vp) (nominal, $\pm 1.5 \times 10^{10}$ vp) AZD1222 on Days 1 and 29.
Reporting group title	Placebo
Reporting group description:	Participants were randomized to receive 2 IM doses of placebo matching with AZD1222 on Days 1 and 29.

### Primary: Number of Participants With Binary Response

End point title	Number of Participants With Binary Response
End point description:	A binary response, whereby a participant with negative serostatus at baseline is defined as a COVID-19 case if their first case of SARS-CoV-2 RT-PCR-positive symptomatic illness occurs $\geq 15$ days post second dose of study intervention. Otherwise, a participant is not defined as a COVID-19 case. The primary efficacy analysis was performed once approximately 150 events meeting the primary efficacy outcome measure definition had occurred across the AZD1222 and placebo groups. The fully vaccinated analysis set (FVS) included all participants in the full analysis set (FAS) who were seronegative at baseline, received 2 doses of study intervention, and who remained on-study 15 days after their second dose without having had a prior SARS-CoV-2 RT-PCR-positive confirmed COVID-19 infection.
End point type	Primary
End point timeframe:	From 15 days post second dose up to data cut-off date (DCO) of 05 March 2021 or study discontinuation or unblinding or receipt of non-study COVID-19 vaccination, up to a maximum of 17 weeks

End point values	AZD1222	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17662	8550		
Units: participants	73	130		

### Statistical analyses

Statistical analysis title	Treatment ratio in binary response
Statistical analysis description:	The 95% confidence interval (CI) and p-value were estimated based on Poisson regression with robust variance (including study arm and stratification factor [age group at informed consent] as covariates, and log of the follow up time as an offset).
Comparison groups	AZD1222 v Placebo

Number of subjects included in analysis	26212
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Poisson regression with robust variance
Parameter estimate	Vaccine efficacy
Point estimate	73.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	65.34
upper limit	80.47

### Primary: Number of Participants With Adverse Events (AEs) Post Each Dose of Study Intervention

End point title	Number of Participants With Adverse Events (AEs) Post Each Dose of Study Intervention <sup>[1]</sup>
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End point description:

An AE is the development of any untoward medical occurrence in a clinical study participant administered medicinal product and which does not necessarily have a causal relationship with this medicinal product. An AE can therefore be any unfavorable and unintended sign, symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. The safety analysis set included all participants who received at least 1 dose of study intervention. Here, 'n' is number of participants analyzed at specific time point.

End point type	Primary
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End point timeframe:

From Day 1 up to 28 days post second dose of study intervention, approximately 57 days

Notes:

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

Justification: Only descriptive statistical analysis was performed for the primary endpoint.

End point values	AZD1222	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	21587	10792		
Units: participants				
After first dose (n= 21587, 10792)	5736	1926		
After second dose (n= 20773, 9947)	5074	1797		
After any dose (n= 21587, 10792)	8771	3201		

### Statistical analyses

No statistical analyses for this end point

### Primary: Number of Participants With Serious Adverse Events (SAE), Medically Attended Adverse Events (MAAE), and Adverse Event of Special Interest (AESI) Throughout the Study

End point title	Number of Participants With Serious Adverse Events (SAE), Medically Attended Adverse Events (MAAE), and Adverse Event
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## End point description:

An SAE is an AE occurring during any study phase that fulfils 1 or more of the following criteria: death; immediately life-threatening; in-participant hospitalization or prolongation of existing hospitalization; persistent or significant disability or incapacity; congenital abnormality or birth defect; an important medical event. AESIs were events of scientific and medical interest specific to the further understanding of the study intervention safety profile and required close monitoring and rapid communication by the investigators to the sponsor. MAAEs are defined as AEs leading to medically-attended visits that were not routine visits for physical examination or vaccination, such as an emergency room visit, or an otherwise unscheduled visit to or from medical personnel (medical doctor) for any reason. Different follow-up time between AZD1222 and Placebo groups (20223 versus 3893 participant years). The safety analysis set.

End point type	Primary
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## End point timeframe:

From Day 1 up to 2 years of follow-up post first dose or study discontinuation or receipt of non-study COVID-19 vaccination, a maximum of approximately 760 days

## Notes:

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

Justification: Only descriptive statistical analysis was performed for the primary endpoint.

End point values	AZD1222	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	21587	10793		
Units: participants				
SAEs	621	136		
MAAEs	4750	1256		
AESIs	2516	591		

## Statistical analyses

No statistical analyses for this end point

### Primary: Number of Participants With Local and Systemic Solicited AEs in the Substudy Only

End point title	Number of Participants With Local and Systemic Solicited AEs in the Substudy Only <sup>[3]</sup>
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## End point description:

Solicited AEs are local or systemic predefined events for assessment of reactogenicity. Solicited AEs were collected in a e-Diary only for participants in the substudy. The safety analysis set included all participants who received at least 1 dose of study intervention. Only participants included in the substudy were analyzed. Here, 'n' is number of participants analyzed at specific time point.

End point type	Primary
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## End point timeframe:

From Day 1 up to 7 days post each dose of study intervention, approximately 14 days

## Notes:

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

Justification: Only descriptive statistical analysis was performed for the primary endpoint.

<b>End point values</b>	AZD1222	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2037	1013		
Units: participants				
Solicited local AEs: After 1st dose(n=1830,920)	1250	173		
Solicited local AEs: After 2nd dose(n=1829,908)	977	120		
Solicited local AEs: After any dose(n=1944,979)	1440	239		
Solicited systemic AEs: After 1st dose(n=1842,924)	1191	415		
Solicited systemic AEs: After 2nd dose(n=1821,905)	862	314		
Solicited systemic AEs: After any dose(n=1947,980)	1395	519		

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of Participants With First COVID-19 Symptomatic Illness Using Centers for Disease Control and Prevention (CDC) Criteria Post Second Dose of Study Intervention

End point title	Number of Participants With First COVID-19 Symptomatic Illness Using Centers for Disease Control and Prevention (CDC) Criteria Post Second Dose of Study Intervention
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End point description:

The incidence of the first case of SARS-CoV-2 RT-PCR-positive symptomatic illness occurring  $\geq 15$  days post second dose of study intervention using CDC criteria. Participant must present with at least 1 of the following symptoms per CDC criteria: fever, shortness of breath, difficulty breathing, chills, cough, fatigue, muscle aches, body aches, headache, new loss of taste, new loss of smell, sore throat, congestion, runny nose, nausea, vomiting, or diarrhea. The FVS included all participants in the full analysis set who were seronegative at baseline, received 2 doses of study intervention, and who remained on-study 15 days after their second dose without having had a prior SARS-CoV-2 RT-PCR-positive confirmed COVID-19 infection.

End point type	Secondary
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End point timeframe:

From 15 days post second dose up to DCO of 05 March 2021 or study discontinuation or unblinding or receipt of non-study COVID-19 vaccination, up to a maximum of 17 weeks

<b>End point values</b>	AZD1222	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17662	8550		
Units: participants	95	145		

### Statistical analyses

<b>Statistical analysis title</b>	Treatment difference: COVID-19 symptomatic illness
Statistical analysis description:	
The 95% CI and p-value were estimated based on Poisson regression with robust variance (including study arm and stratification factor [age group at informed consent] as covariates, and log of the follow up time as an offset).	
Comparison groups	AZD1222 v Placebo
Number of subjects included in analysis	26212
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Poisson regression with robust variance
Parameter estimate	Vaccine efficacy
Point estimate	69.65
Confidence interval	
level	95 %
sides	2-sided
lower limit	60.68
upper limit	76.57

### **Secondary: Number of Participants With First Post-intervention Response for SARS-CoV-2 Nucleocapsid Antibodies Post Second Dose of Study**

End point title	Number of Participants With First Post-intervention Response for SARS-CoV-2 Nucleocapsid Antibodies Post Second Dose of Study
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End point description:

The incidence of the first post-intervention response (negative at baseline to positive post intervention with study intervention) for SARS-CoV-2 nucleocapsid antibodies occurring  $\geq 15$  days post second dose of study intervention (key secondary endpoint). The FVS included all participants in the FAS who were seronegative at baseline, received 2 doses of study intervention, and who remained on-study 15 days after their second dose without having had a prior SARS-CoV-2 RT-PCR-positive confirmed COVID-19 infection.

End point type	Secondary
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End point timeframe:

From 15 days post second dose up to DCO of 05 March 2021 or study discontinuation or unblinding or receipt of non-study COVID-19 vaccination, up to a maximum of 17 weeks

<b>End point values</b>	AZD1222	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17662	8550		
Units: participants	156	202		

### **Statistical analyses**

<b>Statistical analysis title</b>	Treatment difference: Nucleocapsid antibodies
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Statistical analysis description:

The 95% CI and p-value were estimated based on Poisson regression with robust variance (including study arm and stratification factor [age group at informed consent] as covariates, and log of the follow

up time as an offset).

