Clinical trial results:
A phase 3 multicenter, randomized, prospective, open-label trial of standard chemoimmunotherapy (FCR/BR) versus rituximab plus venetoclax (RVe) versus obinutuzumab (GA101) plus venetoclax (GVe) versus obinutuzumab plus ibrutinib plus venetoclax (GIVe) in fit patients with previously untreated chronic lymphocytic leukemia (CLL) without del(17p) or TP53 mutation.

Summary

EudraCT number	2015-004936-36
Trial protocol	SE DK DE AT FI BE IE
Global end of trial date	29 February 2024

Results information

Result version number	v1 (current)
This version publication date	12 March 2025
First version publication date	12 March 2025

Trial information

Trial identification

Sponsor protocol code	CLL13

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02950051
WHO universal trial number (UTN)	-
Other trial identifiers	Sponsor`s number: UNI-KOELN-2751

Notes:

Sponsors

Sponsor organisation name	UNIVERSITY OF COLOGNE
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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	29 February 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	29 February 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of the study is to evaluate the efficacy of obinutuzumab (GA101) plus venetoclax (GVe) versus standard chemoimmunotherapy (BR/FCR) [concerning MRD negativity measured by flow cytometry in peripheral blood (PB) at month 15] and obinutuzumab plus ibrutinib plus venetoclax (GIVe) versus standard chemoimmunotherapy (BR/FCR) [concerning progression free survival (PFS)] in previously untreated, fit CLL patients without del(17p) or TP53 mutation.

Protection of trial subjects:

Safety measures to prevent or to manage known risks associated with CLL, such as infections or cytopenia or known adverse reactions related to any of the IMPs have been included in the protocol. Chapter 8 of the protocol included sections how to prevent and manage known side effects, including detailed instruction about premedication, modifications and treatment discontinuation. The protocol includes sections with prohibited, permitted and medication used with caution for each study medication, especially for known interactions with CYP3A4 inhibitors or inducers.

Background therapy:

For a long time, chemoimmunotherapy with fludarabine, cyclophsophamid and rituximab (FCR) for patients ≤ 65 or bendamustine plus rituximab for patients > 65 years, was considered standard first-line treatment for patients with CLL. Since several novel targeted agents such as the Btk-inhibitor ibrutinib (formerly PCI-32765), the PI3K-inhibitor CAL-101 (idelalisib) and the Bcl2-antagonist venetoclax (ABT-199, GDC-0199) have become available, the treatment landscape for CLL as faced profound changes. These new targeted agents were tested in phase-II and III-studies and showed a favorable toxicity profile and a promising efficacy with a potentially synergistic mechanism of action. The PI3K-inhibitor Idealisib has been approved for treatment of relapsed CLL as well as frontline therapy of CLL with TP53 mut/del.
The combination of venetoclax and CD20-antibodies is approved for firstline therapy (obinutuzumab) as well as in relapsed disease (rituximab). Btk-inhibitors are approved as monotherapy in firstline treatment and relapsed disease or in combination with venetoclax or CD-20 antibodies for first line therapy.
The addition of the Btk-inhibitor ibrutinib to the venetoclax plus CD20-anitbody based combination, is expected to add significant activity by targeting a third mechanism order to drive CLL cells into apoptosis.
The aim of the CLL13 trial is to evaluate, wether the standard chemoimmunotherapy in the frontline treatment of physically fit patients in CLL can be replaced by combinations of venetoclax (and ibrutinib) with anti-CD20-antibodies, which may induce extremely long lasting remissions.

Evidence for comparator:

Chemoimmunotherapy is the standard of care in first-line treatment of CLL. In patients < 65years, the combination of fludarabine, cyclophsophamid and rituximab is considered standard treatment, while patients >65 years usually receive bendamustine plus rituximab.
However, these conventional chemoimmunotherapies are associated with side effects caused by the rather unspecific mode of action of the chemotherapy. Therefore, there is a need for alternative, chemotherapy-free regimes. Published data support that targeted agents may show a promising response rate while having a favorable safety profile with lower rates of toxicity. All agents used in this trial have been approved in firstline treatment or in relapsed disease, as monotherapy or as combination

therapy for patients with CLL.

Actual start date of recruitment	13 December 2016
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	Switzerland: 82
Country: Number of subjects enrolled	Netherlands: 185
Country: Number of subjects enrolled	Sweden: 53
Country: Number of subjects enrolled	Austria: 36
Country: Number of subjects enrolled	Belgium: 31
Country: Number of subjects enrolled	Denmark: 113
Country: Number of subjects enrolled	Finland: 21
Country: Number of subjects enrolled	Germany: 333
Country: Number of subjects enrolled	Ireland: 38
Country: Number of subjects enrolled	Israel: 34
Worldwide total number of subjects	926
EEA total number of subjects	810

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)	564
From 65 to 84 years	362
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Between Dec 13, 2016, and Oct 13, 2019, 1080 patients were screened for eligibility. 926 were enrolled, 154 excluded. 229 were assigned to receive chemoimmunotherapy (150 FCR, 79 BR), 237 were assigned to receive venetoclax+rituxumab, 229 were assigned to venetoclax+obinutuzumab and 231 were allocated to venetoclax+obinutuzumab+ibrutinib.

Pre-assignment

Screening details:

From 154 screening failures, 136 did not meet eligibility criteria, 4 were not included due to physician´s decision and 14 due to patient´s decision.

Period 1

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

Blinding implementation details:

Not applicable

Arms

Are arms mutually exclusive?	Yes
Arm title	Standard chemoimmunotherapy (SCIT)

Arm description:

The SCIT treatment consists of 6 cycles, each with a precise duration of 28 days.
Patients ≤ 65 years will receive 6 cycles of fludarabine, cyclophosphamide and rituximab (FCR).
Patients > 65 years will receive 6 cycles of bendamusine and rituximab (BR).

Arm type	Active comparator
Investigational medicinal product name	Fludarabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Patients will receive fludarabine on days 1-3 of cycle 1-6.
Cycle 1-6
Day 1 fludarabine 25mg/m² i.v.,
day 2 fludarabine 25mg/m² i.v.
day 3 fludarabine 25mg/m² i.v.

Investigational medicinal product name	Cyclophosphamide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Patients will receive cyclophsophamide on days 1-3 of cycle 1-6.
Cycle 1-6
Day 1 cyclophosphamide 250mg/m² i.v.,
day 2 cyclophosphamide 250mg/m² i.v.
day 3 cyclophosphamide 250mg/m² i.v.

Investigational medicinal product name	Rituximab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Patients will receive rituximab (MabThera®) intravenously before the application of chemotherapy with premedication according to clinical practice of the participating sites.

Cycle 1: 375 mg/ m² i.v.
Cycles 2-6: 500 mg/ m² i.v

Investigational medicinal product name	Rituximab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Patients will receive rituximab (MabThera®) intravenously before the application of Bendamustine with premedication according to clinical practice of the participating sites.

Cycle 1: 375 mg/ m² i.v.
Cycle 2-6: 500 mg/ m² i.v.

Investigational medicinal product name	Bendamustine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for concentrate and solution for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Patients will receive bendamustine on day 1 and 2 of cycle 1-6.
Cycle 1-6
Day 1 bendamustine 90mg/m² i.v.,
day 2 bendamustine 90mg/m² i.v.

Arm title	Venetoclax, rituximab (RVe)

Arm description:

The RVe treatment consists of 12 cycles, each with a precise duration of 28 days.

Arm type	Experimental
Investigational medicinal product name	Rituximab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Patients will receive rituximab (MabThera®) intravenously:

Cycle 1:
Day 1: 375 mg/ m² i.v.

Cycle 2-6:
Day 1: 500 mg/ m² i.v.

Investigational medicinal product name	Venetoclax
Investigational medicinal product code	ABT 199
Other name	
Pharmaceutical forms	Film-coated tablet

Routes of administration	Oral use

Dosage and administration details:

Patients will receive the first dosage of venetoclax on day 22 of cycle 1. The daily intake of venetoclax starts with a weekly dose ramp-up to final dose

Venetoclax p.o.:
Cycle 1:
Days 22-28: venetoclax 20 mg (2 tabl. at 10 mg)
Cycle 2:
Days 1-7: venetoclax 50 mg (1 tabl. at 50 mg)
Days 8-14: venetoclax 100 mg (1 tabl. at 100 mg)
Days 15-21: venetoclax 200 mg (2 tabl. at 100 mg)
Days 22-28: venetoclax 400 mg (4 tabl. at 100 mg)
Cycles 3-12:
Days 1-28: venetoclax 400 mg (4 tabl. at 100 mg)
Due to the risk of adverse events, especially tumor-lysis-syndromes (TLS), the dose of venetoclax will be increased slowly every week until the final dose of 400 mg is reached (ramp-up). In order to diagnose a TLS at an early stage certain safety measures as specified in the study protocol must be followed.
On days with administration of both, venetoclax and rituximab, oral intake of venetoclax will be followed by intravenous administration of rituximab.

Arm title	Venetoclax, obinutuzumab (GVe)

Arm description:

The GVe treatment consists of 12 cycles, each with a precise duration of 28 days.

Arm type	Experimental
Investigational medicinal product name	Venetoclax
Investigational medicinal product code	ABT 199
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Patients will receive the first dosage of venetoclax on day 22 of cycle 1. The daily intake of venetoclax starts with a weekly dose ramp-up to final dose

Venetoclax p.o.:
Cycle 1:
Days 22-28: venetoclax 20 mg (2 tabl. at 10 mg)
Cycle 2:
Days 1-7: venetoclax 50 mg (1 tabl. at 50 mg)
Days 8-14: venetoclax 100 mg (1 tabl. at 100 mg)
Days 15-21: venetoclax 200 mg (2 tabl. at 100 mg)
Days 22-28: venetoclax 400 mg (4 tabl. at 100 mg)
Cycles 3-12:
Days 1-28: venetoclax 400 mg (4 tabl. at 100 mg)
Due to the risk of adverse events, especially tumor-lysis-syndromes (TLS), the dose of venetoclax will be increased slowly every week until the final dose of 400 mg is reached (ramp-up). In order to diagnose a TLS at an early stage certain safety measures as specified in the study protocol must be followed.
On days with administration of both, venetoclax and obinutzumab, oral intake of venetoclax will be followed by intravenous administration of obinutuzumab.

Investigational medicinal product name	Obinutuzumab
Investigational medicinal product code	GA 101
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Patients will receive obinutuzumab infusions on days 1 (and 2), 8 and 15 during the first cycle, as well as on day 1 of cycles 2-6.
Obinutuzumab i.v. infusion:
Cycle 1:
Day 1: obinutuzumab 100 mg
Day 1 (or 2): obinutuzumab 900 mg
Day 8: obinutuzumab 1000 mg

Day 15: obinutuzumab 1000 mg

Cycles 2-6:
Day 1: obinutuzumab1000 mg

The first infusion of obinutuzumab may be administered at the full dose (1000 mg) on day 1 of the first cycle if the infusion of a test-dosage of 100 mg is well tolerated by the patient. Alternatively, if the first 100mg infusion on day 1 is not tolerated well, the remaining 900 mg of the first dose should be administered on day 2.

Arm title	Venetoclax, obinutuzmab, ibrutinib (GIVe)

Arm description:

The GIVe treatment consists of 12 cycles (ibrutinib might be given up to 36 cycles), each with a precise duration of 28 days.

Arm type	Experimental
Investigational medicinal product name	Venetoclax
Investigational medicinal product code	ABT 199
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Patients will receive the first dosage of venetoclax on day 22 of cycle 1. The daily intake of venetoclax starts with a weekly dose ramp-up to final dose.
Venetoclax p.o.:
Cycle 1:
Days 22-28: 20 mg (2 tabl. at 10 mg)
Cycle 2:
Days 1-7: 50 mg (1 tabl. at 50 mg)
Days 8-14: 100 mg (1 tabl. at 100 mg)
Days 15-21: 200 mg (2 tabl. at 100 mg)
Days 22-28: 400 mg (4 tabl. at 100 mg)
Cycles 3-12:
Days 1-28: 400 mg (4 tabl. at 100 mg)
Due to the risk of adverse events, especially tumor-lysis-syndromes (TLS), the dose of venetoclax will be increased slowly every week until the final dose of 400 mg is reached (ramp-up). In order to diagnose a TLS at an early stage certain safety measures as specified in the study protocol must be followed.On days with administration of more than one study drug, oral intake of ibrutinib (before breakfast) will be followed by oral intake of venetoclax (during breakfast), at least iv administration of obinutuzumab will take place if applicable.

Investigational medicinal product name	Obinutuzumab
Investigational medicinal product code	GA 101
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Patients will receive obinutuzumab infusions on days 1 (and 2), 8 and 15 during the first cycle, as well as on day 1 of cycles 2-6.
obinutuzumab i.v. infusion:
Cycle 1:
Day 1: obinutuzumab 100 mg
Day 1 (or 2): obinutuzumab 900 mg
Day 8: obinutuzumab 1000 mg
Day 15: obinutuzumab 1000 mg

Cycles 2-6:
Day 1: obinutuzumab1000 mg

Investigational medicinal product name	Ibrutinib
Investigational medicinal product code	PCI-32765
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Patients will receive ibrutinib as a daily oral dosage of 420 mg starting on cycle 1 day 1 until MRD negativity (i.e. < 10-4) in peripheral blood and confirmed by a bone marrow aspirate or by two consecutive peripheral blood samples (cycle 9/12 or 12/15; all other patients will continue treatment) or 36 months of treatment are reached.

Ibrutinib p.o.:
Cycles 1-12:
Days 1-28: 420mg daily

Cycles 13-36:
Days 1-28: ibrutinib 420 mg daily

Number of subjects in period 1	Standard chemoimmunotherapy (SCIT)	Venetoclax, rituximab (RVe)	Venetoclax, obinutuzumab (GVe)
Started	229	237	229
Completed	176	219	214
Not completed	53	18	15
Adverse event, non-fatal	32	11	9
Death	-	1	1
Non-compliance	2	-	1
Progressive disease	2	4	3
Did not receive any study treatment	13	-	1
other reason	4	2	-

Number of subjects in period 1	Venetoclax, obinutuzmab, ibrutinib (GIVe)
Started	231
Completed	199
Not completed	32
Adverse event, non-fatal	27
Death	2
Non-compliance	-
Progressive disease	-
Did not receive any study treatment	-
other reason	3

Baseline characteristics

Reporting groups	
Reporting group title	Standard chemoimmunotherapy (SCIT)
Reporting group description:	
The SCIT treatment consists of 6 cycles, each with a precise duration of 28 days. Patients ≤ 65 years will receive 6 cycles of fludarabine, cyclophosphamide and rituximab (FCR). Patients > 65 years will receive 6 cycles of bendamusine and rituximab (BR).	
Reporting group title	Venetoclax, rituximab (RVe)
Reporting group description:	
The RVe treatment consists of 12 cycles, each with a precise duration of 28 days.	
Reporting group title	Venetoclax, obinutuzumab (GVe)
Reporting group description:	
The GVe treatment consists of 12 cycles, each with a precise duration of 28 days.	
Reporting group title	Venetoclax, obinutuzmab, ibrutinib (GIVe)
Reporting group description:	
The GIVe treatment consists of 12 cycles (ibrutinib might be given up to 36 cycles), each with a precise duration of 28 days.	

Reporting group values	Standard chemoimmunotherapy (SCIT)	Venetoclax, rituximab (RVe)	Venetoclax, obinutuzumab (GVe)
Number of subjects	229	237	229
Age categorical Units: Subjects			
Adults (18-64 years)	145	141	139
From 65-84 years	84	96	90
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	66	62	58
Male	163	175	171
Country Units: Subjects			
Germany	85	85	81
Denmark	25	31	25
Netherlands	43	47	49
Sweden	14	13	17
Switzerland	21	21	21
Belgium	12	7	5
Austria	8	9	11
Finland	6	4	5
Ireland	8	9	10
Israel	7	11	5
Binet stage Units: Subjects			
Binet A	63	61	58
Binet B	84	92	91
Binet C	82	84	80
IGHV mutational status Units: Subjects			

unmutated	131	134	130
mutated	95	95	89
not evaluable	3	8	9
missing information	0	0	1
CLL-IPI risk group Units: Subjects			
low	36	39	32
intermediate	67	66	76
high	122	123	109
very high	0	0	0
missing information	4	9	12
Complex karyotype Units: Subjects			
< 3 aberrations	177	187	182
≥ 3 and < 5 aberrations	30	34	25
≥ 5 aberrations	16	10	11
missing information	6	6	11
Binet stage used for stratification Units: Subjects			
Binet A	61	62	60
Binet B	85	90	90
Binet C	83	85	79

Reporting group values	Venetoclax, obinutuzmab, ibrutinib (GIVe)	Total	
Number of subjects	231	926	
Age categorical Units: Subjects			
Adults (18-64 years)	139	564	
From 65-84 years	92	362	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	73	259	
Male	158	667	
Country Units: Subjects			
Germany	82	333	
Denmark	32	113	
Netherlands	46	185	
Sweden	9	53	
Switzerland	19	82	
Belgium	7	31	
Austria	8	36	
Finland	6	21	
Ireland	11	38	
Israel	11	34	
Binet stage Units: Subjects			
Binet A	63	245	
Binet B	84	351	

Binet C	84	330	
IGHV mutational status Units: Subjects			
unmutated	123	518	
mutated	101	380	
not evaluable	7	27	
missing information	0	1	
CLL-IPI risk group Units: Subjects			
low	36	143	
intermediate	85	294	
high	101	455	
very high	0	0	
missing information	9	34	
Complex karyotype Units: Subjects			
< 3 aberrations	196	742	
≥ 3 and < 5 aberrations	21	110	
≥ 5 aberrations	6	43	
missing information	8	31	
Binet stage used for stratification Units: Subjects			
Binet A	63	246	
Binet B	84	349	
Binet C	84	331	

End points

End points reporting groups

Reporting group title	Standard chemoimmunotherapy (SCIT)
Reporting group description:	
The SCIT treatment consists of 6 cycles, each with a precise duration of 28 days. Patients ≤ 65 years will receive 6 cycles of fludarabine, cyclophosphamide and rituximab (FCR). Patients > 65 years will receive 6 cycles of bendamusine and rituximab (BR).	
Reporting group title	Venetoclax, rituximab (RVe)
Reporting group description:	
The RVe treatment consists of 12 cycles, each with a precise duration of 28 days.	
Reporting group title	Venetoclax, obinutuzumab (GVe)
Reporting group description:	
The GVe treatment consists of 12 cycles, each with a precise duration of 28 days.	
Reporting group title	Venetoclax, obinutuzmab, ibrutinib (GIVe)
Reporting group description:	
The GIVe treatment consists of 12 cycles (ibrutinib might be given up to 36 cycles), each with a precise duration of 28 days.	

Primary: Progression free survival (PFS) [GIVe versus SCIT]

End point title	Progression free survival (PFS) [GIVe versus SCIT][1]
End point description:	
One co-primary efficacy endpoint is the investigator-assessed PFS, defined as the time from randomization to the first occurrence of progression or relapse (determined using standard IWCLL guidelines [2008]), or death from any cause, whichever occurs first. For patients who have not progressed, relapsed, or died at the time of analysis, PFS will be censored on the date of the last tumor assessment. In case of initiation of subsequent anti-leukemic treatment without documented disease progression patient will be censored at last tumor assessment prior to start of subsequent therapy. If no tumor assessments were performed after the screening visit, PFS will be censored at the time of randomization + 1 day. Median PFS and the 97.5% CI will be estimated using Kaplan-Meier survival methodology, with the Kaplan-Meier survival curve presented to provide a visual description. PFS rates for 1, 2 and 3 years etc. after randomization will be reported.	
End point type	Primary
End point timeframe:	
Data will be collected from randomization until last visit of each study subject.	

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The statistics for the comparisons of the other arms are reported in a separate endpoint as only the comparison between GIVE versus SCIT was considered as primary endpoint in this analysis. The other comparisons are considered as secondary endpoint and are reported as secondary endpoint accordingly.

End point values	Standard chemoimmunotherapy (SCIT)	Venetoclax, obinutuzmab, ibrutinib (GIVe)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	229	231[2]		
Units: Percentage				
number (not applicable)				
1-year survival	93.4	98.3		
2-year survival	82.6	96.1		

3-year survival	75.9	91.3		
4-year survival	60.8	85.9		
5-year survival	50.7	81.3		
Median PFS (months)	61.2	0		

Notes:

[2] - Median PFS was not reached in this subgroup

Statistical analyses

Statistical analysis title	Two-sided stratified log-rank test (GIVe vs SCIT)

Statistical analysis description:

PFS treatment comparison of GIVe and SCIT will be performed using a two-sided stratified log-rank test (considering the
stratification factors age (with a cut-off of 65 years) and Binet stage). The co-primary endpoint PFS [GIVe vs. SCIT] has been formally tested during the "interim analysis of the co-primary endpoint PFS" with the data cut-off 2022.01.20. There is no alpha spend in the current analysis of the co-primary endpoint [PFS: GIVe vs. SCIT].

Comparison groups	Standard chemoimmunotherapy (SCIT) v Venetoclax, obinutuzmab, ibrutinib (GIVe)
Number of subjects included in analysis	460
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Logrank

Statistical analysis title	Cox regression (GIVe vs SCIT)

Statistical analysis description:

Estimates of the treatment effect will be expressed as HR including 97.5% CI estimated through a stratified Cox proportional hazards analysis (considering the stratification factors age (with a cut-off of 65 years) and Binet stage).

Comparison groups	Standard chemoimmunotherapy (SCIT) v Venetoclax, obinutuzmab, ibrutinib (GIVe)
Number of subjects included in analysis	460
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Cox proportional hazard
Point estimate	0.344
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	0.235
upper limit	0.503

Primary: MRD negativity in peripheral blood at month 15 [GVe versus SCIT]

End point title	MRD negativity in peripheral blood at month 15 [GVe versus SCIT][3]

End point description:

One co-primary objective of the study is to assess the MRD negativity rate. MRD negativity is defined as <1 CLL-cell among 10,000 leukocytes analyzed [0.01%], i.e. < 10-4. Values above [≥10-4] will be considered as MRD positive.

The MRD negativity rate in PB at MO 15 is defined as the proportion of MRD negative patients at MO 15 based on the ITT population (= number of MRD negative patients divided by the number of the ITT population). Patients without an MRD sample in peripheral blood at MO 15 will be counted as MRD positive patients.

End point type	Primary

End point timeframe:

15 months after start of treatment.

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The statistics for the comparisons of the other arms are reported in a separate endpoint as only the comparison between GVE versus SCIT was considered as primary endpoint in this analysis. The other comparisons are considered as secondary endpoint and are reported as secondary endpoint accordingly.

End point values	Standard chemoimmunotherapy (SCIT)	Venetoclax, rituximab (RVe)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	229	229		
Units: percentage				
number (confidence interval 97.5%)				
MRD negativity rate	52 (44.4 to 59.5)	86.5 (80.6 to 91.1)		

Statistical analyses

Statistical analysis title	Cochran-Mantel-Haenszel test (GVe vs SCIT)

Statistical analysis description:

MRD negativity rate of GVe and SCIT will be compared using Cochran-Mantel-Haenszel test stratified by age (with a cut-off of 65 years) and Binet stage. The co-primary endpoint MRD in PB at MO15 [GVe vs. SCIT] has been formally tested during the "co-primary endpoint analysis of MRD negativity rate at month 15" with the data cut-off 2021.02.28. There is no alpha spend in the current analysis of the co-primary endpoint [MRD in PB at MO15: GVe vs. SCIT].

Comparison groups	Standard chemoimmunotherapy (SCIT) v Venetoclax, rituximab (RVe)
Number of subjects included in analysis	458
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel

Secondary: Overall survival (OS)

End point title	Overall survival (OS)

End point description:

Overall survival will be measured from the date of randomization to the date of death due to any cause. Patients who have not yet died at the time of analysis will be censored at the time of last observation they were assessed to be alive.

End point type	Secondary

End point timeframe:

Data for this endpoint will be collected from the date of randomization until last visit of each study

subject.

End point values	Standard chemoimmunotherapy (SCIT)	Venetoclax, rituximab (RVe)	Venetoclax, obinutuzumab (GVe)	Venetoclax, obinutuzmab, ibrutinib (GIVe)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	229[4]	237[5]	229[6]	231[7]
Units: percent				
number (not applicable)				
1-year survival	99.1	97.9	99.1	98.7
2-year survival	98.6	97.9	98.2	97
3-year survival	95.7	96.6	96.5	95.6
4-year survival	93.8	96.2	95.2	94.7
5-year survival	90.7	94.7	93.6	94.3
Median OS (months)	0	0	0	0

Notes:

[4] - Median OS was not reached in this subgroup

[5] - Median OS was not reached in this subgroup

[6] - Median OS was not reached in this subgroup

[7] - Median OS was not reached in this subgroup

Statistical analyses

Statistical analysis title	Two-sided log-rank test (GIVe vs SCIT)

Statistical analysis description:

Treatment comparison for the secondary efficacy parameter OS will be performed using a two-sided non-stratified log-rank test. There is no alpha spend in the analysis of secondary endpoints.

Comparison groups	Standard chemoimmunotherapy (SCIT) v Venetoclax, obinutuzmab, ibrutinib (GIVe)
Number of subjects included in analysis	460
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.175
Method	Logrank

Statistical analysis title	Cox proportional hazards analysis (GIVe vs SCIT)

Statistical analysis description:

Estimates of the treatment effect will be expressed by the hazard ratio (HR) including the 97.5% confidence interval estimated through a non-stratified Cox proportional hazard regression model.

Comparison groups	Venetoclax, obinutuzmab, ibrutinib (GIVe) v Standard chemoimmunotherapy (SCIT)
Number of subjects included in analysis	460
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Cox proportional hazard
Point estimate	0.617

Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	0.275
upper limit	1.382

Statistical analysis title	Two-sided log-rank test (GVe vs SCIT)

Statistical analysis description:

Treatment comparison for the secondary efficacy parameter OS will be performed using a two-sided non-stratified log-rank test. There is no alpha spend in the analysis of secondary endpoints.

Comparison groups	Standard chemoimmunotherapy (SCIT) v Venetoclax, obinutuzumab (GVe)
Number of subjects included in analysis	458
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.423
Method	Logrank

Statistical analysis title	Cox proportional hazards analysis (GVe vs SCIT)

Statistical analysis description:

Estimates of the treatment effect will be expressed by the hazard ratio (HR) including the 97.5% confidence interval estimated through a non-stratified Cox proportional hazard regression model.

Comparison groups	Venetoclax, obinutuzumab (GVe) v Standard chemoimmunotherapy (SCIT)
Number of subjects included in analysis	458
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Cox proportional hazard
Point estimate	0.762
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	0.356
upper limit	1.631

Statistical analysis title	Two-sided log-rank test (RVe vs SCIT)

Statistical analysis description:

Treatment comparison for the secondary efficacy parameter OS will be performed using a two-sided non-stratified log-rank test. There is no alpha spend in the analysis of secondary endpoints.

Comparison groups	Standard chemoimmunotherapy (SCIT) v Venetoclax, rituximab (RVe)

Number of subjects included in analysis	466
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.255
Method	Logrank

Statistical analysis title	Cox proportional hazards analysis (RVe vs SCIT)

Statistical analysis description:

Estimates of the treatment effect will be expressed by the hazard ratio (HR) including the 97.5% confidence interval estimated through a non-stratified Cox proportional hazard regression model.

Comparison groups	Standard chemoimmunotherapy (SCIT) v Venetoclax, rituximab (RVe)
Number of subjects included in analysis	466
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Cox proportional hazard
Point estimate	0.676
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	0.312
upper limit	1.468

Statistical analysis title	Two-sided log-rank test (GIVe vs GVe)

Statistical analysis description:

Treatment comparison for the secondary efficacy parameter OS will be performed using a two-sided non-stratified log-rank test. There is no alpha spend in the analysis of secondary endpoints.

Comparison groups	Venetoclax, obinutuzumab (GVe) v Venetoclax, obinutuzmab, ibrutinib (GIVe)
Number of subjects included in analysis	460
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.564
Method	Logrank

Statistical analysis title	Cox proportional hazards analysis (GIVe vs GVe)

Statistical analysis description:

Estimates of the treatment effect will be expressed by the hazard ratio (HR) including the 97.5% confidence interval estimated through a non-stratified Cox proportional hazard regression model.

Comparison groups	Venetoclax, obinutuzumab (GVe) v Venetoclax, obinutuzmab, ibrutinib (GIVe)

Number of subjects included in analysis	460
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Cox proportional hazard
Point estimate	0.806
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	0.349
upper limit	1.862

Statistical analysis title	Two-sided log-rank test (GVe vs RVe)

Statistical analysis description:

Treatment comparison for the secondary efficacy parameter OS will be performed using a two-sided non-stratified log-rank test. There is no alpha spend in the analysis of secondary endpoints.

Comparison groups	Venetoclax, obinutuzumab (GVe) v Venetoclax, rituximab (RVe)
Number of subjects included in analysis	466
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.678
Method	Logrank

Statistical analysis title	Cox proportional hazards analysis (GVe vs RVe)

Statistical analysis description:

Estimates of the treatment effect will be expressed by the hazard ratio (HR) including the 97.5% confidence interval estimated through a non-stratified Cox proportional hazard regression model.

Comparison groups	Venetoclax, obinutuzumab (GVe) v Venetoclax, rituximab (RVe)
Number of subjects included in analysis	466
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Cox proportional hazard
Point estimate	1.162
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	0.517
upper limit	2.613

Statistical analysis title	Two-sided log-rank test (GIVe vs RVe)

Statistical analysis description:

Treatment comparison for the secondary efficacy parameter OS will be performed using a two-sided non-stratified log-rank test. There is no alpha spend in the analysis of secondary endpoints.

Comparison groups	Venetoclax, obinutuzmab, ibrutinib (GIVe) v Venetoclax, rituximab (RVe)

Number of subjects included in analysis	468
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.784
Method	Logrank

Statistical analysis title	Cox proportional hazards analysis (GIVe vs RVe)

Statistical analysis description:

Estimates of the treatment effect will be expressed by the hazard ratio (HR) including the 97.5% confidence interval estimated through a non-stratified Cox proportional hazard regression model.

Comparison groups	Venetoclax, obinutuzmab, ibrutinib (GIVe) v Venetoclax, rituximab (RVe)
Number of subjects included in analysis	468
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Cox proportional hazard
Point estimate	0.901
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	0.385
upper limit	2.108

Secondary: Time to next treatment (TTNT)

End point title	Time to next treatment (TTNT)

End point description:

TTNT will be measured from the date of randomization until the date of first anti-leukemic treatment. Patients for whom no subsequent anti-leukemic treatment is documented will be censored at the time of last observation they were assessed to be free from subsequent treatment.

End point type	Secondary

End point timeframe:

Data for this endpoint will be collected from the date of randomization until last visit of each study subject.

End point values	Standard chemoimmunotherapy (SCIT)	Venetoclax, rituximab (RVe)	Venetoclax, obinutuzumab (GVe)	Venetoclax, obinutuzmab, ibrutinib (GIVe)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	229[8]	237[9]	229[10]	231[11]
Units: percent				
number (not applicable)				
1-year survival	97.7	97.9	98.7	100
2-year survival	93.4	95.3	97.8	100
3-year survival	87.1	91.8	94.6	98.6
4-year survival	77.5	83.9	90	95.4

5-year survival	67.1	77.1	87.5	92.6
Median months	0	0	0	0

Notes:

[8] - Median TTNT was not reached in this subgroup

[9] - Median TTNT was not reached in this subgroup

[10] - Median TTNT was not reached in this subgroup

[11] - Median TTNT was not reached in this subgroup

Statistical analyses

Statistical analysis title	Two-sided log-rank test (GIVe vs SCIT)
Statistical analysis description:	
Treatment comparison for the secondary efficacy parameter TTNT will be performed using a two-sided non-stratified log-rank test. There is no alpha spend in the analysis of secondary endpoints.	
Comparison groups	Standard chemoimmunotherapy (SCIT) v Venetoclax, obinutuzmab, ibrutinib (GIVe)
Number of subjects included in analysis	460
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.0001
Method	Logrank

Statistical analysis title	Cox proportional hazards analysis (GIVe vs SCIT)
Statistical analysis description:	
Estimates of the treatment effect will be expressed by the hazard ratio (HR) including the 97.5% confidence interval estimated through a non-stratified Cox proportional hazard regression model.	
Comparison groups	Standard chemoimmunotherapy (SCIT) v Venetoclax, obinutuzmab, ibrutinib (GIVe)
Number of subjects included in analysis	460
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Cox proportional hazard
Point estimate	0.218
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	0.123
upper limit	0.386

Statistical analysis title	Two-sided log-rank test (GVe vs SCIT)
Statistical analysis description:	
Treatment comparison for the secondary efficacy parameter TTNT will be performed using a two-sided non-stratified log-rank test. There is no alpha spend in the analysis of secondary endpoints.	
Comparison groups	Venetoclax, obinutuzumab (GVe) v Standard chemoimmunotherapy (SCIT)

Number of subjects included in analysis	458
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.0001
Method	Logrank

Statistical analysis title	Cox proportional hazards analysis (GVe vs SCIT)

Statistical analysis description:

Estimates of the treatment effect will be expressed by the hazard ratio (HR) including the 97.5% confidence interval estimated through a non-stratified Cox proportional hazard regression model.

