



Clinical trial results: Strategic Timing of AntiRetroviral Treatment(START) Summary

EudraCT number	2008-006439-12
Trial protocol	BE FI ES DE GB GR IT SE PT IE EE NO AT CZ
Global end of trial date	27 July 2022

Results information

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

Trial information

Trial identification

Sponsor protocol code	INSIGHT001:START
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00867048
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Regents of the University of Minnesota
Sponsor organisation address	Office of the Vice President for Research, 420 Johnston Hall, 101 Pleasant St. SE, Minneapolis, United States, 55455
Public contact	Jens Lundgren, CHIP - Rigshospitalet, University of Copenhagen, 45 3545 5757, jens.lundgren@regionh.dk
Scientific contact	Jens Lundgren, CHIP - Rigshospitalet, University of Copenhagen, 45 3545 5757, jens.lundgren@regionh.dk

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	30 June 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	27 July 2022
Global end of trial reached?	Yes
Global end of trial date	27 July 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of START was to determine whether starting ART early (at CD4 > 500) is superior to deferring ART until indicated by (then-current) guidelines at delaying the occurrence of a composite outcome consisting of AIDS, non-AIDS, or death from any cause.

Based on two scientific hypotheses, both which take advantage of the randomized design of START and the extended follow-up through 2021, the primary objective of the extended follow-up period was to determine whether the benefit of early ART as compared to deferred ART in delaying the occurrence of a composite outcome consisting of AIDS, non-AIDS, or death from any cause is maintained, increased or reduced.

Protection of trial subjects:

Participants were in regular contact with the study site, as this was where they were getting their primary care for HIV infection. Any side effects or necessary changes in medication could be identified promptly.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 April 2009
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Morocco: 43
Country: Number of subjects enrolled	Uganda: 348
Country: Number of subjects enrolled	Denmark: 33
Country: Number of subjects enrolled	Luxembourg: 5
Country: Number of subjects enrolled	Switzerland: 31
Country: Number of subjects enrolled	Argentina: 216
Country: Number of subjects enrolled	Australia: 109
Country: Number of subjects enrolled	Chile: 76
Country: Number of subjects enrolled	India: 91
Country: Number of subjects enrolled	Israel: 28
Country: Number of subjects enrolled	Malaysia: 18
Country: Number of subjects enrolled	Mexico: 48
Country: Number of subjects enrolled	Nigeria: 49
Country: Number of subjects enrolled	Thailand: 247
Country: Number of subjects enrolled	Brazil: 619

Country: Number of subjects enrolled	Mali: 41
Country: Number of subjects enrolled	Peru: 215
Country: Number of subjects enrolled	United States: 507
Country: Number of subjects enrolled	South Africa: 518
Country: Number of subjects enrolled	Norway: 15
Country: Number of subjects enrolled	Poland: 68
Country: Number of subjects enrolled	Portugal: 67
Country: Number of subjects enrolled	Spain: 234
Country: Number of subjects enrolled	Sweden: 2
Country: Number of subjects enrolled	United Kingdom: 339
Country: Number of subjects enrolled	Austria: 7
Country: Number of subjects enrolled	Belgium: 102
Country: Number of subjects enrolled	Czechia: 13
Country: Number of subjects enrolled	Estonia: 8
Country: Number of subjects enrolled	Finland: 23
Country: Number of subjects enrolled	France: 111
Country: Number of subjects enrolled	Germany: 312
Country: Number of subjects enrolled	Greece: 101
Country: Number of subjects enrolled	Ireland: 7
Country: Number of subjects enrolled	Italy: 33
Worldwide total number of subjects	4684
EEA total number of subjects	1141

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)	4653
From 65 to 84 years	31
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Adults with documented HIV infection and a current CD4+ cell count > 500 cells/mm³ who have never received antiretroviral treatment

Period 1

Period 1 title	Entire trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Immediate antiretroviral therapy

Arm description:

Antiretroviral-naïve participants with HIV infection and CD4+ > 500 cell/mm³ will begin antiretroviral treatment immediately following randomization with regimen of any approved drugs, as determined by their treating clinician

Arm type	Experimental
Investigational medicinal product name	Antiretroviral therapy
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, Tablet
Routes of administration	Oral use

Dosage and administration details:

For each participant, the clinician constructed a first-line antiretroviral regimen per current treatment guidelines from drugs approved for use in that country.

Arm title	Deferred antiretroviral therapy
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Arm description:

Participants with HIV infection and CD4 > 500 cell/mm³ deferred ART initiation until their CD4 dropped to < 350 cell/mm³ or an AIDS-related condition developed.

Arm type	Standard of care
Investigational medicinal product name	Antiretroviral therapy
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet, Capsule
Routes of administration	Oral use

Dosage and administration details:

For each participant, the clinician constructed a first-line antiretroviral regimen per current treatment guidelines from drugs approved for use in that country.

Number of subjects in period 1	Immediate antiretroviral therapy	Deferred antiretroviral therapy
Started	2325	2359
Completed	2325	2359

Baseline characteristics

Reporting groups

Reporting group title	Immediate antiretroviral therapy
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Reporting group description:

Antiretroviral-naïve participants with HIV infection and CD4+ > 500 cell/mm³ will begin antiretroviral treatment immediately following randomization with regimen of any approved drugs, as determined by their treating clinician

Reporting group title	Deferred antiretroviral therapy
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Reporting group description:

Participants with HIV infection and CD4 > 500 cell/mm³ deferred ART initiation until their CD4 dropped to < 350 cell/mm³ or an AIDS-related condition developed.