Comparison groups	AZD1222 v Placebo
Number of subjects included in analysis	26212
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Poisson regression with robust variance
Parameter estimate	Vaccine efficacy
Point estimate	64.32
Confidence interval	
level	95 %
sides	2-sided
lower limit	56.05
upper limit	71.03

### **Secondary: Number of Participants With First COVID-19 Symptomatic Illness Using University of Oxford-Defined Symptom Criteria Post Second Dose of Study Intervention**

End point title	Number of Participants With First COVID-19 Symptomatic Illness Using University of Oxford-Defined Symptom Criteria Post Second Dose of Study Intervention
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End point description:

The incidence of the first case of SARS-CoV-2 RT-PCR-positive symptomatic illness occurring  $\geq 15$  days post second dose of study intervention using University of Oxford-defined symptom criteria: new onset of fever ( $> 100$  °Fahrenheit [ $> 37.8$  °Celsius]), cough, shortness of breath, or anosmia/ageusia. The FVS included all participants in the FAS who were seronegative at baseline, received 2 doses of study intervention, and who remained on-study 15 days after their second dose without having had a prior SARS-CoV-2 RT-PCR-positive confirmed COVID-19 infection.

End point type	Secondary
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End point timeframe:

From 15 days post second dose up to DCO of 05 March 2021 or study discontinuation or unblinding or receipt of non-study COVID-19 vaccination, up to a maximum of 17 weeks

<b>End point values</b>	AZD1222	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17662	8550		
Units: participants	86	136		

### **Statistical analyses**

<b>Statistical analysis title</b>	Treatment difference: COVID-19 symptomatic illness
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Statistical analysis description:

The 95% CI and p-value were estimated based on Poisson regression with robust variance (including study arm and stratification factor [age group at informed consent] as covariates, and log of the follow up time as an offset).

Comparison groups	AZD1222 v Placebo
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Number of subjects included in analysis	26212
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Poisson regression with robust variance
Parameter estimate	Vaccine efficacy
Point estimate	70.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	61.62
upper limit	77.64

### Secondary: Number of Participants With First Symptomatic COVID-19 Regardless of Evidence of Prior SARS-CoV-2 Infection Post Second Dose of Study Intervention

End point title	Number of Participants With First Symptomatic COVID-19 Regardless of Evidence of Prior SARS-CoV-2 Infection Post Second Dose of Study Intervention
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End point description:

The incidence of the first case of SARS-CoV-2 RT-PCR-positive symptomatic illness occurring  $\geq 15$  days post second dose of study intervention regardless of evidence of prior SARS-CoV-2 infection (key secondary endpoint). The FVS regardless of prior SARS-COV-2 infection included all participants in the FAS who were seronegative at baseline, received 2 doses of study intervention, and who remained on-study 15 days after their second dose.

End point type	Secondary
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End point timeframe:

From 15 days post second dose up to DCO of 05 March 2021 or study discontinuation or unblinding or receipt of non-study COVID-19 vaccination, up to a maximum of 17 weeks

End point values	AZD1222	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18563	9031		
Units: participants	76	135		

### Statistical analyses

Statistical analysis title	Treatment difference: First symptomatic COVID-19
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Statistical analysis description:

The 95% CI and p-value were estimated based on Poisson regression with robust variance (including study arm and stratification factor [age group at informed consent] as covariates, and log of the follow up time as an offset).

Comparison groups	AZD1222 v Placebo
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Number of subjects included in analysis	27594
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Poisson regression with robust variance
Parameter estimate	Vaccine efficacy
Point estimate	73.68
Confidence interval	
level	95 %
sides	2-sided
lower limit	65.13
upper limit	80.13

### Secondary: Number of Participants With COVID-19 Severe or Critical Symptomatic Illness Post Second Dose of Study Intervention

End point title	Number of Participants With COVID-19 Severe or Critical Symptomatic Illness Post Second Dose of Study Intervention
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End point description:

The incidence of SARS-CoV-2 RT-PCR-positive severe or critical symptomatic illness occurring  $\geq 15$  days post second dose of study intervention. The severity of COVID-19 was evaluated in participants with symptoms of COVID-19. Following are the findings regarding severe or critical symptomatic COVID-19: clinical signs at rest indicative of severe systemic illness; respiratory failure; evidence of shock; significant acute renal, hepatic, or neurologic dysfunction; admission to an intensive care unit; and death (key secondary endpoint). The FVS included all participants in the FAS who were seronegative at baseline, received 2 doses of study intervention, and who remained on-study 15 days after their second dose without having had a prior SARS-CoV-2 RT-PCR-positive confirmed COVID-19 infection.

End point type	Secondary
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End point timeframe:

From 15 days post second dose up to DCO of 05 March 2021 or study discontinuation or unblinding or receipt of non-study COVID-19 vaccination, up to a maximum of 17 weeks

End point values	AZD1222	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17662	8550		
Units: participants	0	8		

### Statistical analyses

Statistical analysis title	Treatment difference: COVID-19 symptomatic illness
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Statistical analysis description:

The exact 1-sided 97.5% CI and p-value were estimated based on stratified Poisson regression with exact conditional method (including study arm and stratification factor [age group at informed consent] as strata factor and log of total number of participants for each combination of study arm and strata as an offset).

Comparison groups	AZD1222 v Placebo
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Number of subjects included in analysis	26212
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Poisson regression exact conditional
Parameter estimate	Vaccine efficacy
Point estimate	100
Confidence interval	
level	Other: 97.5 %
sides	1-sided
lower limit	71.62

### Secondary: Number of Participants With COVID-19-Related Emergency Department Visits Post Second Dose of Study Intervention

End point title	Number of Participants With COVID-19-Related Emergency Department Visits Post Second Dose of Study Intervention
End point description:	
The incidence of COVID-19-related emergency department visits occurring $\geq$ 15 days post second dose of study intervention (key secondary endpoint). The FVS included all participants in the FAS who were seronegative at baseline, received 2 doses of study intervention, and who remained on-study 15 days after their second dose without having had a prior SARS-CoV-2 RT-PCR-positive confirmed COVID-19 infection.	
End point type	Secondary
End point timeframe:	
From 15 days post second dose up to DCO of 05 March 2021 or study discontinuation or unblinding or receipt of non-study COVID-19 vaccination, up to a maximum of 17 weeks	

End point values	AZD1222	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17662	8550		
Units: participants	1	9		

### Statistical analyses

Statistical analysis title	Treatment difference: Emergency department visits
Statistical analysis description:	
The 95% CI and p-value were estimated based on Poisson regression with robust variance (including study arm and stratification factor [age group at informed consent] as covariates, and log of the follow up time as an offset).	
Comparison groups	AZD1222 v Placebo

Number of subjects included in analysis	26212
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.005
Method	Poisson regression with robust variance
Parameter estimate	Vaccine efficacy
Point estimate	94.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	58.98
upper limit	99.34

### Secondary: Number of Participants With COVID-19 Severe or Critical Symptomatic Illness Post First Dose of Study Intervention

End point title	Number of Participants With COVID-19 Severe or Critical Symptomatic Illness Post First Dose of Study Intervention
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End point description:

The incidence of SARS-CoV-2 RT-PCR-positive severe or critical symptomatic illness occurring post first dose of study intervention. The severity of COVID-19 was evaluated in participants with symptoms of COVID-19. Following are the findings regarding severe or critical symptomatic COVID-19: clinical signs at rest indicative of severe systemic illness; respiratory failure; evidence of shock; significant acute renal, hepatic, or neurologic dysfunction; admission to an intensive care unit; and death. The FAS included all randomized participants who received at least 1 dose of study intervention, irrespective of their protocol adherence and continued participation in the study. Only participants who are seronegative at baseline were analyzed.

End point type	Secondary
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End point timeframe:

From 15 days post second dose up to DCO of 05 March 2021 or study discontinuation or unblinding or receipt of non-study COVID-19 vaccination, up to a maximum of 17 weeks

End point values	AZD1222	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20589	10300		
Units: participants	5	16		

### Statistical analyses

Statistical analysis title	Treatment difference: COVID-19 symptomatic illness
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Statistical analysis description:

The 95% CI were estimated based on Poisson regression with robust variance (including study arm and age group at screening (18-65 years, ≥ 65 years) as covariates and log of the follow-up time as an offset).

Comparison groups	AZD1222 v Placebo
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Number of subjects included in analysis	30889
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Poisson regression with robust variance
Parameter estimate	Vaccine efficacy
Point estimate	84.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	58.97
upper limit	94.5

**Secondary: Geometric Mean Titers (GMTs) for SARS-CoV-2 Spike (S) and Receptor Binding Domain (RBD) Antibodies as Measured by Meso Scale Discovery (MSD) Serology Assay**

End point title	Geometric Mean Titers (GMTs) for SARS-CoV-2 Spike (S) and Receptor Binding Domain (RBD) Antibodies as Measured by Meso Scale Discovery (MSD) Serology Assay
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End point description:

The GMT was calculated as the antilogarithm of  $\Sigma(\log \text{ base } 2 \text{ transformed titer}/n)$ , i.e. as the anti-logarithm transformation of the mean of the log-transformed titer, where 'n' is the number of participants with titer information. The immunogenicity analysis population included all participants in the safety analysis set who had no protocol deviations judged to have the potential to interfere with the generation or interpretation of an immune response. Only participants included in the substudy were analyzed. Here, 'n' is number of participants analyzed at specific time point.