Comparison groups	Standard chemoimmunotherapy (SCIT) v Venetoclax, obinutuzumab (GVe)
Number of subjects included in analysis	458
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Cox proportional hazard
Point estimate	0.429
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	0.273
upper limit	0.676

Statistical analysis title	Two-sided log-rank test (RVe vs SCIT)

Statistical analysis description:

Treatment comparison for the secondary efficacy parameter TTNT will be performed using a two-sided non-stratified log-rank test. There is no alpha spend in the analysis of secondary endpoints.

Comparison groups	Venetoclax, rituximab (RVe) v Standard chemoimmunotherapy (SCIT)
Number of subjects included in analysis	466
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.204
Method	Logrank

Statistical analysis title	Cox proportional hazards analysis (RVe vs SCIT)

Statistical analysis description:

Estimates of the treatment effect will be expressed by the hazard ratio (HR) including the 97.5% confidence interval estimated through a non-stratified Cox proportional hazard regression model.

Comparison groups	Standard chemoimmunotherapy (SCIT) v Venetoclax, rituximab (RVe)

Number of subjects included in analysis	466
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Cox proportional hazard
Point estimate	0.806
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	0.55
upper limit	1.181

Statistical analysis title	Two-sided log-rank test (GIVe vs GVe)

Statistical analysis description:

Treatment comparison for the secondary efficacy parameter TTNT will be performed using a two-sided non-stratified log-rank test. There is no alpha spend in the analysis of secondary endpoints.

Comparison groups	Venetoclax, obinutuzumab (GVe) v Venetoclax, obinutuzmab, ibrutinib (GIVe)
Number of subjects included in analysis	460
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.01
Method	Logrank

Statistical analysis title	Cox proportional hazards analysis (GIVe vs GVe)

Statistical analysis description:

Estimates of the treatment effect will be expressed by the hazard ratio (HR) including the 97.5% confidence interval estimated through a non-stratified Cox proportional hazard regression model.

Comparison groups	Venetoclax, obinutuzmab, ibrutinib (GIVe) v Venetoclax, obinutuzumab (GVe)
Number of subjects included in analysis	460
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Cox proportional hazard
Point estimate	0.498
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	0.268
upper limit	0.925

Statistical analysis title	Two-sided log-rank test (GVe vs RVe)

Statistical analysis description:

Treatment comparison for the secondary efficacy parameter TTNT will be performed using a two-sided non-stratified log-rank test. There is no alpha spend in the analysis of secondary endpoints.

Comparison groups	Venetoclax, obinutuzumab (GVe) v Venetoclax, rituximab (RVe)

Number of subjects included in analysis	466
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0014
Method	Logrank

Statistical analysis title	Cox proportional hazards analysis (GVe vs RVe)

Statistical analysis description:

Estimates of the treatment effect will be expressed by the hazard ratio (HR) including the 97.5% confidence interval estimated through a non-stratified Cox proportional hazard regression model.

Comparison groups	Venetoclax, rituximab (RVe) v Venetoclax, obinutuzumab (GVe)
Number of subjects included in analysis	466
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Cox proportional hazard
Point estimate	0.529
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	0.337
upper limit	0.833

Statistical analysis title	Two-sided log-rank test (GIVe vs RVe)

Statistical analysis description:

Treatment comparison for the secondary efficacy parameter TTNT will be performed using a two-sided non-stratified log-rank test. There is no alpha spend in the analysis of secondary endpoints.

Comparison groups	Venetoclax, rituximab (RVe) v Venetoclax, obinutuzmab, ibrutinib (GIVe)
Number of subjects included in analysis	468
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.0001
Method	Logrank

Statistical analysis title	Cox proportional hazards analysis (GIVe vs RVe)

Statistical analysis description:

Estimates of the treatment effect will be expressed by the hazard ratio (HR) including the 97.5% confidence interval estimated through a non-stratified Cox proportional hazard regression model.

Comparison groups	Venetoclax, rituximab (RVe) v Venetoclax, obinutuzmab, ibrutinib (GIVe)

Number of subjects included in analysis	468
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Cox proportional hazard
Point estimate	0.266
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	0.151
upper limit	0.471

Secondary: Response rate at month 15

End point title	Response rate at month 15

End point description:

The overall response rate (ORR) will be defined as the proportion of patients having achieved a CR/CRi, clinical CR/CRi or PR (including PR with lymphocytosis) (according to the iwCLL guidelines (2008)) at MO 15 (= number of patients with response CR/CRi, clinical CR/CRi or PR (with or without lymphocytosis) divided by the ITT population).

End point type	Secondary

End point timeframe:

15 months after start of treatment.

End point values	Standard chemoimmunotherapy (SCIT)	Venetoclax, rituximab (RVe)	Venetoclax, obinutuzumab (GVe)	Venetoclax, obinutuzmab, ibrutinib (GIVe)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	229	237	229	231
Units: Patients				
CR	73	112	124	128
CRi	9	2	4	9
Clinical CR	51	29	21	24
Clinical CRi	5	0	3	4
PR	47	78	68	53
SD	3	0	0	0
PD	7	1	2	1
Missing	34	15	7	12

Statistical analyses

No statistical analyses for this end point

Secondary: PFS (all other comparisons except for [GIVe versus SCIT])

End point title	PFS (all other comparisons except for [GIVe versus SCIT])

End point description:

Progression-free survival is defined as the time from randomization to the first occurrence of progression or relapse (determined using standard IWCLL guidelines [2008]), or death from any cause, whichever occurs first. For patients who have not progressed, relapsed, or died at the time of analysis, PFS will be censored on the date of the last tumor assessment. In case of initiation of subsequent anti-leukemic treatment without documented disease progression patient will be censored at last tumor assessment prior to start of subsequent therapy. If no tumor assessments were performed after the screening visit, PFS will be censored at the time of randomization + 1 day.
Median PFS and the 97.5% CI will be estimated using Kaplan-Meier survival methodology, with the Kaplan-Meier survival curve presented to provide a visual description. PFS rates for 1, 2 and 3 years etc. after randomization will be reported.

End point type	Secondary

End point timeframe:

Data will be collected from randomization until last visit of each study subject

End point values	Standard chemoimmunotherapy (SCIT)	Venetoclax, rituximab (RVe)	Venetoclax, obinutuzumab (GVe)	Venetoclax, obinutuzmab, ibrutinib (GIVe)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	229	237	229[12]	231[13]
Units: percent				
number (not applicable)				
1-year survival	93.4	96.6	97.4	98.3
2-year survival	82.6	91.9	92.5	96.1
3-year survival	75.9	80.7	88.6	91.3
4-year survival	60.8	71.1	81.9	85.9
5-year survival	50.7	57.4	69.8	81.3
Median PFS (months)	61.2	64.5	0	0

Notes:

[12] - Median PFS was not reached in this subgroup

[13] - Median PFS was not reached in this subgroup

Statistical analyses

Statistical analysis title	Two-sided log-rank test (GVe vs SCIT)

Statistical analysis description:

PFS treatment comparisons will be performed using two-sided stratified log-rank tests (considering the stratification factors age (with a cut-off of 65 years) and Binet stage). There is no alpha spend in the current analysis of the co-primary endpoint of PFS.

Comparison groups	Venetoclax, obinutuzumab (GVe) v Standard chemoimmunotherapy (SCIT)
Number of subjects included in analysis	458
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.0001
Method	Logrank

Statistical analysis title	Cox proportional hazards analysis (GVe vs SCIT)

Statistical analysis description:

Estimates of the treatment effect will be expressed as HR including 97.5% CI estimated through a stratified Cox proportional hazards analysis (considering the stratification factors age (with a cut-off of 65 years) and Binet stage).

Comparison groups	Standard chemoimmunotherapy (SCIT) v Venetoclax, obinutuzumab (GVe)
Number of subjects included in analysis	458
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Cox proportional hazard
Point estimate	0.544
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	0.389
upper limit	0.761

Statistical analysis title	Two-sided log-rank test (RVe vs SCIT)

Statistical analysis description:

PFS treatment comparisons will be performed using two-sided stratified log-rank tests (considering the stratification factors age (with a cut-off of 65 years) and Binet stage). There is no alpha spend in the current analysis of the co-primary endpoint of PFS.

Comparison groups	Standard chemoimmunotherapy (SCIT) v Venetoclax, rituximab (RVe)
Number of subjects included in analysis	466
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.53
Method	Logrank

Statistical analysis title	Cox proportional hazards analysis (RVe vs SCIT)

Statistical analysis description:

Estimates of the treatment effect will be expressed as HR including 97.5% CI estimated through a stratified Cox proportional hazards analysis (considering the stratification factors age (with a cut-off of 65 years) and Binet stage).

Comparison groups	Standard chemoimmunotherapy (SCIT) v Venetoclax, rituximab (RVe)
Number of subjects included in analysis	466
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Cox proportional hazard
Point estimate	0.919
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	0.681
upper limit	1.241

Statistical analysis title	Two-sided log-rank test (GIVe vs GVe)

Statistical analysis description:

PFS treatment comparisons will be performed using two-sided stratified log-rank tests (considering the stratification factors age (with a cut-off of 65 years) and Binet stage). There is no alpha spend in the current analysis of the co-primary endpoint of PFS.

Comparison groups	Venetoclax, obinutuzumab (GVe) v Venetoclax, obinutuzmab, ibrutinib (GIVe)
Number of subjects included in analysis	460
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0046
Method	Logrank

Statistical analysis title	Cox proportional hazards analysis (GIVe vs GVe)

Statistical analysis description:

Estimates of the treatment effect will be expressed as HR including 97.5% CI estimated through a stratified Cox proportional hazards analysis (considering the stratification factors age (with a cut-off of 65 years) and Binet stage).

Comparison groups	Venetoclax, obinutuzumab (GVe) v Venetoclax, obinutuzmab, ibrutinib (GIVe)
Number of subjects included in analysis	460
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Cox proportional hazard
Point estimate	0.607
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	0.407
upper limit	0.905

Statistical analysis title	Two-sided log-rank test (GVe vs RVe)

Statistical analysis description:

PFS treatment comparisons will be performed using two-sided stratified log-rank tests (considering the stratification factors age (with a cut-off of 65 years) and Binet stage). There is no alpha spend in the current analysis of the co-primary endpoint of PFS.

Comparison groups	Venetoclax, obinutuzumab (GVe) v Venetoclax, rituximab (RVe)
Number of subjects included in analysis	466
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.00019
Method	Logrank

Statistical analysis title	Cox proportional hazards analysis (GVe vs RVe)

Statistical analysis description:

Estimates of the treatment effect will be expressed as HR including 97.5% CI estimated through a stratified Cox proportional hazards analysis (considering the stratification factors age (with a cut-off of 65 years) and Binet stage).

Comparison groups	Venetoclax, obinutuzumab (GVe) v Venetoclax, rituximab (RVe)
Number of subjects included in analysis	466
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Cox proportional hazard
Point estimate	0.586
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	0.424
upper limit	0.811

Statistical analysis title	Two-sided log-rank test (GIVe vs RVe)

Statistical analysis description:

PFS treatment comparisons will be performed using two-sided stratified log-rank tests (considering the stratification factors age (with a cut-off of 65 years) and Binet stage). There is no alpha spend in the current analysis of the co-primary endpoint of PFS.

Comparison groups	Venetoclax, obinutuzmab, ibrutinib (GIVe) v Venetoclax, rituximab (RVe)
Number of subjects included in analysis	468
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.0001
Method	Logrank

Statistical analysis title	Cox proportional hazards analysis (GIVe vs RVe)

Statistical analysis description:

Estimates of the treatment effect will be expressed as HR including 97.5% CI estimated through a stratified Cox proportional hazards analysis (considering the stratification factors age (with a cut-off of 65 years) and Binet stage).

Comparison groups	Venetoclax, obinutuzmab, ibrutinib (GIVe) v Venetoclax, rituximab (RVe)
Number of subjects included in analysis	468
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Cox proportional hazard
Point estimate	0.347
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	0.238
upper limit	0.506

Secondary: MRD negativity in peripheral blood at month 15 (except for [GVe versus SCIT])

End point title	MRD negativity in peripheral blood at month 15 (except for [GVe versus SCIT])

End point description:

MRD negativity is defined as <1 CLL-cell among 10,000 leukocytes analyzed [0.01%], i.e. < 10-4. Values above [≥10-4] will be considered as MRD positive.
The MRD negativity rate in PB at MO 15 is defined as the proportion of MRD negative patients at MO 15 based on the ITT population (= number of MRD negative patients divided by the number of the ITT population). Patients without an MRD sample in peripheral blood at MO 15 will be counted as MRD positive patients.

End point type	Secondary

End point timeframe:

15 months after start of treatment.

End point values	Standard chemoimmunotherapy (SCIT)	Venetoclax, rituximab (RVe)	Venetoclax, obinutuzumab (GVe)	Venetoclax, obinutuzmab, ibrutinib (GIVe)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	229	237	229	231
Units: percent				
number (confidence interval 97.5%)				
MRD negativity rate	52 (44.4 to 59.5)	57 (49.5 to 64.2)	86.5 (80.6 to 91.1)	92.2 (87.3 to 95.7)

Statistical analyses

Statistical analysis title	Cochran-Mantel-Haenszel test (GIVe vs SCIT)

Statistical analysis description:

MRD negativity rates of treatment groups will be compared using Cochran-Mantel-Haenszel test stratified by age (with a cut-off of 65 years) and Binet stage. There is no alpha spend in the current analysis of the co-primary endpoint of MRD negativity rate at month 15.

Comparison groups	Standard chemoimmunotherapy (SCIT) v Venetoclax, obinutuzmab, ibrutinib (GIVe)
Number of subjects included in analysis	460
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Cochran-Mantel-Haenszel test (RVe vs SCIT)

Statistical analysis description:

MRD negativity rates of treatment groups will be compared using Cochran-Mantel-Haenszel test

stratified by age (with a cut-off of 65 years) and Binet stage. There is no alpha spend in the current analysis of the co-primary endpoint of MRD negativity rate at month 15.

Comparison groups	Standard chemoimmunotherapy (SCIT) v Venetoclax, rituximab (RVe)
Number of subjects included in analysis	466
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.317
Method	Cochran-Mantel-Haenszel

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Timeframe for AE	
Adverse event reporting additional description:	
AE additional description	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	19.0

Reporting groups	
Reporting group title	GVe arm
Reporting group description: -	
Reporting group title	SCIT arm
Reporting group description: -	
Reporting group title	RVe arm
Reporting group description: -	
Reporting group title	GIVe arm
Reporting group description: -	

Serious adverse events	GVe arm	SCIT arm	RVe arm
Total subjects affected by serious adverse events			
subjects affected / exposed	136 / 228 (59.65%)	145 / 216 (67.13%)	131 / 237 (55.27%)
number of deaths (all causes)	15	19	15
number of deaths resulting from adverse events	14	18	14
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute myeloid leukaemia	Additional description: Acute myeloid leukaemia		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenocarcinoma pancreas	Additional description: Adenocarcinoma pancreas		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal cell carcinoma	Additional description: Basal cell carcinoma		
subjects affected / exposed	3 / 228 (1.32%)	4 / 216 (1.85%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	1 / 3	3 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Bladder cancer	Additional description: Bladder cancer		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Bowen's disease	Additional description: Bowen's disease		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer	Additional description: Breast cancer		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	2 / 237 (0.84%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chondrosarcoma	Additional description: Chondrosarcoma		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Central nervous system leukaemia	Additional description: Central nervous system leukaemia		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon cancer	Additional description: Colon cancer		
subjects affected / exposed	0 / 228 (0.00%)	2 / 216 (0.93%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Dedifferentiated liposarcoma	Additional description: Dedifferentiated liposarcoma		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Follicular lymphoma	Additional description: Follicular lymphoma		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glioblastoma	Additional description: Glioblastoma		

subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Hepatocellular carcinoma	Additional description: Hepatocellular carcinoma		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Hypopharyngeal cancer	Additional description: Hypopharyngeal cancer		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipoma	Additional description: Lipoma		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm of unknown primary site	Additional description: Malignant neoplasm of unknown primary site		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Lung adenocarcinoma	Additional description: Lung adenocarcinoma		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung neoplasm malignant	Additional description: Lung neoplasm malignant		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Malignant melanoma	Additional description: Malignant melanoma		
subjects affected / exposed	2 / 228 (0.88%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mantle cell lymphoma	Additional description: Mantle cell lymphoma		

subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningioma	Additional description: Meningioma		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningioma benign	Additional description: Meningioma benign		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic gastric cancer	Additional description: Metastatic gastric cancer		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Myelodysplastic syndrome	Additional description: Myelodysplastic syndrome		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myxoid liposarcoma	Additional description: Myxoid liposarcoma		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-small cell lung cancer	Additional description: Non-small cell lung cancer		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal adenocarcinoma	Additional description: Oesophageal adenocarcinoma		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Oesophageal carcinoma	Additional description: Oesophageal carcinoma		

subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian adenoma	Additional description: Ovarian adenoma		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Phaeochromocytoma	Additional description: Phaeochromocytoma		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Plasma cell myeloma	Additional description: Plasma cell myeloma		
subjects affected / exposed	0 / 228 (0.00%)	2 / 216 (0.93%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papillary thyroid cancer	Additional description: Papillary thyroid cancer		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polycythaemia vera	Additional description: Polycythaemia vera		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer	Additional description: Prostate cancer		
subjects affected / exposed	4 / 228 (1.75%)	3 / 216 (1.39%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	1 / 4	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Prostate cancer metastatic	Additional description: Prostate cancer metastatic		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Rectal adenocarcinoma	Additional description: Rectal adenocarcinoma		

subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal cancer	Additional description: Rectal cancer		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	2 / 237 (0.84%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Cell Carcinoma	Additional description: Renal Cell Carcinoma		
subjects affected / exposed	1 / 228 (0.44%)	2 / 216 (0.93%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Richter's syndrome	Additional description: Richter's syndrome		
subjects affected / exposed	7 / 228 (3.07%)	5 / 216 (2.31%)	6 / 237 (2.53%)
occurrences causally related to treatment / all	0 / 7	1 / 5	0 / 6
deaths causally related to treatment / all	0 / 2	1 / 3	0 / 4
Salivary gland adenoma	Additional description: Salivary gland adenoma		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salivary gland cancer	Additional description: Salivary gland cancer		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seborrhoeic keratosis	Additional description: Seborrhoeic keratosis		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of skin	Additional description: Squamous cell carcinoma of skin		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin squamous cell carcinoma metastatic	Additional description: Skin squamous cell carcinoma metastatic		

subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Small cell lung cancer	Additional description: Small cell lung cancer		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue sarcoma	Additional description: Soft tissue sarcoma		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord neoplasm	Additional description: Spinal cord neoplasm		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma	Additional description: Squamous cell carcinoma		
subjects affected / exposed	4 / 228 (1.75%)	6 / 216 (2.78%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 4	2 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine leiomyoma	Additional description: Uterine leiomyoma		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Aortic aneurysm	Additional description: Aortic aneurysm		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic stenosis	Additional description: Aortic stenosis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blue toe syndrome	Additional description: Blue toe syndrome		

subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis	Additional description: Deep vein thrombosis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension	Additional description: Hypertension		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	2 / 237 (0.84%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive crisis	Additional description: Hypertensive crisis		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension	Additional description: Hypotension		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic hypotension	Additional description: Orthostatic hypotension		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral arterial occlusive disease	Additional description: Peripheral arterial occlusive disease		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral ischaemia	Additional description: Peripheral ischaemia		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polyarteritis nodosa	Additional description: Polyarteritis nodosa		

subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombophlebitis	Additional description: Thrombophlebitis		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Chest tube removal	Additional description: Chest tube removal		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystectomy	Additional description: Cholecystectomy		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary arterial stent insertion	Additional description: Coronary arterial stent insertion		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery bypass	Additional description: Coronary artery bypass		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epidermoid cyst excision	Additional description: Epidermoid cyst excision		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ethmoid sinus surgery	Additional description: Ethmoid sinus surgery		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrectomy	Additional description: Gastrectomy		

subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip arthroplasty	Additional description: Hip arthroplasty		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip surgery	Additional description: Hip surgery		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Adverse drug reaction	Additional description: Adverse drug reaction		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthenia	Additional description: Asthenia		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain	Additional description: Chest pain		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death	Additional description: Death		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue	Additional description: Fatigue		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration	Additional description: General physical health deterioration		

subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza like illness	Additional description: Influenza like illness		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise	Additional description: Malaise		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral	Additional description: Oedema peripheral		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Puncture site haematoma	Additional description: Puncture site haematoma		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia	Additional description: Pyrexia		
subjects affected / exposed	8 / 228 (3.51%)	10 / 216 (4.63%)	8 / 237 (3.38%)
occurrences causally related to treatment / all	7 / 8	11 / 12	5 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction	Additional description: Anaphylactic reaction		
subjects affected / exposed	3 / 228 (1.32%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	1 / 3	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytokine release syndrome	Additional description: Cytokine release syndrome		
subjects affected / exposed	2 / 228 (0.88%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	2 / 2	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug hypersensitivity	Additional description: Drug hypersensitivity		

subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity	Additional description: Hypersensitivity		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sarcoidosis	Additional description: Sarcoidosis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Benign prostatic hyperplasia	Additional description: Benign prostatic hyperplasia		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Genital prolapse	Additional description: Genital prolapse		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Menorrhagia	Additional description: Menorrhagia		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectocele	Additional description: Rectocele		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Bronchial obstruction	Additional description: Bronchial obstruction		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0

Bronchitis chronic	Additional description: Bronchitis chronic		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Dyspnoea	Additional description: Dyspnoea		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Nasal septum disorder	Additional description: Nasal septum disorder		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Obliterative bronchiolitis	Additional description: Obliterative bronchiolitis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pleural effusion	Additional description: Pleural effusion		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pleuritic pain	Additional description: Pleuritic pain		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonitis	Additional description: Pneumonitis		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumothorax	Additional description: Pneumothorax		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pulmonary embolism	Additional description: Pulmonary embolism

subjects affected / exposed	2 / 228 (0.88%)	2 / 216 (0.93%)	3 / 237 (1.27%)
occurrences causally related to treatment / all	1 / 2	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary fibrosis	Additional description: Pulmonary fibrosis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary mass	Additional description: Pulmonary mass		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure	Additional description: Respiratory failure		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper-airway cough syndrome	Additional description: Upper-airway cough syndrome		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Completed suicide	Additional description: Completed suicide		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Delirium	Additional description: Delirium		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression	Additional description: Depression		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Insomnia	Additional description: Insomnia		

subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide attempt	Additional description: Suicide attempt		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood lactate dehydrogenase increased	Additional description: Blood lactate dehydrogenase increased		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	2 / 237 (0.84%)
occurrences causally related to treatment / all	1 / 1	0 / 0	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatine increased	Additional description: Blood creatine increased		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatine phosphokinase increased	Additional description: Blood creatine phosphokinase increased		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased	Additional description: Blood creatinine increased		
subjects affected / exposed	2 / 228 (0.88%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood phosphorus increased	Additional description: Blood phosphorus increased		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood potassium increased	Additional description: Blood potassium increased		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic enzyme increased	Additional description: Hepatic enzyme increased		

subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medical observation	Additional description: Medical observation		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial necrosis marker increased	Additional description: Myocardial necrosis marker increased		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
N-terminal prohormone brain natriuretic peptide increased	Additional description: N-terminal prohormone brain natriuretic peptide increased		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatic specific antigen increased	Additional description: Prostatic specific antigen increased		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SARS-CoV-2 test positive	Additional description: SARS-CoV-2 test positive		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transaminases increased	Additional description: Transaminases increased		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Alcohol poisoning	Additional description: Alcohol poisoning		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Ankle fracture	Additional description: Ankle fracture		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Forearm fracture	Additional description: Forearm fracture		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Facial bones fracture	Additional description: Facial bones fracture		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Fall	Additional description: Fall		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Femoral neck fracture	Additional description: Femoral neck fracture		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Femur fracture	Additional description: Femur fracture		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Fibula fracture	Additional description: Fibula fracture		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Foot fracture	Additional description: Foot fracture		
subjects affected / exposed	0 / 228 (0.00%)	2 / 216 (0.93%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hand fracture	Additional description: Hand fracture

subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture	Additional description: Hip fracture		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture	Additional description: Humerus fracture		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction	Additional description: Infusion related reaction		
subjects affected / exposed	20 / 228 (8.77%)	9 / 216 (4.17%)	20 / 237 (8.44%)
occurrences causally related to treatment / all	22 / 22	10 / 12	22 / 22
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Kidney rupture	Additional description: Kidney rupture		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar vertebral fracture	Additional description: Lumbar vertebral fracture		
subjects affected / exposed	0 / 228 (0.00%)	2 / 216 (0.93%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple fractures	Additional description: Multiple fractures		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple injuries	Additional description: Multiple injuries		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscus injury	Additional description: Meniscus injury		

subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haematoma	Additional description: Post procedural haematoma		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural intestinal perforation	Additional description: Procedural intestinal perforation		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reactive gastropathy	Additional description: Reactive gastropathy		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Silicosis	Additional description: Silicosis		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident	Additional description: Road traffic accident		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skull fracture	Additional description: Skull fracture		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture	Additional description: Spinal compression fracture		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal fracture	Additional description: Spinal fracture		

subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thermal burn	Additional description: Thermal burn		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma	Additional description: Subdural haematoma		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thoracic vertebral fracture	Additional description: Thoracic vertebral fracture		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia fracture	Additional description: Tibia fracture		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ulna fracture	Additional description: Ulna fracture		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrist fracture	Additional description: Wrist fracture		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Adenomatous polyposis coli	Additional description: Adenomatous polyposis coli		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			

Acute coronary syndrome	Additional description: Acute coronary syndrome		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Acute myocardial infarction	Additional description: Acute myocardial infarction		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Atrial tachycardia	Additional description: Atrial tachycardia		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Aortic valve disease	Additional description: Aortic valve disease		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Arteriosclerosis coronary artery	Additional description: Arteriosclerosis coronary artery		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Atrial fibrillation	Additional description: Atrial fibrillation		
subjects affected / exposed	3 / 228 (1.32%)	7 / 216 (3.24%)	3 / 237 (1.27%)
occurrences causally related to treatment / all	2 / 4	2 / 7	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Atrial flutter	Additional description: Atrial flutter		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Angina pectoris	Additional description: Angina pectoris		
subjects affected / exposed	2 / 228 (0.88%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 2	2 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Atrioventricular block	Additional description: Atrioventricular block

subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest	Additional description: Cardiac arrest		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Cardiac failure	Additional description: Cardiac failure		
subjects affected / exposed	2 / 228 (0.88%)	1 / 216 (0.46%)	2 / 237 (0.84%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cardiac failure congestive	Additional description: Cardiac failure congestive		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiomyopathy	Additional description: Cardiomyopathy		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease	Additional description: Coronary artery disease		
subjects affected / exposed	3 / 228 (1.32%)	1 / 216 (0.46%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracardiac thrombus	Additional description: Intracardiac thrombus		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction	Additional description: Myocardial infarction		
subjects affected / exposed	0 / 228 (0.00%)	2 / 216 (0.93%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocarditis	Additional description: Myocarditis		

subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis	Additional description: Pericarditis		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Palpitations	Additional description: Palpitations		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion	Additional description: Pericardial effusion		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus node dysfunction	Additional description: Sinus node dysfunction		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress cardiomyopathy	Additional description: Stress cardiomyopathy		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia	Additional description: Supraventricular tachycardia		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular fibrillation	Additional description: Ventricular fibrillation		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Carotid artery stenosis	Additional description: Carotid artery stenosis		

subjects affected / exposed	2 / 228 (0.88%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery occlusion	Additional description: Carotid artery occlusion		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebellar stroke	Additional description: Cerebellar stroke		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haemorrhage	Additional description: Cerebral haemorrhage		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral ischaemia	Additional description: Cerebral ischaemia		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident	Additional description: Cerebrovascular accident		
subjects affected / exposed	0 / 228 (0.00%)	2 / 216 (0.93%)	2 / 237 (0.84%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysaesthesia	Additional description: Dysaesthesia		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness	Additional description: Dizziness		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolic cerebral infarction	Additional description: Embolic cerebral infarction		

subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis autoimmune	Additional description: Encephalitis autoimmune		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy	Additional description: Epilepsy		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic stroke	Additional description: Haemorrhagic stroke		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Headache	Additional description: Headache		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke	Additional description: Ischaemic stroke		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Myasthenia gravis	Additional description: Myasthenia gravis		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polyneuropathy	Additional description: Polyneuropathy		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure	Additional description: Seizure		

subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope	Additional description: Syncope		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombotic stroke	Additional description: Thrombotic stroke		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxic leukoencephalopathy	Additional description: Toxic leukoencephalopathy		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient global amnesia	Additional description: Transient global amnesia		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack	Additional description: Transient ischaemic attack		
subjects affected / exposed	0 / 228 (0.00%)	2 / 216 (0.93%)	2 / 237 (0.84%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vocal cord paresis	Additional description: Vocal cord paresis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia	Additional description: Anaemia		
subjects affected / exposed	2 / 228 (0.88%)	4 / 216 (1.85%)	2 / 237 (0.84%)
occurrences causally related to treatment / all	1 / 2	2 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aplasia pure red cell	Additional description: Aplasia pure red cell		

subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune haemolytic anaemia	Additional description: Autoimmune haemolytic anaemia		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune neutropenia	Additional description: Autoimmune neutropenia		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia	Additional description: Febrile neutropenia		
subjects affected / exposed	8 / 228 (3.51%)	21 / 216 (9.72%)	7 / 237 (2.95%)
occurrences causally related to treatment / all	6 / 8	23 / 26	7 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolytic anaemia	Additional description: Haemolytic anaemia		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune thrombocytopenia	Additional description: Immune thrombocytopenia		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukostasis syndrome	Additional description: Leukostasis syndrome		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenitis	Additional description: Lymphadenitis		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphocytosis	Additional description: Lymphocytosis		

subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia	Additional description: Neutropenia		
subjects affected / exposed	4 / 228 (1.75%)	2 / 216 (0.93%)	3 / 237 (1.27%)
occurrences causally related to treatment / all	4 / 4	2 / 2	4 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia	Additional description: Pancytopenia		
subjects affected / exposed	2 / 228 (0.88%)	1 / 216 (0.46%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	2 / 2	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenomegaly	Additional description: Splenomegaly		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia	Additional description: Thrombocytopenia		
subjects affected / exposed	8 / 228 (3.51%)	2 / 216 (0.93%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	7 / 8	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo	Additional description: Vertigo		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertigo positional	Additional description: Vertigo positional		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Acute macular outer retinopathy	Additional description: Acute macular outer retinopathy		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cataract	Additional description: Cataract		

subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dacryostenosis acquired	Additional description: Dacryostenosis acquired		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eyelid cyst	Additional description: Eyelid cyst		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Macular hole	Additional description: Macular hole		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Optic ischaemic neuropathy	Additional description: Optic ischaemic neuropathy		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal detachment	Additional description: Retinal detachment		
subjects affected / exposed	2 / 228 (0.88%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous stasis retinopathy	Additional description: Venous stasis retinopathy		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain	Additional description: Abdominal pain		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal hernia	Additional description: Abdominal hernia		

subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper	Additional description: Abdominal pain upper		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea	Additional description: Diarrhoea		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum intestinal	Additional description: Diverticulum intestinal		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal perforation	Additional description: Duodenal perforation		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer haemorrhage	Additional description: Duodenal ulcer haemorrhage		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enlarged uvula	Additional description: Enlarged uvula		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epiploic appendagitis	Additional description: Epiploic appendagitis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erosive oesophagitis	Additional description: Erosive oesophagitis		

subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis	Additional description: Gastritis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis erosive	Additional description: Gastritis erosive		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage	Additional description: Gastrointestinal haemorrhage		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease	Additional description: Gastrooesophageal reflux disease		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic erosive gastritis	Additional description: Haemorrhagic erosive gastritis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus	Additional description: Ileus		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired gastric emptying	Additional description: Impaired gastric emptying		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia	Additional description: Inguinal hernia		

subjects affected / exposed	0 / 228 (0.00%)	3 / 216 (1.39%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Irritable bowel syndrome	Additional description: Irritable bowel syndrome		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea	Additional description: Nausea		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 2	2 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal rupture	Additional description: Oesophageal rupture		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis	Additional description: Pancreatitis		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatolithiasis	Additional description: Pancreatolithiasis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis	Additional description: Stomatitis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage	Additional description: Upper gastrointestinal haemorrhage		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Bile duct stenosis	Additional description: Bile duct stenosis		

subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary colic	Additional description: Biliary colic		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis	Additional description: Cholecystitis		
subjects affected / exposed	3 / 228 (1.32%)	4 / 216 (1.85%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute	Additional description: Cholecystitis acute		
subjects affected / exposed	2 / 228 (0.88%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis	Additional description: Cholelithiasis		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder polyp	Additional description: Gallbladder polyp		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatotoxicity	Additional description: Hepatotoxicity		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver disorder	Additional description: Liver disorder		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcapsular hepatic haematoma	Additional description: Subcapsular hepatic haematoma		

subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Actinic keratosis	Additional description: Actinic keratosis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis	Additional description: Dermatitis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis allergic	Additional description: Dermatitis allergic		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erythema multiforme	Additional description: Erythema multiforme		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash	Additional description: Rash		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash maculo-papular	Additional description: Rash maculo-papular		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury	Additional description: Acute kidney injury		
subjects affected / exposed	0 / 228 (0.00%)	2 / 216 (0.93%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Nephrolithiasis	Additional description: Nephrolithiasis		

subjects affected / exposed	2 / 228 (0.88%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal colic	Additional description: Renal colic		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureterolithiasis	Additional description: Ureterolithiasis		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral caruncle	Additional description: Urethral caruncle		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral stenosis	Additional description: Urethral stenosis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention	Additional description: Urinary retention		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Goitre	Additional description: Goitre		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthyroidism	Additional description: Hyperthyroidism		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			

Arthralgia	Additional description: Arthralgia		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Back pain	Additional description: Back pain		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Bursitis	Additional description: Bursitis		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Dupuytren's contracture	Additional description: Dupuytren's contracture		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Gouty arthritis	Additional description: Gouty arthritis		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Haemarthrosis	Additional description: Haemarthrosis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Haematoma muscle	Additional description: Haematoma muscle		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hypercreatinaemia	Additional description: Hypercreatinaemia		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Intervertebral disc protrusion	Additional description: Intervertebral disc protrusion

subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal pain	Additional description: Musculoskeletal pain		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity	Additional description: Pain in extremity		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteochondrosis	Additional description: Osteochondrosis		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis	Additional description: Osteonecrosis		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoporotic fracture	Additional description: Osteoporotic fracture		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis	Additional description: Osteoarthritis		
subjects affected / exposed	4 / 228 (1.75%)	2 / 216 (0.93%)	2 / 237 (0.84%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periarthritis	Additional description: Periarthritis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polymyalgia rheumatica	Additional description: Polymyalgia rheumatica		

subjects affected / exposed	2 / 228 (0.88%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator cuff syndrome	Additional description: Rotator cuff syndrome		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scleroderma	Additional description: Scleroderma		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal column stenosis	Additional description: Spinal column stenosis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal pain	Additional description: Spinal pain		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tenosynovitis	Additional description: Tenosynovitis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Anal abscess	Additional description: Anal abscess		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess limb	Additional description: Abscess limb		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess	Additional description: Abscess		

subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis	Additional description: Appendicitis		
subjects affected / exposed	2 / 228 (0.88%)	1 / 216 (0.46%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	1 / 2	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis perforated	Additional description: Appendicitis perforated		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asymptomatic COVID-19	Additional description: Asymptomatic COVID-19		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia	Additional description: Bacteraemia		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial infection	Additional description: Bacterial infection		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atypical pneumonia	Additional description: Atypical pneumonia		
subjects affected / exposed	0 / 228 (0.00%)	2 / 216 (0.93%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Bronchitis	Additional description: Bronchitis		
subjects affected / exposed	1 / 228 (0.44%)	2 / 216 (0.93%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopulmonary aspergillosis	Additional description: Bronchopulmonary aspergillosis		

subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral aspergillosis	Additional description: Cerebral aspergillosis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cellulitis	Additional description: Cellulitis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic sinusitis	Additional description: Chronic sinusitis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Corona virus infection	Additional description: Corona virus infection		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronavirus infection	Additional description: Coronavirus infection		
subjects affected / exposed	0 / 228 (0.00%)	3 / 216 (1.39%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19	Additional description: COVID-19		
subjects affected / exposed	13 / 228 (5.70%)	6 / 216 (2.78%)	13 / 237 (5.49%)
occurrences causally related to treatment / all	0 / 13	0 / 6	0 / 14
deaths causally related to treatment / all	0 / 3	0 / 2	0 / 0
COVID-19 pneumonia	Additional description: COVID-19 pneumonia		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	3 / 237 (1.27%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cryptococcal fungaemia	Additional description: Cryptococcal fungaemia		

subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis	Additional description: Cystitis		
subjects affected / exposed	0 / 228 (0.00%)	2 / 216 (0.93%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus infection	Additional description: Cytomegalovirus infection		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus infection reactivation	Additional description: Cytomegalovirus infection reactivation		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis	Additional description: Diverticulitis		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis fungal	Additional description: Encephalitis fungal		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocarditis	Additional description: Endocarditis		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas	Additional description: Erysipelas		
subjects affected / exposed	3 / 228 (1.32%)	4 / 216 (1.85%)	2 / 237 (0.84%)
occurrences causally related to treatment / all	0 / 3	2 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epididymitis	Additional description: Epididymitis		

subjects affected / exposed	3 / 228 (1.32%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	2 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epstein-Barr virus infection	Additional description: Epstein-Barr virus infection		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Enterocolitis infectious	Additional description: Enterocolitis infectious		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection	Additional description: Escherichia urinary tract infection		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile infection	Additional description: Febrile infection		
subjects affected / exposed	0 / 228 (0.00%)	5 / 216 (2.31%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	5 / 5	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia bacteraemia	Additional description: Escherichia bacteraemia		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder empyema	Additional description: Gallbladder empyema		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis	Additional description: Gastroenteritis		
subjects affected / exposed	2 / 228 (0.88%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal infection	Additional description: Gastrointestinal infection		

subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Genital herpes zoster	Additional description: Genital herpes zoster		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Giardiasis	Additional description: Giardiasis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis B	Additional description: Hepatitis B		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis B reactivation	Additional description: Hepatitis B reactivation		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis E	Additional description: Hepatitis E		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster	Additional description: Herpes zoster		
subjects affected / exposed	0 / 228 (0.00%)	8 / 216 (3.70%)	2 / 237 (0.84%)
occurrences causally related to treatment / all	0 / 0	4 / 8	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster meningoencephalitis	Additional description: Herpes zoster meningoencephalitis		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster reactivation	Additional description: Herpes zoster reactivation		

subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impetigo	Additional description: Impetigo		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected seroma	Additional description: Infected seroma		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection	Additional description: Infection		
subjects affected / exposed	3 / 228 (1.32%)	5 / 216 (2.31%)	6 / 237 (2.53%)
occurrences causally related to treatment / all	2 / 3	3 / 6	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infectious pleural effusion	Additional description: Infectious pleural effusion		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective exacerbation of chronic obstructive airways disease	Additional description: Infective exacerbation of chronic obstructive airways disease		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza	Additional description: Influenza		
subjects affected / exposed	2 / 228 (0.88%)	7 / 216 (3.24%)	7 / 237 (2.95%)
occurrences causally related to treatment / all	0 / 2	2 / 7	2 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Keratitis bacterial	Additional description: Keratitis bacterial		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Kidney infection	Additional description: Kidney infection		

subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngitis	Additional description: Laryngitis		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection	Additional description: Lower respiratory tract infection		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Lung infection	Additional description: Lung infection		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lyme disease	Additional description: Lyme disease		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymph gland infection	Additional description: Lymph gland infection		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised infection	Additional description: Localised infection		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis	Additional description: Meningitis		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis viral	Additional description: Meningitis viral		

subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mycoplasma infection	Additional description: Mycoplasma infection		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic infection	Additional description: Neutropenic infection		
subjects affected / exposed	2 / 228 (0.88%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	2 / 2	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelitis	Additional description: Myelitis		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis	Additional description: Osteomyelitis		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic abscess	Additional description: Pelvic abscess		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis	Additional description: Pharyngitis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papilloma viral infection	Additional description: Papilloma viral infection		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection	Additional description: Parainfluenzae virus infection		

subjects affected / exposed	0 / 228 (0.00%)	2 / 216 (0.93%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural infection	Additional description: Pleural infection		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia	Additional description: Pneumocystis jirovecii pneumonia		
subjects affected / exposed	0 / 228 (0.00%)	3 / 216 (1.39%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia	Additional description: Pneumonia		
subjects affected / exposed	17 / 228 (7.46%)	18 / 216 (8.33%)	17 / 237 (7.17%)
occurrences causally related to treatment / all	12 / 25	12 / 24	4 / 19
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 1
Pneumonia adenoviral	Additional description: Pneumonia adenoviral		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia influenzal	Additional description: Pneumonia influenzal		
subjects affected / exposed	0 / 228 (0.00%)	2 / 216 (0.93%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia legionella	Additional description: Pneumonia legionella		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia mycoplasmal	Additional description: Pneumonia mycoplasmal		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia pneumococcal	Additional description: Pneumonia pneumococcal		

subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia staphylococcal	Additional description: Pneumonia staphylococcal		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia streptococcal	Additional description: Pneumonia streptococcal		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia fungal	Additional description: Pneumonia fungal		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonas infection	Additional description: Pseudomonas infection		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	2 / 237 (0.84%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal abscess	Additional description: Rectal abscess		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection	Additional description: Respiratory syncytial virus infection		
subjects affected / exposed	0 / 228 (0.00%)	2 / 216 (0.93%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection	Additional description: Respiratory tract infection		
subjects affected / exposed	2 / 228 (0.88%)	0 / 216 (0.00%)	2 / 237 (0.84%)
occurrences causally related to treatment / all	2 / 2	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sialoadenitis	Additional description: Sialoadenitis		

subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis	Additional description: Sepsis		
subjects affected / exposed	3 / 228 (1.32%)	3 / 216 (1.39%)	2 / 237 (0.84%)
occurrences causally related to treatment / all	0 / 3	2 / 3	1 / 2
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 1
Septic shock	Additional description: Septic shock		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Sinobronchitis	Additional description: Sinobronchitis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin infection	Additional description: Skin infection		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis	Additional description: Sinusitis		
subjects affected / exposed	2 / 228 (0.88%)	1 / 216 (0.46%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 2	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal infection	Additional description: Staphylococcal infection		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal infection	Additional description: Streptococcal infection		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal sepsis	Additional description: Streptococcal sepsis		

subjects affected / exposed	0 / 228 (0.00%)	2 / 216 (0.93%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous abscess	Additional description: Subcutaneous abscess		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suspected COVID-19	Additional description: Suspected COVID-19		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal sepsis	Additional description: Staphylococcal sepsis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth abscess	Additional description: Tooth abscess		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth infection	Additional description: Tooth infection		
subjects affected / exposed	2 / 228 (0.88%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection	Additional description: Upper respiratory tract infection		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	3 / 237 (1.27%)
occurrences causally related to treatment / all	0 / 1	1 / 1	2 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection	Additional description: Viral infection		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vestibular neuronitis	Additional description: Vestibular neuronitis		

subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection	Additional description: Urinary tract infection		
subjects affected / exposed	2 / 228 (0.88%)	4 / 216 (1.85%)	6 / 237 (2.53%)
occurrences causally related to treatment / all	1 / 5	2 / 4	5 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration	Additional description: Dehydration		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperphosphataemia	Additional description: Hyperphosphataemia		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	4 / 237 (1.69%)
occurrences causally related to treatment / all	1 / 1	1 / 1	5 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia	Additional description: Hyperglycaemia		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia	Additional description: Hyperkalaemia		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	2 / 237 (0.84%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia	Additional description: Hyponatraemia		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperuricaemia	Additional description: Hyperuricaemia		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	3 / 237 (1.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia	Additional description: Hypoglycaemia		

subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Hypokalaemia	Additional description: Hypokalaemia		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophosphataemia	Additional description: Hypophosphataemia		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour lysis syndrome	Additional description: Tumour lysis syndrome		
subjects affected / exposed	9 / 228 (3.95%)	4 / 216 (1.85%)	11 / 237 (4.64%)
occurrences causally related to treatment / all	9 / 9	4 / 4	12 / 12
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	GIVe arm		
Total subjects affected by serious adverse events			
subjects affected / exposed	146 / 231 (63.20%)		
number of deaths (all causes)	13		
number of deaths resulting from adverse events	13		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute myeloid leukaemia	Additional description: Acute myeloid leukaemia		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	1 / 1		
Adenocarcinoma pancreas	Additional description: Adenocarcinoma pancreas		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Basal cell carcinoma	Additional description: Basal cell carcinoma		
subjects affected / exposed	4 / 231 (1.73%)		
occurrences causally related to treatment / all	3 / 5		
deaths causally related to treatment / all	0 / 0		

Bladder cancer	Additional description: Bladder cancer		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Bowen's disease	Additional description: Bowen's disease		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Breast cancer	Additional description: Breast cancer		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Chondrosarcoma	Additional description: Chondrosarcoma		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Central nervous system leukaemia	Additional description: Central nervous system leukaemia		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Colon cancer	Additional description: Colon cancer		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		

Dedifferentiated liposarcoma	Additional description: Dedifferentiated liposarcoma		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Follicular lymphoma	Additional description: Follicular lymphoma		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Glioblastoma	Additional description: Glioblastoma

subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Hepatocellular carcinoma	Additional description: Hepatocellular carcinoma		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypopharyngeal cancer	Additional description: Hypopharyngeal cancer		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lipoma	Additional description: Lipoma		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Malignant neoplasm of unknown primary site	Additional description: Malignant neoplasm of unknown primary site		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lung adenocarcinoma	Additional description: Lung adenocarcinoma		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lung neoplasm malignant	Additional description: Lung neoplasm malignant		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Malignant melanoma	Additional description: Malignant melanoma		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mantle cell lymphoma	Additional description: Mantle cell lymphoma		

subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Meningioma	Additional description: Meningioma		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Meningioma benign	Additional description: Meningioma benign		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metastatic gastric cancer	Additional description: Metastatic gastric cancer		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myelodysplastic syndrome	Additional description: Myelodysplastic syndrome		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myxoid liposarcoma	Additional description: Myxoid liposarcoma		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Non-small cell lung cancer	Additional description: Non-small cell lung cancer		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Oesophageal adenocarcinoma	Additional description: Oesophageal adenocarcinoma		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Oesophageal carcinoma	Additional description: Oesophageal carcinoma		

subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ovarian adenoma	Additional description: Ovarian adenoma		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Phaeochromocytoma	Additional description: Phaeochromocytoma		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Plasma cell myeloma	Additional description: Plasma cell myeloma		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Papillary thyroid cancer	Additional description: Papillary thyroid cancer		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Polycythaemia vera	Additional description: Polycythaemia vera		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Prostate cancer	Additional description: Prostate cancer		
subjects affected / exposed	4 / 231 (1.73%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 1		
Prostate cancer metastatic	Additional description: Prostate cancer metastatic		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rectal adenocarcinoma	Additional description: Rectal adenocarcinoma		

subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rectal cancer	Additional description: Rectal cancer		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal Cell Carcinoma	Additional description: Renal Cell Carcinoma		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Richter's syndrome	Additional description: Richter's syndrome		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Salivary gland adenoma	Additional description: Salivary gland adenoma		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Salivary gland cancer	Additional description: Salivary gland cancer		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Seborrhoeic keratosis	Additional description: Seborrhoeic keratosis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Squamous cell carcinoma of skin	Additional description: Squamous cell carcinoma of skin		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin squamous cell carcinoma metastatic	Additional description: Skin squamous cell carcinoma metastatic		

subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Small cell lung cancer	Additional description: Small cell lung cancer		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	1 / 1		
Soft tissue sarcoma	Additional description: Soft tissue sarcoma		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spinal cord neoplasm	Additional description: Spinal cord neoplasm		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Squamous cell carcinoma	Additional description: Squamous cell carcinoma		
subjects affected / exposed	3 / 231 (1.30%)		
occurrences causally related to treatment / all	2 / 3		
deaths causally related to treatment / all	0 / 0		
Uterine leiomyoma	Additional description: Uterine leiomyoma		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Aortic aneurysm	Additional description: Aortic aneurysm		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Aortic stenosis	Additional description: Aortic stenosis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blue toe syndrome	Additional description: Blue toe syndrome		

subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Deep vein thrombosis	Additional description: Deep vein thrombosis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypertension	Additional description: Hypertension		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Hypertensive crisis	Additional description: Hypertensive crisis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypotension	Additional description: Hypotension		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Orthostatic hypotension	Additional description: Orthostatic hypotension		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peripheral arterial occlusive disease	Additional description: Peripheral arterial occlusive disease		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peripheral ischaemia	Additional description: Peripheral ischaemia		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Polyarteritis nodosa	Additional description: Polyarteritis nodosa		

subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thrombophlebitis	Additional description: Thrombophlebitis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			
Chest tube removal	Additional description: Chest tube removal		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholecystectomy	Additional description: Cholecystectomy		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Coronary arterial stent insertion	Additional description: Coronary arterial stent insertion		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Coronary artery bypass	Additional description: Coronary artery bypass		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Epidermoid cyst excision	Additional description: Epidermoid cyst excision		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ethmoid sinus surgery	Additional description: Ethmoid sinus surgery		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrectomy	Additional description: Gastrectomy		

subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hip arthroplasty	Additional description: Hip arthroplasty		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hip surgery	Additional description: Hip surgery		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Adverse drug reaction	Additional description: Adverse drug reaction		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Asthenia	Additional description: Asthenia		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chest pain	Additional description: Chest pain		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Death	Additional description: Death		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Fatigue	Additional description: Fatigue		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General physical health deterioration	Additional description: General physical health deterioration		

subjects affected / exposed	2 / 231 (0.87%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Influenza like illness	Additional description: Influenza like illness		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Malaise	Additional description: Malaise		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Oedema peripheral	Additional description: Oedema peripheral		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Puncture site haematoma	Additional description: Puncture site haematoma		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pyrexia	Additional description: Pyrexia		
subjects affected / exposed	4 / 231 (1.73%)		
occurrences causally related to treatment / all	4 / 4		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Anaphylactic reaction	Additional description: Anaphylactic reaction		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cytokine release syndrome	Additional description: Cytokine release syndrome		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Drug hypersensitivity	Additional description: Drug hypersensitivity		

subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypersensitivity	Additional description: Hypersensitivity		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sarcoidosis	Additional description: Sarcoidosis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Benign prostatic hyperplasia	Additional description: Benign prostatic hyperplasia		
subjects affected / exposed	3 / 231 (1.30%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Genital prolapse	Additional description: Genital prolapse		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Menorrhagia	Additional description: Menorrhagia		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Rectocele	Additional description: Rectocele		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Bronchial obstruction	Additional description: Bronchial obstruction		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Bronchitis chronic	Additional description: Bronchitis chronic		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Dyspnoea	Additional description: Dyspnoea		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Nasal septum disorder	Additional description: Nasal septum disorder		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Obliterative bronchiolitis	Additional description: Obliterative bronchiolitis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Pleural effusion	Additional description: Pleural effusion		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Pleuritic pain	Additional description: Pleuritic pain		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Pneumonitis	Additional description: Pneumonitis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Pneumothorax	Additional description: Pneumothorax		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		

Pulmonary embolism	Additional description: Pulmonary embolism

subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary fibrosis	Additional description: Pulmonary fibrosis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Pulmonary mass	Additional description: Pulmonary mass		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory failure	Additional description: Respiratory failure		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Upper-airway cough syndrome	Additional description: Upper-airway cough syndrome		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Completed suicide	Additional description: Completed suicide		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Delirium	Additional description: Delirium		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Depression	Additional description: Depression		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Insomnia	Additional description: Insomnia		

subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Suicide attempt	Additional description: Suicide attempt		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Investigations			
Blood lactate dehydrogenase increased	Additional description: Blood lactate dehydrogenase increased		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood creatine increased	Additional description: Blood creatine increased		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood creatine phosphokinase increased	Additional description: Blood creatine phosphokinase increased		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood creatinine increased	Additional description: Blood creatinine increased		
subjects affected / exposed	3 / 231 (1.30%)		
occurrences causally related to treatment / all	2 / 3		
deaths causally related to treatment / all	0 / 0		
Blood phosphorus increased	Additional description: Blood phosphorus increased		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood potassium increased	Additional description: Blood potassium increased		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatic enzyme increased	Additional description: Hepatic enzyme increased		

subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Medical observation	Additional description: Medical observation		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Myocardial necrosis marker increased	Additional description: Myocardial necrosis marker increased		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
N-terminal prohormone brain natriuretic peptide increased	Additional description: N-terminal prohormone brain natriuretic peptide increased		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Prostatic specific antigen increased	Additional description: Prostatic specific antigen increased		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
SARS-CoV-2 test positive	Additional description: SARS-CoV-2 test positive		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Transaminases increased	Additional description: Transaminases increased		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Alcohol poisoning	Additional description: Alcohol poisoning		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Ankle fracture	Additional description: Ankle fracture		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Forearm fracture	Additional description: Forearm fracture		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Facial bones fracture	Additional description: Facial bones fracture		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Fall	Additional description: Fall		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Femoral neck fracture	Additional description: Femoral neck fracture		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Femur fracture	Additional description: Femur fracture		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Fibula fracture	Additional description: Fibula fracture		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Foot fracture	Additional description: Foot fracture		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Hand fracture	Additional description: Hand fracture

subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hip fracture	Additional description: Hip fracture		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Humerus fracture	Additional description: Humerus fracture		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infusion related reaction	Additional description: Infusion related reaction		
subjects affected / exposed	11 / 231 (4.76%)		
occurrences causally related to treatment / all	10 / 11		
deaths causally related to treatment / all	0 / 0		
Kidney rupture	Additional description: Kidney rupture		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lumbar vertebral fracture	Additional description: Lumbar vertebral fracture		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Multiple fractures	Additional description: Multiple fractures		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Multiple injuries	Additional description: Multiple injuries		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Meniscus injury	Additional description: Meniscus injury		

subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Post procedural haematoma	Additional description: Post procedural haematoma		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Procedural intestinal perforation	Additional description: Procedural intestinal perforation		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reactive gastropathy	Additional description: Reactive gastropathy		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Silicosis	Additional description: Silicosis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Road traffic accident	Additional description: Road traffic accident		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skull fracture	Additional description: Skull fracture		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spinal compression fracture	Additional description: Spinal compression fracture		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Spinal fracture	Additional description: Spinal fracture		

subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Thermal burn	Additional description: Thermal burn		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Subdural haematoma	Additional description: Subdural haematoma		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thoracic vertebral fracture	Additional description: Thoracic vertebral fracture		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tibia fracture	Additional description: Tibia fracture		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ulna fracture	Additional description: Ulna fracture		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Wrist fracture	Additional description: Wrist fracture		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Congenital, familial and genetic disorders			
Adenomatous polyposis coli	Additional description: Adenomatous polyposis coli		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			

Acute coronary syndrome	Additional description: Acute coronary syndrome		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Acute myocardial infarction	Additional description: Acute myocardial infarction		
subjects affected / exposed	3 / 231 (1.30%)		
occurrences causally related to treatment / all	1 / 3		
deaths causally related to treatment / all	0 / 0		

Atrial tachycardia	Additional description: Atrial tachycardia		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Aortic valve disease	Additional description: Aortic valve disease		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Arteriosclerosis coronary artery	Additional description: Arteriosclerosis coronary artery		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Atrial fibrillation	Additional description: Atrial fibrillation		
subjects affected / exposed	6 / 231 (2.60%)		
occurrences causally related to treatment / all	4 / 7		
deaths causally related to treatment / all	0 / 0		

Atrial flutter	Additional description: Atrial flutter		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Angina pectoris	Additional description: Angina pectoris		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		

Atrioventricular block	Additional description: Atrioventricular block

subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac arrest	Additional description: Cardiac arrest		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac failure	Additional description: Cardiac failure		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac failure congestive	Additional description: Cardiac failure congestive		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiomyopathy	Additional description: Cardiomyopathy		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Coronary artery disease	Additional description: Coronary artery disease		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Intracardiac thrombus	Additional description: Intracardiac thrombus		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myocardial infarction	Additional description: Myocardial infarction		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Myocarditis	Additional description: Myocarditis		

subjects affected / exposed	2 / 231 (0.87%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Pericarditis	Additional description: Pericarditis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Palpitations	Additional description: Palpitations		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pericardial effusion	Additional description: Pericardial effusion		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Sinus node dysfunction	Additional description: Sinus node dysfunction		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Stress cardiomyopathy	Additional description: Stress cardiomyopathy		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Supraventricular tachycardia	Additional description: Supraventricular tachycardia		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Ventricular fibrillation	Additional description: Ventricular fibrillation		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Carotid artery stenosis	Additional description: Carotid artery stenosis		

subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Carotid artery occlusion	Additional description: Carotid artery occlusion		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebellar stroke	Additional description: Cerebellar stroke		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cerebral haemorrhage	Additional description: Cerebral haemorrhage		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Cerebral ischaemia	Additional description: Cerebral ischaemia		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebrovascular accident	Additional description: Cerebrovascular accident		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Dysaesthesia	Additional description: Dysaesthesia		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dizziness	Additional description: Dizziness		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Embolic cerebral infarction	Additional description: Embolic cerebral infarction		

subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Encephalitis autoimmune	Additional description: Encephalitis autoimmune		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Epilepsy	Additional description: Epilepsy		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Haemorrhagic stroke	Additional description: Haemorrhagic stroke		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Headache	Additional description: Headache		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Ischaemic stroke	Additional description: Ischaemic stroke		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Myasthenia gravis	Additional description: Myasthenia gravis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Polyneuropathy	Additional description: Polyneuropathy		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Seizure	Additional description: Seizure		

subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Syncope	Additional description: Syncope		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Thrombotic stroke	Additional description: Thrombotic stroke		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Toxic leukoencephalopathy	Additional description: Toxic leukoencephalopathy		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	1 / 1		
Transient global amnesia	Additional description: Transient global amnesia		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Transient ischaemic attack	Additional description: Transient ischaemic attack		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vocal cord paresis	Additional description: Vocal cord paresis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Anaemia	Additional description: Anaemia		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		
Aplasia pure red cell	Additional description: Aplasia pure red cell		

subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Autoimmune haemolytic anaemia	Additional description: Autoimmune haemolytic anaemia		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Autoimmune neutropenia	Additional description: Autoimmune neutropenia		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Febrile neutropenia	Additional description: Febrile neutropenia		
subjects affected / exposed	17 / 231 (7.36%)		
occurrences causally related to treatment / all	17 / 18		
deaths causally related to treatment / all	0 / 0		
Haemolytic anaemia	Additional description: Haemolytic anaemia		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Immune thrombocytopenia	Additional description: Immune thrombocytopenia		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Leukostasis syndrome	Additional description: Leukostasis syndrome		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Lymphadenitis	Additional description: Lymphadenitis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lymphocytosis	Additional description: Lymphocytosis		

subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Neutropenia	Additional description: Neutropenia		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancytopenia	Additional description: Pancytopenia		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Splenomegaly	Additional description: Splenomegaly		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thrombocytopenia	Additional description: Thrombocytopenia		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		
Ear and labyrinth disorders			
Vertigo	Additional description: Vertigo		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vertigo positional	Additional description: Vertigo positional		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Acute macular outer retinopathy	Additional description: Acute macular outer retinopathy		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cataract	Additional description: Cataract		

subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dacryostenosis acquired	Additional description: Dacryostenosis acquired		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eyelid cyst	Additional description: Eyelid cyst		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Macular hole	Additional description: Macular hole		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Optic ischaemic neuropathy	Additional description: Optic ischaemic neuropathy		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Retinal detachment	Additional description: Retinal detachment		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Venous stasis retinopathy	Additional description: Venous stasis retinopathy		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal pain	Additional description: Abdominal pain		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Abdominal hernia	Additional description: Abdominal hernia		

subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal pain upper	Additional description: Abdominal pain upper		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Diarrhoea	Additional description: Diarrhoea		
subjects affected / exposed	4 / 231 (1.73%)		
occurrences causally related to treatment / all	5 / 6		
deaths causally related to treatment / all	0 / 0		
Diverticulum intestinal	Additional description: Diverticulum intestinal		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Duodenal perforation	Additional description: Duodenal perforation		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Duodenal ulcer haemorrhage	Additional description: Duodenal ulcer haemorrhage		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Enlarged uvula	Additional description: Enlarged uvula		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Epiploic appendagitis	Additional description: Epiploic appendagitis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Erosive oesophagitis	Additional description: Erosive oesophagitis		

subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastritis	Additional description: Gastritis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastritis erosive	Additional description: Gastritis erosive		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal haemorrhage	Additional description: Gastrointestinal haemorrhage		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Gastrooesophageal reflux disease	Additional description: Gastrooesophageal reflux disease		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Haemorrhagic erosive gastritis	Additional description: Haemorrhagic erosive gastritis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ileus	Additional description: Ileus		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Impaired gastric emptying	Additional description: Impaired gastric emptying		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Inguinal hernia	Additional description: Inguinal hernia		

subjects affected / exposed	2 / 231 (0.87%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Irritable bowel syndrome	Additional description: Irritable bowel syndrome		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nausea	Additional description: Nausea		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oesophageal rupture	Additional description: Oesophageal rupture		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Pancreatitis	Additional description: Pancreatitis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancreatolithiasis	Additional description: Pancreatolithiasis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Stomatitis	Additional description: Stomatitis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Upper gastrointestinal haemorrhage	Additional description: Upper gastrointestinal haemorrhage		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Bile duct stenosis	Additional description: Bile duct stenosis		

subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Biliary colic	Additional description: Biliary colic		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Cholecystitis	Additional description: Cholecystitis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cholecystitis acute	Additional description: Cholecystitis acute		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cholelithiasis	Additional description: Cholelithiasis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gallbladder polyp	Additional description: Gallbladder polyp		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatotoxicity	Additional description: Hepatotoxicity		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		
Liver disorder	Additional description: Liver disorder		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Subcapsular hepatic haematoma	Additional description: Subcapsular hepatic haematoma		

subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Actinic keratosis	Additional description: Actinic keratosis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dermatitis	Additional description: Dermatitis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Dermatitis allergic	Additional description: Dermatitis allergic		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Erythema multiforme	Additional description: Erythema multiforme		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rash	Additional description: Rash		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Rash maculo-papular	Additional description: Rash maculo-papular		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Acute kidney injury	Additional description: Acute kidney injury		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Nephrolithiasis	Additional description: Nephrolithiasis		

subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal colic	Additional description: Renal colic		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ureterolithiasis	Additional description: Ureterolithiasis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urethral caruncle	Additional description: Urethral caruncle		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urethral stenosis	Additional description: Urethral stenosis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary retention	Additional description: Urinary retention		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Endocrine disorders			
Goitre	Additional description: Goitre		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyperthyroidism	Additional description: Hyperthyroidism		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			

Arthralgia	Additional description: Arthralgia		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		

Back pain	Additional description: Back pain		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Bursitis	Additional description: Bursitis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Dupuytren's contracture	Additional description: Dupuytren's contracture		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Gouty arthritis	Additional description: Gouty arthritis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Haemarthrosis	Additional description: Haemarthrosis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		

Haematoma muscle	Additional description: Haematoma muscle		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Hypercreatinaemia	Additional description: Hypercreatinaemia		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		