Reporting group values	Immediate antiretroviral therapy	Deferred antiretroviral therapy	Total
Number of subjects	2325	2359	4684
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	2308	2345	4653
From 65-84 years	17	14	31
85 years and over	0	0	0
Age continuous			
Units: years			
arithmetic mean	36.8	36.8	
standard deviation	± 10.2	± 10.1	-
Gender categorical			
Units: Subjects			
Female	624	633	1257
Male	1701	1726	3427

Subject analysis sets

Subject analysis set title	All participants with documented HIV infection
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Subject analysis set type	Full analysis
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Subject analysis set description:

Among the 4688 putatively HIV-infected participants enrolled, 4 were ultimately found to be not infected with HIV. These 4 participants are not included in outcome analyses.

Reporting group values	All participants with documented HIV infection		
Number of subjects	4684		

Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	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)	4653		
From 65-84 years	31		
85 years and over	0		
Age continuous Units: years			
arithmetic mean	36.8		
standard deviation	± 10.2		
Gender categorical Units: Subjects			
Female	1257		
Male	3427		

End points

End points reporting groups

Reporting group title	Immediate antiretroviral therapy
Reporting group description: Antiretroviral-naïve participants with HIV infection and CD4+ > 500 cell/mm ³ will begin antiretroviral treatment immediately following randomization with regimen of any approved drugs, as determined by their treating clinician	
Reporting group title	Deferred antiretroviral therapy
Reporting group description: Participants with HIV infection and CD4 > 500 cell/mm ³ deferred ART initiation until their CD4 dropped to < 350 cell/mm ³ or an AIDS-related condition developed.	
Subject analysis set title	All participants with documented HIV infection
Subject analysis set type	Full analysis
Subject analysis set description: Among the 4688 putatively HIV-infected participants enrolled, 4 were ultimately found to be not infected with HIV. These 4 participants are not included in outcome analyses.	

Primary: Composite primary outcome

End point title	Composite primary outcome
End point description: Composite endpoint of an AIDS event, serious non-AIDS event (cardiovascular disease, non-AIDS cancer, end-stage renal disease, decompensated liver disease), or death from any cause.	
End point type	Primary
End point timeframe: Randomization through 31 December 2021	

End point values	Immediate antiretroviral therapy	Deferred antiretroviral therapy		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2325	2359		
Units: participants	133	215		

Statistical analyses

Statistical analysis title	Composite primary outcome
Statistical analysis description: Cox regression, time to first event. Hazard ratio Immediate/Deferred (95% confidence interval); pvalue; alpha=0.05; 2-sided. Model stratified by geographic region.	
Comparison groups	Immediate antiretroviral therapy v Deferred antiretroviral therapy

Number of subjects included in analysis	4684
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cox proportional hazards regression
Parameter estimate	Hazard ratio (HR)
Point estimate	0.61
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.49
upper limit	0.76

Secondary: AIDS or AIDS-related death

End point title	AIDS or AIDS-related death
End point description: A component of the composite primary endpoint. Time to first event: AIDS event or death from AIDS-related event	
End point type	Secondary
End point timeframe: Randomization through 31 December 2021	

End point values	Immediate antiretroviral therapy	Deferred antiretroviral therapy		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2325	2359		
Units: participants	31	83		

Statistical analyses

Statistical analysis title	AIDS
Comparison groups	Immediate antiretroviral therapy v Deferred antiretroviral therapy
Number of subjects included in analysis	4684
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cox proportional hazards regression
Parameter estimate	Hazard ratio (HR)
Point estimate	0.37

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.25
upper limit	0.56

Secondary: Serious non-AIDS

End point title	Serious non-AIDS
End point description:	
A component of the composite primary outcome. Time to first event: cardiovascular disease, end-stage renal disease, decompensated liver diseases, non-AIDS-associated cancer, death from causes other than AIDS.	
End point type	Secondary
End point timeframe:	
Randomization through 31 December 2021	

End point values	Immediate antiretroviral therapy	Deferred antiretroviral therapy		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2325	2359		
Units: participants	107	137		

Statistical analyses

Statistical analysis title	Serious non-AIDS
Comparison groups	Immediate antiretroviral therapy v Deferred antiretroviral therapy
Number of subjects included in analysis	4684
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.053
Method	Cox proportional hazards regression
Parameter estimate	Hazard ratio (HR)
Point estimate	0.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.61
upper limit	1

Secondary: All-cause mortality

End point title	All-cause mortality
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End point description:

A component of the primary composite outcome. Time-to-event analysis.

End point type Secondary

End point timeframe:

Randomization through 31 December 2021

End point values	Immediate antiretroviral therapy	Deferred antiretroviral therapy		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2325	2359		
Units: participants	66	85		

Statistical analyses

Statistical analysis title	All-cause mortality
Comparison groups	Immediate antiretroviral therapy v Deferred antiretroviral therapy
Number of subjects included in analysis	4684
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.13
Method	Cox proportional hazards regression
Parameter estimate	Hazard ratio (HR)
Point estimate	0.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.57
upper limit	1.08

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

Randomization through 31 December 2017 for serious adverse events; deaths are reported through 31 December 2021.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	25.0
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Reporting groups

Reporting group title	Immediate antiretroviral therapy
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Reporting group description:

Participants with HIV infection and CD4+ > 500 cell/mm³ will begin antiretroviral treatment with regimen of any approved drugs, as determined by their treating clinician.

Non-serious events were not reported in this trial.

Reporting group title	Deferred antiretroviral therapy
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Reporting group description:

Participants with HIV infection and CD4 > 500 cells/mm³ waited until they met global treatment guidelines to begin antiretroviral therapy (i.e., until CD4 cell count dropped below 350 cell/mm³ or an AIDS-related condition developed).

Non-serious events were not reported in this trial.

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: No non-serious adverse events were collected in START. As a strategy trial, all medications being used were approved and being used within indication.

Serious adverse events	Immediate antiretroviral therapy	Deferred antiretroviral therapy	
Total subjects affected by serious adverse events			
subjects affected / exposed	430 / 2325 (18.49%)	498 / 2359 (21.11%)	
number of deaths (all causes)	66	85	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma gastric			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adrenal adenoma			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal cancer			

subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Anal squamous cell carcinoma		
subjects affected / exposed	0 / 2325 (0.00%)	2 / 2359 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Benign hydatidiform mole		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (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	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Burkitt's lymphoma		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Cancer pain		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Castleman's disease		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cervix carcinoma		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Clear cell renal cell carcinoma		

subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Extragenital primary seminoma (pure)		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fibrosarcoma		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lung adenocarcinoma		
subjects affected / exposed	1 / 2325 (0.04%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Lung cancer metastatic		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
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	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Meningioma benign		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to liver		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Metastasis		

subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metastatic malignant melanoma		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Myeloid leukaemia		
subjects affected / exposed	0 / 2325 (0.00%)	2 / 2359 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Neurilemmoma benign		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neuroendocrine carcinoma		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neuroma		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Non-small cell lung cancer metastatic		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Papillary thyroid cancer		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal cancer		

subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (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 / 2325 (0.00%)	1 / 2359 (0.04%)
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 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Small cell lung cancer metastatic		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Squamous cell carcinoma of lung		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Testicular germ cell cancer		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
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 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Transitional cell cancer of the renal pelvis and ureter		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Transitional cell carcinoma metastatic		

subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Uterine leiomyoma			
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal carcinoma			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Vascular disorders			
Aortic aneurysm			
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortitis			
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deep vein thrombosis			
subjects affected / exposed	5 / 2325 (0.22%)	3 / 2359 (0.13%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertension			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hypertensive crisis			
subjects affected / exposed	2 / 2325 (0.09%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral arterial occlusive disease			

subjects affected / exposed	2 / 2325 (0.09%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery thrombosis			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral ischaemia			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vena cava thrombosis			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Appendicectomy			
subjects affected / exposed	0 / 2325 (0.00%)	2 / 2359 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pregnancy, puerperium and perinatal conditions			
Abortion incomplete			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abortion spontaneous			
subjects affected / exposed	1 / 2325 (0.04%)	4 / 2359 (0.17%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abortion threatened			
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

Cephalo-pelvic disproportion			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ectopic pregnancy			
subjects affected / exposed	4 / 2325 (0.17%)	2 / 2359 (0.08%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foetal death			
subjects affected / exposed	2 / 2325 (0.09%)	3 / 2359 (0.13%)	
occurrences causally related to treatment / all	0 / 2	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foetal distress syndrome			
subjects affected / exposed	4 / 2325 (0.17%)	5 / 2359 (0.21%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gestational hypertension			
subjects affected / exposed	1 / 2325 (0.04%)	2 / 2359 (0.08%)	
occurrences causally related to treatment / all	0 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage in pregnancy			
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oligohydramnios			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pre-eclampsia			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Premature delivery			

subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Premature labour			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Premature rupture of membranes			
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prolonged labour			
subjects affected / exposed	2 / 2325 (0.09%)	2 / 2359 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ruptured ectopic pregnancy			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Umbilical cord prolapse			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (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			
Chest pain			
subjects affected / exposed	1 / 2325 (0.04%)	4 / 2359 (0.17%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chills			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Complication of device insertion			

subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Death		
subjects affected / exposed	4 / 2325 (0.17%)	12 / 2359 (0.51%)
occurrences causally related to treatment / all	0 / 4	0 / 12
deaths causally related to treatment / all	0 / 4	0 / 12
Drowning		
subjects affected / exposed	0 / 2325 (0.00%)	2 / 2359 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2
Drug withdrawal syndrome		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fatigue		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gait disturbance		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Influenza like illness		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Impaired self-care		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple organ dysfunction syndrome		

subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Necrobiosis		
subjects affected / exposed	0 / 2325 (0.00%)	2 / 2359 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Non-cardiac chest pain		
subjects affected / exposed	2 / 2325 (0.09%)	2 / 2359 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral swelling		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pyrexia		
subjects affected / exposed	8 / 2325 (0.34%)	11 / 2359 (0.47%)
occurrences causally related to treatment / all	0 / 8	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Strangulated hernia		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Systemic inflammatory response syndrome		
subjects affected / exposed	1 / 2325 (0.04%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Abscess neck		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Acute hepatitis B		

subjects affected / exposed	0 / 2325 (0.00%)	2 / 2359 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	1 / 2325 (0.04%)	2 / 2359 (0.08%)	
occurrences causally related to treatment / all	1 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaphylactic shock			
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug hypersensitivity			
subjects affected / exposed	1 / 2325 (0.04%)	3 / 2359 (0.13%)	
occurrences causally related to treatment / all	1 / 1	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sarcoidosis			
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Social circumstances			
Homicide			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Substance use			
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Abnormal uterine bleeding			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Benign prostatic hyperplasia			
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystocele			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Genital rash			
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intermenstrual bleeding			
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
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 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Priapism			
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
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 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Testicular pain			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Testicular torsion			

subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine adhesions			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal prolapse			
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Acute respiratory failure			
subjects affected / exposed	2 / 2325 (0.09%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Aspiration			
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthma			
subjects affected / exposed	4 / 2325 (0.17%)	5 / 2359 (0.21%)	
occurrences causally related to treatment / all	0 / 5	0 / 8	
deaths causally related to treatment / all	0 / 1	0 / 0	
Chronic obstructive pulmonary disease			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cough			

subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dyspnoea		
subjects affected / exposed	1 / 2325 (0.04%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Obstructive airways disorder		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Pleural effusion		
subjects affected / exposed	2 / 2325 (0.09%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pleurisy		
subjects affected / exposed	0 / 2325 (0.00%)	2 / 2359 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumothorax		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary embolism		
subjects affected / exposed	3 / 2325 (0.13%)	5 / 2359 (0.21%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory failure		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Restrictive pulmonary disease		

subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsillar hypertrophy			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheomalacia			
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Acute psychosis			
subjects affected / exposed	0 / 2325 (0.00%)	2 / 2359 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute stress disorder			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Affective disorder			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Agitation			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol abuse			
subjects affected / exposed	1 / 2325 (0.04%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol withdrawal syndrome			

subjects affected / exposed	1 / 2325 (0.04%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Alcoholism		
subjects affected / exposed	2 / 2325 (0.09%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anxiety		
subjects affected / exposed	1 / 2325 (0.04%)	3 / 2359 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Bipolar I disorder		
subjects affected / exposed	1 / 2325 (0.04%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bipolar disorder		
subjects affected / exposed	3 / 2325 (0.13%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Burnout syndrome		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiovascular somatic symptom disorder		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Completed suicide		
subjects affected / exposed	1 / 2325 (0.04%)	5 / 2359 (0.21%)
occurrences causally related to treatment / all	0 / 1	1 / 5
deaths causally related to treatment / all	0 / 1	1 / 5
Conversion disorder		

subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Delirium		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Depression		
subjects affected / exposed	8 / 2325 (0.34%)	13 / 2359 (0.55%)
occurrences causally related to treatment / all	1 / 9	0 / 18
deaths causally related to treatment / all	0 / 0	0 / 0
Depression suicidal		
subjects affected / exposed	3 / 2325 (0.13%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	1 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Drug abuse		
subjects affected / exposed	1 / 2325 (0.04%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Drug dependence		
subjects affected / exposed	1 / 2325 (0.04%)	2 / 2359 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hallucination		
subjects affected / exposed	2 / 2325 (0.09%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hallucination, auditory		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Homicidal ideation		

subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intentional self-injury		
subjects affected / exposed	1 / 2325 (0.04%)	2 / 2359 (0.08%)
occurrences causally related to treatment / all	1 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Major depression		
subjects affected / exposed	7 / 2325 (0.30%)	3 / 2359 (0.13%)
occurrences causally related to treatment / all	2 / 8	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Mental disorder		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Panic attack		
subjects affected / exposed	2 / 2325 (0.09%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Persecutory delusion		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Psychiatric decompensation		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Psychotic disorder		
subjects affected / exposed	2 / 2325 (0.09%)	2 / 2359 (0.08%)
occurrences causally related to treatment / all	1 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Schizoaffective disorder		

subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Schizophrenia			
subjects affected / exposed	0 / 2325 (0.00%)	2 / 2359 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Self-injurious ideation			
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Substance abuse			
subjects affected / exposed	0 / 2325 (0.00%)	3 / 2359 (0.13%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Substance-induced mood disorder			
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Substance-induced psychotic disorder			
subjects affected / exposed	3 / 2325 (0.13%)	3 / 2359 (0.13%)	
occurrences causally related to treatment / all	3 / 6	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicidal ideation			
subjects affected / exposed	14 / 2325 (0.60%)	16 / 2359 (0.68%)	
occurrences causally related to treatment / all	9 / 22	3 / 22	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicide attempt			
subjects affected / exposed	24 / 2325 (1.03%)	20 / 2359 (0.85%)	
occurrences causally related to treatment / all	9 / 34	4 / 22	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Autoimmune hepatitis			

subjects affected / exposed	1 / 2325 (0.04%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Biliary colic		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cholangitis		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis		
subjects affected / exposed	3 / 2325 (0.13%)	4 / 2359 (0.17%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis acute		
subjects affected / exposed	2 / 2325 (0.09%)	5 / 2359 (0.21%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 1
Cholecystitis chronic		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cholelithiasis		
subjects affected / exposed	2 / 2325 (0.09%)	2 / 2359 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cholelithiasis migration		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Drug-induced liver injury		

subjects affected / exposed	2 / 2325 (0.09%)	2 / 2359 (0.08%)	
occurrences causally related to treatment / all	2 / 2	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cirrhosis			
subjects affected / exposed	0 / 2325 (0.00%)	2 / 2359 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic failure			
subjects affected / exposed	0 / 2325 (0.00%)	2 / 2359 (0.08%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	1 / 1	
Hepatitis			
subjects affected / exposed	2 / 2325 (0.09%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	1 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis acute			
subjects affected / exposed	1 / 2325 (0.04%)	3 / 2359 (0.13%)	
occurrences causally related to treatment / all	0 / 1	2 / 4	
deaths causally related to treatment / all	0 / 0	1 / 1	
Hyperbilirubinaemia			
subjects affected / exposed	3 / 2325 (0.13%)	2 / 2359 (0.08%)	
occurrences causally related to treatment / all	4 / 4	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver disorder			
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Blood glucose increased			
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			