End point type	Secondary
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End point timeframe:

Baseline (Day 1) and Days 15, 29, 43, 57, 90, 180, 360, and 730

<b>End point values</b>	AZD1222	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2008	1002		
Units: arbitrary units per milliliter (AU/mL)				
geometric mean (confidence interval 95%)				
S Antibody Titer: Day 1 (n=2008, 1002)	53.18 (50.37 to 56.14)	54.68 (50.10 to 59.69)		
S Antibody Titer: Day 15 (n=1897, 949)	1820.10 (1696.48 to 1952.72)	53.47 (48.88 to 58.50)		
S Antibody Titer: Day 29 (n=1428, 708)	5782.09 (5389.88 to 6202.84)	53.64 (47.98 to 59.97)		
S Antibody Titer: Day 43 (n=1809, 899)	24105.87 (22945.04 to 25325.44)	58.15 (52.68 to 64.18)		
S Antibody Titer: Day 57 (n=1760, 829)	19488.64 (18521.81 to 20505.92)	58.30 (52.35 to 64.94)		

S Antibody Titer: Day 90 (n=1675, 643)	14583.30 (13839.22 to 15367.38)	87.51 (74.78 to 102.42)	
S Antibody Titer: Day 180 (n=1217, 147)	7483.04 (6911.35 to 8102.02)	266.47 (161.19 to 440.49)	
S Antibody Titer: Day 360 (n=874, 47)	6686.81 (5779.74 to 7736.24)	1268.45 (489.80 to 3284.98)	
S Antibody Titer: Day 730 (n=276, 22)	186727.78 (154395.93 to 225830.20)	19093.94 (5685.04 to 64129.44)	
RBD Antibody Titer: Day 1 (n=2008, 1002)	133.6 (129.1 to 138.4)	138.9 (130.9 to 147.3)	
RBD Antibody Titer: Day 15 (n=1897, 949)	965.0 (897.0 to 1038.1)	138.6 (130.5 to 147.1)	
RBD Antibody Titer: Day 29 (n=1427, 708)	5176.6 (4794.8 to 5588.9)	143.0 (132.4 to 154.3)	
RBD Antibody Titer: Day 43 (n=1809, 899)	29351.9 (27875.6 to 30906.4)	145.7 (136.0 to 156.1)	
RBD Antibody Titer: Day 57 (n=1760, 829)	23840.6 (22614.3 to 25133.3)	151.6 (140.3 to 163.8)	
RBD Antibody Titer: Day 90 (n=1675, 643)	17499.9 (16559.1 to 18494.1)	192.6 (171.0 to 217.0)	
RBD Antibody Titer: Day 180 (n=1217, 147)	8333.1 (7647.9 to 9079.7)	481.6 (314.8 to 736.7)	
RBD Antibody Titer: Day 360 (n=874, 47)	7499.2 (6417.7 to 8763.1)	1912.3 (839.0 to 4358.5)	
RBD Antibody Titer: Day 730 (n=276, 22)	276381.8 (227665.9 to 335521.9)	19319.4 (5290.3 to 70551.9)	

## Statistical analyses

No statistical analyses for this end point

### Secondary: Geometric Mean Fold Rise (GMFR) for SARS-CoV-2 S and RBD Antibodies as Measured by MSD Serology Assay

End point title	Geometric Mean Fold Rise (GMFR) for SARS-CoV-2 S and RBD Antibodies as Measured by MSD Serology Assay
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End point description:

The fold rise was calculated as the ratio of the post-vaccination titer level to the pre-vaccination titer level. GMFR was calculated as anti-logarithm of  $\Sigma (\log \text{ base } 2 \text{ transformed } (\text{post-vaccination titer}/ \text{pre-vaccination titer})/n)$ . Where 'n' is the number of participants with titer information. The immunogenicity analysis population included all participants in the safety analysis set who had no protocol deviations judged to have the potential to interfere with the generation or interpretation of an immune response. Only participants included in the substudy were analyzed. Here, 'n' is number of participants analyzed at specific time point.

End point type	Secondary
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End point timeframe:

Days 15, 29, 43, 57, 90, 180, 360, and 730

<b>End point values</b>	AZD1222	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1885	943		
Units: ratio				
geometric mean (confidence interval 95%)				
S Antibody Titer: Day 15 (n=1885, 943)	34.28 (31.87 to 36.86)	0.97 (0.94 to 1.00)		
S Antibody Titer: Day 29 (n=1420, 706)	108.35 (99.95 to 117.45)	0.92 (0.87 to 0.96)		
S Antibody Titer: Day 43 (n=1797, 894)	455.38 (425.71 to 487.12)	1.08 (1.02 to 1.14)		
S Antibody Titer: Day 57 (n=1746, 823)	373.44 (348.12 to 400.60)	1.10 (1.02 to 1.19)		
S Antibody Titer: Day 90 (n=1664, 638)	274.05 (255.01 to 294.50)	1.61 (1.41 to 1.85)		
S Antibody Titer: Day 180 (n=1207, 146)	138.44 (125.37 to 152.88)	3.33 (2.07 to 5.37)		
S Antibody Titer: Day 360 (n=866, 46)	121.12 (102.89 to 142.58)	17.44 (6.75 to 45.07)		
S Antibody Titer: Day 730 (n=273, 22)	3506.74 (2808.52 to 4378.55)	295.66 (89.07 to 981.35)		
RBD Antibody Titer: Day 15 (n=1885, 943)	7.24 (6.76 to 7.76)	1.00 (0.98 to 1.02)		
RBD Antibody Titer: Day 29 (n=1419, 706)	39.01 (36.10 to 42.17)	1.01 (0.98 to 1.03)		
RBD Antibody Titer: Day 43 (n=1797, 894)	219.94 (207.28 to 233.37)	1.05 (1.01 to 1.09)		
RBD Antibody Titer: Day 57 (n=1746, 823)	178.61 (167.97 to 189.92)	1.10 (1.04 to 1.16)		
RBD Antibody Titer: Day 90 (n=1664, 638)	130.46 (122.53 to 138.89)	1.41 (1.27 to 1.57)		
RBD Antibody Titer: Day 180 (n=1207, 146)	61.69 (56.27 to 67.62)	3.13 (2.11 to 4.65)		
RBD Antibody Titer: Day 360 (n=866, 46)	53.91 (45.86 to 63.37)	11.18 (4.91 to 25.45)		
RBD Antibody Titer: Day 730 (n=273, 22)	2103.65 (1706.88 to 2592.64)	106.35 (29.93 to 377.87)		

## Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Participants With Seroresponse to the S and RBD Antigens of AZD1222 as Measured by MSD Serology Assay

End point title	Percentage of Participants With Seroresponse to the S and RBD Antigens of AZD1222 as Measured by MSD Serology Assay
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End point description:

The fold rise was calculated as the ratio of the post-vaccination titer level to the pre-vaccination titer level. The percentage of participants with a post-intervention seroresponse ( $\geq 4$ -fold rise in titers from baseline value to 28 days post each dose) to the S and RBD antigens of AZD1222 as measured by MSD serology assay is reported. The immunogenicity analysis population included all participants in the safety analysis set who had no protocol deviations judged to have the potential to interfere with the generation or interpretation of an immune response. Only participants included in the substudy were analyzed. Here, 'n' is number of participants analyzed at specific time point.

End point type	Secondary
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End point timeframe:

Days 15, 29, 43, 57, 90, 180, 360, and 730

End point values	AZD1222	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1885	943		
Units: percentage of participants				
number (not applicable)				
S Antibody Titer: Day 15 (n=1885, 943)	89.8	1.1		
S Antibody Titer: Day 29 (n=1420, 706)	97.1	1.6		
S Antibody Titer: Day 43 (n=1797, 894)	99.4	2.5		
S Antibody Titer: Day 57 (n=1746, 823)	99.3	3.2		
S Antibody Titer: Day 90 (n=1664, 638)	99.3	8.9		
S Antibody Titer: Day 180 (n=1207, 146)	98.3	23.3		
S Antibody Titer: Day 360 (n=866, 46)	96.1	54.3		
S Antibody Titer: Day 730 (n=273, 22)	100.0	90.9		
RBD Antibody Titer: Day 15 (n=1885, 943)	61.3	0.4		
RBD Antibody Titer: Day 29 (n=1419, 706)	92.2	1.0		
RBD Antibody Titer: Day 43 (n=1797, 894)	98.8	2.0		
RBD Antibody Titer: Day 57 (n=1746, 823)	98.7	2.6		
RBD Antibody Titer: Day 90 (n=1664, 638)	98.6	7.7		
RBD Antibody Titer: Day 180 (n=1207, 146)	96.3	22.6		
RBD Antibody Titer: Day 360 (n=866, 46)	89.8	50.0		
RBD Antibody Titer: Day 730 (n=273, 22)	99.3	86.4		

### Statistical analyses

No statistical analyses for this end point

## Secondary: GMTs for SARS-CoV-2 Neutralizing Antibodies as Measured by Pseudo-neutralization Assay

End point title	GMTs for SARS-CoV-2 Neutralizing Antibodies as Measured by Pseudo-neutralization Assay
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### End point description:

The GMT was calculated as the antilogarithm of  $\Sigma(\log \text{ base } 2 \text{ transformed titer}/n)$ , i.e. as the anti-logarithm transformation of the mean of the log-transformed titer, where 'n' is the number of participants with titer information. The immunogenicity analysis population included all participants in the safety analysis set who had no protocol deviations judged to have the potential to interfere with the generation or interpretation of an immune response. Only participants included in the substudy were analyzed. Here, 'n' is number of participants analyzed at specific time point.