Intervertebral disc protrusion	Additional description: Intervertebral disc protrusion

subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal pain	Additional description: Musculoskeletal pain		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Pain in extremity	Additional description: Pain in extremity		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Osteochondrosis	Additional description: Osteochondrosis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Osteonecrosis	Additional description: Osteonecrosis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Osteoporotic fracture	Additional description: Osteoporotic fracture		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Osteoarthritis	Additional description: Osteoarthritis		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Periarthritis	Additional description: Periarthritis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Polymyalgia rheumatica	Additional description: Polymyalgia rheumatica		

subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rotator cuff syndrome	Additional description: Rotator cuff syndrome		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Scleroderma	Additional description: Scleroderma		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Spinal column stenosis	Additional description: Spinal column stenosis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Spinal pain	Additional description: Spinal pain		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tenosynovitis	Additional description: Tenosynovitis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Anal abscess	Additional description: Anal abscess		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		
Abscess limb	Additional description: Abscess limb		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abscess	Additional description: Abscess		

subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Appendicitis	Additional description: Appendicitis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Appendicitis perforated	Additional description: Appendicitis perforated		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Asymptomatic COVID-19	Additional description: Asymptomatic COVID-19		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bacteraemia	Additional description: Bacteraemia		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bacterial infection	Additional description: Bacterial infection		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Atypical pneumonia	Additional description: Atypical pneumonia		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchitis	Additional description: Bronchitis		
subjects affected / exposed	3 / 231 (1.30%)		
occurrences causally related to treatment / all	2 / 3		
deaths causally related to treatment / all	0 / 0		
Bronchopulmonary aspergillosis	Additional description: Bronchopulmonary aspergillosis		

subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Cerebral aspergillosis	Additional description: Cerebral aspergillosis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cellulitis	Additional description: Cellulitis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Chronic sinusitis	Additional description: Chronic sinusitis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Corona virus infection	Additional description: Corona virus infection		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Coronavirus infection	Additional description: Coronavirus infection		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
COVID-19	Additional description: COVID-19		
subjects affected / exposed	8 / 231 (3.46%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 1		
COVID-19 pneumonia	Additional description: COVID-19 pneumonia		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cryptococcal fungaemia	Additional description: Cryptococcal fungaemia		

subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Cystitis	Additional description: Cystitis		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Cytomegalovirus infection	Additional description: Cytomegalovirus infection		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cytomegalovirus infection reactivation	Additional description: Cytomegalovirus infection reactivation		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diverticulitis	Additional description: Diverticulitis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Encephalitis fungal	Additional description: Encephalitis fungal		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	1 / 1		
Endocarditis	Additional description: Endocarditis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Erysipelas	Additional description: Erysipelas		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Epididymitis	Additional description: Epididymitis		

subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Epstein-Barr virus infection	Additional description: Epstein-Barr virus infection		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Enterocolitis infectious	Additional description: Enterocolitis infectious		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Escherichia urinary tract infection	Additional description: Escherichia urinary tract infection		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Febrile infection	Additional description: Febrile infection		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Escherichia bacteraemia	Additional description: Escherichia bacteraemia		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gallbladder empyema	Additional description: Gallbladder empyema		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis	Additional description: Gastroenteritis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal infection	Additional description: Gastrointestinal infection		

subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Genital herpes zoster	Additional description: Genital herpes zoster		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Giardiasis	Additional description: Giardiasis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatitis B	Additional description: Hepatitis B		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatitis B reactivation	Additional description: Hepatitis B reactivation		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatitis E	Additional description: Hepatitis E		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Herpes zoster	Additional description: Herpes zoster		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Herpes zoster meningoencephalitis	Additional description: Herpes zoster meningoencephalitis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Herpes zoster reactivation	Additional description: Herpes zoster reactivation		

subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Impetigo	Additional description: Impetigo		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infected seroma	Additional description: Infected seroma		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infection	Additional description: Infection		
subjects affected / exposed	5 / 231 (2.16%)		
occurrences causally related to treatment / all	3 / 6		
deaths causally related to treatment / all	0 / 0		
Infectious pleural effusion	Additional description: Infectious pleural effusion		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infective exacerbation of chronic obstructive airways disease	Additional description: Infective exacerbation of chronic obstructive airways disease		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Influenza	Additional description: Influenza		
subjects affected / exposed	5 / 231 (2.16%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Keratitis bacterial	Additional description: Keratitis bacterial		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Kidney infection	Additional description: Kidney infection		

subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Laryngitis	Additional description: Laryngitis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lower respiratory tract infection	Additional description: Lower respiratory tract infection		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lung infection	Additional description: Lung infection		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lyme disease	Additional description: Lyme disease		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lymph gland infection	Additional description: Lymph gland infection		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Localised infection	Additional description: Localised infection		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Meningitis	Additional description: Meningitis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Meningitis viral	Additional description: Meningitis viral		

subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Mycoplasma infection	Additional description: Mycoplasma infection		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neutropenic infection	Additional description: Neutropenic infection		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Myelitis	Additional description: Myelitis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Osteomyelitis	Additional description: Osteomyelitis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pelvic abscess	Additional description: Pelvic abscess		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pharyngitis	Additional description: Pharyngitis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Papilloma viral infection	Additional description: Papilloma viral infection		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Parainfluenzae virus infection	Additional description: Parainfluenzae virus infection		

subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pleural infection	Additional description: Pleural infection		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumocystis jirovecii pneumonia	Additional description: Pneumocystis jirovecii pneumonia		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia	Additional description: Pneumonia		
subjects affected / exposed	19 / 231 (8.23%)		
occurrences causally related to treatment / all	14 / 22		
deaths causally related to treatment / all	0 / 0		
Pneumonia adenoviral	Additional description: Pneumonia adenoviral		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia influenzal	Additional description: Pneumonia influenzal		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia legionella	Additional description: Pneumonia legionella		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia mycoplasmal	Additional description: Pneumonia mycoplasmal		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia pneumococcal	Additional description: Pneumonia pneumococcal		

subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia staphylococcal	Additional description: Pneumonia staphylococcal		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia streptococcal	Additional description: Pneumonia streptococcal		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Pneumonia fungal	Additional description: Pneumonia fungal		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Pseudomonas infection	Additional description: Pseudomonas infection		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rectal abscess	Additional description: Rectal abscess		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory syncytial virus infection	Additional description: Respiratory syncytial virus infection		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory tract infection	Additional description: Respiratory tract infection		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sialoadenitis	Additional description: Sialoadenitis		

subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sepsis	Additional description: Sepsis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Septic shock	Additional description: Septic shock		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sinobronchitis	Additional description: Sinobronchitis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Skin infection	Additional description: Skin infection		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Sinusitis	Additional description: Sinusitis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Staphylococcal infection	Additional description: Staphylococcal infection		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Streptococcal infection	Additional description: Streptococcal infection		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Streptococcal sepsis	Additional description: Streptococcal sepsis		

subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Subcutaneous abscess	Additional description: Subcutaneous abscess		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Suspected COVID-19	Additional description: Suspected COVID-19		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Staphylococcal sepsis	Additional description: Staphylococcal sepsis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Tooth abscess	Additional description: Tooth abscess		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tooth infection	Additional description: Tooth infection		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Upper respiratory tract infection	Additional description: Upper respiratory tract infection		
subjects affected / exposed	4 / 231 (1.73%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Viral infection	Additional description: Viral infection		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vestibular neuronitis	Additional description: Vestibular neuronitis		

subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection	Additional description: Urinary tract infection		
subjects affected / exposed	7 / 231 (3.03%)		
occurrences causally related to treatment / all	4 / 9		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Dehydration	Additional description: Dehydration		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hyperphosphataemia	Additional description: Hyperphosphataemia		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Hyperglycaemia	Additional description: Hyperglycaemia		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyperkalaemia	Additional description: Hyperkalaemia		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Hyponatraemia	Additional description: Hyponatraemia		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyperuricaemia	Additional description: Hyperuricaemia		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Hypoglycaemia	Additional description: Hypoglycaemia		

subjects affected / exposed	0 / 231 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypokalaemia	Additional description: Hypokalaemia		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypophosphataemia	Additional description: Hypophosphataemia		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		
Tumour lysis syndrome	Additional description: Tumour lysis syndrome		
subjects affected / exposed	6 / 231 (2.60%)		
occurrences causally related to treatment / all	6 / 6		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	GVe arm	SCIT arm	RVe arm
Total subjects affected by non-serious adverse events			
subjects affected / exposed	224 / 228 (98.25%)	214 / 216 (99.07%)	233 / 237 (98.31%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma of colon	Additional description: Adenocarcinoma of colon		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Anogenital warts	Additional description: Anogenital warts		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Angiomyolipoma	Additional description: Angiomyolipoma		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Basal cell carcinoma	Additional description: Basal cell carcinoma		
subjects affected / exposed	5 / 228 (2.19%)	15 / 216 (6.94%)	11 / 237 (4.64%)
occurrences (all)	5	19	14

Benign soft tissue neoplasm	Additional description: Benign soft tissue neoplasm		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Bowen's disease	Additional description: Bowen's disease		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	1 / 237 (0.42%)
occurrences (all)	0	2	1
Choroid melanoma	Additional description: Choroid melanoma		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Colon adenoma	Additional description: Colon adenoma		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Colon cancer	Additional description: Colon cancer		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	2 / 237 (0.84%)
occurrences (all)	0	0	2
Cutaneous T-cell lymphoma	Additional description: Cutaneous T-cell lymphoma		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Erythroplasia	Additional description: Erythroplasia		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Fibroma	Additional description: Fibroma		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Haemangioma	Additional description: Haemangioma		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	2 / 237 (0.84%)
occurrences (all)	1	0	2
Haemangioma of liver	Additional description: Haemangioma of liver		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Keratoacanthoma	Additional description: Keratoacanthoma		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Lipoma	Additional description: Lipoma		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0

Malignant melanoma	Additional description: Malignant melanoma		
subjects affected / exposed	3 / 228 (1.32%)	2 / 216 (0.93%)	1 / 237 (0.42%)
occurrences (all)	4	2	1
Melanocytic naevus	Additional description: Melanocytic naevus		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Malignant melanoma in situ	Additional description: Malignant melanoma in situ		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Myelodysplastic syndrome	Additional description: Myelodysplastic syndrome		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Myelofibrosis	Additional description: Myelofibrosis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Non-small cell lung cancer	Additional description: Non-small cell lung cancer		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Papilloma	Additional description: Papilloma		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Plasmacytoma	Additional description: Plasmacytoma		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Polycythaemia vera	Additional description: Polycythaemia vera		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Prostate cancer	Additional description: Prostate cancer		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	1 / 237 (0.42%)
occurrences (all)	1	1	1
Schwannoma	Additional description: Schwannoma		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Seborrhoeic keratosis	Additional description: Seborrhoeic keratosis		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0

Richter's syndrome	Additional description: Richter's syndrome		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	1 / 237 (0.42%)
occurrences (all)	1	1	1
Skin papilloma	Additional description: Skin papilloma		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	3 / 237 (1.27%)
occurrences (all)	1	0	3
Squamous cell carcinoma	Additional description: Squamous cell carcinoma		
subjects affected / exposed	3 / 228 (1.32%)	5 / 216 (2.31%)	1 / 237 (0.42%)
occurrences (all)	3	7	1
T-cell lymphoma	Additional description: T-cell lymphoma		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Thyroid neoplasm	Additional description: Thyroid neoplasm		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Transitional cell carcinoma	Additional description: Transitional cell carcinoma		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Vascular disorders			
Aortic aneurysm	Additional description: Aortic aneurysm		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Aortic dilatation	Additional description: Aortic dilatation		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Arteriosclerosis	Additional description: Arteriosclerosis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Blood pressure fluctuation	Additional description: Blood pressure fluctuation		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Blue toe syndrome	Additional description: Blue toe syndrome		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Circulatory collapse	Additional description: Circulatory collapse		

subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Deep vein thrombosis	Additional description: Deep vein thrombosis		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Embolism	Additional description: Embolism		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	1 / 237 (0.42%)
occurrences (all)	0	1	1
Flushing	Additional description: Flushing		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	1 / 237 (0.42%)
occurrences (all)	1	1	1
Gestational hypertension	Additional description: Gestational hypertension		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Haematoma	Additional description: Haematoma		
subjects affected / exposed	9 / 228 (3.95%)	4 / 216 (1.85%)	4 / 237 (1.69%)
occurrences (all)	9	5	4
Haemorrhage	Additional description: Haemorrhage		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Hot flush	Additional description: Hot flush		
subjects affected / exposed	1 / 228 (0.44%)	2 / 216 (0.93%)	5 / 237 (2.11%)
occurrences (all)	1	3	6
Hypotension	Additional description: Hypotension		
subjects affected / exposed	5 / 228 (2.19%)	10 / 216 (4.63%)	5 / 237 (2.11%)
occurrences (all)	5	11	7
Hypertensive crisis	Additional description: Hypertensive crisis		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	2 / 237 (0.84%)
occurrences (all)	1	0	3
Hypertension	Additional description: Hypertension		
subjects affected / exposed	23 / 228 (10.09%)	6 / 216 (2.78%)	17 / 237 (7.17%)
occurrences (all)	25	10	17
Peripheral arterial occlusive disease	Additional description: Peripheral arterial occlusive disease		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Peripheral coldness	Additional description: Peripheral coldness		

subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Phlebitis	Additional description: Phlebitis		
subjects affected / exposed	3 / 228 (1.32%)	4 / 216 (1.85%)	2 / 237 (0.84%)
occurrences (all)	3	4	2
Poor peripheral circulation	Additional description: Poor peripheral circulation		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Raynaud's phenomenon	Additional description: Raynaud's phenomenon		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	1	0	1
Thrombophlebitis	Additional description: Thrombophlebitis		
subjects affected / exposed	2 / 228 (0.88%)	2 / 216 (0.93%)	0 / 237 (0.00%)
occurrences (all)	2	2	0
Thrombophlebitis superficial	Additional description: Thrombophlebitis superficial		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	1	1	0
Thrombosis	Additional description: Thrombosis		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Varicose vein	Additional description: Varicose vein		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Vasculitis	Additional description: Vasculitis		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Venous thrombosis	Additional description: Venous thrombosis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Cranial remodelling therapy	Additional description: Cranial remodelling therapy		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Endodontic procedure	Additional description: Endodontic procedure		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0

Joint irrigation	Additional description: Joint irrigation		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Mastoidectomy	Additional description: Mastoidectomy		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Polypectomy	Additional description: Polypectomy		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	1	0	1
Tooth extraction	Additional description: Tooth extraction		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Axillary pain	Additional description: Axillary pain		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Asthenia	Additional description: Asthenia		
subjects affected / exposed	5 / 228 (2.19%)	9 / 216 (4.17%)	2 / 237 (0.84%)
occurrences (all)	5	10	2
Catheter site extravasation	Additional description: Catheter site extravasation		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Catheter site pain	Additional description: Catheter site pain		
subjects affected / exposed	0 / 228 (0.00%)	2 / 216 (0.93%)	1 / 237 (0.42%)
occurrences (all)	0	2	1
Catheter site swelling	Additional description: Catheter site swelling		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Chest discomfort	Additional description: Chest discomfort		
subjects affected / exposed	4 / 228 (1.75%)	1 / 216 (0.46%)	3 / 237 (1.27%)
occurrences (all)	4	1	3
Chest pain	Additional description: Chest pain		
subjects affected / exposed	2 / 228 (0.88%)	11 / 216 (5.09%)	7 / 237 (2.95%)
occurrences (all)	3	11	7
Chills	Additional description: Chills		

subjects affected / exposed	13 / 228 (5.70%)	13 / 216 (6.02%)	13 / 237 (5.49%)
occurrences (all)	13	15	14
Catheter site bruise	Additional description: Catheter site bruise		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Cyst	Additional description: Cyst		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Drug intolerance	Additional description: Drug intolerance		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Discomfort	Additional description: Discomfort		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Extravasation	Additional description: Extravasation		
subjects affected / exposed	0 / 228 (0.00%)	2 / 216 (0.93%)	0 / 237 (0.00%)
occurrences (all)	0	2	0
Face oedema	Additional description: Face oedema		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Fatigue	Additional description: Fatigue		
subjects affected / exposed	76 / 228 (33.33%)	74 / 216 (34.26%)	79 / 237 (33.33%)
occurrences (all)	92	91	92
Feeling cold	Additional description: Feeling cold		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	1	0	1
Gait disturbance	Additional description: Gait disturbance		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Feeling hot	Additional description: Feeling hot		
subjects affected / exposed	2 / 228 (0.88%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	2	1	0
General physical health deterioration	Additional description: General physical health deterioration		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	2 / 237 (0.84%)
occurrences (all)	0	1	2
Inflammation	Additional description: Inflammation		

subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Induration	Additional description: Induration		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Influenza like illness	Additional description: Influenza like illness		
subjects affected / exposed	26 / 228 (11.40%)	10 / 216 (4.63%)	11 / 237 (4.64%)
occurrences (all)	32	11	12
Infusion site extravasation	Additional description: Infusion site extravasation		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	2 / 237 (0.84%)
occurrences (all)	0	1	2
Injection site pain	Additional description: Injection site pain		
subjects affected / exposed	0 / 228 (0.00%)	3 / 216 (1.39%)	0 / 237 (0.00%)
occurrences (all)	0	3	0
Injection site reaction	Additional description: Injection site reaction		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	1 / 237 (0.42%)
occurrences (all)	0	1	1
Injection site swelling	Additional description: Injection site swelling		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	1	1	0
Malaise	Additional description: Malaise		
subjects affected / exposed	6 / 228 (2.63%)	2 / 216 (0.93%)	6 / 237 (2.53%)
occurrences (all)	6	4	6
Mass	Additional description: Mass		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Mucosal inflammation	Additional description: Mucosal inflammation		
subjects affected / exposed	1 / 228 (0.44%)	3 / 216 (1.39%)	3 / 237 (1.27%)
occurrences (all)	1	3	4
Non-cardiac chest pain	Additional description: Non-cardiac chest pain		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	2 / 237 (0.84%)
occurrences (all)	0	1	2
Oedema	Additional description: Oedema		
subjects affected / exposed	5 / 228 (2.19%)	9 / 216 (4.17%)	4 / 237 (1.69%)
occurrences (all)	6	12	5
Oedema peripheral	Additional description: Oedema peripheral		

subjects affected / exposed	6 / 228 (2.63%)	10 / 216 (4.63%)	14 / 237 (5.91%)
occurrences (all)	6	13	14
Pain	Additional description: Pain		
subjects affected / exposed	8 / 228 (3.51%)	4 / 216 (1.85%)	0 / 237 (0.00%)
occurrences (all)	8	4	0
Papillitis	Additional description: Papillitis		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Peripheral oedema neonatal	Additional description: Peripheral oedema neonatal		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling	Additional description: Peripheral swelling		
subjects affected / exposed	3 / 228 (1.32%)	2 / 216 (0.93%)	4 / 237 (1.69%)
occurrences (all)	3	2	4
Pyrexia	Additional description: Pyrexia		
subjects affected / exposed	52 / 228 (22.81%)	45 / 216 (20.83%)	30 / 237 (12.66%)
occurrences (all)	70	67	32
Swelling	Additional description: Swelling		
subjects affected / exposed	2 / 228 (0.88%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	2	0	0
Systemic inflammatory response syndrome	Additional description: Systemic inflammatory response syndrome		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Thirst	Additional description: Thirst		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Tissue infiltration	Additional description: Tissue infiltration		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Anaphylactic reaction	Additional description: Anaphylactic reaction		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Autoimmune disorder	Additional description: Autoimmune disorder		

subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	2 / 237 (0.84%)
occurrences (all)	0	0	2
Cytokine release syndrome	Additional description: Cytokine release syndrome		
subjects affected / exposed	3 / 228 (1.32%)	1 / 216 (0.46%)	4 / 237 (1.69%)
occurrences (all)	4	1	4
Drug hypersensitivity	Additional description: Drug hypersensitivity		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	2 / 237 (0.84%)
occurrences (all)	0	0	2
Hypersensitivity	Additional description: Hypersensitivity		
subjects affected / exposed	10 / 228 (4.39%)	15 / 216 (6.94%)	4 / 237 (1.69%)
occurrences (all)	10	16	5
Hypogammaglobulinaemia	Additional description: Hypogammaglobulinaemia		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	1 / 237 (0.42%)
occurrences (all)	0	1	1
Immune reconstitution inflammatory syndrome	Additional description: Immune reconstitution inflammatory syndrome		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Immunodeficiency	Additional description: Immunodeficiency		
subjects affected / exposed	0 / 228 (0.00%)	2 / 216 (0.93%)	0 / 237 (0.00%)
occurrences (all)	0	2	0
Seasonal allergy	Additional description: Seasonal allergy		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Secondary immunodeficiency	Additional description: Secondary immunodeficiency		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	1 / 237 (0.42%)
occurrences (all)	1	1	1
Selective IgG subclass deficiency	Additional description: Selective IgG subclass deficiency		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Reproductive system and breast disorders			
Balanoposthitis	Additional description: Balanoposthitis		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Benign prostatic hyperplasia	Additional description: Benign prostatic hyperplasia		

subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	1	1	0
Breast induration	Additional description: Breast induration		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Breast pain	Additional description: Breast pain		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	2 / 237 (0.84%)
occurrences (all)	0	1	2
Dyspareunia	Additional description: Dyspareunia		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Endometriosis	Additional description: Endometriosis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Erectile dysfunction	Additional description: Erectile dysfunction		
subjects affected / exposed	2 / 228 (0.88%)	2 / 216 (0.93%)	1 / 237 (0.42%)
occurrences (all)	2	2	1
Haematospermia	Additional description: Haematospermia		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Hypomenorrhoea	Additional description: Hypomenorrhoea		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Menopausal symptoms	Additional description: Menopausal symptoms		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Menorrhagia	Additional description: Menorrhagia		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Menstruation irregular	Additional description: Menstruation irregular		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Nipple pain	Additional description: Nipple pain		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Ovarian hyperfunction	Additional description: Ovarian hyperfunction		

subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Penis disorder	Additional description: Penis disorder		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Pelvic pain	Additional description: Pelvic pain		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Prostatic hypoplasia	Additional description: Prostatic hypoplasia		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Prostatitis	Additional description: Prostatitis		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Scrotal oedema	Additional description: Scrotal oedema		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Testicular disorder	Additional description: Testicular disorder		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Testicular pain	Additional description: Testicular pain		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Vaginal haemorrhage	Additional description: Vaginal haemorrhage		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Vaginal discharge	Additional description: Vaginal discharge		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal pruritus	Additional description: Vulvovaginal pruritus		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Asthma	Additional description: Asthma		

subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Bronchospasm	Additional description: Bronchospasm		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Chronic obstructive pulmonary disease	Additional description: Chronic obstructive pulmonary disease		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	4
Cough	Additional description: Cough		
subjects affected / exposed	37 / 228 (16.23%)	25 / 216 (11.57%)	19 / 237 (8.02%)
occurrences (all)	45	26	20
Dysaesthesia pharynx	Additional description: Dysaesthesia pharynx		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Dysphonia	Additional description: Dysphonia		
subjects affected / exposed	3 / 228 (1.32%)	3 / 216 (1.39%)	4 / 237 (1.69%)
occurrences (all)	3	4	5
Dyspnoea	Additional description: Dyspnoea		
subjects affected / exposed	11 / 228 (4.82%)	14 / 216 (6.48%)	21 / 237 (8.86%)
occurrences (all)	11	14	26
Dyspnoea exertional	Additional description: Dyspnoea exertional		
subjects affected / exposed	3 / 228 (1.32%)	3 / 216 (1.39%)	3 / 237 (1.27%)
occurrences (all)	3	3	3
Epistaxis	Additional description: Epistaxis		
subjects affected / exposed	3 / 228 (1.32%)	3 / 216 (1.39%)	4 / 237 (1.69%)
occurrences (all)	3	3	5
Haemoptysis	Additional description: Haemoptysis		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Hiccups	Additional description: Hiccups		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	2	0
Hyperventilation	Additional description: Hyperventilation		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0

Interstitial lung disease	Additional description: Interstitial lung disease		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Laryngeal inflammation	Additional description: Laryngeal inflammation		
subjects affected / exposed	1 / 228 (0.44%)	2 / 216 (0.93%)	1 / 237 (0.42%)
occurrences (all)	1	2	1
Nasal congestion	Additional description: Nasal congestion		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	1	0	1
Nasal discomfort	Additional description: Nasal discomfort		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Nasal dryness	Additional description: Nasal dryness		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Nasal inflammation	Additional description: Nasal inflammation		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Nasal obstruction	Additional description: Nasal obstruction		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Nasal ulcer	Additional description: Nasal ulcer		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain	Additional description: Oropharyngeal pain		
subjects affected / exposed	13 / 228 (5.70%)	8 / 216 (3.70%)	14 / 237 (5.91%)
occurrences (all)	14	10	16
Pharyngeal inflammation	Additional description: Pharyngeal inflammation		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Pleural effusion	Additional description: Pleural effusion		
subjects affected / exposed	1 / 228 (0.44%)	2 / 216 (0.93%)	0 / 237 (0.00%)
occurrences (all)	1	2	0
Pneumonitis	Additional description: Pneumonitis		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	2 / 237 (0.84%)
occurrences (all)	1	1	2

Productive cough	Additional description: Productive cough		
subjects affected / exposed	1 / 228 (0.44%)	3 / 216 (1.39%)	4 / 237 (1.69%)
occurrences (all)	2	3	4
Pulmonary embolism	Additional description: Pulmonary embolism		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	1	0	1
Pulmonary hypertension	Additional description: Pulmonary hypertension		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Pulmonary pain	Additional description: Pulmonary pain		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic	Additional description: Rhinitis allergic		
subjects affected / exposed	2 / 228 (0.88%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	2	0	2
Respiratory alkalosis	Additional description: Respiratory alkalosis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea	Additional description: Rhinorrhoea		
subjects affected / exposed	3 / 228 (1.32%)	1 / 216 (0.46%)	1 / 237 (0.42%)
occurrences (all)	3	1	1
Sinus pain	Additional description: Sinus pain		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Sleep apnoea syndrome	Additional description: Sleep apnoea syndrome		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Tachypnoea	Additional description: Tachypnoea		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Throat clearing	Additional description: Throat clearing		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Throat irritation	Additional description: Throat irritation		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0

Throatache	Additional description: Throatache		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome	Additional description: Upper-airway cough syndrome		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Wheezing	Additional description: Wheezing		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Abnormal dreams	Additional description: Abnormal dreams		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Agitation	Additional description: Agitation		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	2 / 237 (0.84%)
occurrences (all)	1	1	2
Aggression	Additional description: Aggression		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Adjustment disorder	Additional description: Adjustment disorder		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Anxiety	Additional description: Anxiety		
subjects affected / exposed	3 / 228 (1.32%)	3 / 216 (1.39%)	3 / 237 (1.27%)
occurrences (all)	3	3	3
Apathy	Additional description: Apathy		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Bruxism	Additional description: Bruxism		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Confusional state	Additional description: Confusional state		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Depression	Additional description: Depression		

subjects affected / exposed	2 / 228 (0.88%)	4 / 216 (1.85%)	4 / 237 (1.69%)
occurrences (all)	2	5	4
Delirium	Additional description: Delirium		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Depressed mood	Additional description: Depressed mood		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Disorientation	Additional description: Disorientation		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Hallucination	Additional description: Hallucination		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Hyperarousal	Additional description: Hyperarousal		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Illusion	Additional description: Illusion		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Insomnia	Additional description: Insomnia		
subjects affected / exposed	7 / 228 (3.07%)	11 / 216 (5.09%)	10 / 237 (4.22%)
occurrences (all)	9	11	10
Irritability	Additional description: Irritability		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Panic attack	Additional description: Panic attack		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	2
Restlessness	Additional description: Restlessness		
subjects affected / exposed	2 / 228 (0.88%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	2	0	0
Sleep disorder	Additional description: Sleep disorder		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	6 / 237 (2.53%)
occurrences (all)	1	0	8
Somnambulism	Additional description: Somnambulism		

subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Stress	Additional description: Stress		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Investigations			
Activated partial thromboplastin time prolonged	Additional description: Activated partial thromboplastin time prolonged		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased	Additional description: Alanine aminotransferase increased		
subjects affected / exposed	15 / 228 (6.58%)	1 / 216 (0.46%)	3 / 237 (1.27%)
occurrences (all)	16	1	3
Amylase increased	Additional description: Amylase increased		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Aspartate aminotransferase increased	Additional description: Aspartate aminotransferase increased		
subjects affected / exposed	10 / 228 (4.39%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	10	0	0
Blood immunoglobulin G decreased	Additional description: Blood immunoglobulin G decreased		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Basophil count decreased	Additional description: Basophil count decreased		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Blood alkaline phosphatase increased	Additional description: Blood alkaline phosphatase increased		
subjects affected / exposed	4 / 228 (1.75%)	1 / 216 (0.46%)	2 / 237 (0.84%)
occurrences (all)	4	1	2
Blood bilirubin increased	Additional description: Blood bilirubin increased		
subjects affected / exposed	4 / 228 (1.75%)	0 / 216 (0.00%)	3 / 237 (1.27%)
occurrences (all)	7	0	3
Blood calcium decreased	Additional description: Blood calcium decreased		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Blood chloride increased	Additional description: Blood chloride increased		

subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	2 / 237 (0.84%)
occurrences (all)	0	0	2
Blood creatine increased	Additional description: Blood creatine increased		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Blood creatinine increased	Additional description: Blood creatinine increased		
subjects affected / exposed	5 / 228 (2.19%)	7 / 216 (3.24%)	13 / 237 (5.49%)
occurrences (all)	6	7	19
Blood glucose increased	Additional description: Blood glucose increased		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Blood immunoglobulin M decreased	Additional description: Blood immunoglobulin M decreased		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Blood lactate dehydrogenase increased	Additional description: Blood lactate dehydrogenase increased		
subjects affected / exposed	2 / 228 (0.88%)	1 / 216 (0.46%)	9 / 237 (3.80%)
occurrences (all)	2	1	11
Blood phosphorus increased	Additional description: Blood phosphorus increased		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	6 / 237 (2.53%)
occurrences (all)	1	1	8
Blood potassium decreased	Additional description: Blood potassium decreased		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Blood potassium increased	Additional description: Blood potassium increased		
subjects affected / exposed	2 / 228 (0.88%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	2	0	1
Blood pressure increased	Additional description: Blood pressure increased		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased	Additional description: Blood thyroid stimulating hormone increased		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Blood urea increased	Additional description: Blood urea increased		

subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	2
Blood uric acid decreased	Additional description: Blood uric acid decreased		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Blood uric acid increased	Additional description: Blood uric acid increased		
subjects affected / exposed	2 / 228 (0.88%)	0 / 216 (0.00%)	2 / 237 (0.84%)
occurrences (all)	2	0	2
Body temperature increased	Additional description: Body temperature increased		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Blood iron decreased	Additional description: Blood iron decreased		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Cardiac murmur	Additional description: Cardiac murmur		
subjects affected / exposed	2 / 228 (0.88%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	2	0	0
Bronchoscopy	Additional description: Bronchoscopy		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
C-reactive protein	Additional description: C-reactive protein		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
C-reactive protein increased	Additional description: C-reactive protein increased		
subjects affected / exposed	2 / 228 (0.88%)	2 / 216 (0.93%)	2 / 237 (0.84%)
occurrences (all)	3	2	2
Cortisol decreased	Additional description: Cortisol decreased		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Enterococcus test positive	Additional description: Enterococcus test positive		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Eosinophil count decreased	Additional description: Eosinophil count decreased		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Free haemoglobin present	Additional description: Free haemoglobin present		

subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased	Additional description: Gamma-glutamyltransferase increased		
subjects affected / exposed	6 / 228 (2.63%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	7	1	0
Glomerular filtration rate decreased	Additional description: Glomerular filtration rate decreased		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Heart rate irregular	Additional description: Heart rate irregular		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Hepatic enzyme abnormal	Additional description: Hepatic enzyme abnormal		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased	Additional description: Hepatic enzyme increased		
subjects affected / exposed	5 / 228 (2.19%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	5	0	2
Hepatitis B DNA increased	Additional description: Hepatitis B DNA increased		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Immunoglobulins decreased	Additional description: Immunoglobulins decreased		
subjects affected / exposed	2 / 228 (0.88%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	2	1	0
Inflammatory marker increased	Additional description: Inflammatory marker increased		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
International normalised ratio increased	Additional description: International normalised ratio increased		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Intraocular pressure increased	Additional description: Intraocular pressure increased		
subjects affected / exposed	2 / 228 (0.88%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	2	0	0
Left ventricular end-diastolic pressure decreased	Additional description: Left ventricular end-diastolic pressure decreased		

subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Lipase increased	Additional description: Lipase increased		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Liver function test increased	Additional description: Liver function test increased		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Monocyte count decreased	Additional description: Monocyte count decreased		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	2
Myocardial necrosis marker increased	Additional description: Myocardial necrosis marker increased		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
N-terminal prohormone brain natriuretic peptide increased	Additional description: N-terminal prohormone brain natriuretic peptide increased		
subjects affected / exposed	0 / 228 (0.00%)	2 / 216 (0.93%)	0 / 237 (0.00%)
occurrences (all)	0	2	0
Neutrophil count decreased	Additional description: Neutrophil count decreased		
subjects affected / exposed	33 / 228 (14.47%)	22 / 216 (10.19%)	31 / 237 (13.08%)
occurrences (all)	56	27	44
Platelet count decreased	Additional description: Platelet count decreased		
subjects affected / exposed	14 / 228 (6.14%)	8 / 216 (3.70%)	8 / 237 (3.38%)
occurrences (all)	19	9	8
Procalcitonin increased	Additional description: Procalcitonin increased		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Reticulocyte count decreased	Additional description: Reticulocyte count decreased		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
SARS-CoV-2 test positive	Additional description: SARS-CoV-2 test positive		
subjects affected / exposed	0 / 228 (0.00%)	2 / 216 (0.93%)	1 / 237 (0.42%)
occurrences (all)	0	2	1
Serum ferritin decreased	Additional description: Serum ferritin decreased		

subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Transaminases increased	Additional description: Transaminases increased		
subjects affected / exposed	2 / 228 (0.88%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	2	0	0
Transferrin decreased	Additional description: Transferrin decreased		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 decreased	Additional description: Vitamin B12 decreased		
subjects affected / exposed	2 / 228 (0.88%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	2	0	0
Weight decreased	Additional description: Weight decreased		
subjects affected / exposed	7 / 228 (3.07%)	6 / 216 (2.78%)	2 / 237 (0.84%)
occurrences (all)	9	6	2
Weight increased	Additional description: Weight increased		
subjects affected / exposed	8 / 228 (3.51%)	5 / 216 (2.31%)	6 / 237 (2.53%)
occurrences (all)	8	9	6
White blood cell count decreased	Additional description: White blood cell count decreased		
subjects affected / exposed	8 / 228 (3.51%)	9 / 216 (4.17%)	5 / 237 (2.11%)
occurrences (all)	13	9	8
White blood cell count increased	Additional description: White blood cell count increased		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	1 / 237 (0.42%)
occurrences (all)	0	1	1
Injury, poisoning and procedural complications			
Arthropod bite	Additional description: Arthropod bite		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	4 / 237 (1.69%)
occurrences (all)	1	1	4
Animal bite	Additional description: Animal bite		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Bone contusion	Additional description: Bone contusion		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Chest injury	Additional description: Chest injury		

subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Clavicle fracture	Additional description: Clavicle fracture		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Contusion	Additional description: Contusion		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	1 / 237 (0.42%)
occurrences (all)	1	1	1
Ear canal injury	Additional description: Ear canal injury		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Epicondylitis	Additional description: Epicondylitis		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Face injury	Additional description: Face injury		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Fall	Additional description: Fall		
subjects affected / exposed	5 / 228 (2.19%)	3 / 216 (1.39%)	0 / 237 (0.00%)
occurrences (all)	5	4	0
Foreign body in eye	Additional description: Foreign body in eye		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Fracture	Additional description: Fracture		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Hand fracture	Additional description: Hand fracture		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	1	1	0
Head injury	Additional description: Head injury		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction	Additional description: Infusion related reaction		
subjects affected / exposed	101 / 228 (44.30%)	65 / 216 (30.09%)	67 / 237 (28.27%)
occurrences (all)	111	74	88
Injury	Additional description: Injury		

subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Ligament injury	Additional description: Ligament injury		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Joint capsule rupture	Additional description: Joint capsule rupture		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Ligament sprain	Additional description: Ligament sprain		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Limb injury	Additional description: Limb injury		
subjects affected / exposed	0 / 228 (0.00%)	2 / 216 (0.93%)	0 / 237 (0.00%)
occurrences (all)	0	2	0
Mallet finger	Additional description: Mallet finger		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	1 / 237 (0.42%)
occurrences (all)	0	1	1
Meniscus injury	Additional description: Meniscus injury		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Mouth injury	Additional description: Mouth injury		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Multiple fractures	Additional description: Multiple fractures		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Muscle strain	Additional description: Muscle strain		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Nasal injury	Additional description: Nasal injury		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Paravenous drug administration	Additional description: Paravenous drug administration		
subjects affected / exposed	1 / 228 (0.44%)	2 / 216 (0.93%)	0 / 237 (0.00%)
occurrences (all)	1	2	0
Procedural pain	Additional description: Procedural pain		

subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Post-traumatic neck syndrome	Additional description: Post-traumatic neck syndrome		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Road traffic accident	Additional description: Road traffic accident		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Scar	Additional description: Scar		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Skin abrasion	Additional description: Skin abrasion		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	1	0	1
Skin wound	Additional description: Skin wound		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	1	0	1
Spinal compression fracture	Additional description: Spinal compression fracture		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Spinal fracture	Additional description: Spinal fracture		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Tendon rupture	Additional description: Tendon rupture		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Thermal burn	Additional description: Thermal burn		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	1 / 237 (0.42%)
occurrences (all)	0	1	1
Thoracic vertebral fracture	Additional description: Thoracic vertebral fracture		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Tooth injury	Additional description: Tooth injury		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	1	1	0
Transfusion reaction	Additional description: Transfusion reaction		

subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	1	0	1
Traumatic ear amputation	Additional description: Traumatic ear amputation		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Traumatic haematoma	Additional description: Traumatic haematoma		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Vascular access complication	Additional description: Vascular access complication		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Wrist fracture	Additional description: Wrist fracture		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Wound	Additional description: Wound		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Wound complication	Additional description: Wound complication		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	2 / 237 (0.84%)
occurrences (all)	0	0	2
Congenital, familial and genetic disorders			
Cryptorchism	Additional description: Cryptorchism		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Glycogen storage disease type I	Additional description: Glycogen storage disease type I		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Hydrocele	Additional description: Hydrocele		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Ichthyosis	Additional description: Ichthyosis		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Phimosis	Additional description: Phimosis		

subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Cardiac disorders			
Acute coronary syndrome	Additional description: Acute coronary syndrome		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Angina pectoris	Additional description: Angina pectoris		
subjects affected / exposed	3 / 228 (1.32%)	2 / 216 (0.93%)	4 / 237 (1.69%)
occurrences (all)	3	2	5
Arteriosclerosis coronary artery	Additional description: Arteriosclerosis coronary artery		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Arrhythmia	Additional description: Arrhythmia		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	1 / 237 (0.42%)
occurrences (all)	1	1	1
Atrial fibrillation	Additional description: Atrial fibrillation		
subjects affected / exposed	5 / 228 (2.19%)	5 / 216 (2.31%)	5 / 237 (2.11%)
occurrences (all)	5	5	6
Atrial flutter	Additional description: Atrial flutter		
subjects affected / exposed	0 / 228 (0.00%)	2 / 216 (0.93%)	1 / 237 (0.42%)
occurrences (all)	0	3	1
Atrial thrombosis	Additional description: Atrial thrombosis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Atrioventricular block second degree	Additional description: Atrioventricular block second degree		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Bradycardia	Additional description: Bradycardia		
subjects affected / exposed	1 / 228 (0.44%)	2 / 216 (0.93%)	1 / 237 (0.42%)
occurrences (all)	1	2	1
Bundle branch block right	Additional description: Bundle branch block right		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Cardiac discomfort	Additional description: Cardiac discomfort		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1

Cardiac failure	Additional description: Cardiac failure		
subjects affected / exposed	1 / 228 (0.44%)	3 / 216 (1.39%)	2 / 237 (0.84%)
occurrences (all)	1	3	2
Cardiovascular disorder	Additional description: Cardiovascular disorder		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	1 / 237 (0.42%)
occurrences (all)	0	1	1
Coronary artery disease	Additional description: Coronary artery disease		
subjects affected / exposed	2 / 228 (0.88%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	2	0	0
Coronary artery stenosis	Additional description: Coronary artery stenosis		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Extrasystoles	Additional description: Extrasystoles		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Hypertensive heart disease	Additional description: Hypertensive heart disease		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Myocardial ischaemia	Additional description: Myocardial ischaemia		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Palpitations	Additional description: Palpitations		
subjects affected / exposed	3 / 228 (1.32%)	2 / 216 (0.93%)	3 / 237 (1.27%)
occurrences (all)	3	2	3
Pericardial effusion	Additional description: Pericardial effusion		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Right ventricular failure	Additional description: Right ventricular failure		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Sinus tachycardia	Additional description: Sinus tachycardia		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	1	0	1
Supraventricular tachycardia	Additional description: Supraventricular tachycardia		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0

Tachycardia	Additional description: Tachycardia		
subjects affected / exposed	3 / 228 (1.32%)	2 / 216 (0.93%)	4 / 237 (1.69%)
occurrences (all)	4	2	4
Tachycardia paroxysmal	Additional description: Tachycardia paroxysmal		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Ventricular extrasystoles	Additional description: Ventricular extrasystoles		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	2 / 237 (0.84%)
occurrences (all)	0	0	2
Nervous system disorders			
Ageusia	Additional description: Ageusia		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Amnesia	Additional description: Amnesia		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	1	0	1
Aphasia	Additional description: Aphasia		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	2 / 237 (0.84%)
occurrences (all)	1	0	2
Ataxia	Additional description: Ataxia		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Balance disorder	Additional description: Balance disorder		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Burning sensation	Additional description: Burning sensation		
subjects affected / exposed	2 / 228 (0.88%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	2	0	0
Carpal tunnel syndrome	Additional description: Carpal tunnel syndrome		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	4 / 237 (1.69%)
occurrences (all)	1	0	4
Cervicobrachial syndrome	Additional description: Cervicobrachial syndrome		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Carotid artery stenosis	Additional description: Carotid artery stenosis		

subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Concentration impairment	Additional description: Concentration impairment		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Cognitive disorder	Additional description: Cognitive disorder		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Cubital tunnel syndrome	Additional description: Cubital tunnel syndrome		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Depressed level of consciousness	Additional description: Depressed level of consciousness		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention	Additional description: Disturbance in attention		
subjects affected / exposed	5 / 228 (2.19%)	2 / 216 (0.93%)	3 / 237 (1.27%)
occurrences (all)	5	2	3
Dizziness	Additional description: Dizziness		
subjects affected / exposed	21 / 228 (9.21%)	12 / 216 (5.56%)	20 / 237 (8.44%)
occurrences (all)	28	15	24
Dizziness postural	Additional description: Dizziness postural		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Dysaesthesia	Additional description: Dysaesthesia		
subjects affected / exposed	2 / 228 (0.88%)	2 / 216 (0.93%)	2 / 237 (0.84%)
occurrences (all)	2	2	2
Dysgeusia	Additional description: Dysgeusia		
subjects affected / exposed	6 / 228 (2.63%)	9 / 216 (4.17%)	3 / 237 (1.27%)
occurrences (all)	6	9	3
Facial paralysis	Additional description: Facial paralysis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Formication	Additional description: Formication		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Hand-arm vibration syndrome	Additional description: Hand-arm vibration syndrome		

subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Head discomfort	Additional description: Head discomfort		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	1	1	0
Headache	Additional description: Headache		
subjects affected / exposed	36 / 228 (15.79%)	22 / 216 (10.19%)	23 / 237 (9.70%)
occurrences (all)	45	29	26
Hypoaesthesia	Additional description: Hypoaesthesia		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	2 / 237 (0.84%)
occurrences (all)	0	1	2
Hypertonia	Additional description: Hypertonia		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Hypotonia	Additional description: Hypotonia		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Intention tremor	Additional description: Intention tremor		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Lumbar radiculopathy	Additional description: Lumbar radiculopathy		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Memory impairment	Additional description: Memory impairment		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	1	0	2
Mental impairment	Additional description: Mental impairment		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Migraine	Additional description: Migraine		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	1 / 237 (0.42%)
occurrences (all)	1	1	1
Muscle spasticity	Additional description: Muscle spasticity		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Neuromuscular blockade	Additional description: Neuromuscular blockade		

subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Olfactory nerve disorder	Additional description: Olfactory nerve disorder		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral	Additional description: Neuropathy peripheral		
subjects affected / exposed	3 / 228 (1.32%)	4 / 216 (1.85%)	1 / 237 (0.42%)
occurrences (all)	3	4	1
Orthostatic intolerance	Additional description: Orthostatic intolerance		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Paraesthesia	Additional description: Paraesthesia		
subjects affected / exposed	3 / 228 (1.32%)	4 / 216 (1.85%)	3 / 237 (1.27%)
occurrences (all)	3	4	3
Parkinson's disease	Additional description: Parkinson's disease		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Parosmia	Additional description: Parosmia		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Peripheral motor neuropathy	Additional description: Peripheral motor neuropathy		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy	Additional description: Peripheral sensory neuropathy		
subjects affected / exposed	3 / 228 (1.32%)	2 / 216 (0.93%)	5 / 237 (2.11%)
occurrences (all)	4	2	5
Polyneuropathy	Additional description: Polyneuropathy		
subjects affected / exposed	3 / 228 (1.32%)	3 / 216 (1.39%)	2 / 237 (0.84%)
occurrences (all)	3	4	2
Post herpetic neuralgia	Additional description: Post herpetic neuralgia		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Presyncope	Additional description: Presyncope		
subjects affected / exposed	0 / 228 (0.00%)	2 / 216 (0.93%)	0 / 237 (0.00%)
occurrences (all)	0	2	0
Restless legs syndrome	Additional description: Restless legs syndrome		

subjects affected / exposed	2 / 228 (0.88%)	0 / 216 (0.00%)	2 / 237 (0.84%)
occurrences (all)	2	0	2
Sciatica	Additional description: Sciatica		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	1	1	0
Sensory disturbance	Additional description: Sensory disturbance		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	1	0	1
Syncope	Additional description: Syncope		
subjects affected / exposed	4 / 228 (1.75%)	4 / 216 (1.85%)	2 / 237 (0.84%)
occurrences (all)	4	4	2
Somnolence	Additional description: Somnolence		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Taste disorder	Additional description: Taste disorder		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	1 / 237 (0.42%)
occurrences (all)	1	1	1
Transient global amnesia	Additional description: Transient global amnesia		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Tremor	Additional description: Tremor		
subjects affected / exposed	3 / 228 (1.32%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	3	0	1
Trigeminal neuralgia	Additional description: Trigeminal neuralgia		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Visual field defect	Additional description: Visual field defect		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	2 / 237 (0.84%)
occurrences (all)	0	0	3
Blood and lymphatic system disorders			
Agranulocytosis	Additional description: Agranulocytosis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Anaemia	Additional description: Anaemia		
subjects affected / exposed	17 / 228 (7.46%)	31 / 216 (14.35%)	20 / 237 (8.44%)
occurrences (all)	21	42	27

Autoimmune haemolytic anaemia	Additional description: Autoimmune haemolytic anaemia		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Bicytopenia	Additional description: Bicytopenia		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Eosinophilia	Additional description: Eosinophilia		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Febrile neutropenia	Additional description: Febrile neutropenia		
subjects affected / exposed	2 / 228 (0.88%)	6 / 216 (2.78%)	3 / 237 (1.27%)
occurrences (all)	4	6	3
Granulocytopenia	Additional description: Granulocytopenia		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	2 / 237 (0.84%)
occurrences (all)	0	0	2
Haemolysis	Additional description: Haemolysis		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	1	0	1
Haemorrhagic diathesis	Additional description: Haemorrhagic diathesis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Hypoglobulinaemia	Additional description: Hypoglobulinaemia		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Immune thrombocytopenia	Additional description: Immune thrombocytopenia		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	1 / 237 (0.42%)
occurrences (all)	0	1	1
Iron deficiency anaemia	Additional description: Iron deficiency anaemia		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Leukocytosis	Additional description: Leukocytosis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	2 / 237 (0.84%)
occurrences (all)	0	0	2
Leukopenia	Additional description: Leukopenia		
subjects affected / exposed	20 / 228 (8.77%)	33 / 216 (15.28%)	12 / 237 (5.06%)
occurrences (all)	30	48	22

Lymph node pain	Additional description: Lymph node pain		
subjects affected / exposed	2 / 228 (0.88%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	2	1	0
Lymphadenitis	Additional description: Lymphadenitis		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Lymphadenopathy	Additional description: Lymphadenopathy		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Macrocytosis	Additional description: Macrocytosis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Microcytic anaemia	Additional description: Microcytic anaemia		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Neutropenia	Additional description: Neutropenia		
subjects affected / exposed	111 / 228 (48.68%)	107 / 216 (49.54%)	108 / 237 (45.57%)
occurrences (all)	272	209	231
Pancytopenia	Additional description: Pancytopenia		
subjects affected / exposed	0 / 228 (0.00%)	2 / 216 (0.93%)	0 / 237 (0.00%)
occurrences (all)	0	2	0
Reticulocytosis	Additional description: Reticulocytosis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Thrombocytopenia	Additional description: Thrombocytopenia		
subjects affected / exposed	34 / 228 (14.91%)	32 / 216 (14.81%)	18 / 237 (7.59%)
occurrences (all)	40	44	28
Ear and labyrinth disorders			
Auditory disorder	Additional description: Auditory disorder		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Deafness	Additional description: Deafness		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Deafness unilateral	Additional description: Deafness unilateral		

subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Ear haemorrhage	Additional description: Ear haemorrhage		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Ear pain	Additional description: Ear pain		
subjects affected / exposed	1 / 228 (0.44%)	3 / 216 (1.39%)	3 / 237 (1.27%)
occurrences (all)	1	3	3
Hypoacusis	Additional description: Hypoacusis		
subjects affected / exposed	2 / 228 (0.88%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	2	1	0
Middle ear effusion	Additional description: Middle ear effusion		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Middle ear inflammation	Additional description: Middle ear inflammation		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Tinnitus	Additional description: Tinnitus		
subjects affected / exposed	6 / 228 (2.63%)	0 / 216 (0.00%)	4 / 237 (1.69%)
occurrences (all)	6	0	4
Vertigo positional	Additional description: Vertigo positional		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Vertigo	Additional description: Vertigo		
subjects affected / exposed	6 / 228 (2.63%)	8 / 216 (3.70%)	9 / 237 (3.80%)
occurrences (all)	6	8	9
Eye disorders			
Blepharitis	Additional description: Blepharitis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Cataract	Additional description: Cataract		
subjects affected / exposed	2 / 228 (0.88%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	2	0	1
Conjunctival haemorrhage	Additional description: Conjunctival haemorrhage		
subjects affected / exposed	2 / 228 (0.88%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	2	0	0

Corneal erosion	Additional description: Corneal erosion		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Diplopia	Additional description: Diplopia		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Dry eye	Additional description: Dry eye		
subjects affected / exposed	1 / 228 (0.44%)	2 / 216 (0.93%)	1 / 237 (0.42%)
occurrences (all)	1	2	1
Erythema of eyelid	Additional description: Erythema of eyelid		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Exophthalmos	Additional description: Exophthalmos		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Eye haemorrhage	Additional description: Eye haemorrhage		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	2 / 237 (0.84%)
occurrences (all)	0	0	2
Eye inflammation	Additional description: Eye inflammation		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Eye irritation	Additional description: Eye irritation		
subjects affected / exposed	0 / 228 (0.00%)	2 / 216 (0.93%)	0 / 237 (0.00%)
occurrences (all)	0	2	0
Eye oedema	Additional description: Eye oedema		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	1	0	1
Eye pain	Additional description: Eye pain		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Eyelid haematoma	Additional description: Eyelid haematoma		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Eyelid oedema	Additional description: Eyelid oedema		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1

Eyelid ptosis	Additional description: Eyelid ptosis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Eye disorder	Additional description: Eye disorder		
subjects affected / exposed	2 / 228 (0.88%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	2	0	0
Glaucoma	Additional description: Glaucoma		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	1	0	1
Hyalosis asteroid	Additional description: Hyalosis asteroid		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Lacrimation increased	Additional description: Lacrimation increased		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Ocular hyperaemia	Additional description: Ocular hyperaemia		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	1 / 237 (0.42%)
occurrences (all)	0	1	1
Ocular hypertension	Additional description: Ocular hypertension		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Panophthalmitis	Additional description: Panophthalmitis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Periorbital oedema	Additional description: Periorbital oedema		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Photophobia	Additional description: Photophobia		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Retinal haemorrhage	Additional description: Retinal haemorrhage		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Uveitis	Additional description: Uveitis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0

Vitreous detachment	Additional description: Vitreous detachment		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Vitreous disorder	Additional description: Vitreous disorder		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	1	1	0
Vitreous haemorrhage	Additional description: Vitreous haemorrhage		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Visual impairment	Additional description: Visual impairment		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	3 / 237 (1.27%)
occurrences (all)	1	1	3
Vision blurred	Additional description: Vision blurred		
subjects affected / exposed	4 / 228 (1.75%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	4	0	1
Gastrointestinal disorders			
Abdominal pain upper	Additional description: Abdominal pain upper		
subjects affected / exposed	11 / 228 (4.82%)	8 / 216 (3.70%)	11 / 237 (4.64%)
occurrences (all)	12	8	12
Abdominal pain lower	Additional description: Abdominal pain lower		
subjects affected / exposed	1 / 228 (0.44%)	3 / 216 (1.39%)	0 / 237 (0.00%)
occurrences (all)	1	3	0
Abdominal pain	Additional description: Abdominal pain		
subjects affected / exposed	6 / 228 (2.63%)	5 / 216 (2.31%)	14 / 237 (5.91%)
occurrences (all)	6	6	17
Abdominal distension	Additional description: Abdominal distension		
subjects affected / exposed	3 / 228 (1.32%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	3	1	0
Abdominal discomfort	Additional description: Abdominal discomfort		
subjects affected / exposed	3 / 228 (1.32%)	2 / 216 (0.93%)	4 / 237 (1.69%)
occurrences (all)	3	2	4
Anal ulcer	Additional description: Anal ulcer		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Anal pruritus	Additional description: Anal pruritus		

subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	1	0	1
Anal incontinence	Additional description: Anal incontinence		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	1	0	1
Anal haemorrhage	Additional description: Anal haemorrhage		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Anal fissure	Additional description: Anal fissure		
subjects affected / exposed	0 / 228 (0.00%)	3 / 216 (1.39%)	0 / 237 (0.00%)
occurrences (all)	0	3	0
Angular cheilitis	Additional description: Angular cheilitis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer	Additional description: Aphthous ulcer		
subjects affected / exposed	3 / 228 (1.32%)	0 / 216 (0.00%)	2 / 237 (0.84%)
occurrences (all)	3	0	2
Cheilitis	Additional description: Cheilitis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Coeliac disease	Additional description: Coeliac disease		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Colitis	Additional description: Colitis		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Constipation	Additional description: Constipation		
subjects affected / exposed	28 / 228 (12.28%)	64 / 216 (29.63%)	28 / 237 (11.81%)
occurrences (all)	31	73	31
Crohn's disease	Additional description: Crohn's disease		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Dental caries	Additional description: Dental caries		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Diarrhoea	Additional description: Diarrhoea		

subjects affected / exposed	74 / 228 (32.46%)	27 / 216 (12.50%)	72 / 237 (30.38%)
occurrences (all)	108	31	97
Diarrhoea haemorrhagic	Additional description: Diarrhoea haemorrhagic		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Defaecation disorder	Additional description: Defaecation disorder		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Diverticulum intestinal	Additional description: Diverticulum intestinal		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Dry mouth	Additional description: Dry mouth		
subjects affected / exposed	3 / 228 (1.32%)	5 / 216 (2.31%)	2 / 237 (0.84%)
occurrences (all)	3	5	2
Dyspepsia	Additional description: Dyspepsia		
subjects affected / exposed	17 / 228 (7.46%)	3 / 216 (1.39%)	10 / 237 (4.22%)
occurrences (all)	19	3	10
Dysphagia	Additional description: Dysphagia		
subjects affected / exposed	2 / 228 (0.88%)	3 / 216 (1.39%)	2 / 237 (0.84%)
occurrences (all)	2	3	2
Enterovirus infection	Additional description: Enterovirus infection		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Epigastric discomfort	Additional description: Epigastric discomfort		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	3 / 237 (1.27%)
occurrences (all)	0	0	3
Faeces discoloured	Additional description: Faeces discoloured		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Gastric haemorrhage	Additional description: Gastric haemorrhage		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Flatulence	Additional description: Flatulence		
subjects affected / exposed	9 / 228 (3.95%)	3 / 216 (1.39%)	4 / 237 (1.69%)
occurrences (all)	11	3	4
Food poisoning	Additional description: Food poisoning		

subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Frequent bowel movements	Additional description: Frequent bowel movements		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Giant cell epulis	Additional description: Giant cell epulis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Gingival bleeding	Additional description: Gingival bleeding		
subjects affected / exposed	2 / 228 (0.88%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	2	1	0
Gastritis	Additional description: Gastritis		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	1 / 237 (0.42%)
occurrences (all)	1	1	1
Gastrointestinal haemorrhage	Additional description: Gastrointestinal haemorrhage		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal motility disorder	Additional description: Gastrointestinal motility disorder		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal pain	Additional description: Gastrointestinal pain		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal tract irritation	Additional description: Gastrointestinal tract irritation		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Gastrooesophageal reflux disease	Additional description: Gastrooesophageal reflux disease		
subjects affected / exposed	2 / 228 (0.88%)	5 / 216 (2.31%)	9 / 237 (3.80%)
occurrences (all)	2	5	9
Gingival discolouration	Additional description: Gingival discolouration		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Haemorrhoidal haemorrhage	Additional description: Haemorrhoidal haemorrhage		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Haematochezia	Additional description: Haematochezia		

subjects affected / exposed	2 / 228 (0.88%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	2	0	1
Haemorrhoids	Additional description: Haemorrhoids		
subjects affected / exposed	4 / 228 (1.75%)	1 / 216 (0.46%)	3 / 237 (1.27%)
occurrences (all)	4	1	3
Inguinal hernia	Additional description: Inguinal hernia		
subjects affected / exposed	2 / 228 (0.88%)	0 / 216 (0.00%)	2 / 237 (0.84%)
occurrences (all)	2	0	2
Lip dry	Additional description: Lip dry		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Lip pain	Additional description: Lip pain		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Mouth haemorrhage	Additional description: Mouth haemorrhage		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Mouth ulceration	Additional description: Mouth ulceration		
subjects affected / exposed	2 / 228 (0.88%)	2 / 216 (0.93%)	3 / 237 (1.27%)
occurrences (all)	2	2	6
Nausea	Additional description: Nausea		
subjects affected / exposed	69 / 228 (30.26%)	93 / 216 (43.06%)	64 / 237 (27.00%)
occurrences (all)	87	132	86
Odynophagia	Additional description: Odynophagia		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Oesophagitis	Additional description: Oesophagitis		
subjects affected / exposed	2 / 228 (0.88%)	0 / 216 (0.00%)	2 / 237 (0.84%)
occurrences (all)	2	0	2
Oral dysaesthesia	Additional description: Oral dysaesthesia		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Oral mucosal blistering	Additional description: Oral mucosal blistering		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Oral mucosal erythema	Additional description: Oral mucosal erythema		

subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Oral pain	Additional description: Oral pain		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral	Additional description: Paraesthesia oral		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Periodontal disease	Additional description: Periodontal disease		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Proctalgia	Additional description: Proctalgia		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Rectal haemorrhage	Additional description: Rectal haemorrhage		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	1	0	1
Rectal polyp	Additional description: Rectal polyp		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	1	0	1
Salivary gland calculus	Additional description: Salivary gland calculus		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Stomatitis	Additional description: Stomatitis		
subjects affected / exposed	6 / 228 (2.63%)	3 / 216 (1.39%)	3 / 237 (1.27%)
occurrences (all)	6	3	5
Tongue coated	Additional description: Tongue coated		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Tongue discomfort	Additional description: Tongue discomfort		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Tongue disorder	Additional description: Tongue disorder		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Tongue dry	Additional description: Tongue dry		

subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Tooth loss	Additional description: Tooth loss		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Toothache	Additional description: Toothache		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	4 / 237 (1.69%)
occurrences (all)	1	0	4
Vomiting	Additional description: Vomiting		
subjects affected / exposed	14 / 228 (6.14%)	40 / 216 (18.52%)	16 / 237 (6.75%)
occurrences (all)	17	55	21
Hepatobiliary disorders			
Cholecystitis	Additional description: Cholecystitis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Cholelithiasis	Additional description: Cholelithiasis		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Hepatic pain	Additional description: Hepatic pain		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Hepatic steatosis	Additional description: Hepatic steatosis		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Hepatotoxicity	Additional description: Hepatotoxicity		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	1	0	1
Hyperbilirubinaemia	Additional description: Hyperbilirubinaemia		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Liver disorder	Additional description: Liver disorder		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Portal vein dilatation	Additional description: Portal vein dilatation		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1

Portal vein thrombosis	Additional description: Portal vein thrombosis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Actinic keratosis	Additional description: Actinic keratosis		
subjects affected / exposed	5 / 228 (2.19%)	0 / 216 (0.00%)	5 / 237 (2.11%)
occurrences (all)	5	0	5
Alopecia	Additional description: Alopecia		
subjects affected / exposed	2 / 228 (0.88%)	4 / 216 (1.85%)	6 / 237 (2.53%)
occurrences (all)	2	4	6
Blister	Additional description: Blister		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	1 / 237 (0.42%)
occurrences (all)	1	1	1
Blood blister	Additional description: Blood blister		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Cafe au lait spots	Additional description: Cafe au lait spots		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Dermatitis	Additional description: Dermatitis		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	2 / 237 (0.84%)
occurrences (all)	1	0	2
Dermatitis acneiform	Additional description: Dermatitis acneiform		
subjects affected / exposed	1 / 228 (0.44%)	2 / 216 (0.93%)	0 / 237 (0.00%)
occurrences (all)	1	2	0
Dermatitis allergic	Additional description: Dermatitis allergic		
subjects affected / exposed	1 / 228 (0.44%)	2 / 216 (0.93%)	0 / 237 (0.00%)
occurrences (all)	1	3	0
Dermatitis atopic	Additional description: Dermatitis atopic		
subjects affected / exposed	2 / 228 (0.88%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	2	0	0
Dermatitis contact	Additional description: Dermatitis contact		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Dermatitis exfoliative	Additional description: Dermatitis exfoliative		

subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Dermatitis exfoliative generalised	Additional description: Dermatitis exfoliative generalised		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Decubitus ulcer	Additional description: Decubitus ulcer		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Drug eruption	Additional description: Drug eruption		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Dry skin	Additional description: Dry skin		
subjects affected / exposed	16 / 228 (7.02%)	8 / 216 (3.70%)	8 / 237 (3.38%)
occurrences (all)	18	8	8
Ecchymosis	Additional description: Ecchymosis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Eczema	Additional description: Eczema		
subjects affected / exposed	5 / 228 (2.19%)	3 / 216 (1.39%)	13 / 237 (5.49%)
occurrences (all)	5	3	13
Eczema nummular	Additional description: Eczema nummular		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Erythema	Additional description: Erythema		
subjects affected / exposed	6 / 228 (2.63%)	3 / 216 (1.39%)	3 / 237 (1.27%)
occurrences (all)	7	4	4
Erythema nodosum	Additional description: Erythema nodosum		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Eosinophilic cellulitis	Additional description: Eosinophilic cellulitis		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Erythema multiforme	Additional description: Erythema multiforme		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Hand dermatitis	Additional description: Hand dermatitis		

subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Hyperkeratosis	Additional description: Hyperkeratosis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Hyperhidrosis	Additional description: Hyperhidrosis		
subjects affected / exposed	7 / 228 (3.07%)	3 / 216 (1.39%)	3 / 237 (1.27%)
occurrences (all)	8	3	3
Hypertrichosis	Additional description: Hypertrichosis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Intertrigo	Additional description: Intertrigo		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Lentigo	Additional description: Lentigo		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Lichen planus	Additional description: Lichen planus		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Neurodermatitis	Additional description: Neurodermatitis		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Nail discolouration	Additional description: Nail discolouration		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Nail dystrophy	Additional description: Nail dystrophy		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Nail pitting	Additional description: Nail pitting		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Nail ridging	Additional description: Nail ridging		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Nail toxicity	Additional description: Nail toxicity		

subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Night sweats	Additional description: Night sweats		
subjects affected / exposed	7 / 228 (3.07%)	8 / 216 (3.70%)	4 / 237 (1.69%)
occurrences (all)	7	9	4
Onychoclasis	Additional description: Onychoclasis		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	2 / 237 (0.84%)
occurrences (all)	0	1	2
Onycholysis	Additional description: Onycholysis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Papule	Additional description: Papule		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Pemphigoid	Additional description: Pemphigoid		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Petechiae	Additional description: Petechiae		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	1	1	0
Pigmentation disorder	Additional description: Pigmentation disorder		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Rash generalised	Additional description: Rash generalised		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Rash erythematous	Additional description: Rash erythematous		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Pruritus	Additional description: Pruritus		
subjects affected / exposed	15 / 228 (6.58%)	17 / 216 (7.87%)	19 / 237 (8.02%)
occurrences (all)	16	17	20
Pruritus generalised	Additional description: Pruritus generalised		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Psoriasis	Additional description: Psoriasis		

subjects affected / exposed	4 / 228 (1.75%)	2 / 216 (0.93%)	3 / 237 (1.27%)
occurrences (all)	4	2	3
Purpura	Additional description: Purpura		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Rash	Additional description: Rash		
subjects affected / exposed	27 / 228 (11.84%)	33 / 216 (15.28%)	32 / 237 (13.50%)
occurrences (all)	29	38	36
Rash macular	Additional description: Rash macular		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Rash maculo-papular	Additional description: Rash maculo-papular		
subjects affected / exposed	3 / 228 (1.32%)	10 / 216 (4.63%)	8 / 237 (3.38%)
occurrences (all)	3	14	9
Rash pruritic	Additional description: Rash pruritic		
subjects affected / exposed	1 / 228 (0.44%)	2 / 216 (0.93%)	0 / 237 (0.00%)
occurrences (all)	1	2	0
Rash papular	Additional description: Rash papular		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Rosacea	Additional description: Rosacea		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	1	0	1
Solar dermatitis	Additional description: Solar dermatitis		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Skin burning sensation	Additional description: Skin burning sensation		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Skin discolouration	Additional description: Skin discolouration		
subjects affected / exposed	2 / 228 (0.88%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	2	0	0
Skin discomfort	Additional description: Skin discomfort		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Skin disorder	Additional description: Skin disorder		

subjects affected / exposed	2 / 228 (0.88%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	2	0	0
Skin fissures	Additional description: Skin fissures		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Skin hypopigmentation	Additional description: Skin hypopigmentation		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Skin irritation	Additional description: Skin irritation		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Skin lesion	Additional description: Skin lesion		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	1	0	1
Skin mass	Additional description: Skin mass		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	1	0	1
Skin ulcer	Additional description: Skin ulcer		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Suggillation	Additional description: Suggillation		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Telangiectasia	Additional description: Telangiectasia		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Toxic skin eruption	Additional description: Toxic skin eruption		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	1	1	0
Urticaria	Additional description: Urticaria		
subjects affected / exposed	1 / 228 (0.44%)	3 / 216 (1.39%)	2 / 237 (0.84%)
occurrences (all)	1	3	3
Renal and urinary disorders			
Acute kidney injury	Additional description: Acute kidney injury		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	2 / 237 (0.84%)
occurrences (all)	2	1	2

Chromaturia	Additional description: Chromaturia		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Chronic kidney disease	Additional description: Chronic kidney disease		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Cystitis noninfective	Additional description: Cystitis noninfective		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Dysuria	Additional description: Dysuria		
subjects affected / exposed	2 / 228 (0.88%)	6 / 216 (2.78%)	1 / 237 (0.42%)
occurrences (all)	4	6	1
Haematuria	Additional description: Haematuria		
subjects affected / exposed	1 / 228 (0.44%)	2 / 216 (0.93%)	2 / 237 (0.84%)
occurrences (all)	1	2	2
Hydronephrosis	Additional description: Hydronephrosis		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Incontinence	Additional description: Incontinence		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Kidney congestion	Additional description: Kidney congestion		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Leukocyturia	Additional description: Leukocyturia		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Lower urinary tract symptoms	Additional description: Lower urinary tract symptoms		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Micturition disorder	Additional description: Micturition disorder		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Micturition urgency	Additional description: Micturition urgency		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0

Nocturia	Additional description: Nocturia		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	4 / 237 (1.69%)
occurrences (all)	1	1	4
Pollakiuria	Additional description: Pollakiuria		
subjects affected / exposed	3 / 228 (1.32%)	2 / 216 (0.93%)	2 / 237 (0.84%)
occurrences (all)	3	2	2
Polyuria	Additional description: Polyuria		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Renal colic	Additional description: Renal colic		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Renal cyst	Additional description: Renal cyst		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Renal failure	Additional description: Renal failure		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	2
Renal pain	Additional description: Renal pain		
subjects affected / exposed	0 / 228 (0.00%)	3 / 216 (1.39%)	0 / 237 (0.00%)
occurrences (all)	0	3	0
Strangury	Additional description: Strangury		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence	Additional description: Urinary incontinence		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Urinary tract pain	Additional description: Urinary tract pain		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Urinary tract obstruction	Additional description: Urinary tract obstruction		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Urinary tract inflammation	Additional description: Urinary tract inflammation		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0

Urinary retention	Additional description: Urinary retention		
subjects affected / exposed	2 / 228 (0.88%)	1 / 216 (0.46%)	2 / 237 (0.84%)
occurrences (all)	3	1	2
Urge incontinence	Additional description: Urge incontinence		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Goitre	Additional description: Goitre		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism	Additional description: Hyperthyroidism		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Hypothyroidism	Additional description: Hypothyroidism		
subjects affected / exposed	3 / 228 (1.32%)	0 / 216 (0.00%)	2 / 237 (0.84%)
occurrences (all)	3	0	2
Thyroid cyst	Additional description: Thyroid cyst		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Arthropathy	Additional description: Arthropathy		
subjects affected / exposed	2 / 228 (0.88%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	2	0	1
Arthritis	Additional description: Arthritis		
subjects affected / exposed	3 / 228 (1.32%)	2 / 216 (0.93%)	4 / 237 (1.69%)
occurrences (all)	4	3	5
Arthralgia	Additional description: Arthralgia		
subjects affected / exposed	33 / 228 (14.47%)	8 / 216 (3.70%)	25 / 237 (10.55%)
occurrences (all)	42	8	26
Back pain	Additional description: Back pain		
subjects affected / exposed	24 / 228 (10.53%)	12 / 216 (5.56%)	26 / 237 (10.97%)
occurrences (all)	26	13	27
Bone pain	Additional description: Bone pain		
subjects affected / exposed	10 / 228 (4.39%)	2 / 216 (0.93%)	6 / 237 (2.53%)
occurrences (all)	10	2	6
Bursal haematoma	Additional description: Bursal haematoma		

subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Bursitis	Additional description: Bursitis		
subjects affected / exposed	4 / 228 (1.75%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	4	0	0
Cervical spinal stenosis	Additional description: Cervical spinal stenosis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Exostosis	Additional description: Exostosis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Fibromyalgia	Additional description: Fibromyalgia		
subjects affected / exposed	2 / 228 (0.88%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	2	0	1
Flank pain	Additional description: Flank pain		
subjects affected / exposed	4 / 228 (1.75%)	3 / 216 (1.39%)	1 / 237 (0.42%)
occurrences (all)	4	3	1
Groin pain	Additional description: Groin pain		
subjects affected / exposed	3 / 228 (1.32%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	3	1	0
Hypercreatinaemia	Additional description: Hypercreatinaemia		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Intervertebral disc disorder	Additional description: Intervertebral disc disorder		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Intervertebral disc protrusion	Additional description: Intervertebral disc protrusion		
subjects affected / exposed	2 / 228 (0.88%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	2	0	1
Joint effusion	Additional description: Joint effusion		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Joint range of motion decreased	Additional description: Joint range of motion decreased		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	1 / 237 (0.42%)
occurrences (all)	0	1	1
Joint swelling	Additional description: Joint swelling		

subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	3 / 237 (1.27%)
occurrences (all)	1	0	4
Limb discomfort	Additional description: Limb discomfort		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Mobility decreased	Additional description: Mobility decreased		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Muscle fatigue	Additional description: Muscle fatigue		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	2
Muscle hypertrophy	Additional description: Muscle hypertrophy		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Muscle spasms	Additional description: Muscle spasms		
subjects affected / exposed	6 / 228 (2.63%)	5 / 216 (2.31%)	10 / 237 (4.22%)
occurrences (all)	7	5	11
Muscle tightness	Additional description: Muscle tightness		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Muscle twitching	Additional description: Muscle twitching		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Muscular weakness	Additional description: Muscular weakness		
subjects affected / exposed	2 / 228 (0.88%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	2	1	0
Musculoskeletal chest pain	Additional description: Musculoskeletal chest pain		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	1	1	0
Musculoskeletal discomfort	Additional description: Musculoskeletal discomfort		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain	Additional description: Musculoskeletal pain		
subjects affected / exposed	8 / 228 (3.51%)	3 / 216 (1.39%)	12 / 237 (5.06%)
occurrences (all)	8	3	12
Musculoskeletal stiffness	Additional description: Musculoskeletal stiffness		

subjects affected / exposed	2 / 228 (0.88%)	1 / 216 (0.46%)	3 / 237 (1.27%)
occurrences (all)	2	1	3
Myalgia	Additional description: Myalgia		
subjects affected / exposed	16 / 228 (7.02%)	9 / 216 (4.17%)	18 / 237 (7.59%)
occurrences (all)	17	13	19
Neck pain	Additional description: Neck pain		
subjects affected / exposed	5 / 228 (2.19%)	1 / 216 (0.46%)	5 / 237 (2.11%)
occurrences (all)	5	1	5
Myositis	Additional description: Myositis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Osteoarthritis	Additional description: Osteoarthritis		
subjects affected / exposed	3 / 228 (1.32%)	0 / 216 (0.00%)	4 / 237 (1.69%)
occurrences (all)	3	0	4
Osteonecrosis	Additional description: Osteonecrosis		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Osteoporosis	Additional description: Osteoporosis		
subjects affected / exposed	2 / 228 (0.88%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	2	1	0
Pain in extremity	Additional description: Pain in extremity		
subjects affected / exposed	9 / 228 (3.95%)	4 / 216 (1.85%)	12 / 237 (5.06%)
occurrences (all)	9	6	13
Pain in jaw	Additional description: Pain in jaw		
subjects affected / exposed	2 / 228 (0.88%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	2	0	1
Periarthritis	Additional description: Periarthritis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Polyarthritis	Additional description: Polyarthritis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Polymyalgia rheumatica	Additional description: Polymyalgia rheumatica		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Psoriatic arthropathy	Additional description: Psoriatic arthropathy		

subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Rheumatic disorder	Additional description: Rheumatic disorder		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Spinal column stenosis	Additional description: Spinal column stenosis		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Spinal pain	Additional description: Spinal pain		
subjects affected / exposed	2 / 228 (0.88%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	2	1	0
Tendon disorder	Additional description: Tendon disorder		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Tendonitis	Additional description: Tendonitis		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	1	0	1
Vertebral foraminal stenosis	Additional description: Vertebral foraminal stenosis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Infections and infestations			
Abscess limb	Additional description: Abscess limb		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	1	1	0
Abdominal infection	Additional description: Abdominal infection		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Acarodermatitis	Additional description: Acarodermatitis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Abscess	Additional description: Abscess		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	2	1	0
Acute sinusitis	Additional description: Acute sinusitis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1

Atypical pneumonia	Additional description: Atypical pneumonia		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Bacterial blepharitis	Additional description: Bacterial blepharitis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Bacterial food poisoning	Additional description: Bacterial food poisoning		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Bacterial infection	Additional description: Bacterial infection		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Asymptomatic COVID-19	Additional description: Asymptomatic COVID-19		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Bacterial prostatitis	Additional description: Bacterial prostatitis		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Bacteriuria	Additional description: Bacteriuria		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Body tinea	Additional description: Body tinea		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Borrelia infection	Additional description: Borrelia infection		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	1	0	1
Bronchitis bacterial	Additional description: Bronchitis bacterial		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	1	1	0
Bronchopulmonary aspergillosis	Additional description: Bronchopulmonary aspergillosis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Bursitis infective	Additional description: Bursitis infective		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0

Campylobacter gastroenteritis	Additional description: Campylobacter gastroenteritis		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	1	0	1
Candida infection	Additional description: Candida infection		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	1	1	0
Bronchitis	Additional description: Bronchitis		
subjects affected / exposed	17 / 228 (7.46%)	19 / 216 (8.80%)	23 / 237 (9.70%)
occurrences (all)	22	19	24
Cellulitis	Additional description: Cellulitis		
subjects affected / exposed	2 / 228 (0.88%)	1 / 216 (0.46%)	3 / 237 (1.27%)
occurrences (all)	2	1	3
Chronic sinusitis	Additional description: Chronic sinusitis		
subjects affected / exposed	2 / 228 (0.88%)	2 / 216 (0.93%)	1 / 237 (0.42%)
occurrences (all)	2	2	1
Clostridium difficile colitis	Additional description: Clostridium difficile colitis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile infection	Additional description: Clostridium difficile infection		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Conjunctivitis	Additional description: Conjunctivitis		
subjects affected / exposed	8 / 228 (3.51%)	2 / 216 (0.93%)	1 / 237 (0.42%)
occurrences (all)	10	3	1
COVID-19	Additional description: COVID-19		
subjects affected / exposed	37 / 228 (16.23%)	35 / 216 (16.20%)	36 / 237 (15.19%)
occurrences (all)	42	36	41
COVID-19 pneumonia	Additional description: COVID-19 pneumonia		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Cystitis	Additional description: Cystitis		
subjects affected / exposed	6 / 228 (2.63%)	7 / 216 (3.24%)	8 / 237 (3.38%)
occurrences (all)	9	8	11
Cytomegalovirus infection	Additional description: Cytomegalovirus infection		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0

Dacryocanaliculitis	Additional description: Dacryocanaliculitis		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Dacryocystitis	Additional description: Dacryocystitis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Device related infection	Additional description: Device related infection		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Dengue fever	Additional description: Dengue fever		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Diverticulitis	Additional description: Diverticulitis		
subjects affected / exposed	2 / 228 (0.88%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	2	1	0
Ear infection	Additional description: Ear infection		
subjects affected / exposed	2 / 228 (0.88%)	2 / 216 (0.93%)	1 / 237 (0.42%)
occurrences (all)	2	2	1
Ear infection bacterial	Additional description: Ear infection bacterial		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Erythema migrans	Additional description: Erythema migrans		
subjects affected / exposed	0 / 228 (0.00%)	2 / 216 (0.93%)	0 / 237 (0.00%)
occurrences (all)	0	2	0
Enterococcal infection	Additional description: Enterococcal infection		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Enterococcal sepsis	Additional description: Enterococcal sepsis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Epididymitis	Additional description: Epididymitis		
subjects affected / exposed	2 / 228 (0.88%)	0 / 216 (0.00%)	2 / 237 (0.84%)
occurrences (all)	3	0	3
Erysipelas	Additional description: Erysipelas		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	3 / 237 (1.27%)
occurrences (all)	1	0	3

Eye infection	Additional description: Eye infection		
subjects affected / exposed	7 / 228 (3.07%)	0 / 216 (0.00%)	2 / 237 (0.84%)
occurrences (all)	8	0	2
Eyelid infection	Additional description: Eyelid infection		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Febrile infection	Additional description: Febrile infection		
subjects affected / exposed	1 / 228 (0.44%)	3 / 216 (1.39%)	1 / 237 (0.42%)
occurrences (all)	1	3	1
Folliculitis	Additional description: Folliculitis		
subjects affected / exposed	4 / 228 (1.75%)	2 / 216 (0.93%)	2 / 237 (0.84%)
occurrences (all)	4	2	4
Fungal infection	Additional description: Fungal infection		
subjects affected / exposed	1 / 228 (0.44%)	3 / 216 (1.39%)	2 / 237 (0.84%)
occurrences (all)	1	3	2
Fungal skin infection	Additional description: Fungal skin infection		
subjects affected / exposed	2 / 228 (0.88%)	3 / 216 (1.39%)	1 / 237 (0.42%)
occurrences (all)	2	3	1
Furuncle	Additional description: Furuncle		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Genital infection fungal	Additional description: Genital infection fungal		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Genital herpes	Additional description: Genital herpes		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Giardiasis	Additional description: Giardiasis		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Gastric infection	Additional description: Gastric infection		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis	Additional description: Gastroenteritis		
subjects affected / exposed	3 / 228 (1.32%)	6 / 216 (2.78%)	5 / 237 (2.11%)
occurrences (all)	3	6	5

Gastroenteritis caliciviral	Additional description: Gastroenteritis caliciviral		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis viral	Additional description: Gastroenteritis viral		
subjects affected / exposed	1 / 228 (0.44%)	3 / 216 (1.39%)	0 / 237 (0.00%)
occurrences (all)	1	3	0
Gastrointestinal disorders	Additional description: Gastrointestinal disorders		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Gastrointestinal infection	Additional description: Gastrointestinal infection		
subjects affected / exposed	4 / 228 (1.75%)	2 / 216 (0.93%)	3 / 237 (1.27%)
occurrences (all)	4	2	3
Haemophilus infection	Additional description: Haemophilus infection		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	1	0	1
Gingivitis	Additional description: Gingivitis		
subjects affected / exposed	1 / 228 (0.44%)	3 / 216 (1.39%)	2 / 237 (0.84%)
occurrences (all)	1	3	2
Herpes infection	Additional description: Herpes infection		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Helicobacter gastritis	Additional description: Helicobacter gastritis		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	3 / 237 (1.27%)
occurrences (all)	0	1	3
Hepatitis B reactivation	Additional description: Hepatitis B reactivation		
subjects affected / exposed	2 / 228 (0.88%)	1 / 216 (0.46%)	1 / 237 (0.42%)
occurrences (all)	2	1	1
Hepatitis E	Additional description: Hepatitis E		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Hepatitis viral	Additional description: Hepatitis viral		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	1	1	0
Herpes dermatitis	Additional description: Herpes dermatitis		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0

Herpes simplex	Additional description: Herpes simplex		
subjects affected / exposed	6 / 228 (2.63%)	0 / 216 (0.00%)	4 / 237 (1.69%)
occurrences (all)	9	0	5
Herpes simplex reactivation	Additional description: Herpes simplex reactivation		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Hordeolum	Additional description: Hordeolum		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	1 / 237 (0.42%)
occurrences (all)	1	1	1
Herpes zoster	Additional description: Herpes zoster		
subjects affected / exposed	9 / 228 (3.95%)	21 / 216 (9.72%)	13 / 237 (5.49%)
occurrences (all)	9	24	13
Herpes virus infection	Additional description: Herpes virus infection		
subjects affected / exposed	3 / 228 (1.32%)	2 / 216 (0.93%)	3 / 237 (1.27%)
occurrences (all)	5	3	3
Herpes viral infections	Additional description: Herpes viral infections		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Infection	Additional description: Infection		
subjects affected / exposed	14 / 228 (6.14%)	20 / 216 (9.26%)	7 / 237 (2.95%)
occurrences (all)	17	26	11
Infection susceptibility increased	Additional description: Infection susceptibility increased		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Infectious colitis	Additional description: Infectious colitis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Infective iritis	Additional description: Infective iritis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Impetigo	Additional description: Impetigo		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Infected bite	Additional description: Infected bite		
subjects affected / exposed	2 / 228 (0.88%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	2	0	0

Infected dermal cyst	Additional description: Infected dermal cyst		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Infected skin ulcer	Additional description: Infected skin ulcer		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Injection site cellulitis	Additional description: Injection site cellulitis		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Influenza	Additional description: Influenza		
subjects affected / exposed	9 / 228 (3.95%)	9 / 216 (4.17%)	7 / 237 (2.95%)
occurrences (all)	10	10	8
Joint abscess	Additional description: Joint abscess		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	1 / 237 (0.42%)
occurrences (all)	0	1	1
Kidney infection	Additional description: Kidney infection		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	1	1	0
Labyrinthitis	Additional description: Labyrinthitis		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Laryngitis	Additional description: Laryngitis		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	1 / 237 (0.42%)
occurrences (all)	1	1	1
Lip infection	Additional description: Lip infection		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Localised infection	Additional description: Localised infection		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	1 / 237 (0.42%)
occurrences (all)	0	1	1
Lower respiratory tract infection	Additional description: Lower respiratory tract infection		
subjects affected / exposed	3 / 228 (1.32%)	4 / 216 (1.85%)	1 / 237 (0.42%)
occurrences (all)	4	5	1
Lyme disease	Additional description: Lyme disease		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	3 / 237 (1.27%)
occurrences (all)	0	1	3

Lymph gland infection	Additional description: Lymph gland infection		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	1	0	1
Metapneumovirus infection	Additional description: Metapneumovirus infection		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Mucosal infection	Additional description: Mucosal infection		
subjects affected / exposed	3 / 228 (1.32%)	2 / 216 (0.93%)	1 / 237 (0.42%)
occurrences (all)	3	2	1
Nail infection	Additional description: Nail infection		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Nasal candidiasis	Additional description: Nasal candidiasis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis	Additional description: Nasopharyngitis		
subjects affected / exposed	70 / 228 (30.70%)	44 / 216 (20.37%)	55 / 237 (23.21%)
occurrences (all)	99	61	81
Onychomycosis	Additional description: Onychomycosis		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	2 / 237 (0.84%)
occurrences (all)	1	0	2
Neutropenic infection	Additional description: Neutropenic infection		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Omphalitis	Additional description: Omphalitis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Ophthalmic herpes zoster	Additional description: Ophthalmic herpes zoster		
subjects affected / exposed	0 / 228 (0.00%)	2 / 216 (0.93%)	1 / 237 (0.42%)
occurrences (all)	0	2	1
Oral candidiasis	Additional description: Oral candidiasis		
subjects affected / exposed	1 / 228 (0.44%)	6 / 216 (2.78%)	7 / 237 (2.95%)
occurrences (all)	1	6	8
Oral fungal infection	Additional description: Oral fungal infection		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0

Oral herpes	Additional description: Oral herpes		
subjects affected / exposed	12 / 228 (5.26%)	9 / 216 (4.17%)	14 / 237 (5.91%)
occurrences (all)	12	12	16
Oral infection	Additional description: Oral infection		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	1	1	0
Oropharyngeal candidiasis	Additional description: Oropharyngeal candidiasis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Osteomyelitis	Additional description: Osteomyelitis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Otitis media	Additional description: Otitis media		
subjects affected / exposed	5 / 228 (2.19%)	3 / 216 (1.39%)	3 / 237 (1.27%)
occurrences (all)	5	3	3
Otitis media acute	Additional description: Otitis media acute		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Otitis media chronic	Additional description: Otitis media chronic		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Penile infection	Additional description: Penile infection		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Papilloma viral infection	Additional description: Papilloma viral infection		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	1 / 237 (0.42%)
occurrences (all)	1	1	1
Parainfluenzae virus infection	Additional description: Parainfluenzae virus infection		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Paronychia	Additional description: Paronychia		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	1	1	0
Parotitis	Additional description: Parotitis		
subjects affected / exposed	0 / 228 (0.00%)	2 / 216 (0.93%)	0 / 237 (0.00%)
occurrences (all)	0	2	0

Peritonsillar abscess	Additional description: Peritonsillar abscess		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Pharyngitis	Additional description: Pharyngitis		
subjects affected / exposed	1 / 228 (0.44%)	2 / 216 (0.93%)	1 / 237 (0.42%)
occurrences (all)	1	2	1
Pharyngitis bacterial	Additional description: Pharyngitis bacterial		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Pharyngotonsillitis	Additional description: Pharyngotonsillitis		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Pneumonia mycoplasmal	Additional description: Pneumonia mycoplasmal		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Pneumonia streptococcal	Additional description: Pneumonia streptococcal		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Post-acute COVID-19 syndrome	Additional description: Post-acute COVID-19 syndrome		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Postoperative wound infection	Additional description: Postoperative wound infection		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Pneumonia	Additional description: Pneumonia		
subjects affected / exposed	17 / 228 (7.46%)	17 / 216 (7.87%)	10 / 237 (4.22%)
occurrences (all)	19	21	14
Pulpitis dental	Additional description: Pulpitis dental		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Pyelonephritis	Additional description: Pyelonephritis		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Pyuria	Additional description: Pyuria		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0

Respiratory syncytial virus infection	Additional description: Respiratory syncytial virus infection		
subjects affected / exposed	1 / 228 (0.44%)	2 / 216 (0.93%)	0 / 237 (0.00%)
occurrences (all)	1	2	0
Respiratory tract infection	Additional description: Respiratory tract infection		
subjects affected / exposed	16 / 228 (7.02%)	13 / 216 (6.02%)	17 / 237 (7.17%)
occurrences (all)	16	15	21
Respiratory tract infection viral	Additional description: Respiratory tract infection viral		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	1	0	1
Rhinitis	Additional description: Rhinitis		
subjects affected / exposed	8 / 228 (3.51%)	5 / 216 (2.31%)	5 / 237 (2.11%)
occurrences (all)	9	5	5
Sialoadenitis	Additional description: Sialoadenitis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Root canal infection	Additional description: Root canal infection		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	1	0	1
Scarlet fever	Additional description: Scarlet fever		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Scrotal infection	Additional description: Scrotal infection		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Sebaceous gland infection	Additional description: Sebaceous gland infection		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Sinusitis	Additional description: Sinusitis		
subjects affected / exposed	25 / 228 (10.96%)	8 / 216 (3.70%)	12 / 237 (5.06%)
occurrences (all)	38	8	14
Skin infection	Additional description: Skin infection		
subjects affected / exposed	5 / 228 (2.19%)	5 / 216 (2.31%)	3 / 237 (1.27%)
occurrences (all)	5	5	3
Soft tissue infection	Additional description: Soft tissue infection		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0

Staphylococcal infection	Additional description: Staphylococcal infection		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	2 / 237 (0.84%)
occurrences (all)	0	1	2
Subcutaneous abscess	Additional description: Subcutaneous abscess		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Sycosis barbae	Additional description: Sycosis barbae		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Tinea pedis	Additional description: Tinea pedis		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Tinea infection	Additional description: Tinea infection		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Tonsillitis	Additional description: Tonsillitis		
subjects affected / exposed	1 / 228 (0.44%)	2 / 216 (0.93%)	1 / 237 (0.42%)
occurrences (all)	1	2	1
Tooth abscess	Additional description: Tooth abscess		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Tooth infection	Additional description: Tooth infection		
subjects affected / exposed	4 / 228 (1.75%)	1 / 216 (0.46%)	9 / 237 (3.80%)
occurrences (all)	4	1	9
Tracheitis	Additional description: Tracheitis		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Urethritis	Additional description: Urethritis		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Vaginal infection	Additional description: Vaginal infection		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	4 / 237 (1.69%)
occurrences (all)	0	1	5
Urosepsis	Additional description: Urosepsis		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0

Urinary tract infection viral	Additional description: Urinary tract infection viral		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	1	0	1
Urinary tract infection bacterial	Additional description: Urinary tract infection bacterial		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Urinary tract infection	Additional description: Urinary tract infection		
subjects affected / exposed	24 / 228 (10.53%)	16 / 216 (7.41%)	14 / 237 (5.91%)
occurrences (all)	27	20	22
Upper respiratory tract infection	Additional description: Upper respiratory tract infection		
subjects affected / exposed	36 / 228 (15.79%)	39 / 216 (18.06%)	24 / 237 (10.13%)
occurrences (all)	52	56	33
Viral upper respiratory tract infection	Additional description: Viral upper respiratory tract infection		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	2 / 237 (0.84%)
occurrences (all)	1	1	3
Viral sinusitis	Additional description: Viral sinusitis		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Viral infection	Additional description: Viral infection		
subjects affected / exposed	5 / 228 (2.19%)	3 / 216 (1.39%)	5 / 237 (2.11%)
occurrences (all)	7	3	5
Vestibular neuronitis	Additional description: Vestibular neuronitis		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Varicella zoster virus infection	Additional description: Varicella zoster virus infection		
subjects affected / exposed	0 / 228 (0.00%)	3 / 216 (1.39%)	0 / 237 (0.00%)
occurrences (all)	0	3	0
Vulvovaginal candidiasis	Additional description: Vulvovaginal candidiasis		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	1	0	1
Vulvovaginal mycotic infection	Additional description: Vulvovaginal mycotic infection		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Wound infection	Additional description: Wound infection		
subjects affected / exposed	2 / 228 (0.88%)	1 / 216 (0.46%)	1 / 237 (0.42%)
occurrences (all)	2	1	1

Metabolism and nutrition disorders			
Abnormal weight gain	Additional description: Abnormal weight gain		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Acidosis	Additional description: Acidosis		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Alcohol intolerance	Additional description: Alcohol intolerance		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Decreased appetite	Additional description: Decreased appetite		
subjects affected / exposed	11 / 228 (4.82%)	14 / 216 (6.48%)	12 / 237 (5.06%)
occurrences (all)	14	18	12
Diabetes mellitus	Additional description: Diabetes mellitus		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	1	1	0
Dehydration	Additional description: Dehydration		
subjects affected / exposed	1 / 228 (0.44%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	1	1	0
Dyslipidaemia	Additional description: Dyslipidaemia		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Fluid overload	Additional description: Fluid overload		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Folate deficiency	Additional description: Folate deficiency		
subjects affected / exposed	3 / 228 (1.32%)	1 / 216 (0.46%)	1 / 237 (0.42%)
occurrences (all)	3	1	1
Gout	Additional description: Gout		
subjects affected / exposed	0 / 228 (0.00%)	2 / 216 (0.93%)	2 / 237 (0.84%)
occurrences (all)	0	2	2
Hyperphosphataemia	Additional description: Hyperphosphataemia		
subjects affected / exposed	4 / 228 (1.75%)	0 / 216 (0.00%)	10 / 237 (4.22%)
occurrences (all)	4	0	14
Hyperkalaemia	Additional description: Hyperkalaemia		

subjects affected / exposed	8 / 228 (3.51%)	6 / 216 (2.78%)	18 / 237 (7.59%)
occurrences (all)	11	6	26
Hyperglycaemia	Additional description: Hyperglycaemia		
subjects affected / exposed	6 / 228 (2.63%)	3 / 216 (1.39%)	1 / 237 (0.42%)
occurrences (all)	6	3	1
Hypercholesterolaemia	Additional description: Hypercholesterolaemia		
subjects affected / exposed	0 / 228 (0.00%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	0	1	0
Hypercalcaemia	Additional description: Hypercalcaemia		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia	Additional description: Hyponatraemia		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	2 / 237 (0.84%)
occurrences (all)	0	0	2
Hypomagnesaemia	Additional description: Hypomagnesaemia		
subjects affected / exposed	1 / 228 (0.44%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	1	0	0
Hypokalaemia	Additional description: Hypokalaemia		
subjects affected / exposed	5 / 228 (2.19%)	4 / 216 (1.85%)	4 / 237 (1.69%)
occurrences (all)	7	4	5
Hypoferritinaemia	Additional description: Hypoferritinaemia		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia	Additional description: Hypocalcaemia		
subjects affected / exposed	2 / 228 (0.88%)	1 / 216 (0.46%)	2 / 237 (0.84%)
occurrences (all)	2	1	3
Hyperuricaemia	Additional description: Hyperuricaemia		
subjects affected / exposed	7 / 228 (3.07%)	2 / 216 (0.93%)	9 / 237 (3.80%)
occurrences (all)	8	2	9
Hypophosphataemia	Additional description: Hypophosphataemia		
subjects affected / exposed	5 / 228 (2.19%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	11	0	2
Increased appetite	Additional description: Increased appetite		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Iron deficiency	Additional description: Iron deficiency		

subjects affected / exposed	4 / 228 (1.75%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	4	0	1
Iron overload	Additional description: Iron overload		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Obesity	Additional description: Obesity		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Tumour lysis syndrome	Additional description: Tumour lysis syndrome		
subjects affected / exposed	17 / 228 (7.46%)	7 / 216 (3.24%)	19 / 237 (8.02%)
occurrences (all)	20	7	22
Type 2 diabetes mellitus	Additional description: Type 2 diabetes mellitus		
subjects affected / exposed	0 / 228 (0.00%)	0 / 216 (0.00%)	1 / 237 (0.42%)
occurrences (all)	0	0	1
Vitamin D deficiency	Additional description: Vitamin D deficiency		
subjects affected / exposed	2 / 228 (0.88%)	1 / 216 (0.46%)	2 / 237 (0.84%)
occurrences (all)	2	1	2
Vitamin B12 deficiency	Additional description: Vitamin B12 deficiency		
subjects affected / exposed	3 / 228 (1.32%)	1 / 216 (0.46%)	0 / 237 (0.00%)
occurrences (all)	3	1	0

Non-serious adverse events	GIVe arm		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	231 / 231 (100.00%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma of colon	Additional description: Adenocarcinoma of colon		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Anogenital warts	Additional description: Anogenital warts		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Angiomyolipoma	Additional description: Angiomyolipoma		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Basal cell carcinoma	Additional description: Basal cell carcinoma		

subjects affected / exposed	4 / 231 (1.73%)		
occurrences (all)	4		
Benign soft tissue neoplasm	Additional description: Benign soft tissue neoplasm		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Bowen's disease	Additional description: Bowen's disease		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Choroid melanoma	Additional description: Choroid melanoma		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Colon adenoma	Additional description: Colon adenoma		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Colon cancer	Additional description: Colon cancer		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Cutaneous T-cell lymphoma	Additional description: Cutaneous T-cell lymphoma		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Erythroplasia	Additional description: Erythroplasia		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Fibroma	Additional description: Fibroma		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Haemangioma	Additional description: Haemangioma		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Haemangioma of liver	Additional description: Haemangioma of liver		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Keratoacanthoma	Additional description: Keratoacanthoma		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Lipoma	Additional description: Lipoma		

subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Malignant melanoma	Additional description: Malignant melanoma		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Melanocytic naevus	Additional description: Melanocytic naevus		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Malignant melanoma in situ	Additional description: Malignant melanoma in situ		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Myelodysplastic syndrome	Additional description: Myelodysplastic syndrome		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Myelofibrosis	Additional description: Myelofibrosis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Non-small cell lung cancer	Additional description: Non-small cell lung cancer		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Papilloma	Additional description: Papilloma		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Plasmacytoma	Additional description: Plasmacytoma		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Polycythaemia vera	Additional description: Polycythaemia vera		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Prostate cancer	Additional description: Prostate cancer		
subjects affected / exposed	3 / 231 (1.30%)		
occurrences (all)	3		
Schwannoma	Additional description: Schwannoma		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Seborrhoeic keratosis	Additional description: Seborrhoeic keratosis		

subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Richter's syndrome	Additional description: Richter's syndrome		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Skin papilloma	Additional description: Skin papilloma		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Squamous cell carcinoma	Additional description: Squamous cell carcinoma		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
T-cell lymphoma	Additional description: T-cell lymphoma		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Thyroid neoplasm	Additional description: Thyroid neoplasm		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Transitional cell carcinoma	Additional description: Transitional cell carcinoma		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Vascular disorders			
Aortic aneurysm	Additional description: Aortic aneurysm		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Aortic dilatation	Additional description: Aortic dilatation		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Arteriosclerosis	Additional description: Arteriosclerosis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Blood pressure fluctuation	Additional description: Blood pressure fluctuation		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Blue toe syndrome	Additional description: Blue toe syndrome		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		

Circulatory collapse	Additional description: Circulatory collapse		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Deep vein thrombosis	Additional description: Deep vein thrombosis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Embolism	Additional description: Embolism		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Flushing	Additional description: Flushing		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Gestational hypertension	Additional description: Gestational hypertension		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Haematoma	Additional description: Haematoma		
subjects affected / exposed	29 / 231 (12.55%)		
occurrences (all)	35		
Haemorrhage	Additional description: Haemorrhage		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Hot flush	Additional description: Hot flush		
subjects affected / exposed	9 / 231 (3.90%)		
occurrences (all)	9		
Hypotension	Additional description: Hypotension		
subjects affected / exposed	4 / 231 (1.73%)		
occurrences (all)	4		
Hypertensive crisis	Additional description: Hypertensive crisis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Hypertension	Additional description: Hypertension		
subjects affected / exposed	29 / 231 (12.55%)		
occurrences (all)	32		
Peripheral arterial occlusive disease	Additional description: Peripheral arterial occlusive disease		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		

Peripheral coldness	Additional description: Peripheral coldness		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Phlebitis	Additional description: Phlebitis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Poor peripheral circulation	Additional description: Poor peripheral circulation		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Raynaud's phenomenon	Additional description: Raynaud's phenomenon		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Thrombophlebitis	Additional description: Thrombophlebitis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	2		
Thrombophlebitis superficial	Additional description: Thrombophlebitis superficial		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Thrombosis	Additional description: Thrombosis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Varicose vein	Additional description: Varicose vein		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Vasculitis	Additional description: Vasculitis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Venous thrombosis	Additional description: Venous thrombosis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Surgical and medical procedures			
Cranial remodelling therapy	Additional description: Cranial remodelling therapy		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Endodontic procedure	Additional description: Endodontic procedure		

subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Joint irrigation	Additional description: Joint irrigation		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Mastoidectomy	Additional description: Mastoidectomy		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Polypectomy	Additional description: Polypectomy		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Tooth extraction	Additional description: Tooth extraction		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	3		
General disorders and administration site conditions			
Axillary pain	Additional description: Axillary pain		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Asthenia	Additional description: Asthenia		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	3		
Catheter site extravasation	Additional description: Catheter site extravasation		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Catheter site pain	Additional description: Catheter site pain		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Catheter site swelling	Additional description: Catheter site swelling		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Chest discomfort	Additional description: Chest discomfort		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Chest pain	Additional description: Chest pain		

subjects affected / exposed	5 / 231 (2.16%)		
occurrences (all)	5		
Chills	Additional description: Chills		
subjects affected / exposed	14 / 231 (6.06%)		
occurrences (all)	14		
Catheter site bruise	Additional description: Catheter site bruise		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Cyst	Additional description: Cyst		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Drug intolerance	Additional description: Drug intolerance		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Discomfort	Additional description: Discomfort		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Extravasation	Additional description: Extravasation		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Face oedema	Additional description: Face oedema		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Fatigue	Additional description: Fatigue		
subjects affected / exposed	80 / 231 (34.63%)		
occurrences (all)	87		
Feeling cold	Additional description: Feeling cold		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Gait disturbance	Additional description: Gait disturbance		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Feeling hot	Additional description: Feeling hot		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
General physical health deterioration	Additional description: General physical health deterioration		

subjects affected / exposed	4 / 231 (1.73%)		
occurrences (all)	4		
Inflammation	Additional description: Inflammation		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Induration	Additional description: Induration		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Influenza like illness	Additional description: Influenza like illness		
subjects affected / exposed	19 / 231 (8.23%)		
occurrences (all)	21		
Infusion site extravasation	Additional description: Infusion site extravasation		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Injection site pain	Additional description: Injection site pain		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Injection site reaction	Additional description: Injection site reaction		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Injection site swelling	Additional description: Injection site swelling		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Malaise	Additional description: Malaise		
subjects affected / exposed	9 / 231 (3.90%)		
occurrences (all)	12		
Mass	Additional description: Mass		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Mucosal inflammation	Additional description: Mucosal inflammation		
subjects affected / exposed	5 / 231 (2.16%)		
occurrences (all)	6		
Non-cardiac chest pain	Additional description: Non-cardiac chest pain		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Oedema	Additional description: Oedema		

subjects affected / exposed	6 / 231 (2.60%)		
occurrences (all)	6		
Oedema peripheral	Additional description: Oedema peripheral		
subjects affected / exposed	12 / 231 (5.19%)		
occurrences (all)	12		
Pain	Additional description: Pain		
subjects affected / exposed	4 / 231 (1.73%)		
occurrences (all)	4		
Papillitis	Additional description: Papillitis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Peripheral oedema neonatal	Additional description: Peripheral oedema neonatal		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Peripheral swelling	Additional description: Peripheral swelling		
subjects affected / exposed	6 / 231 (2.60%)		
occurrences (all)	7		
Pyrexia	Additional description: Pyrexia		
subjects affected / exposed	26 / 231 (11.26%)		
occurrences (all)	30		
Swelling	Additional description: Swelling		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Systemic inflammatory response syndrome	Additional description: Systemic inflammatory response syndrome		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Thirst	Additional description: Thirst		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Tissue infiltration	Additional description: Tissue infiltration		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Immune system disorders			
Anaphylactic reaction	Additional description: Anaphylactic reaction		

subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Autoimmune disorder	Additional description: Autoimmune disorder		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Cytokine release syndrome	Additional description: Cytokine release syndrome		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Drug hypersensitivity	Additional description: Drug hypersensitivity		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Hypersensitivity	Additional description: Hypersensitivity		
subjects affected / exposed	5 / 231 (2.16%)		
occurrences (all)	5		
Hypogammaglobulinaemia	Additional description: Hypogammaglobulinaemia		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Immune reconstitution inflammatory syndrome	Additional description: Immune reconstitution inflammatory syndrome		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Immunodeficiency	Additional description: Immunodeficiency		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Seasonal allergy	Additional description: Seasonal allergy		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Secondary immunodeficiency	Additional description: Secondary immunodeficiency		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Selective IgG subclass deficiency	Additional description: Selective IgG subclass deficiency		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			

Balanoposthitis	Additional description: Balanoposthitis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Benign prostatic hyperplasia	Additional description: Benign prostatic hyperplasia		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Breast induration	Additional description: Breast induration		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Breast pain	Additional description: Breast pain		
subjects affected / exposed	3 / 231 (1.30%)		
occurrences (all)	3		
Dyspareunia	Additional description: Dyspareunia		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Endometriosis	Additional description: Endometriosis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Erectile dysfunction	Additional description: Erectile dysfunction		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Haematospermia	Additional description: Haematospermia		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Hypomenorrhoea	Additional description: Hypomenorrhoea		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Menopausal symptoms	Additional description: Menopausal symptoms		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Menorrhagia	Additional description: Menorrhagia		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Menstruation irregular	Additional description: Menstruation irregular		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		

Nipple pain	Additional description: Nipple pain		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Ovarian hyperfunction	Additional description: Ovarian hyperfunction		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Penis disorder	Additional description: Penis disorder		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Pelvic pain	Additional description: Pelvic pain		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Prostatic hypoplasia	Additional description: Prostatic hypoplasia		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Prostatitis	Additional description: Prostatitis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Scrotal oedema	Additional description: Scrotal oedema		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Testicular disorder	Additional description: Testicular disorder		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Testicular pain	Additional description: Testicular pain		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Vaginal haemorrhage	Additional description: Vaginal haemorrhage		
subjects affected / exposed	3 / 231 (1.30%)		
occurrences (all)	3		
Vaginal discharge	Additional description: Vaginal discharge		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Vulvovaginal pruritus	Additional description: Vulvovaginal pruritus		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		

Respiratory, thoracic and mediastinal disorders			
Asthma	Additional description: Asthma		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Bronchospasm	Additional description: Bronchospasm		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Chronic obstructive pulmonary disease	Additional description: Chronic obstructive pulmonary disease		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Cough	Additional description: Cough		
subjects affected / exposed	37 / 231 (16.02%)		
occurrences (all)	43		
Dysaesthesia pharynx	Additional description: Dysaesthesia pharynx		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Dysphonia	Additional description: Dysphonia		
subjects affected / exposed	7 / 231 (3.03%)		
occurrences (all)	7		
Dyspnoea	Additional description: Dyspnoea		
subjects affected / exposed	18 / 231 (7.79%)		
occurrences (all)	18		
Dyspnoea exertional	Additional description: Dyspnoea exertional		
subjects affected / exposed	3 / 231 (1.30%)		
occurrences (all)	3		
Epistaxis	Additional description: Epistaxis		
subjects affected / exposed	22 / 231 (9.52%)		
occurrences (all)	27		
Haemoptysis	Additional description: Haemoptysis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Hiccups	Additional description: Hiccups		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Hyperventilation	Additional description: Hyperventilation		

subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Interstitial lung disease	Additional description: Interstitial lung disease		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Laryngeal inflammation	Additional description: Laryngeal inflammation		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Nasal congestion	Additional description: Nasal congestion		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Nasal discomfort	Additional description: Nasal discomfort		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Nasal dryness	Additional description: Nasal dryness		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Nasal inflammation	Additional description: Nasal inflammation		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Nasal obstruction	Additional description: Nasal obstruction		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Nasal ulcer	Additional description: Nasal ulcer		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Oropharyngeal pain	Additional description: Oropharyngeal pain		
subjects affected / exposed	14 / 231 (6.06%)		
occurrences (all)	15		
Pharyngeal inflammation	Additional description: Pharyngeal inflammation		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Pleural effusion	Additional description: Pleural effusion		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Pneumonitis	Additional description: Pneumonitis		

subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Productive cough	Additional description: Productive cough		
subjects affected / exposed	5 / 231 (2.16%)		
occurrences (all)	6		
Pulmonary embolism	Additional description: Pulmonary embolism		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Pulmonary hypertension	Additional description: Pulmonary hypertension		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Pulmonary pain	Additional description: Pulmonary pain		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Rhinitis allergic	Additional description: Rhinitis allergic		
subjects affected / exposed	3 / 231 (1.30%)		
occurrences (all)	3		
Respiratory alkalosis	Additional description: Respiratory alkalosis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Rhinorrhoea	Additional description: Rhinorrhoea		
subjects affected / exposed	4 / 231 (1.73%)		
occurrences (all)	4		
Sinus pain	Additional description: Sinus pain		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Sleep apnoea syndrome	Additional description: Sleep apnoea syndrome		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Tachypnoea	Additional description: Tachypnoea		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Throat clearing	Additional description: Throat clearing		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Throat irritation	Additional description: Throat irritation		

subjects affected / exposed	4 / 231 (1.73%)		
occurrences (all)	5		
Throatache	Additional description: Throatache		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Upper-airway cough syndrome	Additional description: Upper-airway cough syndrome		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Wheezing	Additional description: Wheezing		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Abnormal dreams	Additional description: Abnormal dreams		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Agitation	Additional description: Agitation		
subjects affected / exposed	3 / 231 (1.30%)		
occurrences (all)	3		
Aggression	Additional description: Aggression		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Adjustment disorder	Additional description: Adjustment disorder		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Anxiety	Additional description: Anxiety		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Apathy	Additional description: Apathy		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Bruxism	Additional description: Bruxism		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Confusional state	Additional description: Confusional state		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		

Depression	Additional description: Depression		
subjects affected / exposed	7 / 231 (3.03%)		
occurrences (all)	7		
Delirium	Additional description: Delirium		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Depressed mood	Additional description: Depressed mood		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Disorientation	Additional description: Disorientation		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Hallucination	Additional description: Hallucination		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Hyperarousal	Additional description: Hyperarousal		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Illusion	Additional description: Illusion		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Insomnia	Additional description: Insomnia		
subjects affected / exposed	10 / 231 (4.33%)		
occurrences (all)	11		
Irritability	Additional description: Irritability		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Panic attack	Additional description: Panic attack		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Restlessness	Additional description: Restlessness		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Sleep disorder	Additional description: Sleep disorder		
subjects affected / exposed	4 / 231 (1.73%)		
occurrences (all)	4		

Somnambulism	Additional description: Somnambulism		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Stress	Additional description: Stress		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Investigations			
Activated partial thromboplastin time prolonged	Additional description: Activated partial thromboplastin time prolonged		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Alanine aminotransferase increased	Additional description: Alanine aminotransferase increased		
subjects affected / exposed	9 / 231 (3.90%)		
occurrences (all)	9		
Amylase increased	Additional description: Amylase increased		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Aspartate aminotransferase increased	Additional description: Aspartate aminotransferase increased		
subjects affected / exposed	10 / 231 (4.33%)		
occurrences (all)	12		
Blood immunoglobulin G decreased	Additional description: Blood immunoglobulin G decreased		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Basophil count decreased	Additional description: Basophil count decreased		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Blood alkaline phosphatase increased	Additional description: Blood alkaline phosphatase increased		
subjects affected / exposed	4 / 231 (1.73%)		
occurrences (all)	6		
Blood bilirubin increased	Additional description: Blood bilirubin increased		
subjects affected / exposed	9 / 231 (3.90%)		
occurrences (all)	18		
Blood calcium decreased	Additional description: Blood calcium decreased		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Blood chloride increased	Additional description: Blood chloride increased		

subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Blood creatine increased	Additional description: Blood creatine increased		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Blood creatinine increased	Additional description: Blood creatinine increased		
subjects affected / exposed	7 / 231 (3.03%)		
occurrences (all)	7		
Blood glucose increased	Additional description: Blood glucose increased		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Blood immunoglobulin M decreased	Additional description: Blood immunoglobulin M decreased		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Blood lactate dehydrogenase increased	Additional description: Blood lactate dehydrogenase increased		
subjects affected / exposed	4 / 231 (1.73%)		
occurrences (all)	4		
Blood phosphorus increased	Additional description: Blood phosphorus increased		
subjects affected / exposed	9 / 231 (3.90%)		
occurrences (all)	13		
Blood potassium decreased	Additional description: Blood potassium decreased		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Blood potassium increased	Additional description: Blood potassium increased		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Blood pressure increased	Additional description: Blood pressure increased		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Blood thyroid stimulating hormone increased	Additional description: Blood thyroid stimulating hormone increased		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Blood urea increased	Additional description: Blood urea increased		

subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Blood uric acid decreased	Additional description: Blood uric acid decreased		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Blood uric acid increased	Additional description: Blood uric acid increased		
subjects affected / exposed	5 / 231 (2.16%)		
occurrences (all)	8		
Body temperature increased	Additional description: Body temperature increased		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Blood iron decreased	Additional description: Blood iron decreased		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Cardiac murmur	Additional description: Cardiac murmur		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Bronchoscopy	Additional description: Bronchoscopy		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
C-reactive protein	Additional description: C-reactive protein		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
C-reactive protein increased	Additional description: C-reactive protein increased		
subjects affected / exposed	5 / 231 (2.16%)		
occurrences (all)	5		
Cortisol decreased	Additional description: Cortisol decreased		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Enterococcus test positive	Additional description: Enterococcus test positive		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Eosinophil count decreased	Additional description: Eosinophil count decreased		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Free haemoglobin present	Additional description: Free haemoglobin present		

subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Gamma-glutamyltransferase increased	Additional description: Gamma-glutamyltransferase increased		
subjects affected / exposed	5 / 231 (2.16%)		
occurrences (all)	12		
Glomerular filtration rate decreased	Additional description: Glomerular filtration rate decreased		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Heart rate irregular	Additional description: Heart rate irregular		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Hepatic enzyme abnormal	Additional description: Hepatic enzyme abnormal		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Hepatic enzyme increased	Additional description: Hepatic enzyme increased		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Hepatitis B DNA increased	Additional description: Hepatitis B DNA increased		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Immunoglobulins decreased	Additional description: Immunoglobulins decreased		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Inflammatory marker increased	Additional description: Inflammatory marker increased		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
International normalised ratio increased	Additional description: International normalised ratio increased		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Intraocular pressure increased	Additional description: Intraocular pressure increased		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Left ventricular end-diastolic pressure decreased	Additional description: Left ventricular end-diastolic pressure decreased		

subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Lipase increased	Additional description: Lipase increased		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Liver function test increased	Additional description: Liver function test increased		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Monocyte count decreased	Additional description: Monocyte count decreased		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Myocardial necrosis marker increased	Additional description: Myocardial necrosis marker increased		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
N-terminal prohormone brain natriuretic peptide increased	Additional description: N-terminal prohormone brain natriuretic peptide increased		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Neutrophil count decreased	Additional description: Neutrophil count decreased		
subjects affected / exposed	33 / 231 (14.29%)		
occurrences (all)	48		
Platelet count decreased	Additional description: Platelet count decreased		
subjects affected / exposed	22 / 231 (9.52%)		
occurrences (all)	31		
Procalcitonin increased	Additional description: Procalcitonin increased		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Reticulocyte count decreased	Additional description: Reticulocyte count decreased		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
SARS-CoV-2 test positive	Additional description: SARS-CoV-2 test positive		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Serum ferritin decreased	Additional description: Serum ferritin decreased		

subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Transaminases increased	Additional description: Transaminases increased		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Transferrin decreased	Additional description: Transferrin decreased		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Vitamin B12 decreased	Additional description: Vitamin B12 decreased		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Weight decreased	Additional description: Weight decreased		
subjects affected / exposed	9 / 231 (3.90%)		
occurrences (all)	9		
Weight increased	Additional description: Weight increased		
subjects affected / exposed	7 / 231 (3.03%)		
occurrences (all)	7		
White blood cell count decreased	Additional description: White blood cell count decreased		
subjects affected / exposed	9 / 231 (3.90%)		
occurrences (all)	18		
White blood cell count increased	Additional description: White blood cell count increased		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
Arthropod bite	Additional description: Arthropod bite		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Animal bite	Additional description: Animal bite		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Bone contusion	Additional description: Bone contusion		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Chest injury	Additional description: Chest injury		

subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Clavicle fracture	Additional description: Clavicle fracture		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Contusion	Additional description: Contusion		
subjects affected / exposed	10 / 231 (4.33%)		
occurrences (all)	11		
Ear canal injury	Additional description: Ear canal injury		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Epicondylitis	Additional description: Epicondylitis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Face injury	Additional description: Face injury		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Fall	Additional description: Fall		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Foreign body in eye	Additional description: Foreign body in eye		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Fracture	Additional description: Fracture		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Hand fracture	Additional description: Hand fracture		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Head injury	Additional description: Head injury		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Infusion related reaction	Additional description: Infusion related reaction		
subjects affected / exposed	46 / 231 (19.91%)		
occurrences (all)	54		
Injury	Additional description: Injury		

subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Ligament injury	Additional description: Ligament injury		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Joint capsule rupture	Additional description: Joint capsule rupture		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Ligament sprain	Additional description: Ligament sprain		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Limb injury	Additional description: Limb injury		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	3		
Mallet finger	Additional description: Mallet finger		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Meniscus injury	Additional description: Meniscus injury		
subjects affected / exposed	4 / 231 (1.73%)		
occurrences (all)	4		
Mouth injury	Additional description: Mouth injury		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Multiple fractures	Additional description: Multiple fractures		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Muscle strain	Additional description: Muscle strain		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Nasal injury	Additional description: Nasal injury		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Paravenous drug administration	Additional description: Paravenous drug administration		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Procedural pain	Additional description: Procedural pain		

subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Post-traumatic neck syndrome	Additional description: Post-traumatic neck syndrome		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Road traffic accident	Additional description: Road traffic accident		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Scar	Additional description: Scar		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Skin abrasion	Additional description: Skin abrasion		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Skin wound	Additional description: Skin wound		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Spinal compression fracture	Additional description: Spinal compression fracture		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	6		
Spinal fracture	Additional description: Spinal fracture		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Tendon rupture	Additional description: Tendon rupture		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Thermal burn	Additional description: Thermal burn		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Thoracic vertebral fracture	Additional description: Thoracic vertebral fracture		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Tooth injury	Additional description: Tooth injury		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Transfusion reaction	Additional description: Transfusion reaction		

subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Traumatic ear amputation	Additional description: Traumatic ear amputation		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Traumatic haematoma	Additional description: Traumatic haematoma		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Vascular access complication	Additional description: Vascular access complication		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Wrist fracture	Additional description: Wrist fracture		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Wound	Additional description: Wound		
subjects affected / exposed	4 / 231 (1.73%)		
occurrences (all)	5		
Wound complication	Additional description: Wound complication		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Congenital, familial and genetic disorders			
Cryptorchism	Additional description: Cryptorchism		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Glycogen storage disease type I	Additional description: Glycogen storage disease type I		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Hydrocele	Additional description: Hydrocele		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Ichthyosis	Additional description: Ichthyosis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Phimosis	Additional description: Phimosis		

subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
Acute coronary syndrome	Additional description: Acute coronary syndrome		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Angina pectoris	Additional description: Angina pectoris		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Arteriosclerosis coronary artery	Additional description: Arteriosclerosis coronary artery		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Arrhythmia	Additional description: Arrhythmia		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Atrial fibrillation	Additional description: Atrial fibrillation		
subjects affected / exposed	17 / 231 (7.36%)		
occurrences (all)	19		
Atrial flutter	Additional description: Atrial flutter		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Atrial thrombosis	Additional description: Atrial thrombosis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Atrioventricular block second degree	Additional description: Atrioventricular block second degree		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Bradycardia	Additional description: Bradycardia		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Bundle branch block right	Additional description: Bundle branch block right		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Cardiac discomfort	Additional description: Cardiac discomfort		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		

Cardiac failure	Additional description: Cardiac failure		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Cardiovascular disorder	Additional description: Cardiovascular disorder		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Coronary artery disease	Additional description: Coronary artery disease		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Coronary artery stenosis	Additional description: Coronary artery stenosis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Extrasystoles	Additional description: Extrasystoles		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Hypertensive heart disease	Additional description: Hypertensive heart disease		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Myocardial ischaemia	Additional description: Myocardial ischaemia		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Palpitations	Additional description: Palpitations		
subjects affected / exposed	10 / 231 (4.33%)		
occurrences (all)	13		
Pericardial effusion	Additional description: Pericardial effusion		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Right ventricular failure	Additional description: Right ventricular failure		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Sinus tachycardia	Additional description: Sinus tachycardia		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Supraventricular tachycardia	Additional description: Supraventricular tachycardia		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		

Tachycardia	Additional description: Tachycardia		
subjects affected / exposed	3 / 231 (1.30%)		
occurrences (all)	3		
Tachycardia paroxysmal	Additional description: Tachycardia paroxysmal		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Ventricular extrasystoles	Additional description: Ventricular extrasystoles		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	3		
Nervous system disorders			
Ageusia	Additional description: Ageusia		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Amnesia	Additional description: Amnesia		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Aphasia	Additional description: Aphasia		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Ataxia	Additional description: Ataxia		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Balance disorder	Additional description: Balance disorder		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Burning sensation	Additional description: Burning sensation		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Carpal tunnel syndrome	Additional description: Carpal tunnel syndrome		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Cervicobrachial syndrome	Additional description: Cervicobrachial syndrome		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Carotid artery stenosis	Additional description: Carotid artery stenosis		

subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Concentration impairment	Additional description: Concentration impairment		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Cognitive disorder	Additional description: Cognitive disorder		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Cubital tunnel syndrome	Additional description: Cubital tunnel syndrome		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Depressed level of consciousness	Additional description: Depressed level of consciousness		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Disturbance in attention	Additional description: Disturbance in attention		
subjects affected / exposed	6 / 231 (2.60%)		
occurrences (all)	6		
Dizziness	Additional description: Dizziness		
subjects affected / exposed	23 / 231 (9.96%)		
occurrences (all)	24		
Dizziness postural	Additional description: Dizziness postural		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Dysaesthesia	Additional description: Dysaesthesia		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Dysgeusia	Additional description: Dysgeusia		
subjects affected / exposed	3 / 231 (1.30%)		
occurrences (all)	4		
Facial paralysis	Additional description: Facial paralysis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Formication	Additional description: Formication		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Hand-arm vibration syndrome	Additional description: Hand-arm vibration syndrome		

subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Head discomfort	Additional description: Head discomfort		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Headache	Additional description: Headache		
subjects affected / exposed	39 / 231 (16.88%)		
occurrences (all)	52		
Hypoaesthesia	Additional description: Hypoaesthesia		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Hypertonia	Additional description: Hypertonia		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Hypotonia	Additional description: Hypotonia		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Intention tremor	Additional description: Intention tremor		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Lumbar radiculopathy	Additional description: Lumbar radiculopathy		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Memory impairment	Additional description: Memory impairment		
subjects affected / exposed	5 / 231 (2.16%)		
occurrences (all)	5		
Mental impairment	Additional description: Mental impairment		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Migraine	Additional description: Migraine		
subjects affected / exposed	3 / 231 (1.30%)		
occurrences (all)	3		
Muscle spasticity	Additional description: Muscle spasticity		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Neuromuscular blockade	Additional description: Neuromuscular blockade		

subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Olfactory nerve disorder	Additional description: Olfactory nerve disorder		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Neuropathy peripheral	Additional description: Neuropathy peripheral		
subjects affected / exposed	5 / 231 (2.16%)		
occurrences (all)	6		
Orthostatic intolerance	Additional description: Orthostatic intolerance		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Paraesthesia	Additional description: Paraesthesia		
subjects affected / exposed	9 / 231 (3.90%)		
occurrences (all)	10		
Parkinson's disease	Additional description: Parkinson's disease		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Parosmia	Additional description: Parosmia		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Peripheral motor neuropathy	Additional description: Peripheral motor neuropathy		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Peripheral sensory neuropathy	Additional description: Peripheral sensory neuropathy		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Polyneuropathy	Additional description: Polyneuropathy		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Post herpetic neuralgia	Additional description: Post herpetic neuralgia		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Presyncope	Additional description: Presyncope		
subjects affected / exposed	4 / 231 (1.73%)		
occurrences (all)	5		
Restless legs syndrome	Additional description: Restless legs syndrome		

subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Sciatica	Additional description: Sciatica		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Sensory disturbance	Additional description: Sensory disturbance		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Syncope	Additional description: Syncope		
subjects affected / exposed	4 / 231 (1.73%)		
occurrences (all)	4		
Somnolence	Additional description: Somnolence		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Taste disorder	Additional description: Taste disorder		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Transient global amnesia	Additional description: Transient global amnesia		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	2		
Tremor	Additional description: Tremor		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Trigeminal neuralgia	Additional description: Trigeminal neuralgia		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Visual field defect	Additional description: Visual field defect		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Agranulocytosis	Additional description: Agranulocytosis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Anaemia	Additional description: Anaemia		
subjects affected / exposed	20 / 231 (8.66%)		
occurrences (all)	25		

Autoimmune haemolytic anaemia	Additional description: Autoimmune haemolytic anaemia		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	2		
Bicytopenia	Additional description: Bicytopenia		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Eosinophilia	Additional description: Eosinophilia		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Febrile neutropenia	Additional description: Febrile neutropenia		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Granulocytopenia	Additional description: Granulocytopenia		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Haemolysis	Additional description: Haemolysis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Haemorrhagic diathesis	Additional description: Haemorrhagic diathesis		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Hypoglobulinaemia	Additional description: Hypoglobulinaemia		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Immune thrombocytopenia	Additional description: Immune thrombocytopenia		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Iron deficiency anaemia	Additional description: Iron deficiency anaemia		
subjects affected / exposed	4 / 231 (1.73%)		
occurrences (all)	4		
Leukocytosis	Additional description: Leukocytosis		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Leukopenia	Additional description: Leukopenia		
subjects affected / exposed	17 / 231 (7.36%)		
occurrences (all)	27		

Lymph node pain	Additional description: Lymph node pain		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Lymphadenitis	Additional description: Lymphadenitis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Lymphadenopathy	Additional description: Lymphadenopathy		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Macrocytosis	Additional description: Macrocytosis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Microcytic anaemia	Additional description: Microcytic anaemia		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Neutropenia	Additional description: Neutropenia		
subjects affected / exposed	110 / 231 (47.62%)		
occurrences (all)	237		
Pancytopenia	Additional description: Pancytopenia		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Reticulocytosis	Additional description: Reticulocytosis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Thrombocytopenia	Additional description: Thrombocytopenia		
subjects affected / exposed	52 / 231 (22.51%)		
occurrences (all)	77		
Ear and labyrinth disorders			
Auditory disorder	Additional description: Auditory disorder		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Deafness	Additional description: Deafness		
subjects affected / exposed	4 / 231 (1.73%)		
occurrences (all)	4		
Deafness unilateral	Additional description: Deafness unilateral		

subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Ear haemorrhage	Additional description: Ear haemorrhage		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Ear pain	Additional description: Ear pain		
subjects affected / exposed	4 / 231 (1.73%)		
occurrences (all)	4		
Hypoacusis	Additional description: Hypoacusis		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Middle ear effusion	Additional description: Middle ear effusion		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Middle ear inflammation	Additional description: Middle ear inflammation		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Tinnitus	Additional description: Tinnitus		
subjects affected / exposed	3 / 231 (1.30%)		
occurrences (all)	3		
Vertigo positional	Additional description: Vertigo positional		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Vertigo	Additional description: Vertigo		
subjects affected / exposed	10 / 231 (4.33%)		
occurrences (all)	12		
Eye disorders			
Blepharitis	Additional description: Blepharitis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Cataract	Additional description: Cataract		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Conjunctival haemorrhage	Additional description: Conjunctival haemorrhage		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		

Corneal erosion	Additional description: Corneal erosion		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Diplopia	Additional description: Diplopia		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Dry eye	Additional description: Dry eye		
subjects affected / exposed	6 / 231 (2.60%)		
occurrences (all)	6		
Erythema of eyelid	Additional description: Erythema of eyelid		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Exophthalmos	Additional description: Exophthalmos		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Eye haemorrhage	Additional description: Eye haemorrhage		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Eye inflammation	Additional description: Eye inflammation		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Eye irritation	Additional description: Eye irritation		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Eye oedema	Additional description: Eye oedema		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Eye pain	Additional description: Eye pain		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Eyelid haematoma	Additional description: Eyelid haematoma		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Eyelid oedema	Additional description: Eyelid oedema		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		

Eyelid ptosis	Additional description: Eyelid ptosis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Eye disorder	Additional description: Eye disorder		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Glaucoma	Additional description: Glaucoma		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Hyalosis asteroid	Additional description: Hyalosis asteroid		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Lacrimation increased	Additional description: Lacrimation increased		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Ocular hyperaemia	Additional description: Ocular hyperaemia		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Ocular hypertension	Additional description: Ocular hypertension		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Panophthalmitis	Additional description: Panophthalmitis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Periorbital oedema	Additional description: Periorbital oedema		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Photophobia	Additional description: Photophobia		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Retinal haemorrhage	Additional description: Retinal haemorrhage		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Uveitis	Additional description: Uveitis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		

Vitreous detachment	Additional description: Vitreous detachment		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Vitreous disorder	Additional description: Vitreous disorder		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Vitreous haemorrhage	Additional description: Vitreous haemorrhage		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Visual impairment	Additional description: Visual impairment		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Vision blurred	Additional description: Vision blurred		
subjects affected / exposed	7 / 231 (3.03%)		
occurrences (all)	7		
Gastrointestinal disorders			
Abdominal pain upper	Additional description: Abdominal pain upper		
subjects affected / exposed	21 / 231 (9.09%)		
occurrences (all)	23		
Abdominal pain lower	Additional description: Abdominal pain lower		
subjects affected / exposed	3 / 231 (1.30%)		
occurrences (all)	3		
Abdominal pain	Additional description: Abdominal pain		
subjects affected / exposed	15 / 231 (6.49%)		
occurrences (all)	15		
Abdominal distension	Additional description: Abdominal distension		
subjects affected / exposed	3 / 231 (1.30%)		
occurrences (all)	3		
Abdominal discomfort	Additional description: Abdominal discomfort		
subjects affected / exposed	6 / 231 (2.60%)		
occurrences (all)	7		
Anal ulcer	Additional description: Anal ulcer		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Anal pruritus	Additional description: Anal pruritus		

subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Anal incontinence	Additional description: Anal incontinence		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Anal haemorrhage	Additional description: Anal haemorrhage		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Anal fissure	Additional description: Anal fissure		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Angular cheilitis	Additional description: Angular cheilitis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Aphthous ulcer	Additional description: Aphthous ulcer		
subjects affected / exposed	3 / 231 (1.30%)		
occurrences (all)	3		
Cheilitis	Additional description: Cheilitis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Coeliac disease	Additional description: Coeliac disease		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Colitis	Additional description: Colitis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Constipation	Additional description: Constipation		
subjects affected / exposed	29 / 231 (12.55%)		
occurrences (all)	32		
Crohn's disease	Additional description: Crohn's disease		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Dental caries	Additional description: Dental caries		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Diarrhoea	Additional description: Diarrhoea		

subjects affected / exposed	118 / 231 (51.08%)		
occurrences (all)	177		
Diarrhoea haemorrhagic	Additional description: Diarrhoea haemorrhagic		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Defaecation disorder	Additional description: Defaecation disorder		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Diverticulum intestinal	Additional description: Diverticulum intestinal		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Dry mouth	Additional description: Dry mouth		
subjects affected / exposed	10 / 231 (4.33%)		
occurrences (all)	10		
Dyspepsia	Additional description: Dyspepsia		
subjects affected / exposed	27 / 231 (11.69%)		
occurrences (all)	28		
Dysphagia	Additional description: Dysphagia		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Enterovirus infection	Additional description: Enterovirus infection		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Epigastric discomfort	Additional description: Epigastric discomfort		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Faeces discoloured	Additional description: Faeces discoloured		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Gastric haemorrhage	Additional description: Gastric haemorrhage		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Flatulence	Additional description: Flatulence		
subjects affected / exposed	8 / 231 (3.46%)		
occurrences (all)	8		
Food poisoning	Additional description: Food poisoning		

subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Frequent bowel movements	Additional description: Frequent bowel movements		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Giant cell epulis	Additional description: Giant cell epulis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Gingival bleeding	Additional description: Gingival bleeding		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Gastritis	Additional description: Gastritis		
subjects affected / exposed	3 / 231 (1.30%)		
occurrences (all)	3		
Gastrointestinal haemorrhage	Additional description: Gastrointestinal haemorrhage		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Gastrointestinal motility disorder	Additional description: Gastrointestinal motility disorder		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Gastrointestinal pain	Additional description: Gastrointestinal pain		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Gastrointestinal tract irritation	Additional description: Gastrointestinal tract irritation		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Gastrooesophageal reflux disease	Additional description: Gastrooesophageal reflux disease		
subjects affected / exposed	8 / 231 (3.46%)		
occurrences (all)	8		
Gingival discolouration	Additional description: Gingival discolouration		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Haemorrhoidal haemorrhage	Additional description: Haemorrhoidal haemorrhage		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Haematochezia	Additional description: Haematochezia		

subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Haemorrhoids	Additional description: Haemorrhoids		
subjects affected / exposed	3 / 231 (1.30%)		
occurrences (all)	3		
Inguinal hernia	Additional description: Inguinal hernia		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Lip dry	Additional description: Lip dry		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Lip pain	Additional description: Lip pain		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Mouth haemorrhage	Additional description: Mouth haemorrhage		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Mouth ulceration	Additional description: Mouth ulceration		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Nausea	Additional description: Nausea		
subjects affected / exposed	77 / 231 (33.33%)		
occurrences (all)	100		
Odynophagia	Additional description: Odynophagia		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Oesophagitis	Additional description: Oesophagitis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Oral dysaesthesia	Additional description: Oral dysaesthesia		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Oral mucosal blistering	Additional description: Oral mucosal blistering		
subjects affected / exposed	3 / 231 (1.30%)		
occurrences (all)	3		
Oral mucosal erythema	Additional description: Oral mucosal erythema		

subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Oral pain	Additional description: Oral pain		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	3		
Paraesthesia oral	Additional description: Paraesthesia oral		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Periodontal disease	Additional description: Periodontal disease		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Proctalgia	Additional description: Proctalgia		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Rectal haemorrhage	Additional description: Rectal haemorrhage		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Rectal polyp	Additional description: Rectal polyp		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Salivary gland calculus	Additional description: Salivary gland calculus		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Stomatitis	Additional description: Stomatitis		
subjects affected / exposed	12 / 231 (5.19%)		
occurrences (all)	14		
Tongue coated	Additional description: Tongue coated		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Tongue discomfort	Additional description: Tongue discomfort		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Tongue disorder	Additional description: Tongue disorder		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Tongue dry	Additional description: Tongue dry		

subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Tooth loss	Additional description: Tooth loss		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Toothache	Additional description: Toothache		
subjects affected / exposed	6 / 231 (2.60%)		
occurrences (all)	6		
Vomiting	Additional description: Vomiting		
subjects affected / exposed	24 / 231 (10.39%)		
occurrences (all)	36		
Hepatobiliary disorders			
Cholecystitis	Additional description: Cholecystitis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Cholelithiasis	Additional description: Cholelithiasis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Hepatic pain	Additional description: Hepatic pain		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Hepatic steatosis	Additional description: Hepatic steatosis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Hepatotoxicity	Additional description: Hepatotoxicity		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Hyperbilirubinaemia	Additional description: Hyperbilirubinaemia		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Liver disorder	Additional description: Liver disorder		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Portal vein dilatation	Additional description: Portal vein dilatation		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		

Portal vein thrombosis	Additional description: Portal vein thrombosis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Actinic keratosis	Additional description: Actinic keratosis		
subjects affected / exposed	3 / 231 (1.30%)		
occurrences (all)	3		
Alopecia	Additional description: Alopecia		
subjects affected / exposed	4 / 231 (1.73%)		
occurrences (all)	4		
Blister	Additional description: Blister		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Blood blister	Additional description: Blood blister		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Cafe au lait spots	Additional description: Cafe au lait spots		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Dermatitis	Additional description: Dermatitis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Dermatitis acneiform	Additional description: Dermatitis acneiform		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Dermatitis allergic	Additional description: Dermatitis allergic		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Dermatitis atopic	Additional description: Dermatitis atopic		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Dermatitis contact	Additional description: Dermatitis contact		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Dermatitis exfoliative	Additional description: Dermatitis exfoliative		

subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Dermatitis exfoliative generalised	Additional description: Dermatitis exfoliative generalised		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Decubitus ulcer	Additional description: Decubitus ulcer		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Drug eruption	Additional description: Drug eruption		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Dry skin	Additional description: Dry skin		
subjects affected / exposed	17 / 231 (7.36%)		
occurrences (all)	17		
Ecchymosis	Additional description: Ecchymosis		
subjects affected / exposed	5 / 231 (2.16%)		
occurrences (all)	6		
Eczema	Additional description: Eczema		
subjects affected / exposed	12 / 231 (5.19%)		
occurrences (all)	12		
Eczema nummular	Additional description: Eczema nummular		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Erythema	Additional description: Erythema		
subjects affected / exposed	4 / 231 (1.73%)		
occurrences (all)	4		
Erythema nodosum	Additional description: Erythema nodosum		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Eosinophilic cellulitis	Additional description: Eosinophilic cellulitis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Erythema multiforme	Additional description: Erythema multiforme		
subjects affected / exposed	3 / 231 (1.30%)		
occurrences (all)	3		
Hand dermatitis	Additional description: Hand dermatitis		

subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Hyperkeratosis	Additional description: Hyperkeratosis		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Hyperhidrosis	Additional description: Hyperhidrosis		
subjects affected / exposed	6 / 231 (2.60%)		
occurrences (all)	6		
Hypertrichosis	Additional description: Hypertrichosis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Intertrigo	Additional description: Intertrigo		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Lentigo	Additional description: Lentigo		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Lichen planus	Additional description: Lichen planus		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Neurodermatitis	Additional description: Neurodermatitis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Nail discolouration	Additional description: Nail discolouration		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Nail dystrophy	Additional description: Nail dystrophy		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Nail pitting	Additional description: Nail pitting		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Nail ridging	Additional description: Nail ridging		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Nail toxicity	Additional description: Nail toxicity		

subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Night sweats	Additional description: Night sweats		
subjects affected / exposed	4 / 231 (1.73%)		
occurrences (all)	4		
Onychoclasis	Additional description: Onychoclasis		
subjects affected / exposed	6 / 231 (2.60%)		
occurrences (all)	6		
Onycholysis	Additional description: Onycholysis		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Papule	Additional description: Papule		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Pemphigoid	Additional description: Pemphigoid		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Petechiae	Additional description: Petechiae		
subjects affected / exposed	12 / 231 (5.19%)		
occurrences (all)	17		
Pigmentation disorder	Additional description: Pigmentation disorder		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Rash generalised	Additional description: Rash generalised		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Rash erythematous	Additional description: Rash erythematous		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Pruritus	Additional description: Pruritus		
subjects affected / exposed	17 / 231 (7.36%)		
occurrences (all)	17		
Pruritus generalised	Additional description: Pruritus generalised		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Psoriasis	Additional description: Psoriasis		

subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	3		
Purpura	Additional description: Purpura		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Rash	Additional description: Rash		
subjects affected / exposed	37 / 231 (16.02%)		
occurrences (all)	49		
Rash macular	Additional description: Rash macular		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Rash maculo-papular	Additional description: Rash maculo-papular		
subjects affected / exposed	9 / 231 (3.90%)		
occurrences (all)	12		
Rash pruritic	Additional description: Rash pruritic		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Rash papular	Additional description: Rash papular		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Rosacea	Additional description: Rosacea		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Solar dermatitis	Additional description: Solar dermatitis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Skin burning sensation	Additional description: Skin burning sensation		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Skin discolouration	Additional description: Skin discolouration		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Skin discomfort	Additional description: Skin discomfort		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Skin disorder	Additional description: Skin disorder		

subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Skin fissures	Additional description: Skin fissures		
subjects affected / exposed	3 / 231 (1.30%)		
occurrences (all)	3		
Skin hypopigmentation	Additional description: Skin hypopigmentation		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Skin irritation	Additional description: Skin irritation		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Skin lesion	Additional description: Skin lesion		
subjects affected / exposed	4 / 231 (1.73%)		
occurrences (all)	4		
Skin mass	Additional description: Skin mass		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Skin ulcer	Additional description: Skin ulcer		
subjects affected / exposed	3 / 231 (1.30%)		
occurrences (all)	3		
Suggillation	Additional description: Suggillation		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Telangiectasia	Additional description: Telangiectasia		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Toxic skin eruption	Additional description: Toxic skin eruption		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Urticaria	Additional description: Urticaria		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	2		
Renal and urinary disorders			
Acute kidney injury	Additional description: Acute kidney injury		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		

Chromaturia	Additional description: Chromaturia		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Chronic kidney disease	Additional description: Chronic kidney disease		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Cystitis noninfective	Additional description: Cystitis noninfective		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Dysuria	Additional description: Dysuria		
subjects affected / exposed	3 / 231 (1.30%)		
occurrences (all)	3		
Haematuria	Additional description: Haematuria		
subjects affected / exposed	8 / 231 (3.46%)		
occurrences (all)	8		
Hydronephrosis	Additional description: Hydronephrosis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Incontinence	Additional description: Incontinence		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Kidney congestion	Additional description: Kidney congestion		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Leukocyturia	Additional description: Leukocyturia		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Lower urinary tract symptoms	Additional description: Lower urinary tract symptoms		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Micturition disorder	Additional description: Micturition disorder		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Micturition urgency	Additional description: Micturition urgency		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		

Nocturia	Additional description: Nocturia		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Pollakiuria	Additional description: Pollakiuria		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Polyuria	Additional description: Polyuria		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Renal colic	Additional description: Renal colic		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Renal cyst	Additional description: Renal cyst		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Renal failure	Additional description: Renal failure		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Renal pain	Additional description: Renal pain		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Strangury	Additional description: Strangury		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Urinary incontinence	Additional description: Urinary incontinence		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Urinary tract pain	Additional description: Urinary tract pain		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Urinary tract obstruction	Additional description: Urinary tract obstruction		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Urinary tract inflammation	Additional description: Urinary tract inflammation		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		

Urinary retention	Additional description: Urinary retention		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Urge incontinence	Additional description: Urge incontinence		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Endocrine disorders			
Goitre	Additional description: Goitre		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Hyperthyroidism	Additional description: Hyperthyroidism		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Hypothyroidism	Additional description: Hypothyroidism		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Thyroid cyst	Additional description: Thyroid cyst		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Arthropathy	Additional description: Arthropathy		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Arthritis	Additional description: Arthritis		
subjects affected / exposed	7 / 231 (3.03%)		
occurrences (all)	9		
Arthralgia	Additional description: Arthralgia		
subjects affected / exposed	44 / 231 (19.05%)		
occurrences (all)	53		
Back pain	Additional description: Back pain		
subjects affected / exposed	28 / 231 (12.12%)		
occurrences (all)	31		
Bone pain	Additional description: Bone pain		
subjects affected / exposed	5 / 231 (2.16%)		
occurrences (all)	5		
Bursal haematoma	Additional description: Bursal haematoma		

subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Bursitis	Additional description: Bursitis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Cervical spinal stenosis	Additional description: Cervical spinal stenosis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Exostosis	Additional description: Exostosis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Fibromyalgia	Additional description: Fibromyalgia		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Flank pain	Additional description: Flank pain		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Groin pain	Additional description: Groin pain		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Hypercreatinaemia	Additional description: Hypercreatinaemia		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Intervertebral disc disorder	Additional description: Intervertebral disc disorder		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Intervertebral disc protrusion	Additional description: Intervertebral disc protrusion		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Joint effusion	Additional description: Joint effusion		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	3		
Joint range of motion decreased	Additional description: Joint range of motion decreased		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Joint swelling	Additional description: Joint swelling		

subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	2		
Limb discomfort	Additional description: Limb discomfort		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Mobility decreased	Additional description: Mobility decreased		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Muscle fatigue	Additional description: Muscle fatigue		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Muscle hypertrophy	Additional description: Muscle hypertrophy		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Muscle spasms	Additional description: Muscle spasms		
subjects affected / exposed	21 / 231 (9.09%)		
occurrences (all)	24		
Muscle tightness	Additional description: Muscle tightness		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Muscle twitching	Additional description: Muscle twitching		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Muscular weakness	Additional description: Muscular weakness		
subjects affected / exposed	3 / 231 (1.30%)		
occurrences (all)	3		
Musculoskeletal chest pain	Additional description: Musculoskeletal chest pain		
subjects affected / exposed	5 / 231 (2.16%)		
occurrences (all)	5		
Musculoskeletal discomfort	Additional description: Musculoskeletal discomfort		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Musculoskeletal pain	Additional description: Musculoskeletal pain		
subjects affected / exposed	8 / 231 (3.46%)		
occurrences (all)	8		
Musculoskeletal stiffness	Additional description: Musculoskeletal stiffness		

subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Myalgia	Additional description: Myalgia		
subjects affected / exposed	15 / 231 (6.49%)		
occurrences (all)	16		
Neck pain	Additional description: Neck pain		
subjects affected / exposed	3 / 231 (1.30%)		
occurrences (all)	3		
Myositis	Additional description: Myositis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Osteoarthritis	Additional description: Osteoarthritis		
subjects affected / exposed	3 / 231 (1.30%)		
occurrences (all)	3		
Osteonecrosis	Additional description: Osteonecrosis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Osteoporosis	Additional description: Osteoporosis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Pain in extremity	Additional description: Pain in extremity		
subjects affected / exposed	7 / 231 (3.03%)		
occurrences (all)	7		
Pain in jaw	Additional description: Pain in jaw		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Periarthritis	Additional description: Periarthritis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	2		
Polyarthritis	Additional description: Polyarthritis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Polymyalgia rheumatica	Additional description: Polymyalgia rheumatica		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Psoriatic arthropathy	Additional description: Psoriatic arthropathy		

subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Rheumatic disorder	Additional description: Rheumatic disorder		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Spinal column stenosis	Additional description: Spinal column stenosis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Spinal pain	Additional description: Spinal pain		
subjects affected / exposed	4 / 231 (1.73%)		
occurrences (all)	4		
Tendon disorder	Additional description: Tendon disorder		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Tendonitis	Additional description: Tendonitis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Vertebral foraminal stenosis	Additional description: Vertebral foraminal stenosis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Infections and infestations			
Abscess limb	Additional description: Abscess limb		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Abdominal infection	Additional description: Abdominal infection		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Acarodermatitis	Additional description: Acarodermatitis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Abscess	Additional description: Abscess		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	2		
Acute sinusitis	Additional description: Acute sinusitis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	2		

Atypical pneumonia	Additional description: Atypical pneumonia		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Bacterial blepharitis	Additional description: Bacterial blepharitis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Bacterial food poisoning	Additional description: Bacterial food poisoning		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Bacterial infection	Additional description: Bacterial infection		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Asymptomatic COVID-19	Additional description: Asymptomatic COVID-19		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Bacterial prostatitis	Additional description: Bacterial prostatitis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Bacteriuria	Additional description: Bacteriuria		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Body tinea	Additional description: Body tinea		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Borrelia infection	Additional description: Borrelia infection		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Bronchitis bacterial	Additional description: Bronchitis bacterial		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Bronchopulmonary aspergillosis	Additional description: Bronchopulmonary aspergillosis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Bursitis infective	Additional description: Bursitis infective		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		

Campylobacter gastroenteritis	Additional description: Campylobacter gastroenteritis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Candida infection	Additional description: Candida infection		
subjects affected / exposed	3 / 231 (1.30%)		
occurrences (all)	3		
Bronchitis	Additional description: Bronchitis		
subjects affected / exposed	27 / 231 (11.69%)		
occurrences (all)	29		
Cellulitis	Additional description: Cellulitis		
subjects affected / exposed	3 / 231 (1.30%)		
occurrences (all)	4		
Chronic sinusitis	Additional description: Chronic sinusitis		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	3		
Clostridium difficile colitis	Additional description: Clostridium difficile colitis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Clostridium difficile infection	Additional description: Clostridium difficile infection		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Conjunctivitis	Additional description: Conjunctivitis		
subjects affected / exposed	17 / 231 (7.36%)		
occurrences (all)	22		
COVID-19	Additional description: COVID-19		
subjects affected / exposed	42 / 231 (18.18%)		
occurrences (all)	48		
COVID-19 pneumonia	Additional description: COVID-19 pneumonia		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Cystitis	Additional description: Cystitis		
subjects affected / exposed	11 / 231 (4.76%)		
occurrences (all)	22		
Cytomegalovirus infection	Additional description: Cytomegalovirus infection		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		

Dacryocanaliculitis	Additional description: Dacryocanaliculitis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Dacryocystitis	Additional description: Dacryocystitis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Device related infection	Additional description: Device related infection		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Dengue fever	Additional description: Dengue fever		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Diverticulitis	Additional description: Diverticulitis		
subjects affected / exposed	3 / 231 (1.30%)		
occurrences (all)	3		
Ear infection	Additional description: Ear infection		
subjects affected / exposed	6 / 231 (2.60%)		
occurrences (all)	8		
Ear infection bacterial	Additional description: Ear infection bacterial		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Erythema migrans	Additional description: Erythema migrans		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Enterococcal infection	Additional description: Enterococcal infection		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Enterococcal sepsis	Additional description: Enterococcal sepsis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Epididymitis	Additional description: Epididymitis		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Erysipelas	Additional description: Erysipelas		
subjects affected / exposed	5 / 231 (2.16%)		
occurrences (all)	6		

Eye infection	Additional description: Eye infection		
subjects affected / exposed	3 / 231 (1.30%)		
occurrences (all)	3		
Eyelid infection	Additional description: Eyelid infection		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Febrile infection	Additional description: Febrile infection		
subjects affected / exposed	5 / 231 (2.16%)		
occurrences (all)	5		
Folliculitis	Additional description: Folliculitis		
subjects affected / exposed	3 / 231 (1.30%)		
occurrences (all)	3		
Fungal infection	Additional description: Fungal infection		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Fungal skin infection	Additional description: Fungal skin infection		
subjects affected / exposed	3 / 231 (1.30%)		
occurrences (all)	3		
Furuncle	Additional description: Furuncle		
subjects affected / exposed	3 / 231 (1.30%)		
occurrences (all)	4		
Genital infection fungal	Additional description: Genital infection fungal		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Genital herpes	Additional description: Genital herpes		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Giardiasis	Additional description: Giardiasis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Gastric infection	Additional description: Gastric infection		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Gastroenteritis	Additional description: Gastroenteritis		
subjects affected / exposed	8 / 231 (3.46%)		
occurrences (all)	8		

Gastroenteritis caliciviral	Additional description: Gastroenteritis caliciviral		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Gastroenteritis viral	Additional description: Gastroenteritis viral		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders	Additional description: Gastrointestinal disorders		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Gastrointestinal infection	Additional description: Gastrointestinal infection		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Haemophilus infection	Additional description: Haemophilus infection		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Gingivitis	Additional description: Gingivitis		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	3		
Herpes infection	Additional description: Herpes infection		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Helicobacter gastritis	Additional description: Helicobacter gastritis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Hepatitis B reactivation	Additional description: Hepatitis B reactivation		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Hepatitis E	Additional description: Hepatitis E		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Hepatitis viral	Additional description: Hepatitis viral		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Herpes dermatitis	Additional description: Herpes dermatitis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		

Herpes simplex	Additional description: Herpes simplex		
subjects affected / exposed	5 / 231 (2.16%)		
occurrences (all)	5		
Herpes simplex reactivation	Additional description: Herpes simplex reactivation		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Hordeolum	Additional description: Hordeolum		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Herpes zoster	Additional description: Herpes zoster		
subjects affected / exposed	8 / 231 (3.46%)		
occurrences (all)	8		
Herpes virus infection	Additional description: Herpes virus infection		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Herpes viral infections	Additional description: Herpes viral infections		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Infection	Additional description: Infection		
subjects affected / exposed	9 / 231 (3.90%)		
occurrences (all)	10		
Infection susceptibility increased	Additional description: Infection susceptibility increased		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Infectious colitis	Additional description: Infectious colitis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Infective iritis	Additional description: Infective iritis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Impetigo	Additional description: Impetigo		
subjects affected / exposed	3 / 231 (1.30%)		
occurrences (all)	3		
Infected bite	Additional description: Infected bite		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		

Infected dermal cyst	Additional description: Infected dermal cyst		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Infected skin ulcer	Additional description: Infected skin ulcer		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Injection site cellulitis	Additional description: Injection site cellulitis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Influenza	Additional description: Influenza		
subjects affected / exposed	7 / 231 (3.03%)		
occurrences (all)	8		
Joint abscess	Additional description: Joint abscess		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Kidney infection	Additional description: Kidney infection		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Labyrinthitis	Additional description: Labyrinthitis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Laryngitis	Additional description: Laryngitis		
subjects affected / exposed	3 / 231 (1.30%)		
occurrences (all)	3		
Lip infection	Additional description: Lip infection		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Localised infection	Additional description: Localised infection		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	2		
Lower respiratory tract infection	Additional description: Lower respiratory tract infection		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	5		
Lyme disease	Additional description: Lyme disease		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		

Lymph gland infection	Additional description: Lymph gland infection		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Metapneumovirus infection	Additional description: Metapneumovirus infection		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Mucosal infection	Additional description: Mucosal infection		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Nail infection	Additional description: Nail infection		
subjects affected / exposed	3 / 231 (1.30%)		
occurrences (all)	3		
Nasal candidiasis	Additional description: Nasal candidiasis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Nasopharyngitis	Additional description: Nasopharyngitis		
subjects affected / exposed	46 / 231 (19.91%)		
occurrences (all)	68		
Onychomycosis	Additional description: Onychomycosis		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Neutropenic infection	Additional description: Neutropenic infection		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Omphalitis	Additional description: Omphalitis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Ophthalmic herpes zoster	Additional description: Ophthalmic herpes zoster		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Oral candidiasis	Additional description: Oral candidiasis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Oral fungal infection	Additional description: Oral fungal infection		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		

Oral herpes	Additional description: Oral herpes		
subjects affected / exposed	8 / 231 (3.46%)		
occurrences (all)	8		
Oral infection	Additional description: Oral infection		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Oropharyngeal candidiasis	Additional description: Oropharyngeal candidiasis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Osteomyelitis	Additional description: Osteomyelitis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Otitis media	Additional description: Otitis media		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Otitis media acute	Additional description: Otitis media acute		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Otitis media chronic	Additional description: Otitis media chronic		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Penile infection	Additional description: Penile infection		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Papilloma viral infection	Additional description: Papilloma viral infection		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Parainfluenzae virus infection	Additional description: Parainfluenzae virus infection		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Paronychia	Additional description: Paronychia		
subjects affected / exposed	3 / 231 (1.30%)		
occurrences (all)	3		
Parotitis	Additional description: Parotitis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		

Peritonsillar abscess	Additional description: Peritonsillar abscess		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Pharyngitis	Additional description: Pharyngitis		
subjects affected / exposed	4 / 231 (1.73%)		
occurrences (all)	4		
Pharyngitis bacterial	Additional description: Pharyngitis bacterial		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Pharyngotonsillitis	Additional description: Pharyngotonsillitis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Pneumonia mycoplasmal	Additional description: Pneumonia mycoplasmal		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Pneumonia streptococcal	Additional description: Pneumonia streptococcal		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Post-acute COVID-19 syndrome	Additional description: Post-acute COVID-19 syndrome		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Postoperative wound infection	Additional description: Postoperative wound infection		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Pneumonia	Additional description: Pneumonia		
subjects affected / exposed	23 / 231 (9.96%)		
occurrences (all)	30		
Pulpitis dental	Additional description: Pulpitis dental		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Pyelonephritis	Additional description: Pyelonephritis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Pyuria	Additional description: Pyuria		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		

Respiratory syncytial virus infection	Additional description: Respiratory syncytial virus infection		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Respiratory tract infection	Additional description: Respiratory tract infection		
subjects affected / exposed	12 / 231 (5.19%)		
occurrences (all)	14		
Respiratory tract infection viral	Additional description: Respiratory tract infection viral		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Rhinitis	Additional description: Rhinitis		
subjects affected / exposed	8 / 231 (3.46%)		
occurrences (all)	9		
Sialoadenitis	Additional description: Sialoadenitis		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Root canal infection	Additional description: Root canal infection		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Scarlet fever	Additional description: Scarlet fever		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Scrotal infection	Additional description: Scrotal infection		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Sebaceous gland infection	Additional description: Sebaceous gland infection		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Sinusitis	Additional description: Sinusitis		
subjects affected / exposed	18 / 231 (7.79%)		
occurrences (all)	21		
Skin infection	Additional description: Skin infection		
subjects affected / exposed	5 / 231 (2.16%)		
occurrences (all)	7		
Soft tissue infection	Additional description: Soft tissue infection		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		

Staphylococcal infection	Additional description: Staphylococcal infection		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Subcutaneous abscess	Additional description: Subcutaneous abscess		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Sycosis barbae	Additional description: Sycosis barbae		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Tinea pedis	Additional description: Tinea pedis		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	3		
Tinea infection	Additional description: Tinea infection		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Tonsillitis	Additional description: Tonsillitis		
subjects affected / exposed	6 / 231 (2.60%)		
occurrences (all)	6		
Tooth abscess	Additional description: Tooth abscess		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Tooth infection	Additional description: Tooth infection		
subjects affected / exposed	4 / 231 (1.73%)		
occurrences (all)	4		
Tracheitis	Additional description: Tracheitis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Urethritis	Additional description: Urethritis		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Vaginal infection	Additional description: Vaginal infection		
subjects affected / exposed	6 / 231 (2.60%)		
occurrences (all)	6		
Urosepsis	Additional description: Urosepsis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		

Urinary tract infection viral	Additional description: Urinary tract infection viral		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Urinary tract infection bacterial	Additional description: Urinary tract infection bacterial		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	2		
Urinary tract infection	Additional description: Urinary tract infection		
subjects affected / exposed	29 / 231 (12.55%)		
occurrences (all)	47		
Upper respiratory tract infection	Additional description: Upper respiratory tract infection		
subjects affected / exposed	37 / 231 (16.02%)		
occurrences (all)	55		
Viral upper respiratory tract infection	Additional description: Viral upper respiratory tract infection		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Viral sinusitis	Additional description: Viral sinusitis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Viral infection	Additional description: Viral infection		
subjects affected / exposed	4 / 231 (1.73%)		
occurrences (all)	5		
Vestibular neuronitis	Additional description: Vestibular neuronitis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Varicella zoster virus infection	Additional description: Varicella zoster virus infection		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Vulvovaginal candidiasis	Additional description: Vulvovaginal candidiasis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Vulvovaginal mycotic infection	Additional description: Vulvovaginal mycotic infection		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Wound infection	Additional description: Wound infection		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		

Metabolism and nutrition disorders			
Abnormal weight gain	Additional description: Abnormal weight gain		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Acidosis	Additional description: Acidosis		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Alcohol intolerance	Additional description: Alcohol intolerance		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Decreased appetite	Additional description: Decreased appetite		
subjects affected / exposed	16 / 231 (6.93%)		
occurrences (all)	19		
Diabetes mellitus	Additional description: Diabetes mellitus		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Dehydration	Additional description: Dehydration		
subjects affected / exposed	2 / 231 (0.87%)		
occurrences (all)	2		
Dyslipidaemia	Additional description: Dyslipidaemia		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Fluid overload	Additional description: Fluid overload		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Folate deficiency	Additional description: Folate deficiency		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Gout	Additional description: Gout		
subjects affected / exposed	3 / 231 (1.30%)		
occurrences (all)	4		
Hyperphosphataemia	Additional description: Hyperphosphataemia		
subjects affected / exposed	6 / 231 (2.60%)		
occurrences (all)	6		
Hyperkalaemia	Additional description: Hyperkalaemia		

subjects affected / exposed	10 / 231 (4.33%)		
occurrences (all)	11		
Hyperglycaemia	Additional description: Hyperglycaemia		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Hypercholesterolaemia	Additional description: Hypercholesterolaemia		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Hypercalcaemia	Additional description: Hypercalcaemia		
subjects affected / exposed	4 / 231 (1.73%)		
occurrences (all)	5		
Hyponatraemia	Additional description: Hyponatraemia		
subjects affected / exposed	5 / 231 (2.16%)		
occurrences (all)	6		
Hypomagnesaemia	Additional description: Hypomagnesaemia		
subjects affected / exposed	5 / 231 (2.16%)		
occurrences (all)	6		
Hypokalaemia	Additional description: Hypokalaemia		
subjects affected / exposed	14 / 231 (6.06%)		
occurrences (all)	20		
Hypoferritinaemia	Additional description: Hypoferritinaemia		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Hypocalcaemia	Additional description: Hypocalcaemia		
subjects affected / exposed	6 / 231 (2.60%)		
occurrences (all)	8		
Hyperuricaemia	Additional description: Hyperuricaemia		
subjects affected / exposed	9 / 231 (3.90%)		
occurrences (all)	10		
Hypophosphataemia	Additional description: Hypophosphataemia		
subjects affected / exposed	9 / 231 (3.90%)		
occurrences (all)	15		
Increased appetite	Additional description: Increased appetite		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Iron deficiency	Additional description: Iron deficiency		

subjects affected / exposed	9 / 231 (3.90%)		
occurrences (all)	9		
Iron overload	Additional description: Iron overload		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Obesity	Additional description: Obesity		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		
Tumour lysis syndrome	Additional description: Tumour lysis syndrome		
subjects affected / exposed	13 / 231 (5.63%)		
occurrences (all)	13		
Type 2 diabetes mellitus	Additional description: Type 2 diabetes mellitus		
subjects affected / exposed	0 / 231 (0.00%)		
occurrences (all)	0		
Vitamin D deficiency	Additional description: Vitamin D deficiency		
subjects affected / exposed	5 / 231 (2.16%)		
occurrences (all)	5		
Vitamin B12 deficiency	Additional description: Vitamin B12 deficiency		
subjects affected / exposed	1 / 231 (0.43%)		
occurrences (all)	1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
20 February 2017	Israel and Ireland were included as participating countries. Availability of SmPC as reference document for Venetoclax due to approval by EMA in December 2016, additionally, new data for administration of venetoclax became available. The study duration was adapted after start of recruitment. The recommended porphylaxis in case of HBV DNA detection was adapted following the newest guidelines. Due to new safety information for obinutuzumab regarding infections, dose and schedule modifications in the RVe/GVe or GIVe arm were adapted. New safety information for ibrutinib regarding interstitial lung disease became available and was included in the protocol. Ultrasound testing at baseline was deleted from the protocol, as CT/MRI is mandatory at baseline.
13 July 2017	The non-use of Rituximab bio-similars was specified in the protocol. MRD measurements are no longer performed by four-color, but by multi-colour-flow-cytometry. Dose and schedule modifications for venetoclax in case of febrile neutropenia and thrombocytopenia during ramp up were clarified. An additional appendix for TLS-risk-mangement was added.
05 September 2017	Amendment following updated Venetoclax IMPD. Changes in PIC due to EU general data protection regulation werde made, not all countries were affected.
12 December 2018	Cancer Trials Ireland and the Israeli CLL Study Group were added as participating study group in the title. Additional participating protocol committee members were added as well as the coordinating physician. Accepted delay of study visits was extended to +/- 14 days. Prior treatment with rituximab was added as an exclusion criterion. Hospitalization as prophylaxis of TLS in venetoclax as well as the 2h-post-venetoclax laboratory assessment were not necessarily recommended anymore. Non TLS-related hyperphosphatemia is not a reason for interruption of venetoclax treatment anymore. Due to possibly increased rate of aspergilloses in iburtinib-containing treatment, recommendations concercning infection prophylaxis were added to the protocol. Adjustments according to SmPC of venetoclax were made.
19 February 2020	Changes on frequency of HBV PCR testing were made, pelvis and was included in radiological assessment at baseline, additional sampling (ctDNA) from pB was added in the protocol. Adjustments in safety reporting were made.
26 April 2021	Adjustments and specifications of the statistical chapter were made, MRD analysis by MGS was added as an exploratory endpoint. A chapter regarding Benefit-Risk-Assessment during the Covid-19 pandemic was added to the protocol.
26 April 2021	non-substantial amendment. New SmPCs available
12 December 2022	FU intervals were updated and extended to 13 months.

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/37172204

http://www.ncbi.nlm.nih.gov/pubmed/32601378

http://www.ncbi.nlm.nih.gov/pubmed/37163621

http://www.ncbi.nlm.nih.gov/pubmed/38821083