Abdominal injury			
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Accidental overdose			
subjects affected / exposed	3 / 2325 (0.13%)	4 / 2359 (0.17%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Accidental poisoning			
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol poisoning			
subjects affected / exposed	1 / 2325 (0.04%)	3 / 2359 (0.13%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Ankle fracture			
subjects affected / exposed	4 / 2325 (0.17%)	4 / 2359 (0.17%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back injury			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carbon monoxide poisoning			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Clavicle fracture			
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Contusion			

subjects affected / exposed	2 / 2325 (0.09%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Craniocerebral injury		
subjects affected / exposed	2 / 2325 (0.09%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0
Extradural haematoma		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Eye injury		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Facial bones fracture		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fall		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Femoral neck fracture		
subjects affected / exposed	2 / 2325 (0.09%)	2 / 2359 (0.08%)
occurrences causally related to treatment / all	0 / 2	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Femur fracture		
subjects affected / exposed	1 / 2325 (0.04%)	2 / 2359 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Fibula fracture		

subjects affected / exposed	0 / 2325 (0.00%)	2 / 2359 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Foot fracture		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Forearm fracture		
subjects affected / exposed	1 / 2325 (0.04%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Foreign body in gastrointestinal tract		
subjects affected / exposed	0 / 2325 (0.00%)	2 / 2359 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Fracture of penis		
subjects affected / exposed	0 / 2325 (0.00%)	3 / 2359 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal procedural complication		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal stoma complication		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gun shot wound		
subjects affected / exposed	1 / 2325 (0.04%)	4 / 2359 (0.17%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 2
Hand fracture		

subjects affected / exposed	3 / 2325 (0.13%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Head injury		
subjects affected / exposed	3 / 2325 (0.13%)	5 / 2359 (0.21%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Humerus fracture		
subjects affected / exposed	2 / 2325 (0.09%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Injury		
subjects affected / exposed	0 / 2325 (0.00%)	2 / 2359 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Intentional overdose		
subjects affected / exposed	2 / 2325 (0.09%)	2 / 2359 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Joint dislocation		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Joint injury		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ligament injury		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Limb injury		

subjects affected / exposed	1 / 2325 (0.04%)	2 / 2359 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Limb traumatic amputation		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
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	2 / 2325 (0.09%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar vertebral fracture		
subjects affected / exposed	2 / 2325 (0.09%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Meniscus injury		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple fractures		
subjects affected / exposed	2 / 2325 (0.09%)	4 / 2359 (0.17%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple injuries		
subjects affected / exposed	1 / 2325 (0.04%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Nasal injury		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Patella fracture		

subjects affected / exposed	1 / 2325 (0.04%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax traumatic			
subjects affected / exposed	0 / 2325 (0.00%)	2 / 2359 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post concussion syndrome			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post lumbar puncture syndrome			
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haematoma			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haematuria			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haemorrhage			
subjects affected / exposed	0 / 2325 (0.00%)	2 / 2359 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post-traumatic neck syndrome			
subjects affected / exposed	2 / 2325 (0.09%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural complication			

subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Radius fracture		
subjects affected / exposed	2 / 2325 (0.09%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Reactive gastropathy		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
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	2 / 2325 (0.09%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Road traffic accident		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Scrotal haematoma		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Skin laceration		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Soft tissue injury		
subjects affected / exposed	2 / 2325 (0.09%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal cord injury cervical		

subjects affected / exposed	2 / 2325 (0.09%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Stab wound		
subjects affected / exposed	2 / 2325 (0.09%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Subdural haematoma		
subjects affected / exposed	1 / 2325 (0.04%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tendon injury		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tendon rupture		
subjects affected / exposed	2 / 2325 (0.09%)	2 / 2359 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Testicular injury		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Thermal burn		
subjects affected / exposed	2 / 2325 (0.09%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Tibia fracture		
subjects affected / exposed	1 / 2325 (0.04%)	2 / 2359 (0.08%)
occurrences causally related to treatment / all	1 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Toxicity to various agents		

subjects affected / exposed	1 / 2325 (0.04%)	2 / 2359 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic haematoma		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic haemothorax		
subjects affected / exposed	1 / 2325 (0.04%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic intracranial haemorrhage		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Upper limb fracture		
subjects affected / exposed	2 / 2325 (0.09%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular graft occlusion		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular graft thrombosis		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Wound dehiscence		
subjects affected / exposed	2 / 2325 (0.09%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Wrist fracture		

subjects affected / exposed	1 / 2325 (0.04%)	2 / 2359 (0.08%)	
occurrences causally related to treatment / all	1 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Alagille syndrome			
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anencephaly			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital hydrocephalus			
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital hydronephrosis			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Microcephaly			
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Patent ductus arteriosus			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheo-oesophageal fistula			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular septal defect			

subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	1 / 2325 (0.04%)	1 / 2359 (0.04%)	
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	8 / 2325 (0.34%)	6 / 2359 (0.25%)	
occurrences causally related to treatment / all	3 / 8	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina pectoris			
subjects affected / exposed	0 / 2325 (0.00%)	2 / 2359 (0.08%)	
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	2 / 2325 (0.09%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve stenosis			
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arrhythmia			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Arteriosclerosis coronary artery			
subjects affected / exposed	0 / 2325 (0.00%)	2 / 2359 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			

subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Atrial flutter		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac failure		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac failure acute		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac failure congestive		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiomyopathy		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery disease		
subjects affected / exposed	2 / 2325 (0.09%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Foetal arrhythmia		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mitral valve incompetence		

subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
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	5 / 2325 (0.22%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	1 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Palpitations			
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Silent myocardial infarction			
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus tachycardia			
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subvalvular aortic stenosis			
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Supraventricular tachycardia			
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular tachycardia			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Aphasia			

subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arachnoid cyst		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bell's palsy		
subjects affected / exposed	1 / 2325 (0.04%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cauda equina syndrome		
subjects affected / exposed	1 / 2325 (0.04%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Central nervous system lesion		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral haemorrhage		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Cerebrovascular accident		
subjects affected / exposed	2 / 2325 (0.09%)	5 / 2359 (0.21%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Cognitive disorder		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Demyelination		

subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dizziness		
subjects affected / exposed	3 / 2325 (0.13%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	2 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Drug withdrawal convulsions		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Encephalopathy		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Epilepsy		
subjects affected / exposed	3 / 2325 (0.13%)	2 / 2359 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Facial paresis		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Generalised tonic-clonic seizure		
subjects affected / exposed	2 / 2325 (0.09%)	2 / 2359 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Guillain-Barre syndrome		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
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 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Haemorrhagic transformation stroke		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Headache		
subjects affected / exposed	3 / 2325 (0.13%)	3 / 2359 (0.13%)
occurrences causally related to treatment / all	2 / 3	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic encephalopathy		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	1 / 1
Hydrocephalus		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Idiopathic intracranial hypertension		
subjects affected / exposed	1 / 2325 (0.04%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intracranial mass		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metabolic encephalopathy		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Migraine		

subjects affected / exposed	1 / 2325 (0.04%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neuropathy peripheral		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Paraesthesia		
subjects affected / exposed	1 / 2325 (0.04%)	2 / 2359 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Partial seizures		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Petit mal epilepsy		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Polyneuropathy		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Postictal state		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Seizure		
subjects affected / exposed	2 / 2325 (0.09%)	3 / 2359 (0.13%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal cord compression		

subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	2 / 2325 (0.09%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient ischaemic attack			
subjects affected / exposed	2 / 2325 (0.09%)	2 / 2359 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vlith nerve paralysis			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	5 / 2325 (0.22%)	7 / 2359 (0.30%)	
occurrences causally related to treatment / all	1 / 6	4 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile bone marrow aplasia			
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphadenopathy			
subjects affected / exposed	1 / 2325 (0.04%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenia			
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Normochromic normocytic anaemia			

subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile neutropenia			
subjects affected / exposed	1 / 2325 (0.04%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancytopenia			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	0 / 2325 (0.00%)	2 / 2359 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (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 / 2325 (0.00%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo positional			
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Opsoclonus myoclonus			
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal artery occlusion			

subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disorder of orbit			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vision blurred			
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal hernia			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			
subjects affected / exposed	2 / 2325 (0.09%)	2 / 2359 (0.08%)	
occurrences causally related to treatment / all	0 / 2	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain lower			
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain upper			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal strangulated hernia			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute abdomen			

subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Alcoholic pancreatitis		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Anal fissure		
subjects affected / exposed	2 / 2325 (0.09%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anal haemorrhage		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Anal pruritus		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Anogenital dysplasia		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis		
subjects affected / exposed	4 / 2325 (0.17%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis ulcerative		
subjects affected / exposed	4 / 2325 (0.17%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diarrhoea		

subjects affected / exposed	3 / 2325 (0.13%)	4 / 2359 (0.17%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal ulcer		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal ulcer perforation		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dysphagia		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Enteritis		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Faecaloma		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Food poisoning		
subjects affected / exposed	1 / 2325 (0.04%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Functional gastrointestinal disorder		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric disorder		

subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis		
subjects affected / exposed	2 / 2325 (0.09%)	3 / 2359 (0.13%)
occurrences causally related to treatment / all	0 / 2	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal haemorrhage		
subjects affected / exposed	0 / 2325 (0.00%)	2 / 2359 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal toxicity		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrooesophageal reflux disease		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhoidal haemorrhage		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhoids thrombosed		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hiatus hernia		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ileus		

subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Inflammatory bowel disease		
subjects affected / exposed	0 / 2325 (0.00%)	2 / 2359 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Inguinal hernia		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Inguinal hernia, obstructive		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal obstruction		
subjects affected / exposed	4 / 2325 (0.17%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Intra-abdominal fluid collection		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (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 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mallory-Weiss syndrome		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Megacolon		

subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Obstruction gastric		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Odynophagia		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal achalasia		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal rupture		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis		
subjects affected / exposed	0 / 2325 (0.00%)	2 / 2359 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis acute		
subjects affected / exposed	1 / 2325 (0.04%)	4 / 2359 (0.17%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Proctitis		
subjects affected / exposed	2 / 2325 (0.09%)	5 / 2359 (0.21%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal haemorrhage		

subjects affected / exposed	1 / 2325 (0.04%)	3 / 2359 (0.13%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal perforation			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retroperitoneal haemorrhage			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	2 / 2325 (0.09%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Strangulated umbilical hernia			
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tooth impacted			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Umbilical hernia			
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Dermal cyst			

subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Drug eruption		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Erythema multiforme		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Panniculitis		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rash		
subjects affected / exposed	0 / 2325 (0.00%)	2 / 2359 (0.08%)
occurrences causally related to treatment / all	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Skin lesion		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Skin necrosis		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Toxic skin eruption		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Xanthoma		

subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	11 / 2325 (0.47%)	6 / 2359 (0.25%)	
occurrences causally related to treatment / all	0 / 11	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 2	
Anuria			
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus urinary			
subjects affected / exposed	1 / 2325 (0.04%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic nephropathy			
subjects affected / exposed	1 / 2325 (0.04%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
End stage renal disease			
subjects affected / exposed	1 / 2325 (0.04%)	3 / 2359 (0.13%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glomerulonephritis			
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrolithiasis			
subjects affected / exposed	3 / 2325 (0.13%)	4 / 2359 (0.17%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephropathy			

subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nephrotic syndrome		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal colic		
subjects affected / exposed	1 / 2325 (0.04%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal failure		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ureterolithiasis		
subjects affected / exposed	1 / 2325 (0.04%)	2 / 2359 (0.08%)
occurrences causally related to treatment / all	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Urethral stenosis		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary bladder haemorrhage		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary retention		
subjects affected / exposed	2 / 2325 (0.09%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract obstruction		

subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis reactive			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain			
subjects affected / exposed	3 / 2325 (0.13%)	3 / 2359 (0.13%)	
occurrences causally related to treatment / all	0 / 3	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bursitis			
subjects affected / exposed	0 / 2325 (0.00%)	2 / 2359 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fracture nonunion			
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc disorder			
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc protrusion			

subjects affected / exposed	4 / 2325 (0.17%)	4 / 2359 (0.17%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar spinal stenosis		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Muscle spasms		
subjects affected / exposed	2 / 2325 (0.09%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Muscular weakness		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Musculoskeletal chest pain		
subjects affected / exposed	4 / 2325 (0.17%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Osteoarthritis		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Osteonecrosis		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pain in extremity		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Polyarthritis		

subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhabdomyolysis			
subjects affected / exposed	2 / 2325 (0.09%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal stenosis			
subjects affected / exposed	1 / 2325 (0.04%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Synovitis			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal infection			
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Abscess			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess limb			
subjects affected / exposed	7 / 2325 (0.30%)	4 / 2359 (0.17%)	
occurrences causally related to treatment / all	0 / 7	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute hepatitis C			

subjects affected / exposed	4 / 2325 (0.17%)	2 / 2359 (0.08%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Anal abscess		
subjects affected / exposed	5 / 2325 (0.22%)	13 / 2359 (0.55%)
occurrences causally related to treatment / all	0 / 6	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Appendicitis		
subjects affected / exposed	24 / 2325 (1.03%)	17 / 2359 (0.72%)
occurrences causally related to treatment / all	0 / 24	0 / 17
deaths causally related to treatment / all	0 / 0	0 / 0
Appendicitis perforated		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Arteriovenous graft site abscess		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Arthritis bacterial		
subjects affected / exposed	0 / 2325 (0.00%)	2 / 2359 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bacteraemia		
subjects affected / exposed	0 / 2325 (0.00%)	2 / 2359 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bacterial diarrhoea		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bacterial pyelonephritis		

subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchitis		
subjects affected / exposed	3 / 2325 (0.13%)	2 / 2359 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchitis viral		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Burn infection		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Campylobacter gastroenteritis		
subjects affected / exposed	1 / 2325 (0.04%)	2 / 2359 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Campylobacter sepsis		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Catheter site infection		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cellulitis		
subjects affected / exposed	5 / 2325 (0.22%)	10 / 2359 (0.42%)
occurrences causally related to treatment / all	0 / 5	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Cellulitis staphylococcal		

subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Complicated appendicitis		
subjects affected / exposed	1 / 2325 (0.04%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cryptosporidiosis infection		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dengue fever		
subjects affected / exposed	2 / 2325 (0.09%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dengue haemorrhagic fever		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Device related infection		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic foot infection		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diarrhoea infectious		
subjects affected / exposed	1 / 2325 (0.04%)	2 / 2359 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulitis		

subjects affected / exposed	1 / 2325 (0.04%)	3 / 2359 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulitis intestinal haemorrhagic		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dysentery		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Embolic pneumonia		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Endocarditis		
subjects affected / exposed	1 / 2325 (0.04%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Endocarditis bacterial		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Epididymitis		
subjects affected / exposed	4 / 2325 (0.17%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Epiglottic abscess		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Erysipelas		

subjects affected / exposed	2 / 2325 (0.09%)	4 / 2359 (0.17%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia pyelonephritis		
subjects affected / exposed	1 / 2325 (0.04%)	3 / 2359 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia urinary tract infection		
subjects affected / exposed	2 / 2325 (0.09%)	2 / 2359 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Extradural abscess		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Febrile infection		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fournier's gangrene		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Furuncle		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis		
subjects affected / exposed	4 / 2325 (0.17%)	10 / 2359 (0.42%)
occurrences causally related to treatment / all	0 / 4	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis Escherichia coli		

subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis bacterial		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis cryptosporidial		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis salmonella		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis shigella		
subjects affected / exposed	2 / 2325 (0.09%)	2 / 2359 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis viral		
subjects affected / exposed	1 / 2325 (0.04%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal infection		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Genital herpes simplex		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
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 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gonorrhoea		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Groin abscess		
subjects affected / exposed	2 / 2325 (0.09%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
HIV associated nephropathy		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
HIV peripheral neuropathy		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis A		
subjects affected / exposed	6 / 2325 (0.26%)	4 / 2359 (0.17%)
occurrences causally related to treatment / all	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis C		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Herpes simplex necrotising retinopathy		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Herpes zoster		

subjects affected / exposed	2 / 2325 (0.09%)	3 / 2359 (0.13%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Infected skin ulcer		
subjects affected / exposed	1 / 2325 (0.04%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infection		
subjects affected / exposed	0 / 2325 (0.00%)	2 / 2359 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Influenza		
subjects affected / exposed	3 / 2325 (0.13%)	7 / 2359 (0.30%)
occurrences causally related to treatment / all	0 / 3	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral discitis		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Liver abscess		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestine infection		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
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 / 2325 (0.00%)	2 / 2359 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lower respiratory tract infection		

subjects affected / exposed	2 / 2325 (0.09%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lymph node abscess		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphogranuloma venereum		
subjects affected / exposed	1 / 2325 (0.04%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Malaria		
subjects affected / exposed	4 / 2325 (0.17%)	9 / 2359 (0.38%)
occurrences causally related to treatment / all	0 / 4	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Meningitis		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Meningitis streptococcal		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Meningitis viral		
subjects affected / exposed	1 / 2325 (0.04%)	2 / 2359 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Meningoencephalitis herpetic		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mononucleosis syndrome		

subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mycobacterium abscessus infection		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Necrotising fasciitis		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neurosyphilis		
subjects affected / exposed	2 / 2325 (0.09%)	6 / 2359 (0.25%)
occurrences causally related to treatment / all	0 / 2	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Neutropenic sepsis		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ophthalmic herpes zoster		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Wound sepsis		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Orchitis		
subjects affected / exposed	2 / 2325 (0.09%)	4 / 2359 (0.17%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Osteomyelitis		

subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Osteomyelitis chronic		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Otitis media acute		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Paronychia		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Parotid abscess		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Parotitis		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic inflammatory disease		
subjects affected / exposed	2 / 2325 (0.09%)	4 / 2359 (0.17%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Perirectal abscess		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peritonitis		

subjects affected / exposed	1 / 2325 (0.04%)	2 / 2359 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Peritonsillar abscess		
subjects affected / exposed	3 / 2325 (0.13%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pertussis		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pharyngitis		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pharyngotonsillitis		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pilonidal disease		
subjects affected / exposed	2 / 2325 (0.09%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumococcal bacteraemia		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia		
subjects affected / exposed	2 / 2325 (0.09%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0
Pneumonia aspiration		

subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (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 / 2325 (0.04%)	2 / 2359 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Proctitis chlamydial		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis		
subjects affected / exposed	4 / 2325 (0.17%)	2 / 2359 (0.08%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis acute		
subjects affected / exposed	3 / 2325 (0.13%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pyomyositis		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal abscess		
subjects affected / exposed	1 / 2325 (0.04%)	2 / 2359 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Renal abscess		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rubella		

subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Scrotal abscess		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Secondary syphilis		
subjects affected / exposed	1 / 2325 (0.04%)	3 / 2359 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Sepsis		
subjects affected / exposed	2 / 2325 (0.09%)	6 / 2359 (0.25%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 2
Sepsis syndrome		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Septic shock		
subjects affected / exposed	2 / 2325 (0.09%)	3 / 2359 (0.13%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Shigella infection		
subjects affected / exposed	2 / 2325 (0.09%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Soft tissue infection		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal abscess		

subjects affected / exposed	0 / 2325 (0.00%)	2 / 2359 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal sepsis		
subjects affected / exposed	0 / 2325 (0.00%)	2 / 2359 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal skin infection		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Streptococcal bacteraemia		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Streptococcal sepsis		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Strongyloidiasis		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subcutaneous abscess		
subjects affected / exposed	1 / 2325 (0.04%)	3 / 2359 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Syphilis		
subjects affected / exposed	0 / 2325 (0.00%)	4 / 2359 (0.17%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Tertiary syphilis		

subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tonsillitis		
subjects affected / exposed	0 / 2325 (0.00%)	3 / 2359 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Tonsillitis streptococcal		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tooth abscess		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tuberculosis		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Tubo-ovarian abscess		
subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Typhoid fever		
subjects affected / exposed	1 / 2325 (0.04%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Upper respiratory tract infection		
subjects affected / exposed	1 / 2325 (0.04%)	2 / 2359 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract infection		

subjects affected / exposed	5 / 2325 (0.22%)	3 / 2359 (0.13%)	
occurrences causally related to treatment / all	0 / 7	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			
subjects affected / exposed	0 / 2325 (0.00%)	2 / 2359 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicella			
subjects affected / exposed	1 / 2325 (0.04%)	1 / 2359 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral infection			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral pharyngitis			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection			
subjects affected / exposed	0 / 2325 (0.00%)	2 / 2359 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection staphylococcal			
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Abnormal loss of weight			

subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dehydration		
subjects affected / exposed	2 / 2325 (0.09%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetes mellitus		
subjects affected / exposed	0 / 2325 (0.00%)	2 / 2359 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetes mellitus inadequate control		
subjects affected / exposed	2 / 2325 (0.09%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic ketoacidosis		
subjects affected / exposed	0 / 2325 (0.00%)	2 / 2359 (0.08%)
occurrences causally related to treatment / all	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic metabolic decompensation		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gout		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperglycaemia		
subjects affected / exposed	1 / 2325 (0.04%)	0 / 2359 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypokalaemia		

subjects affected / exposed	0 / 2325 (0.00%)	1 / 2359 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 0.1 %

Non-serious adverse events	Immediate antiretroviral therapy	Deferred antiretroviral therapy	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 2325 (0.00%)	0 / 2359 (0.00%)	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
25 October 2010	Removed "consecutive" from CD4 eligibility criterion (2 CD4+ cell counts > 500 cells/mL) Clarified exclusion criteria 3 and 7 to specify that these were as assessed at randomization and before randomization respectively. Incorporated language regarding appropriate clinical management for participants in the deferred group whose CD4+ cell count is declining. Sample size section modified after performing the planned sample size re-estimation.
01 February 2016	The Data Safety Monitoring Board (DSMB) unblinded the trial on 26 May 2015. At a planned review the DSMB informed the trial leadership and sponsor that an interim monitoring boundary for efficacy had been crossed and recommended all participants begin antiretroviral therapy and continue follow-up. This protocol version described follow-up through 2021. Study objectives were revised and expanded, but the primary endpoint remains the same. Data collection reduced. Antiretroviral therapy will continue to be provided through the study through 2017 only; alternate arrangements for therapy must be made before that time.
28 August 2017	Further reduced data collection to one time point/year, to be collected primarily by abstraction from medical records of participants' regular care. Serious events no longer reported on a real-time basis or forwarded to regulators by the sponsor. Unscheduled hospitalizations will continue to be reported as part of the annual data collection.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/26192873>

<http://www.ncbi.nlm.nih.gov/pubmed/37213438>