End point type	Secondary
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### End point timeframe:

Baseline (Day 1) and Days 15, 29, 43, 57, 90, 180, and 360

End point values	AZD1222	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1943	973		
Units: AU/mL				
geometric mean (confidence interval 95%)				
Day 1 (n=1943, 973)	20.6 (20.3 to 20.9)	21.4 (20.7 to 22.0)		
Day 15 (n=1747, 920)	41.7 (39.3 to 44.2)	21.7 (20.9 to 22.4)		
Day 29 (n=1227, 682)	65.9 (60.8 to 71.4)	23.0 (21.8 to 24.3)		
Day 43 (n=1642, 876)	221.3 (208.4 to 235.0)	22.6 (21.6 to 23.5)		
Day 57 (n=1469, 777)	251.8 (235.7 to 269.0)	23.3 (22.1 to 24.6)		
Day 90 (n=60, 21)	206.1 (150.3 to 282.6)	37.5 (15.0 to 94.1)		
Day 180 (n=283, 127)	112.9 (90.4 to 141.0)	51.3 (37.4 to 70.4)		
Day 360 (n=27, 14)	265.7 (94.0 to 751.1)	46.3 (20.1 to 106.4)		

## Statistical analyses

No statistical analyses for this end point

## Secondary: GMFR for SARS-CoV-2 Neutralizing Antibodies as Measured by Pseudo-neutralization Assay

End point title	GMFR for SARS-CoV-2 Neutralizing Antibodies as Measured by Pseudo-neutralization Assay
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### End point description:

The fold rise was calculated as the ratio of the post-vaccination titer level to the pre-vaccination titer level. GMFR was calculated as anti-logarithm of  $\Sigma(\log \text{ base } 2 \text{ transformed (post-vaccination titer/ pre-vaccination titer)}/n)$ . Where 'n' is the number of participants with titer information. The immunogenicity analysis population included all participants in the safety analysis set who had no protocol deviations judged to have the potential to interfere with the generation or interpretation of an immune response.

Only participants included in the substudy were analyzed. Here, 'n' is number of participants analyzed at specific time point.

End point type	Secondary
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End point timeframe:

Days 15, 29, 43, 57, 90, 180, and 360

<b>End point values</b>	AZD1222	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1705	896		
Units: ratio				
geometric mean (confidence interval 95%)				
Day 15 (n=1705, 896)	2.03 (1.92 to 2.15)	1.01 (0.99 to 1.03)		
Day 29 (n=1200, 670)	3.24 (2.99 to 3.50)	1.07 (1.02 to 1.11)		
Day 43 (n=1597, 854)	10.91 (10.27 to 11.58)	1.05 (1.01 to 1.08)		
Day 57 (n=1432, 759)	12.32 (11.54 to 13.16)	1.08 (1.03 to 1.14)		
Day 90 (n=60, 20)	9.95 (7.33 to 13.51)	1.94 (0.74 to 5.09)		
Day 180 (n=274, 123)	5.37 (4.30 to 6.71)	2.22 (1.65 to 3.00)		
Day 360 (n=26, 14)	12.64 (4.31 to 37.11)	2.31 (1.01 to 5.32)		

## Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Participants With Seroresponse to SARS-CoV-2 Neutralizing Antibodies of AZD1222 as Measured by Pseudo-neutralization Assay

End point title	Percentage of Participants With Seroresponse to SARS-CoV-2 Neutralizing Antibodies of AZD1222 as Measured by Pseudo-neutralization Assay
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End point description:

The fold rise was calculated as the ratio of the post-vaccination titer level to the pre-vaccination titer level. The percentage of participants with a post-intervention seroresponse ( $\geq 4$ -fold rise in titers from baseline value to 28 days post each dose) to SARS-CoV-2 neutralizing antibodies of AZD1222 as measured by pseudo-neutralization assay is reported. The immunogenicity analysis population included all participants in the safety analysis set who had no protocol deviations judged to have the potential to interfere with the generation or interpretation of an immune response. Only participants included in the substudy were analyzed. Here, 'n' is number of participants analyzed at specific time point.

End point type	Secondary
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End point timeframe:

Days 15, 29, 43, 57, 90, 180, and 360

<b>End point values</b>	AZD1222	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1705	896		
Units: percentage of participants				
number (not applicable)				
Day 15 (n=1705, 896)	24.8	0.3		
Day 29 (n=1200, 670)	41.1	1.8		
Day 43 (n=1597, 854)	84.4	1.9		
Day 57 (n=1432, 759)	84.4	2.2		
Day 90 (n=60, 20)	83.3	10.0		
Day 180 (n=274, 123)	51.5	22.0		
Day 360 (n=26, 14)	53.8	28.6		

## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of Participants With COVID-19 Symptomatic Illness Post First Dose of Study Intervention

End point title	Number of Participants With COVID-19 Symptomatic Illness Post First Dose of Study Intervention
End point description:	The incidence of SARS-CoV-2 RT-PCR-positive symptomatic illness occurring post first dose of study intervention. The FAS included all randomized participants who received at least 1 dose of study intervention, irrespective of their protocol adherence and continued participation in the study. Only participants who are seronegative at baseline were analyzed.
End point type	Secondary
End point timeframe:	From Day 1 up to DCO of 05 March 2021 or study discontinuation or unblinding or receipt of non-study COVID-19 vaccination, up to a maximum of approximately 27 weeks

<b>End point values</b>	AZD1222	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20589	10300		
Units: participants	287	303		

## Statistical analyses

<b>Statistical analysis title</b>	Treatment difference: COVID-19 symptomatic illness
Statistical analysis description:	The 95% CI were estimated based on Poisson regression with robust variance (including study arm and age group at screening (18-65 years, ≥ 65 years) as covariates and log of the follow-up time as an offset).
Comparison groups	AZD1222 v Placebo

Number of subjects included in analysis	30889
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Vaccine efficacy
Point estimate	54.47
Confidence interval	
level	95 %
sides	2-sided
lower limit	46.48
upper limit	61.26

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

For SAEs: From first dose of study intervention up to 2 years of follow-up post first dose, a maximum of approximately 760 days;

For non-serious AEs: From first dose of study intervention up to 28 days post each dose, a maximum of approximately 57 days.

Adverse event reporting additional description:

The safety analysis set included all participants who received at least 1 dose of study intervention. Adverse events data reported for double-blind period only. All-cause mortality data reported for overall period (double-blind period and unblinded period).

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	23.1
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### Reporting groups

Reporting group title	Placebo
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Reporting group description:

Participants received 2 IM doses of placebo matching with AZD1222 on Days 1 and 29.

Reporting group title	AZD1222
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Reporting group description:

Participants received 2 IM doses of  $5 \times 10^{10}$  vp (nominal,  $\pm 1.5 \times 10^{10}$  vp) AZD1222 on Days 1 and 29.

<b>Serious adverse events</b>	Placebo	AZD1222	
Total subjects affected by serious adverse events			
subjects affected / exposed	467 / 10793 (4.33%)	1039 / 21587 (4.81%)	
number of deaths (all causes)	33	62	
number of deaths resulting from adverse events	33	62	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bladder cancer			
subjects affected / exposed	2 / 10793 (0.02%)	2 / 21587 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acral lentiginous melanoma			
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute monocytic leukaemia			

subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Acute myeloid leukaemia		
subjects affected / exposed	1 / 10793 (0.01%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Adenocarcinoma of colon		
subjects affected / exposed	3 / 10793 (0.03%)	7 / 21587 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Adenocarcinoma pancreas		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Astrocytoma		
subjects affected / exposed	2 / 10793 (0.02%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
B-cell lymphoma		
subjects affected / exposed	1 / 10793 (0.01%)	3 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Basal cell carcinoma		
subjects affected / exposed	1 / 10793 (0.01%)	3 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Benign neoplasm of bladder		
subjects affected / exposed	1 / 10793 (0.01%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign salivary gland neoplasm		

subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic lymphocytic leukaemia		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder neoplasm		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder transitional cell carcinoma		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Borderline mucinous tumour of ovary		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Brain neoplasm		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Breast cancer		
subjects affected / exposed	7 / 10793 (0.06%)	11 / 21587 (0.05%)
occurrences causally related to treatment / all	0 / 7	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Breast cancer female		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Breast cancer male		

subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Breast cancer metastatic</b>		
subjects affected / exposed	1 / 10793 (0.01%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Breast cancer recurrent</b>		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Breast cancer stage I</b>		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Breast cancer stage II</b>		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cerebral haemangioma</b>		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cervix carcinoma</b>		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cervix carcinoma stage IV</b>		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cholangiocarcinoma</b>		

subjects affected / exposed	2 / 10793 (0.02%)	3 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Choroid melanoma		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colorectal cancer metastatic		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Glioblastoma		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Colorectal adenocarcinoma		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Colon cancer stage IV		
subjects affected / exposed	2 / 10793 (0.02%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Colon cancer stage III		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Colon cancer metastatic		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colon cancer		

subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Colon adenoma		
subjects affected / exposed	1 / 10793 (0.01%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Clear cell renal cell carcinoma		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diffuse large B-cell lymphoma		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ductal adenocarcinoma of pancreas		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Endometrial cancer		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Ependymoma		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Follicular thyroid cancer		
subjects affected / exposed	1 / 10793 (0.01%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal tract adenoma		

subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colorectal cancer		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Invasive ductal breast carcinoma		
subjects affected / exposed	7 / 10793 (0.06%)	13 / 21587 (0.06%)
occurrences causally related to treatment / all	0 / 7	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Invasive breast carcinoma		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intraductal proliferative breast lesion		
subjects affected / exposed	2 / 10793 (0.02%)	7 / 21587 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Intraductal papillary breast neoplasm		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Huerthle cell carcinoma		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hormone receptor positive breast cancer		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haemangioma of bone		

subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Glioma		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Glioblastoma multiforme		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Invasive lobular breast carcinoma		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Lung adenocarcinoma stage III		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung adenocarcinoma		
subjects affected / exposed	1 / 10793 (0.01%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Lipoma		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lip squamous cell carcinoma		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lip and/or oral cavity cancer		

subjects affected / exposed	1 / 10793 (0.01%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Lentigo maligna		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngeal squamous cell carcinoma		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung carcinoma cell type unspecified stage IV		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mucoepidermoid carcinoma		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphoma		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant anorectal neoplasm		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant melanoma		
subjects affected / exposed	2 / 10793 (0.02%)	9 / 21587 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant neoplasm of ampulla of Vater		

subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Malignant neoplasm of pleura</b>		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Malignant neoplasm of thymus</b>		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Malignant splenic neoplasm</b>		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Mantle cell lymphoma</b>		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Metastatic squamous cell carcinoma</b>		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Metastatic carcinoma of the bladder</b>		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Metastases to peritoneum</b>		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Metastases to liver</b>		

subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Metastases to bone</b>		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Meningioma benign</b>		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Meningioma</b>		
subjects affected / exposed	1 / 10793 (0.01%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Lung neoplasm malignant</b>		
subjects affected / exposed	2 / 10793 (0.02%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Myelodysplastic syndrome</b>		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pancreatic carcinoma metastatic</b>		
subjects affected / exposed	1 / 10793 (0.01%)	3 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 2
<b>Neuroendocrine carcinoma of the skin</b>		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Neuroendocrine tumour</b>		

subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Non-Hodgkin's lymphoma		
subjects affected / exposed	2 / 10793 (0.02%)	4 / 21587 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Non-Hodgkin's lymphoma stage III		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Non-small cell lung cancer		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal adenocarcinoma		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal adenocarcinoma stage III		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal cancer metastatic		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal carcinoma		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal squamous cell carcinoma stage II		

subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oligodendroglioma		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian cancer		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian cancer metastatic		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian cancer stage III		
subjects affected / exposed	2 / 10793 (0.02%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neuroendocrine carcinoma		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Pancreatic carcinoma stage IV		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cell carcinoma		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Parathyroid tumour benign		

subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pituitary tumour benign		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Plasma cell myeloma		
subjects affected / exposed	1 / 10793 (0.01%)	3 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Plasmacytoma		
subjects affected / exposed	1 / 10793 (0.01%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Polycythaemia vera		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate cancer		
subjects affected / exposed	22 / 10793 (0.20%)	32 / 21587 (0.15%)
occurrences causally related to treatment / all	0 / 22	0 / 34
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate cancer metastatic		
subjects affected / exposed	1 / 10793 (0.01%)	4 / 21587 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate cancer recurrent		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate cancer stage I		

subjects affected / exposed	1 / 10793 (0.01%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate cancer stage II		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate cancer stage III		
subjects affected / exposed	2 / 10793 (0.02%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate cancer stage IV		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal adenocarcinoma		
subjects affected / exposed	1 / 10793 (0.01%)	3 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cancer		
subjects affected / exposed	1 / 10793 (0.01%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Papillary thyroid cancer		
subjects affected / exposed	0 / 10793 (0.00%)	7 / 21587 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cell carcinoma stage IV		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Triple negative breast cancer		

subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sarcoma uterus		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Seminoma		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Signet-ring cell carcinoma		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Sinonasal papilloma		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Small cell lung cancer		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Spinal cord neoplasm		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma		
subjects affected / exposed	1 / 10793 (0.01%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Squamous cell carcinoma of skin		

subjects affected / exposed	0 / 10793 (0.00%)	6 / 21587 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma of the oral cavity		
subjects affected / exposed	1 / 10793 (0.01%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
T-cell lymphoma		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Testicular seminoma (pure)		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Testis cancer		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Throat cancer		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tonsil cancer		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Transitional cell carcinoma		
subjects affected / exposed	1 / 10793 (0.01%)	3 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal melanocytoma		

subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tumour associated fever			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine leiomyoma			
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Granulomatosis with polyangiitis			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive crisis			
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive emergency			
subjects affected / exposed	2 / 10793 (0.02%)	0 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			
subjects affected / exposed	4 / 10793 (0.04%)	3 / 21587 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic aneurysm			

subjects affected / exposed	1 / 10793 (0.01%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic aneurysm rupture		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic dilatation		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic dissection		
subjects affected / exposed	1 / 10793 (0.01%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic stenosis		
subjects affected / exposed	1 / 10793 (0.01%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arterial haemorrhage		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Arteriosclerosis		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Deep vein thrombosis		
subjects affected / exposed	3 / 10793 (0.03%)	13 / 21587 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 1
Embolism		

subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertension		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hypovolaemic shock		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic venous thrombosis		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral arterial occlusive disease		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery haematoma		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery occlusion		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Shock haemorrhagic		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Venous thrombosis limb		

subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Pregnancy, puerperium and perinatal conditions</b>			
Ruptured ectopic pregnancy			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abortion spontaneous			
subjects affected / exposed	3 / 10793 (0.03%)	15 / 21587 (0.07%)	
occurrences causally related to treatment / all	0 / 3	1 / 17	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical incompetence			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ectopic pregnancy			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gestational hypertension			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postpartum haemorrhage			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pre-eclampsia			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Premature delivery			

subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Premature labour			
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stillbirth			
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 10793 (0.01%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Catheter site haematoma			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Catheter site haemorrhage			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest discomfort			
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest pain			
subjects affected / exposed	2 / 10793 (0.02%)	7 / 21587 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			

subjects affected / exposed	4 / 10793 (0.04%)	7 / 21587 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 7
deaths causally related to treatment / all	0 / 4	0 / 7
<b>Drowning</b>		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Hernia</b>		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hypothermia</b>		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Incarcerated hernia</b>		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Non-cardiac chest pain</b>		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Oedema peripheral</b>		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Procedural failure</b>		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pyrexia</b>		

subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Sudden cardiac death</b>			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
<b>Swelling face</b>			
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Multiple organ dysfunction syndrome</b>			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
<b>Immune system disorders</b>			
<b>Drug hypersensitivity</b>			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Hypersensitivity</b>			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Anaphylactic reaction</b>			
subjects affected / exposed	2 / 10793 (0.02%)	4 / 21587 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Reproductive system and breast disorders</b>			
<b>Adenomyosis</b>			
subjects affected / exposed	2 / 10793 (0.02%)	0 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Rectocele			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatitis			
subjects affected / exposed	1 / 10793 (0.01%)	2 / 21587 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign prostatic hyperplasia			
subjects affected / exposed	2 / 10793 (0.02%)	4 / 21587 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast haematoma			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical dysplasia			
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometriosis			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Female genital tract fistula			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Menorrhagia			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian cyst			

subjects affected / exposed	1 / 10793 (0.01%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian cyst ruptured			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal haemorrhage			
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Asthmatic crisis			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic obstructive pulmonary disease			
subjects affected / exposed	1 / 10793 (0.01%)	6 / 21587 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 2	
Chronic respiratory failure			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diaphragmatic paralysis			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea exertional			

subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Epistaxis		
subjects affected / exposed	1 / 10793 (0.01%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Acute pulmonary oedema		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Acute respiratory distress syndrome		
subjects affected / exposed	0 / 10793 (0.00%)	3 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Acute respiratory failure		
subjects affected / exposed	3 / 10793 (0.03%)	11 / 21587 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 11
deaths causally related to treatment / all	0 / 1	0 / 2
Asphyxia		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Aspiration		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Asthma		
subjects affected / exposed	2 / 10793 (0.02%)	3 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Haemoptysis		

subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary mass		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoxia		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Idiopathic pulmonary fibrosis		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Laryngeal leukoplakia		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngeal obstruction		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pleural effusion		
subjects affected / exposed	0 / 10793 (0.00%)	4 / 21587 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Pleuritic pain		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia aspiration		

subjects affected / exposed	1 / 10793 (0.01%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pneumothorax</b>		
subjects affected / exposed	1 / 10793 (0.01%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pulmonary embolism</b>		
subjects affected / exposed	7 / 10793 (0.06%)	29 / 21587 (0.13%)
occurrences causally related to treatment / all	0 / 7	0 / 32
deaths causally related to treatment / all	0 / 1	0 / 3
<b>Pulmonary fibrosis</b>		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pulmonary granuloma</b>		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pulmonary haemorrhage</b>		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pulmonary hypertension</b>		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pulmonary infarction</b>		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Haemothorax</b>		

subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Pulmonary oedema</b>			
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Respiratory failure</b>			
subjects affected / exposed	0 / 10793 (0.00%)	4 / 21587 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 2	
<b>Sleep apnoea syndrome</b>			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Respiratory arrest</b>			
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Psychiatric disorders</b>			
<b>Acute psychosis</b>			
subjects affected / exposed	1 / 10793 (0.01%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Adjustment disorder with depressed mood</b>			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Affective disorder</b>			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Alcohol withdrawal syndrome</b>			

subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Alcoholism		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Anxiety		
subjects affected / exposed	2 / 10793 (0.02%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bipolar I disorder		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bipolar II disorder		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Suicidal ideation		
subjects affected / exposed	5 / 10793 (0.05%)	5 / 21587 (0.02%)
occurrences causally related to treatment / all	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Completed suicide		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2
Delirium		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Delirium tremens		

subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Depression		
subjects affected / exposed	1 / 10793 (0.01%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Depression suicidal		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Major depression		
subjects affected / exposed	1 / 10793 (0.01%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mania		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mental status changes		
subjects affected / exposed	1 / 10793 (0.01%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Post-traumatic stress disorder		
subjects affected / exposed	1 / 10793 (0.01%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Schizoaffective disorder		
subjects affected / exposed	2 / 10793 (0.02%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Schizophrenia		

subjects affected / exposed	2 / 10793 (0.02%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Substance abuse</b>			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Substance-induced psychotic disorder</b>			
subjects affected / exposed	0 / 10793 (0.00%)	3 / 21587 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Bipolar disorder</b>			
subjects affected / exposed	3 / 10793 (0.03%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Suicide attempt</b>			
subjects affected / exposed	3 / 10793 (0.03%)	7 / 21587 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Product issues</b>			
<b>Device breakage</b>			
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Hepatobiliary disorders</b>			
<b>Bile duct stenosis</b>			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Bile duct stone</b>			
subjects affected / exposed	1 / 10793 (0.01%)	2 / 21587 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

Cholangitis			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis			
subjects affected / exposed	2 / 10793 (0.02%)	8 / 21587 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis acute			
subjects affected / exposed	3 / 10793 (0.03%)	9 / 21587 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis			
subjects affected / exposed	3 / 10793 (0.03%)	8 / 21587 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder polyp			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis alcoholic			
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Ischaemic hepatitis			
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaundice			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaundice cholestatic			

subjects affected / exposed	2 / 10793 (0.02%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Portal vein thrombosis			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Anticoagulation drug level above therapeutic			
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Catheterisation cardiac			
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Precancerous cells present			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oxygen saturation decreased			
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic enzyme increased			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heart rate increased			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fibrin D dimer increased			

subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Injury, poisoning and procedural complications</b>			
<b>Accident</b>			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
<b>Accidental overdose</b>			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Acetabulum fracture</b>			
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Acquired encephalocele</b>			
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Alcohol poisoning</b>			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Ankle fracture</b>			
subjects affected / exposed	3 / 10793 (0.03%)	6 / 21587 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Aortic injury</b>			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Bladder injury</b>			

subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Burns second degree		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cartilage injury		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cervical vertebral fracture		
subjects affected / exposed	1 / 10793 (0.01%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Chemical peritonitis		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Head injury		
subjects affected / exposed	1 / 10793 (0.01%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Comminuted fracture		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Concussion		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Contusion		

subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Craniocerebral injury</b>		
subjects affected / exposed	2 / 10793 (0.02%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Facial bones fracture</b>		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Fall</b>		
subjects affected / exposed	0 / 10793 (0.00%)	3 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Femoral neck fracture</b>		
subjects affected / exposed	2 / 10793 (0.02%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Femur fracture</b>		
subjects affected / exposed	6 / 10793 (0.06%)	3 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Fibula fracture</b>		
subjects affected / exposed	1 / 10793 (0.01%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Foot fracture</b>		
subjects affected / exposed	2 / 10793 (0.02%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Forearm fracture</b>		

subjects affected / exposed	1 / 10793 (0.01%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fracture displacement		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gun shot wound		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Hand fracture		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Colon injury		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hip fracture		
subjects affected / exposed	4 / 10793 (0.04%)	6 / 21587 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Medication error		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypobarism		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ilium fracture		

subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Incarcerated incisional hernia		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Incision site haematoma		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Incisional hernia		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Injury		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Intentional overdose		
subjects affected / exposed	1 / 10793 (0.01%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Joint dislocation		
subjects affected / exposed	1 / 10793 (0.01%)	3 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Ligament rupture		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ligament sprain		

subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Limb crushing injury		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lower limb fracture		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar vertebral fracture		
subjects affected / exposed	1 / 10793 (0.01%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Humerus fracture		
subjects affected / exposed	1 / 10793 (0.01%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple injuries		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple fractures		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Overdose		
subjects affected / exposed	1 / 10793 (0.01%)	5 / 21587 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 3
Patella fracture		

subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic fracture		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Periprosthetic fracture		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumothorax traumatic		
subjects affected / exposed	0 / 10793 (0.00%)	3 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural haematuria		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural swelling		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post-traumatic pain		
subjects affected / exposed	1 / 10793 (0.01%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative ileus		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural complication		

subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural intestinal perforation		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Radius fracture		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Reactive gastropathy		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rib fracture		
subjects affected / exposed	1 / 10793 (0.01%)	6 / 21587 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Osteochondral fracture		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Road traffic accident		
subjects affected / exposed	2 / 10793 (0.02%)	3 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 2
Toxicity to various agents		
subjects affected / exposed	2 / 10793 (0.02%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 1
Soft tissue injury		

subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal compression fracture		
subjects affected / exposed	2 / 10793 (0.02%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal cord injury		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Spinal fracture		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Splenic rupture		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Stab wound		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sternal fracture		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Subdural haematoma		
subjects affected / exposed	1 / 10793 (0.01%)	3 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Subdural haemorrhage		

subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tendon injury		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tendon rupture		
subjects affected / exposed	2 / 10793 (0.02%)	4 / 21587 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Thermal burn		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Tibia fracture		
subjects affected / exposed	2 / 10793 (0.02%)	4 / 21587 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Skin laceration		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic haemothorax		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic intracranial haemorrhage		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic liver injury		

subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wrist fracture			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic intracranial haematoma			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Thalassaemia minor			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral arteriovenous malformation haemorrhagic			
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral cavernous malformation			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral palsy			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic arteriovenous malformation			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Hamartoma			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertrophic cardiomyopathy			
subjects affected / exposed	1 / 10793 (0.01%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple congenital abnormalities			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal aplasia			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Atrial flutter			
subjects affected / exposed	2 / 10793 (0.02%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			
subjects affected / exposed	13 / 10793 (0.12%)	21 / 21587 (0.10%)	
occurrences causally related to treatment / all	0 / 13	0 / 22	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriosclerosis coronary artery			
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arrhythmia			
subjects affected / exposed	2 / 10793 (0.02%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve stenosis			

subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Angina unstable		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Angina pectoris		
subjects affected / exposed	1 / 10793 (0.01%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Acute myocardial infarction		
subjects affected / exposed	7 / 10793 (0.06%)	27 / 21587 (0.13%)
occurrences causally related to treatment / all	0 / 7	0 / 27
deaths causally related to treatment / all	0 / 1	0 / 1
Acute left ventricular failure		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Acute coronary syndrome		
subjects affected / exposed	2 / 10793 (0.02%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Atrial tachycardia		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic left ventricular failure		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiomyopathy		

subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardio-respiratory arrest		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2
Cardiac tamponade		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac failure congestive		
subjects affected / exposed	6 / 10793 (0.06%)	9 / 21587 (0.04%)
occurrences causally related to treatment / all	0 / 9	0 / 11
deaths causally related to treatment / all	0 / 1	0 / 1
Cardiac failure acute		
subjects affected / exposed	0 / 10793 (0.00%)	4 / 21587 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac failure		
subjects affected / exposed	0 / 10793 (0.00%)	3 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac disorder		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Cardiac arrest		
subjects affected / exposed	4 / 10793 (0.04%)	5 / 21587 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 3	0 / 3
Bundle branch block right		

subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Brugada syndrome		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bradycardia		
subjects affected / exposed	2 / 10793 (0.02%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block second degree		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block complete		
subjects affected / exposed	3 / 10793 (0.03%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block		
subjects affected / exposed	2 / 10793 (0.02%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiopulmonary failure		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Congestive cardiomyopathy		
subjects affected / exposed	1 / 10793 (0.01%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pericardial effusion		

subjects affected / exposed	0 / 10793 (0.00%)	3 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery dissection		
subjects affected / exposed	1 / 10793 (0.01%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery occlusion		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery stenosis		
subjects affected / exposed	1 / 10793 (0.01%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive heart disease		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Ischaemic cardiomyopathy		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mitral valve incompetence		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mitral valve prolapse		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Myocardial infarction		

subjects affected / exposed	10 / 10793 (0.09%)	12 / 21587 (0.06%)
occurrences causally related to treatment / all	0 / 10	1 / 12
deaths causally related to treatment / all	0 / 2	0 / 3
<b>Myocardial ischaemia</b>		
subjects affected / exposed	2 / 10793 (0.02%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Myocarditis</b>		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Myxomatous mitral valve degeneration</b>		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Non-obstructive cardiomyopathy</b>		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Palpitations</b>		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Coronary artery disease</b>		
subjects affected / exposed	5 / 10793 (0.05%)	25 / 21587 (0.12%)
occurrences causally related to treatment / all	0 / 7	0 / 26
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Pericarditis</b>		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Sinus bradycardia</b>		

subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus node dysfunction			
subjects affected / exposed	1 / 10793 (0.01%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Supraventricular tachycardia			
subjects affected / exposed	2 / 10793 (0.02%)	4 / 21587 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachycardia			
subjects affected / exposed	1 / 10793 (0.01%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Torsade de pointes			
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular fibrillation			
subjects affected / exposed	0 / 10793 (0.00%)	3 / 21587 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular tachycardia			
subjects affected / exposed	1 / 10793 (0.01%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Right ventricular failure			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Cerebral haemorrhage			

subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Alcoholic seizure		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Amnesia		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bulbar palsy		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid artery dissection		
subjects affected / exposed	2 / 10793 (0.02%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid artery stenosis		
subjects affected / exposed	3 / 10793 (0.03%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebellar stroke		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral artery occlusion		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Focal dyscognitive seizures		

subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Embolitic stroke		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral infarction		
subjects affected / exposed	1 / 10793 (0.01%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral venous thrombosis		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebrovascular accident		
subjects affected / exposed	3 / 10793 (0.03%)	6 / 21587 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic inflammatory demyelinating polyradiculoneuropathy		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cognitive disorder		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Corticobasal degeneration		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Delayed myelination		

subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Dementia		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dementia Alzheimer's type		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Demyelinating polyneuropathy		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dizziness		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dysarthria		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Generalised tonic-clonic seizure		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhage intracranial		
subjects affected / exposed	1 / 10793 (0.01%)	3 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0
Metabolic encephalopathy		

subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Headache</b>		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hemianopia</b>		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hemianopia homonymous</b>		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hemiparesis</b>		
subjects affected / exposed	0 / 10793 (0.00%)	3 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hydrocephalus</b>		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hypoaesthesia</b>		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hypoxic-ischaemic encephalopathy</b>		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Internal capsule infarction</b>		

subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intracranial aneurysm		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intraventricular haemorrhage		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic cerebral infarction		
subjects affected / exposed	1 / 10793 (0.01%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic stroke		
subjects affected / exposed	7 / 10793 (0.06%)	15 / 21587 (0.07%)
occurrences causally related to treatment / all	0 / 8	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Loss of consciousness		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar radiculopathy		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbosacral radiculopathy		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhagic transformation stroke		

subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Migraine</b>		
subjects affected / exposed	1 / 10793 (0.01%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Seizure</b>		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Myasthenia gravis</b>		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Myelomalacia</b>		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Myelopathy</b>		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Myoclonic epilepsy</b>		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Neurodegenerative disorder</b>		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Neuropathy peripheral</b>		

subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Normal pressure hydrocephalus		
subjects affected / exposed	1 / 10793 (0.01%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Paraesthesia		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Parkinson's disease		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral sensory neuropathy		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post stroke seizure		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Presyncope		
subjects affected / exposed	1 / 10793 (0.01%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Radiculopathy		
subjects affected / exposed	1 / 10793 (0.01%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sciatica		

subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple sclerosis		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sensory loss		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Subarachnoid haemorrhage		
subjects affected / exposed	1 / 10793 (0.01%)	3 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Syncope		
subjects affected / exposed	4 / 10793 (0.04%)	8 / 21587 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Thalamic infarction		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombotic stroke		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Toxic encephalopathy		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Transient global amnesia		

subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient ischaemic attack			
subjects affected / exposed	8 / 10793 (0.07%)	10 / 21587 (0.05%)	
occurrences causally related to treatment / all	0 / 8	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord compression			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 10793 (0.00%)	6 / 21587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypercoagulation			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iron deficiency anaemia			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenia			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenic cyst			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenic haematoma			

subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenic infarction			
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood loss anaemia			
subjects affected / exposed	3 / 10793 (0.03%)	2 / 21587 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Deafness bilateral			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deafness			
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deafness unilateral			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neurosensory hypoacusis			
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo			

subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo positional			
subjects affected / exposed	0 / 10793 (0.00%)	3 / 21587 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Amaurosis fugax			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine ophthalmopathy			
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Optic ischaemic neuropathy			
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal artery occlusion			
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal detachment			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal vein occlusion			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			

Diverticular perforation			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal hernia			
subjects affected / exposed	0 / 10793 (0.00%)	3 / 21587 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain lower			
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain upper			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal strangulated hernia			
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal wall haematoma			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aphthous ulcer			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic gastritis			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			

subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis ischaemic		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Constipation		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Diarrhoea		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum intestinal		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Incarcerated inguinal hernia		
subjects affected / exposed	2 / 10793 (0.02%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal perforation		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal ulcer haemorrhage		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Erosive oesophagitis		

subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Femoral hernia incarcerated		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Food poisoning		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric fistula		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer haemorrhage		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer perforation		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal haemorrhage		
subjects affected / exposed	2 / 10793 (0.02%)	5 / 21587 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal necrosis		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrooesophageal reflux disease		

subjects affected / exposed	1 / 10793 (0.01%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhoids thrombosed		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hiatus hernia		
subjects affected / exposed	0 / 10793 (0.00%)	4 / 21587 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Ileus		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum intestinal haemorrhagic		
subjects affected / exposed	0 / 10793 (0.00%)	3 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Mesenteric vein thrombosis		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lower gastrointestinal haemorrhage		
subjects affected / exposed	1 / 10793 (0.01%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal ulcer haemorrhage		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal varices haemorrhage		

subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Oesophagitis</b>		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Oesophagitis haemorrhagic</b>		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pancreatic failure</b>		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Pancreatitis</b>		
subjects affected / exposed	2 / 10793 (0.02%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Pancreatitis acute</b>		
subjects affected / exposed	1 / 10793 (0.01%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pancreatitis necrotising</b>		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Inguinal hernia</b>		
subjects affected / exposed	1 / 10793 (0.01%)	3 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Internal hernia</b>		

subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal ischaemia		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal obstruction		
subjects affected / exposed	1 / 10793 (0.01%)	9 / 21587 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal perforation		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestine perforation		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Obstructive pancreatitis		
subjects affected / exposed	1 / 10793 (0.01%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatolithiasis		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pharyngo-oesophageal diverticulum		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal haemorrhage		

subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	5 / 10793 (0.05%)	12 / 21587 (0.06%)	
occurrences causally related to treatment / all	0 / 5	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal perforation			
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Umbilical hernia			
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	1 / 10793 (0.01%)	3 / 21587 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Volvulus			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peptic ulcer haemorrhage			
subjects affected / exposed	1 / 10793 (0.01%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Petechiae			

subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angioedema			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic foot			
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	4 / 10793 (0.04%)	6 / 21587 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute kidney injury			
subjects affected / exposed	6 / 10793 (0.06%)	13 / 21587 (0.06%)	
occurrences causally related to treatment / all	0 / 7	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder outlet obstruction			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder perforation			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic kidney disease			

subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haematuria		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hydronephrosis		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nephropathy toxic		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvi-ureteric obstruction		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal aneurysm		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal failure		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal mass		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal tubular necrosis		

subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Ureterolithiasis</b>			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Urethral caruncle</b>			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Urinary retention</b>			
subjects affected / exposed	2 / 10793 (0.02%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Urinary tract obstruction</b>			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Nephrotic syndrome</b>			
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Endocrine disorders</b>			
<b>Goitre</b>			
subjects affected / exposed	2 / 10793 (0.02%)	0 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Hypothyroidism</b>			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Secondary adrenocortical insufficiency</b>			

subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid mass			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroiditis subacute			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyrotoxic crisis			
subjects affected / exposed	2 / 10793 (0.02%)	0 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhabdomyolysis			
subjects affected / exposed	2 / 10793 (0.02%)	5 / 21587 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain			
subjects affected / exposed	1 / 10793 (0.01%)	4 / 21587 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical spinal stenosis			
subjects affected / exposed	2 / 10793 (0.02%)	2 / 21587 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Costochondritis			

subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Haemarthrosis</b>		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Haematoma muscle</b>		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Intervertebral disc degeneration</b>		
subjects affected / exposed	0 / 10793 (0.00%)	3 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Intervertebral disc protrusion</b>		
subjects affected / exposed	4 / 10793 (0.04%)	5 / 21587 (0.02%)
occurrences causally related to treatment / all	0 / 5	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Limb mass</b>		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Lumbar spinal stenosis</b>		
subjects affected / exposed	2 / 10793 (0.02%)	6 / 21587 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Muscle spasms</b>		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Musculoskeletal chest pain</b>		

subjects affected / exposed	1 / 10793 (0.01%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neck pain		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Osteoarthritis		
subjects affected / exposed	10 / 10793 (0.09%)	14 / 21587 (0.06%)
occurrences causally related to treatment / all	0 / 13	0 / 16
deaths causally related to treatment / all	0 / 0	0 / 0
Pain in extremity		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arthritis		
subjects affected / exposed	0 / 10793 (0.00%)	5 / 21587 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal stenosis		
subjects affected / exposed	3 / 10793 (0.03%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal pain		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spondylolisthesis		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Vertebral foraminal stenosis		

subjects affected / exposed	1 / 10793 (0.01%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Rheumatoid arthritis</b>			
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Rotator cuff syndrome</b>			
subjects affected / exposed	2 / 10793 (0.02%)	0 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Scoliosis</b>			
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Spinal osteoarthritis</b>			
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Spinal synovial cyst</b>			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Infections and infestations</b>			
<b>Abdominal sepsis</b>			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Abdominal abscess</b>			
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Abdominal wall abscess</b>			

subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Abscess limb</b>		
subjects affected / exposed	0 / 10793 (0.00%)	4 / 21587 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Chronic sinusitis</b>		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cholecystitis infective</b>		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cellulitis</b>		
subjects affected / exposed	7 / 10793 (0.06%)	11 / 21587 (0.05%)
occurrences causally related to treatment / all	0 / 8	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Campylobacter colitis</b>		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>COVID-19 pneumonia</b>		
subjects affected / exposed	21 / 10793 (0.19%)	29 / 21587 (0.13%)
occurrences causally related to treatment / all	0 / 23	0 / 34
deaths causally related to treatment / all	0 / 3	0 / 2
<b>COVID-19</b>		
subjects affected / exposed	16 / 10793 (0.15%)	20 / 21587 (0.09%)
occurrences causally related to treatment / all	0 / 17	0 / 23
deaths causally related to treatment / all	0 / 2	0 / 1
<b>Bursitis infective</b>		

subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Balanitis candida</b>		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bacterial pyelonephritis</b>		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bacteraemia</b>		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Arthritis bacterial</b>		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Appendicitis perforated</b>		
subjects affected / exposed	2 / 10793 (0.02%)	4 / 21587 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Appendicitis</b>		
subjects affected / exposed	11 / 10793 (0.10%)	29 / 21587 (0.13%)
occurrences causally related to treatment / all	0 / 11	0 / 31
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Anal abscess</b>		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Encephalitis</b>		

subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulitis intestinal perforated		
subjects affected / exposed	0 / 10793 (0.00%)	3 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulitis		
subjects affected / exposed	1 / 10793 (0.01%)	7 / 21587 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Device related sepsis		
subjects affected / exposed	0 / 10793 (0.00%)	3 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Device related infection		
subjects affected / exposed	3 / 10793 (0.03%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Enterococcal bacteraemia		
subjects affected / exposed	0 / 10793 (0.00%)	3 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Complicated appendicitis		
subjects affected / exposed	2 / 10793 (0.02%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colonic abscess		

subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Coccidioidomycosis		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Clostridium difficile infection		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Clostridium difficile colitis		
subjects affected / exposed	2 / 10793 (0.02%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Enterobacter sepsis		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Coronavirus infection		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Enterococcal sepsis		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Influenza		
subjects affected / exposed	1 / 10793 (0.01%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infective tenosynovitis		

subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infected skin ulcer		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Giardiasis		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal infection		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis viral		
subjects affected / exposed	1 / 10793 (0.01%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis shigella		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis		
subjects affected / exposed	2 / 10793 (0.02%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gangrene		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Focal peritonitis		

subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Extradural abscess		
subjects affected / exposed	0 / 10793 (0.00%)	3 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia urinary tract infection		
subjects affected / exposed	1 / 10793 (0.01%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia pyelonephritis		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia bacteraemia		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Epididymitis		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peritonitis		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Peritonsillar abscess		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Periorbital cellulitis		

subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic abscess		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Parainfluenzae virus infection		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Otitis externa		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Osteomyelitis		
subjects affected / exposed	5 / 10793 (0.05%)	5 / 21587 (0.02%)
occurrences causally related to treatment / all	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Oropharyngeal candidiasis		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Orchitis		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Monkeypox		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Localised infection		

subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestine infection		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Labyrinthitis		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Kidney infection		
subjects affected / exposed	1 / 10793 (0.01%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral discitis		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Perirectal abscess		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia bacterial		
subjects affected / exposed	0 / 10793 (0.00%)	5 / 21587 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia klebsiella		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia legionella		

subjects affected / exposed	1 / 10793 (0.01%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia streptococcal		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural infection		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative abscess		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative wound infection		
subjects affected / exposed	1 / 10793 (0.01%)	3 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pseudomonal sepsis		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Psoas abscess		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis		
subjects affected / exposed	0 / 10793 (0.00%)	5 / 21587 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis acute		

subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cyst infection		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory syncytial virus infection		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
SARS-CoV-2 sepsis		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Salmonellosis		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pharyngitis		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia		
subjects affected / exposed	8 / 10793 (0.07%)	32 / 21587 (0.15%)
occurrences causally related to treatment / all	0 / 9	0 / 36
deaths causally related to treatment / all	0 / 0	0 / 1
Scrotal cellulitis		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular device infection		

subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sepsis syndrome		
subjects affected / exposed	1 / 10793 (0.01%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Septic shock		
subjects affected / exposed	2 / 10793 (0.02%)	5 / 21587 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 0
Sinusitis bacterial		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal bacteraemia		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal infection		
subjects affected / exposed	2 / 10793 (0.02%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal sepsis		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Streptococcal bacteraemia		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Suspected COVID-19		

subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Toxic shock syndrome staphylococcal		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Tubo-ovarian abscess		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract infection		
subjects affected / exposed	2 / 10793 (0.02%)	8 / 21587 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract infection bacterial		
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Urinary tract infection enterococcal		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Urosepsis		
subjects affected / exposed	0 / 10793 (0.00%)	3 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Sepsis		
subjects affected / exposed	3 / 10793 (0.03%)	11 / 21587 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Viral infection		

subjects affected / exposed	1 / 10793 (0.01%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral pericarditis			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
West Nile viral infection			
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	1 / 10793 (0.01%)	2 / 21587 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Failure to thrive			
subjects affected / exposed	0 / 10793 (0.00%)	2 / 21587 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gout			
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypercalcaemia			
subjects affected / exposed	0 / 10793 (0.00%)	4 / 21587 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemia			
subjects affected / exposed	2 / 10793 (0.02%)	1 / 21587 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemic hyperosmolar nonketotic syndrome			

subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperkalaemia		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoglycaemia		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypokalaemia		
subjects affected / exposed	2 / 10793 (0.02%)	2 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hypomagnesaemia		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hyponatraemia		
subjects affected / exposed	4 / 10793 (0.04%)	3 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hypovolaemia		
subjects affected / exposed	1 / 10793 (0.01%)	0 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Obesity		
subjects affected / exposed	0 / 10793 (0.00%)	1 / 21587 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Type 2 diabetes mellitus		

subjects affected / exposed	1 / 10793 (0.01%)	3 / 21587 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Diabetic ketoacidosis</b>		
subjects affected / exposed	4 / 10793 (0.04%)	7 / 21587 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 8
deaths causally related to treatment / all	0 / 1	0 / 0

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

<b>Non-serious adverse events</b>	Placebo	AZD1222
<b>Total subjects affected by non-serious adverse events</b>		
subjects affected / exposed	4234 / 10793 (39.23%)	11846 / 21587 (54.88%)
<b>Nervous system disorders</b>		
Headache		
subjects affected / exposed	996 / 10793 (9.23%)	3511 / 21587 (16.26%)
occurrences (all)	1125	4106
<b>General disorders and administration site conditions</b>		
Pyrexia		
subjects affected / exposed	73 / 10793 (0.68%)	1174 / 21587 (5.44%)
occurrences (all)	78	1209
Fatigue		
subjects affected / exposed	853 / 10793 (7.90%)	2836 / 21587 (13.14%)
occurrences (all)	942	3250
Injection site pain		
subjects affected / exposed	532 / 10793 (4.93%)	3624 / 21587 (16.79%)
occurrences (all)	595	4363
Pain		
subjects affected / exposed	264 / 10793 (2.45%)	1857 / 21587 (8.60%)
occurrences (all)	283	2023
Chills		
subjects affected / exposed	248 / 10793 (2.30%)	2208 / 21587 (10.23%)
occurrences (all)	264	2366

Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	278 / 10793 (2.58%)	1622 / 21587 (7.51%)	
occurrences (all)	296	1736	
Infections and infestations			
COVID-19			
subjects affected / exposed	2715 / 10793 (25.16%)	6207 / 21587 (28.75%)	
occurrences (all)	2921	6717	

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
26 October 2020	Revised important potential risks. Increased the sample size from 30000 to 40000 participants. Added a description of the independent neurological AESI Expert Committee. Expanded the AESI list and specified that AESIs were reported to the Sponsor within one day of becoming aware of the event. New section for evaluation of potential neurological AESIs.
14 December 2020	Revised the first secondary endpoint. Identified the 4 key secondary endpoints. Added an immunogenicity cohort of approximately 300 participants. Reduced the sample size from 40000 back to the original number of 30000. Added text to indicate that experimental vaccinations, other than AZD1222, for prevention of SARS-CoV-2 or COVID-19 are prohibited. Also, noted that participants who choose to receive an authorized COVID-19 vaccine should inform the Investigator so it can be properly documented, and they should be encouraged to continue study conduct. Specified the procedures for unblinding in the event a study participant is contacted about receiving an authorized COVID-19 vaccine. Specified that if the primary endpoint results of the interim or primary analysis are statistically significant, an additional analysis with 5% alpha was performed once all participants had completed the first year of follow up. Revised to indicate how the primary efficacy endpoints and 4 key secondary endpoints were assessed.
19 February 2021	Removed "and Adolescents" from the title and removed text from the study rationale regarding adolescents. Upgraded exploratory endpoint "To estimate the efficacy of AZD1222 compared to saline placebo for the prevention of COVID-19 following the first dose" to secondary endpoint. Removed all references to Part 1 and Part 2 (Parts 1 and 2 were introduced in Amendment 5; an amendment which was not implemented).
29 March 2021	Revised to reflect the addition of an unblinded phase with an open-label dosing option (Part B). The original randomized, double-blind part of the study was labeled as Part A. Added additional exploratory objectives to assess the long-term safety and tolerability of 2 IM doses of AZD1222.

Notes:

### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported