Clinical trial results:
A Phase 1/2, Multicenter, Open-label Study of FT-2102 as a Single Agent and in Combination With Azacitidine or Cytarabine in Patients With Acute Myeloid Leukemia or Myelodysplastic Syndrome With an IDH1 Mutation

Summary

EudraCT number	2017-001051-32
Trial protocol	DE ES GB IT
Global end of trial date	24 January 2024

Results information

Result version number	v1 (current)
This version publication date	10 May 2025
First version publication date	10 May 2025

Trial information

Trial identification

Sponsor protocol code	2102-HEM-101

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02719574
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Novo Nordisk A/S
Sponsor organisation address	Novo Alle, Bagsvaerd, Denmark, 2880
Public contact	Clinical Reporting Office (2834), Novo Nordisk A/S, clinicaltrials@novonordisk.com
Scientific contact	Clinical Reporting Office (2834), Novo Nordisk A/S, clinicaltrials@novonordisk.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	20 December 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	24 January 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Phase 1: To determine the MTDs, the MEDs, dose-limiting toxicities (DLTs), and the RP2Ds of FT-2102 as a single agent, in combination with azacitidine, and in combination with cytarabine in patients with AML or MDS harboring an IDH1-R132 mutation Phase 2: To evaluate the antileukemic and anti myelodysplastic activity of FT-2102 as a single agent or in combination with azacitidine in patients with AML or MDS, respec-tively harboring an IDH1-R132 mutation.

Protection of trial subjects:

The trial was conducted in accordance with the Declaration of Helsinki (Oct 2013) and ICH Good Clinical Practice, including archiving of essential documents (May 1996) and EN ISO 14155 Part 1 and 2 and FDA 21 CFR 312.120.

Background therapy:

NA

Evidence for comparator:

NA

Actual start date of recruitment	22 August 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	Canada: 13
Country: Number of subjects enrolled	Australia: 37
Country: Number of subjects enrolled	France: 96
Country: Number of subjects enrolled	Germany: 7
Country: Number of subjects enrolled	Italy: 17
Country: Number of subjects enrolled	Korea, Republic of: 3
Country: Number of subjects enrolled	Spain: 30
Country: Number of subjects enrolled	United Kingdom: 17
Country: Number of subjects enrolled	United States: 116
Worldwide total number of subjects	336
EEA total number of subjects	150

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)	89
From 65 to 84 years	240
85 years and over	7

Subject disposition

Recruitment

Recruitment details:

Total 336 subjects enrolled in the study. In phase l, 78 subjects were enrolled in single cohorts (FT-2102) and combination cohorts (FT-2102 with azacitidine/cytarabine) and in phase 2, 258 subjects were enrolled in single cohorts (FT-2102) and combination cohorts (FT-2102 with azacitidine).

Pre-assignment

Screening details:

This study is comprised of 3 stages: Phase 1 dose-escalation stage, Phase 1 dose-expansion stage, and Phase 2 stage. Subjects with R/R AML or MDS with IDH1-R132 mutations received FT-2102 alone or with azacitidine/ cytarabine in Phase 1 and 2. Based on totality of data from Phase 1, RP2D for single-agent and combination treatment was determined.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Phase 1: Total FT-2102 (Single Agent)

Arm description:

Subjects with AML or MDS received single agent Olutasidenib (FT-2102) orally once daily (QD) and BID in 28-day cycles at the different dose levels (150 mg and ≤ 300 mg) until MTD or MED achieved.

Arm type	Experimental
Investigational medicinal product name	FT-2102
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Subjects with AML or MDS received single agent of FT-2102 150 mg BID in continuous 28-day cycles.

Arm title	Phase1:TotalFT-2102;FT-2102+azacitidine(Combination Therapy)

Arm description:

Subjects with AML or MDS received combination therapy azacitidine (administered at the dose of 75 mg/m^2 for 7 days IV/SC +FT-2102 150 mg BID per every 28-day cycle) until treatment discontinuation.

Arm type	Experimental
Investigational medicinal product name	FT- 2102+azacitidine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection, Capsule, hard
Routes of administration	Subcutaneous use, Intravenous use, Oral use

Dosage and administration details:

Subjects with AML or MDS received combination therapy azacitidine (administered at the dose of 75 mg/m^2 for 7 days IV/SC per every 28-day cycle +FT-2102 150 mg BID) until treatment discontinuation.

Arm title	Phase 1: FT-2102 +Cytarabine (Combination Therapy)

Arm description:

Subjects with AML harboring IDH1 mutation received FT-2102 in combination with low-dose cytarabine (LDAC) administered at the dose of 20 mg BID SC for 10 days every 28-day cycle until treatment

discontinuation.

Arm type	Experimental
Investigational medicinal product name	FT-2102+cytarabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection, Capsule, hard
Routes of administration	Subcutaneous use, Oral use

Dosage and administration details:

Subjects with AML harboring IDH1 mutation received FT-2102 in combination with LDAC administered at the dose of 20 mg BID SC for 10 days every 28-day.

Arm title	Phase 2: Cohort 1; FT-2102 (Single Agent)

Arm description:

Subjects with relapsed/refractory (R/R) AML received single agent of FT-2102 150 mg BID in continuous 28-day cycles.

Arm type	Experimental
Investigational medicinal product name	FT-2102
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Subjects with R/R AML received single agent of FT-2102 150 mg BID in continuous 28-day cycles.

Arm title	Phase 2: Cohort 2; FT-2102 (Single Agent)

Arm description:

Subjects with AML in morphologic complete remission (CR)/ complete remission with incomplete blood count recovery (CRi) after prior therapy with residual isocitrate dehydrogenase 1 ([IDH1]-R132 mutation were received single agent of FT-2102 150 mg BID in continuous 28-day cycles.

Arm type	Experimental
Investigational medicinal product name	FT-2102
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Subjects with AML in morphologic CR/CRi after prior therapy with residual IDH1-R132 mutation received single agent of FT-2102 150 mg BID in continuous 28-day cycles.

Arm title	Phase 2: Cohort 3; FT-2102 (Single Agent)

Arm description:

Subjects with R/R AML or MDS who were previously treated with FT-2102 and who underwent HSCT on-study then relapsed post-HSCT received single agent of FT-2102 150 mg BID in continuous 28-day cycles.

Arm type	Experimental
Investigational medicinal product name	FT-2102
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Subjects with R/R AML or MDS who were previously treated with FT-2102 and who underwent HSCT on-study then relapsed post-HSCTreceived single agent of FT-2102 150 mg BID in continuous 28-day cycles.

Arm title	Phase 2: Cohort 4; FT-2102+azacitidine (Combination Therapy)

Arm description:

Subjects with relapsed/refractory (R/R) AML that is naïve to prior hypomethylating therapy and IDH1 inhibitor therapy received combination therapy of azacitidine 75 mg/m^2 + FT-2102 150 mg BID in continuous 28-day cycles.

Arm type	Experimental
Investigational medicinal product name	FT-2102+azacitidine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection, Capsule, hard
Routes of administration	Subcutaneous use, Oral use, Intravenous use

Dosage and administration details:

Subjects with R/R AML that is naïve to prior hypomethylating therapy and IDH1 inhibitor therapy received combination therapy of azacitidine+ FT-2102 150 mg BID in continuous 28-day cycles.

Arm title	Phase 2: Cohort 5; FT-2102+azacitidine (Combination Therapy)

Arm description:

Subjects with R/R AML/MDS that have inadequately responded to or have progressed on prior hypo-methylating therapy received combination therapy of azacitidine 75 mg/m^2 + FT-2102 150 mg BID in continuous 28-day cycles.

Arm type	Experimental
Investigational medicinal product name	FT-2102+azacitidine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection, Capsule, hard
Routes of administration	Subcutaneous use, Oral use, Intravenous use

Dosage and administration details:

Subjects with R/R AML/MDS that have inadequately responded to or have progressed on prior hypo-methylating therapy received combination therapy of azacitidine + FT-2102 150 mg BID in continuous 28-day cycles.

Arm title	Phase 2: Cohort 6; FT-2102+azacitidine (Combination Therapy)

Arm description:

Subjects with R/R AML/MDS that have been previously treated with single agent FT-2102 as their last therapy prior to study enrolment received combination therapy of azacitidine + FT-2102 150 mg BID in con-tinuous 28-day cycles. Participants from the FT-2102 single agent cohorts of this study allowed to be enrolled in Cohort 6 after their disease progression.

Arm type	Experimental
Investigational medicinal product name	FT-2102+azacitidine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection, Capsule, hard
Routes of administration	Subcutaneous use, Oral use, Intravenous use

Dosage and administration details:

Subjects with R/R AML/MDS that have been previously treated with single agent FT-2102 as their last therapy prior to study enrolment received combination therapy of azacitidine + FT-2102 150 mg BID in continuous 28-day cycles.

Arm title	Phase 2: Cohort 7; FT-2102 (Single Agent)

Arm description:

Subjects who have not received any prior AML treatment but may have received a prior treatment for another hematologic malignancy be given single agent of FT-2102 150 mg BID in continuous 28-day cycles.

Arm type	Experimental

Investigational medicinal product name	FT-2102
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Subjects who have not received any prior AML treatment but may have received a prior treatment for another hematologic malignancy be given single agent of FT-2102 150 mg BID in continuous 28-day cycles.

Arm title	Phase 2: Cohort 8; FT-2102+azacitidine (Combination Therapy)

Arm description:

Subjects who have not received any prior AML treatment but may have received a prior treatment for another hematologic malignancy be given combination therapy of azacitidine 75 mg/m^2 + FT-2102 150 mg BID in continuous 28-day cycles.

Arm type	Experimental
Investigational medicinal product name	FT-2102+azacitidine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection, Capsule, hard
Routes of administration	Subcutaneous use, Oral use, Intravenous use

Dosage and administration details:

Subjects who have not received any prior AML treatment but may have received a prior treatment for another hematologic malignancy be given combination therapy of azacitidine + FT-2102 150 mg BID in continuous 28-day cycles.

Number of subjects in period 1	Phase 1: Total FT-2102 (Single Agent)	Phase1:TotalFT-2102;FT-2102+azacitidine(Combination Therapy)	Phase 1: FT-2102 +Cytarabine (Combination Therapy)
Started	31	46	1
Completed	0	0	0
Not completed	31	46	1
Adverse event, serious fatal	5	6	-
Protocol Defined Disease Progression	11	14	1
Consent withdrawn by subject	1	-	-
Adverse event, non-fatal	3	3	-
Unknown	6	9	-
Investigator Decision	1	5	-
Transplant	4	9	-
Protocol deviation	-	-	-

Number of subjects in period 1	Phase 2: Cohort 1; FT-2102 (Single Agent)	Phase 2: Cohort 2; FT-2102 (Single Agent)	Phase 2: Cohort 3; FT-2102 (Single Agent)
Started	153	18	5
Completed	0	0	0
Not completed	153	18	5

Adverse event, serious fatal	14	-	-
Protocol Defined Disease Progression	65	8	2
Consent withdrawn by subject	5	-	-
Adverse event, non-fatal	27	-	1
Unknown	20	7	-
Investigator Decision	6	1	2
Transplant	15	2	-
Protocol deviation	1	-	-

Number of subjects in period 1	Phase 2: Cohort 4; FT-2102+azacitidine (Combination Therapy)	Phase 2: Cohort 5; FT-2102+azacitidine (Combination Therapy)	Phase 2: Cohort 6; FT-2102+azacitidine (Combination Therapy)
Started	20	21	20
Completed	0	0	0
Not completed	20	21	20
Adverse event, serious fatal	1	1	2
Protocol Defined Disease Progression	4	9	11
Consent withdrawn by subject	-	1	1
Adverse event, non-fatal	1	1	2
Unknown	5	7	-
Investigator Decision	3	1	3
Transplant	6	1	1
Protocol deviation	-	-	-

Number of subjects in period 1	Phase 2: Cohort 7; FT-2102 (Single Agent)	Phase 2: Cohort 8; FT-2102+azacitidine (Combination Therapy)
Started	10	11
Completed	0	0
Not completed	10	11
Adverse event, serious fatal	-	-
Protocol Defined Disease Progression	3	4
Consent withdrawn by subject	2	-
Adverse event, non-fatal	2	3
Unknown	1	4
Investigator Decision	2	-
Transplant	-	-
Protocol deviation	-	-

Reporting groups

Reporting group title	Phase 1: Total FT-2102 (Single Agent)

Reporting group description:

Subjects with AML or MDS received single agent Olutasidenib (FT-2102) orally once daily (QD) and BID in 28-day cycles at the different dose levels (150 mg and ≤ 300 mg) until MTD or MED achieved.

Reporting group title	Phase1:TotalFT-2102;FT-2102+azacitidine(Combination Therapy)

Reporting group description:

Subjects with AML or MDS received combination therapy azacitidine (administered at the dose of 75 mg/m^2 for 7 days IV/SC +FT-2102 150 mg BID per every 28-day cycle) until treatment discontinuation.

Reporting group title	Phase 1: FT-2102 +Cytarabine (Combination Therapy)

Reporting group description:

Subjects with AML harboring IDH1 mutation received FT-2102 in combination with low-dose cytarabine (LDAC) administered at the dose of 20 mg BID SC for 10 days every 28-day cycle until treatment discontinuation.

Reporting group title	Phase 2: Cohort 1; FT-2102 (Single Agent)

Reporting group description:

Subjects with relapsed/refractory (R/R) AML received single agent of FT-2102 150 mg BID in continuous 28-day cycles.

Reporting group title	Phase 2: Cohort 2; FT-2102 (Single Agent)

Reporting group description:

Subjects with AML in morphologic complete remission (CR)/ complete remission with incomplete blood count recovery (CRi) after prior therapy with residual isocitrate dehydrogenase 1 ([IDH1]-R132 mutation were received single agent of FT-2102 150 mg BID in continuous 28-day cycles.

Reporting group title	Phase 2: Cohort 3; FT-2102 (Single Agent)

Reporting group description:

Subjects with R/R AML or MDS who were previously treated with FT-2102 and who underwent HSCT on-study then relapsed post-HSCT received single agent of FT-2102 150 mg BID in continuous 28-day cycles.

Reporting group title	Phase 2: Cohort 4; FT-2102+azacitidine (Combination Therapy)

Reporting group description:

Subjects with relapsed/refractory (R/R) AML that is naïve to prior hypomethylating therapy and IDH1 inhibitor therapy received combination therapy of azacitidine 75 mg/m^2 + FT-2102 150 mg BID in continuous 28-day cycles.

Reporting group title	Phase 2: Cohort 5; FT-2102+azacitidine (Combination Therapy)

Reporting group description:

Subjects with R/R AML/MDS that have inadequately responded to or have progressed on prior hypo-methylating therapy received combination therapy of azacitidine 75 mg/m^2 + FT-2102 150 mg BID in continuous 28-day cycles.

Reporting group title	Phase 2: Cohort 6; FT-2102+azacitidine (Combination Therapy)

Reporting group description:

Subjects with R/R AML/MDS that have been previously treated with single agent FT-2102 as their last therapy prior to study enrolment received combination therapy of azacitidine + FT-2102 150 mg BID in con-tinuous 28-day cycles. Participants from the FT-2102 single agent cohorts of this study allowed to be enrolled in Cohort 6 after their disease progression.

Reporting group title	Phase 2: Cohort 7; FT-2102 (Single Agent)

Reporting group description:

Subjects who have not received any prior AML treatment but may have received a prior treatment for another hematologic malignancy be given single agent of FT-2102 150 mg BID in continuous 28-day cycles.

Reporting group title	Phase 2: Cohort 8; FT-2102+azacitidine (Combination Therapy)

Reporting group description:

Subjects who have not received any prior AML treatment but may have received a prior treatment for another hematologic malignancy be given combination therapy of azacitidine 75 mg/m^2 + FT-2102 150 mg BID in continuous 28-day cycles.

Reporting group values	Phase 1: Total FT-2102 (Single Agent)	Phase1:TotalFT-2102;FT-2102+azacitidine(Combination Therapy)	Phase 1: FT-2102 +Cytarabine (Combination Therapy)
Number of subjects	31	46	1
Age Categorical Units: subjects			
<65	7	16	0
65 - <75	13	20	0
>=75	11	10	1
Sex: Female, Male Units: subjects			
Female	16	24	0
Male	15	22	1

Reporting group values	Phase 2: Cohort 1; FT-2102 (Single Agent)	Phase 2: Cohort 2; FT-2102 (Single Agent)	Phase 2: Cohort 3; FT-2102 (Single Agent)
Number of subjects	153	18	5
Age Categorical Units: subjects			
<65	37	5	1
65 - <75	68	11	3
>=75	48	2	1
Sex: Female, Male Units: subjects			
Female	74	6	2
Male	79	12	3

Reporting group values	Phase 2: Cohort 4; FT-2102+azacitidine (Combination Therapy)	Phase 2: Cohort 5; FT-2102+azacitidine (Combination Therapy)	Phase 2: Cohort 6; FT-2102+azacitidine (Combination Therapy)
Number of subjects	20	21	20
Age Categorical Units: subjects			
<65	16	3	3
65 - <75	2	9	9
>=75	2	9	8
Sex: Female, Male Units: subjects			
Female	11	7	10
Male	9	14	10

Reporting group values	Phase 2: Cohort 7; FT-2102 (Single Agent)	Phase 2: Cohort 8; FT-2102+azacitidine (Combination Therapy)	Total
Number of subjects	10	11	336

Age Categorical Units: subjects			
<65	0	1	89
65 - <75	3	6	144
>=75	7	4	103
Sex: Female, Male Units: subjects			
Female	6	2	158
Male	4	9	178

Subject analysis sets

Subject analysis set title	Phase 1: Overall
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with AML or MDS received single agent (FT-2102), combination therapy (FT-2102 + azacitidine, FT-2102+ LDAC) starting at 150 mg BID dose level until MTD or MED achieved or treatment discontinuation.

Subject analysis set title	Phase 2: Single Agent Overall
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with R/R AML, AML in morphologic complete remission (CR)/ complete remission with incomplete blood CRi after prior therapy with residual isocitrate dehydrogenase 1 ([IDH1]-R132 mutation, who underwent HSCT on-study then relapsed post-HSCT, have not received any prior AML treatment but may have received a prior treatment for another hematologic malignancy received single agent of FT-2102 150 mg BID in continuous 28-day cycles.

Subject analysis set title	Phase 2: Combination Therapy
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with R/R AML that is naïve to prior hypomethylating therapy and IDH1 inhibitor therapy, with R/R AML/MDS that have inadequately responded to or have progressed on prior hypo-methylating therapy, R/R AML/MDS that have been previously treated with
single agent FT-2102 as their last therapy prior to study enrolment and who have not received any prior AML treatment but may have received a prior treatment for another hematologic malignancy received combination therapy of azacitidine + FT-2102 150 mg BID in continuous 28-day cycles until disease progression.

Subject analysis set title	Phase 1: FT-2102 (Single Agent)
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with AML or MDS received single agent FT-2102 orally BID in 28-day cycles at dose levels of 150 mg until MTD or MED achieved.

Subject analysis set title	Phase 1: Total FT-2102 (Single Agent)
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with AML or MDS received single agent FT-2102 orally QD and BID in 28-day cycles at the different dose levels (150 mg and ≤ 300 mg) until MTD or MED achieved.

Subject analysis set title	Phase 1: FT-2102 + azacitidine (Combination Therapy)
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with AML or MDS received combination therapy (FT-2102 + azacitidine 75 mg/m^2) orally BID in 28-day cycles at dose levels of 150 mg until MTD or MED achieved.

Subject analysis set title	Phase 1: FT-2102 (Single Agent)
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with AML or MDS received single agent FT-2102 orally BID in 28-day cycles at dose levels of 150 mg until MTD or MED achieved.

Subject analysis set title	Phase 1: Total FT-2102 (Single Agent)
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with AML or MDS received single agent FT-2102 orally QD and BID in 28-day cycles at the different dose levels (150 mg and ≤ 300 mg) until MTD or MED achieved.

Subject analysis set title	Phase 1: FT-2102 + azacitidine (Combination Therapy)
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with AML or MDS received combination therapy (FT-2102 + azacitidine 75 mg/m^2) orally BID in 28-day cycles at dose levels of 150 mg until MTD or MED achieved.

Subject analysis set title	Phase 1: FT-2102 100 mg QD (Single Agent)
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with AML or MDS received single agent FT-2102 orally QD in 28-day cycles at dose level of 100 mg until MTD or MED achieved.

Subject analysis set title	Phase 1: FT-2102 150 mg QD (Single Agent)
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with AML or MDS received single agent FT-2102 orally QD in 28-day cycles at dose levels of 150 mg until MTD or MED achieved.

Subject analysis set title	Phase 1: FT-2102 300 mg QD (Single Agent)
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with AML or MDS received single agent FT-2102 orally QD in 28-day cycles at dose levels of 300 mg until MTD or MED achieved.

Subject analysis set title	Phase 1: FT-2102 150 mg BID (Single Agent
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with AML or MDS received single agent FT-2102 orally BID in 28-day cycles at dose levels of 150 mg until MTD or MED achieved.

Subject analysis set title	Phase 1: FT-2102 150 mg QD+azacitidine(Combination Therapy)
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with AML or MDS received combination therapy (FT-2102 + azacitidine 75 mg/m^2) orally QD in 28-day cycles at dose levels of 150 mg until MTD or MED achieved

Subject analysis set title	Phase 1: FT-2102 150 mg BID+azacitidine(Combination Therapy)
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with AML or MDS received combination therapy (FT-2102 + azacitidine 75 mg/m^2) orally BID in 28-day cycles at dose levels of 150 mg until MTD or MED achieved.

Subject analysis set title	Phase: FT-2102 150 mg BID (Single Agent)
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with AML or MDS received single agent FT-2102 orally BID in 28-day cycles at dose levels of 150 mg until MTD or MED achieved.

Subject analysis set title	Phase 1: FT-2102 150 mg BID+azacitidine(Combination Therapy)
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with AML or MDS received combination therapy (FT-2102 + azacitidine 75 mg/m^2) orally BID in 28-day cycles at dose levels of 150 mg until MTD or MED achieved.

Subject analysis set title	Phase 1: FT-2102 150 mg BID (Single Agent)
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with AML or MDS received single agent FT-2102 orally BID in 28-day cycles at dose levels of 150 mg until MTD or MED achieved.

Subject analysis set title	Phase 1: FT-2102 (Single Agent)
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with AML or MDS received single agent FT-2102 orally BID in 28-day cycles at dose levels of 150 mg until MTD or MED achieved.

Subject analysis set title	Phase 1: Total FT-2102 (Single Agent)
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with AML or MDS received single agent FT-2102 orally QD and BID in 28-day cycles at the different dose levels (150 mg and ≤ 300 mg) until MTD or MED achieved.

Subject analysis set title	Phase 1: FT-2102+azacitidine (Combination Therapy)
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with AML or MDS received combination therapy (FT-2102 + azacitidine 75 mg/m^2) orally BID in 28-day cycles at dose levels of 150 mg until MTD or MED achieved.

Subject analysis set title	Phase 1: FT-2102 (Single Agent)
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with acute AML or MDS received single agent FT-2102 orally BID in 28-day cycles at dose levels of 150 mg until MTD or MED achieved.

Subject analysis set title	Phase 1: Total FT-2102 (Single Agent)
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with AML or MDS received single agent FT-2102 orally QD and BID in 28-day cycles at the different dose levels (150 mg and ≤ 300 mg) until MTD or MED achieved.

Subject analysis set title	Phase 1: FT-2102+azacitidine (Combination Therapy)
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with AML or MDS received combination therapy (FT-2102 + azacitidine 75 mg/m^2) orally BID in 28-day cycles at dose levels of 150 mg until MTD or MED achieved.

Reporting group values	Phase 1: Overall	Phase 2: Single Agent Overall	Phase 2: Combination Therapy
Number of subjects	78	186	72
Age Categorical Units: subjects			
<65			
65 - <75			
>=75			
Sex: Female, Male Units: subjects			
Female	40	88	30
Male	38	98	42

Reporting group values	Phase 1: FT-2102 (Single Agent)	Phase 1: Total FT-2102 (Single Agent)	Phase 1: FT-2102 + azacitidine (Combination Therapy)
Number of subjects	16	31	39
Age Categorical Units: subjects			
<65			

65 - <75 >=75			

Sex: Female, Male Units: subjects			
Female Male			

Reporting group values	Phase 1: FT-2102 (Single Agent)	Phase 1: Total FT-2102 (Single Agent)	Phase 1: FT-2102 + azacitidine (Combination Therapy)
Number of subjects	15	30	38
Age Categorical Units: subjects			
<65 65 - <75 >=75			
Sex: Female, Male Units: subjects			
Female Male			

Reporting group values	Phase 1: FT-2102 100 mg QD (Single Agent)	Phase 1: FT-2102 150 mg QD (Single Agent)	Phase 1: FT-2102 300 mg QD (Single Agent)
Number of subjects	3	8	4
Age Categorical Units: subjects			
<65 65 - <75 >=75			
Sex: Female, Male Units: subjects			
Female Male			

Reporting group values	Phase 1: FT-2102 150 mg BID (Single Agent	Phase 1: FT-2102 150 mg QD+azacitidine(Combination Therapy)	Phase 1: FT-2102 150 mg BID+azacitidine(Combination Therapy)
Number of subjects	6	7	8
Age Categorical Units: subjects			
<65 65 - <75 >=75			
Sex: Female, Male Units: subjects			
Female Male			

Reporting group values	Phase: FT-2102 150 mg BID (Single	Phase 1: FT-2102 150 mg	Phase 1: FT-2102 150 mg BID (Single

	Agent)	BID+azacitidine(Combination Therapy)	Agent)
Number of subjects	6	8	6
Age Categorical Units: subjects			
<65 65 - <75 >=75			
Sex: Female, Male Units: subjects			
Female Male			

Reporting group values	Phase 1: FT-2102 (Single Agent)	Phase 1: Total FT-2102 (Single Agent)	Phase 1: FT-2102+azacitidine (Combination Therapy)
Number of subjects	5	10	18
Age Categorical Units: subjects			
<65 65 - <75 >=75			
Sex: Female, Male Units: subjects			
Female Male			

Reporting group values	Phase 1: FT-2102 (Single Agent)	Phase 1: Total FT-2102 (Single Agent)	Phase 1: FT-2102+azacitidine (Combination Therapy)
Number of subjects	2	2	6
Age Categorical Units: subjects			
<65 65 - <75 >=75			
Sex: Female, Male Units: subjects			
Female Male			

End points

End points reporting groups

Reporting group title	Phase 1: Total FT-2102 (Single Agent)

Reporting group description:

Subjects with AML or MDS received single agent Olutasidenib (FT-2102) orally once daily (QD) and BID in 28-day cycles at the different dose levels (150 mg and ≤ 300 mg) until MTD or MED achieved.

Reporting group title	Phase1:TotalFT-2102;FT-2102+azacitidine(Combination Therapy)

Reporting group description:

Subjects with AML or MDS received combination therapy azacitidine (administered at the dose of 75 mg/m^2 for 7 days IV/SC +FT-2102 150 mg BID per every 28-day cycle) until treatment discontinuation.

Reporting group title	Phase 1: FT-2102 +Cytarabine (Combination Therapy)

Reporting group description:

Subjects with AML harboring IDH1 mutation received FT-2102 in combination with low-dose cytarabine (LDAC) administered at the dose of 20 mg BID SC for 10 days every 28-day cycle until treatment discontinuation.

Reporting group title	Phase 2: Cohort 1; FT-2102 (Single Agent)

Reporting group description:

Subjects with relapsed/refractory (R/R) AML received single agent of FT-2102 150 mg BID in continuous 28-day cycles.

Reporting group title	Phase 2: Cohort 2; FT-2102 (Single Agent)

Reporting group description:

Subjects with AML in morphologic complete remission (CR)/ complete remission with incomplete blood count recovery (CRi) after prior therapy with residual isocitrate dehydrogenase 1 ([IDH1]-R132 mutation were received single agent of FT-2102 150 mg BID in continuous 28-day cycles.

Reporting group title	Phase 2: Cohort 3; FT-2102 (Single Agent)

Reporting group description:

Subjects with R/R AML or MDS who were previously treated with FT-2102 and who underwent HSCT on-study then relapsed post-HSCT received single agent of FT-2102 150 mg BID in continuous 28-day cycles.

Reporting group title	Phase 2: Cohort 4; FT-2102+azacitidine (Combination Therapy)

Reporting group description:

Subjects with relapsed/refractory (R/R) AML that is naïve to prior hypomethylating therapy and IDH1 inhibitor therapy received combination therapy of azacitidine 75 mg/m^2 + FT-2102 150 mg BID in continuous 28-day cycles.

Reporting group title	Phase 2: Cohort 5; FT-2102+azacitidine (Combination Therapy)

Reporting group description:

Subjects with R/R AML/MDS that have inadequately responded to or have progressed on prior hypo-methylating therapy received combination therapy of azacitidine 75 mg/m^2 + FT-2102 150 mg BID in continuous 28-day cycles.

Reporting group title	Phase 2: Cohort 6; FT-2102+azacitidine (Combination Therapy)

Reporting group description:

Subjects with R/R AML/MDS that have been previously treated with single agent FT-2102 as their last therapy prior to study enrolment received combination therapy of azacitidine + FT-2102 150 mg BID in con-tinuous 28-day cycles. Participants from the FT-2102 single agent cohorts of this study allowed to be enrolled in Cohort 6 after their disease progression.

Reporting group title	Phase 2: Cohort 7; FT-2102 (Single Agent)

Reporting group description:

Subjects who have not received any prior AML treatment but may have received a prior treatment for another hematologic malignancy be given single agent of FT-2102 150 mg BID in continuous 28-day cycles.

Reporting group title	Phase 2: Cohort 8; FT-2102+azacitidine (Combination Therapy)

Reporting group description:

Subjects who have not received any prior AML treatment but may have received a prior treatment for another hematologic malignancy be given combination therapy of azacitidine 75 mg/m^2 + FT-2102 150 mg BID in continuous 28-day cycles.

Subject analysis set title	Phase 1: Overall
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with AML or MDS received single agent (FT-2102), combination therapy (FT-2102 + azacitidine, FT-2102+ LDAC) starting at 150 mg BID dose level until MTD or MED achieved or treatment discontinuation.

Subject analysis set title	Phase 2: Single Agent Overall
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with R/R AML, AML in morphologic complete remission (CR)/ complete remission with incomplete blood CRi after prior therapy with residual isocitrate dehydrogenase 1 ([IDH1]-R132 mutation, who underwent HSCT on-study then relapsed post-HSCT, have not received any prior AML treatment but may have received a prior treatment for another hematologic malignancy received single agent of FT-2102 150 mg BID in continuous 28-day cycles.

Subject analysis set title	Phase 2: Combination Therapy
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with R/R AML that is naïve to prior hypomethylating therapy and IDH1 inhibitor therapy, with R/R AML/MDS that have inadequately responded to or have progressed on prior hypo-methylating therapy, R/R AML/MDS that have been previously treated with
single agent FT-2102 as their last therapy prior to study enrolment and who have not received any prior AML treatment but may have received a prior treatment for another hematologic malignancy received combination therapy of azacitidine + FT-2102 150 mg BID in continuous 28-day cycles until disease progression.

Subject analysis set title	Phase 1: FT-2102 (Single Agent)
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with AML or MDS received single agent FT-2102 orally BID in 28-day cycles at dose levels of 150 mg until MTD or MED achieved.

Subject analysis set title	Phase 1: Total FT-2102 (Single Agent)
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with AML or MDS received single agent FT-2102 orally QD and BID in 28-day cycles at the different dose levels (150 mg and ≤ 300 mg) until MTD or MED achieved.

Subject analysis set title	Phase 1: FT-2102 + azacitidine (Combination Therapy)
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with AML or MDS received combination therapy (FT-2102 + azacitidine 75 mg/m^2) orally BID in 28-day cycles at dose levels of 150 mg until MTD or MED achieved.

Subject analysis set title	Phase 1: FT-2102 (Single Agent)
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with AML or MDS received single agent FT-2102 orally BID in 28-day cycles at dose levels of 150 mg until MTD or MED achieved.

Subject analysis set title	Phase 1: Total FT-2102 (Single Agent)
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with AML or MDS received single agent FT-2102 orally QD and BID in 28-day cycles at the different dose levels (150 mg and ≤ 300 mg) until MTD or MED achieved.

Subject analysis set title	Phase 1: FT-2102 + azacitidine (Combination Therapy)
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with AML or MDS received combination therapy (FT-2102 + azacitidine 75 mg/m^2) orally BID in 28-day cycles at dose levels of 150 mg until MTD or MED achieved.

Subject analysis set title	Phase 1: FT-2102 100 mg QD (Single Agent)
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with AML or MDS received single agent FT-2102 orally QD in 28-day cycles at dose level of 100 mg until MTD or MED achieved.

Subject analysis set title	Phase 1: FT-2102 150 mg QD (Single Agent)
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with AML or MDS received single agent FT-2102 orally QD in 28-day cycles at dose levels of 150 mg until MTD or MED achieved.

Subject analysis set title	Phase 1: FT-2102 300 mg QD (Single Agent)
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with AML or MDS received single agent FT-2102 orally QD in 28-day cycles at dose levels of 300 mg until MTD or MED achieved.

Subject analysis set title	Phase 1: FT-2102 150 mg BID (Single Agent
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with AML or MDS received single agent FT-2102 orally BID in 28-day cycles at dose levels of 150 mg until MTD or MED achieved.

Subject analysis set title	Phase 1: FT-2102 150 mg QD+azacitidine(Combination Therapy)
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with AML or MDS received combination therapy (FT-2102 + azacitidine 75 mg/m^2) orally QD in 28-day cycles at dose levels of 150 mg until MTD or MED achieved

Subject analysis set title	Phase 1: FT-2102 150 mg BID+azacitidine(Combination Therapy)
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with AML or MDS received combination therapy (FT-2102 + azacitidine 75 mg/m^2) orally BID in 28-day cycles at dose levels of 150 mg until MTD or MED achieved.

Subject analysis set title	Phase: FT-2102 150 mg BID (Single Agent)
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with AML or MDS received single agent FT-2102 orally BID in 28-day cycles at dose levels of 150 mg until MTD or MED achieved.

Subject analysis set title	Phase 1: FT-2102 150 mg BID+azacitidine(Combination Therapy)
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with AML or MDS received combination therapy (FT-2102 + azacitidine 75 mg/m^2) orally BID in 28-day cycles at dose levels of 150 mg until MTD or MED achieved.

Subject analysis set title	Phase 1: FT-2102 150 mg BID (Single Agent)
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with AML or MDS received single agent FT-2102 orally BID in 28-day cycles at dose levels of 150 mg until MTD or MED achieved.

Subject analysis set title	Phase 1: FT-2102 (Single Agent)
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with AML or MDS received single agent FT-2102 orally BID in 28-day cycles at dose levels of 150 mg until MTD or MED achieved.

Subject analysis set title	Phase 1: Total FT-2102 (Single Agent)
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with AML or MDS received single agent FT-2102 orally QD and BID in 28-day cycles at the different dose levels (150 mg and ≤ 300 mg) until MTD or MED achieved.

Subject analysis set title	Phase 1: FT-2102+azacitidine (Combination Therapy)
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with AML or MDS received combination therapy (FT-2102 + azacitidine 75 mg/m^2) orally BID in 28-day cycles at dose levels of 150 mg until MTD or MED achieved.

Subject analysis set title	Phase 1: FT-2102 (Single Agent)
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with acute AML or MDS received single agent FT-2102 orally BID in 28-day cycles at dose levels of 150 mg until MTD or MED achieved.

Subject analysis set title	Phase 1: Total FT-2102 (Single Agent)
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with AML or MDS received single agent FT-2102 orally QD and BID in 28-day cycles at the different dose levels (150 mg and ≤ 300 mg) until MTD or MED achieved.

Subject analysis set title	Phase 1: FT-2102+azacitidine (Combination Therapy)
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with AML or MDS received combination therapy (FT-2102 + azacitidine 75 mg/m^2) orally BID in 28-day cycles at dose levels of 150 mg until MTD or MED achieved.

Primary: Phase 1: Number of Subjects With Treatment emergent Adverse Events (TEAEs) and Serious Adverse Events (SAEs)

End point title	Phase 1: Number of Subjects With Treatment emergent Adverse Events (TEAEs) and Serious Adverse Events (SAEs)[1][2]

End point description:

A TEAE was defined as an AE with onset on or after start of study drug, or any worsening of preexisting medical condition/AE with onset on or after start of study drug and until 28 days after last dose. An AE was defined as any unfavorable and unintended sign (including an abnormal laboratory finding), symptom or disease temporally associated with use of product, whether or not considered related to product. A serious adverse event (SAE) is defined as any untoward medical occurrence that at any dose results in death,or is life-threatening, or requires inpatient hospitalization or causes prolongation of existing hospitalization results in persistent or significant disability/incapacity, or may have caused congenital anomaly/birth defect, or requires intervention to prevent permanent impairment or damage. Number of subjects with TEAEs and SAEs is reported. Safety analysis set included all subjects who have received at least one dose of study drug (FT-2102, azacitidine, or cytarabine).

End point type	Primary

End point timeframe:

Phase 1: From start of drug administration (Day 1) up to 28 days after last dose of study drug (up to 82 months)

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The primary endpoint investigated safety and was analysed using descriptive statistics, and thus no statistical analysis was performed.
[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint applicable for the reported arms only.

End point values	Phase1:TotalFT-2102;FT-2102+azacitidine(Combination Therapy)	Phase 1: FT-2102 (Single Agent)	Phase 1: Total FT-2102 (Single Agent)	Phase 1: FT-2102 + azacitidine (Combination Therapy)
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	46	16	31	39
Units: Subjects				
TEAEs	46	16	31	39
SAEs	36	10	23	30

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Number of Subjects With Change From Baseline in Clinically Significant Abnormal Laboratory Values

End point title	Phase 1: Number of Subjects With Change From Baseline in Clinically Significant Abnormal Laboratory Values[3][4]

End point description:

Number of subjects with change from baseline in clinically significant abnormal laboratory values for hematology, chemistry and coagulation with Grade <1 to 4 is reported. National Cancer Institute - Common Terminology Criteria for Adverse Events (NCI-CTCAE) version 4.03 toxicity grade used to determine severity of AE. Grade 1: mild;asymptomatic/mild symptoms; Grade 2: moderate; minimal; Grade 3: severe/medically significant; Grade 4: life-threatening consequences, Grade 5: death. Activated partial Thromboplastin signifies as "APT". Safety analysis set included all the subjects who have received at least one dose of study drug (FT-2102, azacitidine, or cytarabine).

End point type	Primary

End point timeframe:

Phase 1: From Baseline up to 28 days after last dose of study drug (up to 82 months)

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The primary endpoint investigated safety and was analysed using descriptive statistics, and thus no statistical analysis was performed.
[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint applicable for the reported arms only.

End point values	Phase1:TotalFT-2102;FT-2102+azacitidine(Combination Therapy)	Phase 1: FT-2102 (Single Agent)	Phase 1: Total FT-2102 (Single Agent)	Phase 1: FT-2102 + azacitidine (Combination Therapy)
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	46	16	31	39
Units: Subjects				
Hematology: Hemoglobin; Increase(Grade <1)	45	15	30	38
Hematology: Hemoglobin; Increase (Grade 1)	0	0	0	0
Hematology: Hemoglobin; Increase (Grade 2)	1	0	1	1

Hematology: Hemoglobin; Increase (Grade 3)	0	0	0	0
Hematology: Hemoglobin; Increase (Grade 4)	0	0	0	0
Hematology: Hemoglobin; Increase (Grade 3 or 4)	0	0	0	0
Hematology: Hemoglobin; Decrease (Grade <1)	0	0	0	0
Hematology: Hemoglobin; Decrease (Grade 1)	0	3	3	0
Hematology: Hemoglobin; Decrease (Grade 2)	10	1	7	9
Hematology: Hemoglobin; Decrease (Grade 3)	36	11	20	30
Hematology: Hemoglobin; Decrease (Grade 4)	0	0	0	0
Hematology: Hemoglobin; Decrease(Grade 3 or 4)	36	11	20	30
Hematology: Platelets; Decrease (Grade <1)	0	1	2	0
Hematology: Platelets; Decrease (Grade 1)	0	2	2	0
Hematology: Platelets; Decrease (Grade 2)	3	0	1	3
Hematology: Platelets; Decrease (Grade 3)	6	1	5	5
Hematology: Platelets; Decrease (Grade 4)	37	11	20	31
Hematology: Platelets; Decrease Grade 3 or 4)	43	12	25	36
Hematology: Leukocytes; Increase (Grade <1)	43	14	28	36
Hematology: Leukocytes; Increase (Grade 1)	0	0	0	0
Hematology: Leukocytes; Increase (Grade 2)	0	0	0	0
Hematology: Leukocytes; Increase (Grade 3)	3	1	2	3
Hematology: Leukocytes; Increase (Grade 4)	0	0	0	0
Hematology: Leukocytes; Increase (Grade 3 or 4)	3	1	2	3
Hematology: Leukocytes; Decrease (Grade <1)	2	1	2	1
Hematology: Leukocytes: Decrease (Grade 1)	1	2	3	1
Hematology: Leukocytes; Decrease (Grade 2)	4	1	6	4
Hematology: Leukocytes; Decrease (Grade 3)	16	4	8	14
Hematology: Leukocytes; Decrease (Grade 4)	23	7	11	19
Hematology: Leukocytes; Decrease (Grade 3 or 4)	39	11	19	33
Hematology: Neutrophils; Decrease (Grade <1)	1	1	1	1
Hematology: Neutrophils; Decrease (Grade 1)	0	0	1	0
Hematology: Neutrophils; Decrease (Grade 2)	0	0	0	0
Hematology: Neutrophils; Decrease (Grade 3)	2	2	5	2

Hematology: Neutrophils; Decrease (Grade 4)	43	12	23	36
Hematology: Neutrophils; Decrease (Grade 3 or 4)	45	14	28	38
Hematology: Lymphocytes; Increase (Grade <1)	32	11	19	26
Hematology: Lymphocytes; Increase (Grade 1)	0	0	0	0
Hematology: Lymphocytes; Increase (Grade 2)	12	3	10	11
Hematology: Lymphocytes: Increase (Grade 3)	1	0	0	1
Hematology: Lymphocytes; Increase (Grade 4)	0	0	0	0
Hematology: Lymphocytes; Increase (Grade 3 or 4)	1	0	0	1
Hematology: Lymphocytes; Decrease(Grade <1)	2	1	3	2
Hematology: Lymphocytes; Decrease(Grade 1)	6	2	7	6
Hematology: Lymphocytes; Decrease(Grade 2)	14	5	6	10
Hematology: Lymphocytes; Decrease(Grade 3)	18	5	10	16
Hematology: Lymphocytes; Decrease(Grade 4)	5	1	3	4
Hematology: Lymphocytes; Decrease(Grade 3 or 4)	23	6	13	20
Chemistry: Creatinine; Increase (Grade <1)	3	0	3	2
Chemistry: Creatinine; Increase (Grade 1)	31	12	23	26
Chemistry: Creatinine; Increase (Grade 2)	11	3	4	10
Chemistry: Creatinine; Increase (Grade 3)	1	0	0	1
Chemistry: Creatinine; Increase (Grade 4)	0	0	0	0
Chemistry: Creatinine; Increase (Grade 3 or 4)	1	0	0	1
Chemistry: Calcium; Increase (Grade <1)	39	13	28	35
Chemistry: Calcium; Increase (Grade 1)	4	0	0	3
Chemistry: Calcium; Increase (Grade 2)	0	0	0	0
Chemistry: Calcium; Increase (Grade 3)	1	1	1	0
Chemistry: Calcium; Increase (Grade 4)	0	1	1	0
Chemistry: Calcium; Increase (Grade 3 or 4)	1	2	2	0
Chemistry: Calcium; Decrease(Grade <1)	16	6	12	13
Chemistry: Calcium; Decrease(Grade 1)	26	9	17	23
Chemistry: Calcium; Decrease(Grade 2)	1	0	1	1
Chemistry: Calcium; Decrease(Grade 3)	1	0	0	1
Chemistry: Calcium; Decrease(Grade 4)	0	0	0	0
Chemistry: Calcium; Decrease(Grade 3 or 4)	1	0	0	1
Chemistry: Magnesium; Increase(Grade <1)	40	15	28	33
Chemistry: Magnesium; Increase(Grade 1)	0	0	0	0

Chemistry: Magnesium; Increase(Grade 2)	0	0	0	0
Chemistry: Magnesium; Increase(Grade 3)	5	0	2	5
Chemistry: Magnesium; Increase(Grade 4)	0	0	0	0
Chemistry: Magnesium; Increase(Grade 3 or 4)	5	0	2	5
Chemistry: Magnesium; Decrease(Grade <1)	26	8	17	24
Chemistry: Magnesium; Decrease(Grade 1)	19	7	13	14
Chemistry: Magnesium; Decrease(Grade 2)	0	0	0	0
Chemistry: Magnesium; Decrease(Grade 3)	0	0	0	0
Chemistry: Magnesium; Decrease(Grade 4)	0	0	0	0
Chemistry: Magnesium; Decrease(Grade 3 or 4)	0	0	0	0
Chemistry: Potassium; Increase(Grade <1)	40	13	24	34
Chemistry: Potassium; Increase(Grade 1)	4	1	5	3
Chemistry: Potassium; Increase(Grade 2)	2	1	1	2
Chemistry: Potassium; Increase(Grade 3)	0	0	0	0
Chemistry: Potassium; Increase(Grade 4)	0	0	0	0
Chemistry: Potassium; Increase(Grade 3 or 4)	0	0	0	0
Chemistry: Potassium; Decrease(Grade <1)	23	10	16	21
Chemistry: Potassium; Decrease(Grade 1)	19	3	10	14
Chemistry: Potassium; Decrease(Grade 2)	0	0	0	0
Chemistry: Potassium; Decrease(Grade 3)	4	2	4	4
Chemistry: Potassium; Decrease(Grade 4)	0	0	0	0
Chemistry: Potassium; Decrease (Grade 3 or 4)	4	2	4	4
Chemistry: Sodium; Increase (Grade <1)	41	13	27	34
Chemistry: Sodium; Increase (Grade 1)	5	2	3	5
Chemistry: Sodium; Increase (Grade 2)	0	0	0	0
Chemistry: Sodium; Increase (Grade 3)	0	0	0	0
Chemistry: Sodium; Increase (Grade 4)	0	0	0	0
Chemistry: Sodium; Increase (Grade 3 or 4)	0	0	0	0
Chemistry: Sodium; Decrease (Grade <1)	19	7	15	17
Chemistry: Sodium; Decrease (Grade 1)	24	7	11	19
Chemistry: Sodium; Decrease (Grade 2)	0	0	0	0
Chemistry: Sodium; Decrease (Grade 3)	3	1	4	3
Chemistry: Sodium; Decrease (Grade 4)	0	0	0	0
Chemistry: Sodium; Decrease (Grade 3 or 4)	3	1	4	3

Chemistry: Uric acid; Increase (Grade <1)	31	10	21	25
Chemistry: Uric acid; Increase (Grade 1)	10	5	9	10
Chemistry: Uric acid; Increase (Grade 2)	0	0	0	0
Chemistry: Uric acid; Increase (Grade 3)	0	0	0	0
Chemistry: Uric acid; Increase (Grade 4)	4	0	0	3
Chemistry: Uric acid; Increase (Grade 3 or 4)	4	0	0	3
Chemistry: Albumin; Decrease(Grade <1)	16	6	12	14
Chemistry: Albumin; Decrease(Grade 1)	12	5	10	12
Chemistry: Albumin; Decrease(Grade 2)	16	2	6	12
Chemistry: Albumin; Decrease(Grade 3)	1	2	2	0
Chemistry: Albumin; Decrease(Grade 4)	0	0	0	0
Chemistry: Albumin; Decrease(Grade 3 or 4)	1	2	2	0
Chemistry: Glucose; Increase (Grade <1)	40	13	26	33
Chemistry: Glucose; Increase (Grade 1)	0	0	0	0
Chemistry: Glucose; Increase (Grade 2)	0	0	0	0
Chemistry: Glucose; Increase (Grade 3)	5	1	2	5
Chemistry: Glucose; Increase (Grade 4)	0	1	2	0
Chemistry: Glucose; Increase (Grade 3 or 4)	5	2	4	5
Chemistry: Glucose; Decrease(Grade <1)	39	14	29	32
Chemistry: Glucose; Decrease(Grade 1)	5	1	1	5
Chemistry: Glucose; Decrease(Grade 2)	1	0	0	1
Chemistry: Glucose; Decrease(Grade 3)	0	0	0	0
Chemistry: Glucose; Decrease(Grade 4)	0	0	0	0
Chemistry: Glucose; Decrease(Grade 3 or 4)	0	0	0	0
Chemistry: Lipase; Increase (Grade <1)	18	2	2	18
Chemistry: Lipase; Increase (Grade 1)	0	1	1	0
Chemistry: Lipase; Increase (Grade 2)	0	0	0	0
Chemistry: Lipase; Increase (Grade 3)	2	1	1	2
Chemistry: Lipase; Increase (Grade 4)	0	0	0	0
Chemistry: Lipase; Increase (Grade 3 or 4)	2	1	1	2
Chemistry: Amylase; Decrease(Grade <1)	19	4	5	19
Chemistry: Amylase; Decrease(Grade 1)	0	0	0	0
Chemistry: Amylase; Decrease(Grade 2)	0	0	0	0
Chemistry: Amylase; Decrease(Grade 3)	0	0	0	0
Chemistry: Amylase; Decrease(Grade 4)	0	0	0	0
Chemistry: Amylase; Decrease(Grade 3 or 4)	0	0	0	0
Coagulation: APT Time; Increase(Grade <1)	21	6	7	20
Coagulation: APT Time; Increase(Grade 1)	2	1	1	2
Coagulation: APT Time; Increase(Grade 2)	1	0	0	1

Coagulation: APT Time; Increase(Grade 3)	1	0	0	1
Coagulation: APT Time; Increase(Grade 4)	0	0	0	0
Coagulation: APT Time; Increase (Grade 3 or 4)	1	0	0	1

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Number of Subjects With Change From Baseline in Clinically Significant Abnormal Electrocardiogram (ECG)

End point title	Phase 1: Number of Subjects With Change From Baseline in Clinically Significant Abnormal Electrocardiogram (ECG)[5][6]

End point description:

Number of subjects with change from baseline in clinically significant abnormal ECG parameter (QTcF) is reported. QT interval was the time between the start of the Q wave and the end of the T wave in the cardiac electrical cycle. QTcF was the QT interval corrected for heart rate using Fridericia's formula: QTcF = QT divided by cube root of 60/heart rate. Safety analysis set included all the subjects who have received at least one dose of study drug (FT-2102, azacitidine, or cytarabine). Here, Number of subjects analysed (N)=subjects with available data for this endpoint.

End point type	Primary

End point timeframe:

Phase 1: From Baseline up to 28 days after last dose of study drug (up to 82 months)

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The primary endpoint investigated safety and was analysed using descriptive statistics, and thus no statistical analysis was performed.
[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint applicable for the reported arms only.

End point values	Phase1:TotalFT-2102;FT-2102+azacitidine(Combination Therapy)	Phase 1: FT-2102 (Single Agent)	Phase 1: Total FT-2102 (Single Agent)	Phase 1: FT-2102 + azacitidine (Combination Therapy)
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	15	30	38
Units: Subjects				
<=450 msec	26	10	16	23
>450 to <=480 msec	13	4	11	10
>480 to <=500 msec	2	0	2	1
>500 msec	4	1	1	4
>30 to <=60 msec	14	2	8	13
>60 msec	6	1	2	5

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2: Percentage of Subjects with CR for MDS Assessed by IWG Response Criteria

End point title	Phase 2: Percentage of Subjects with CR for MDS Assessed by IWG Response Criteria[7][8]

End point description:

Percentage of subjects with complete remission (CR) is reported. CR is defined as bone marrow blast ≤ 5% myeloblasts with normal maturation of all cell lines, peripheral blood: Hgb ≥11 grams per deciliter (g/dL), platelets ≥ 100 × 10^9/L, neutrophils ≥ 1.0 × 10^9/L and blasts 0%. FAS included all the subjects who were enrolled in the study and have received at least one dose of FT-2102. This endpoint is applicable for Cohort 4 and 5. Here, N= subjects with available data for this endpoint.

End point type	Primary

End point timeframe:

Phase 2: up to 3 weeks post last dose of study drug or until the introduction of new anticancer therapy, whichever is earlier (up to 82 months)

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The primary endpoint was analysed using descriptive statistics, and thus no statistical analysis was performed.
[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint applicable for the reported arms only.

End point values	Phase 2: Cohort 4; FT-2102+azacitidine (Combination Therapy)	Phase 2: Cohort 5; FT-2102+azacitidine (Combination Therapy)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	8		
Units: Percentage of subjects				
number (confidence interval 95%)	0 (0.0 to 97.5)	13 (0.3 to 52.7)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2, Cohort 1: Percentage of Subjects with Complete Remission (CR) Plus Complete Remission with Partial Hematological Recovery (CRh) for Acute Myeloid Leukemia Assessed by Investigator Based on International Working Group (IWG) Response Criteria

End point title	Phase 2, Cohort 1: Percentage of Subjects with Complete Remission (CR) Plus Complete Remission with Partial Hematological Recovery (CRh) for Acute Myeloid Leukemia Assessed by Investigator Based on International Working Group (IWG) Response Criteria[9][10]

End point description:

Percentage of subjects with CR plus CRh (CR, Molecular CR [CRm], Cytogenetic CR [CRc], CRh) is reported. CR is defined as bone marrow blasts less than (<) 5 percent (%) (in aspirate with spicules and 200 nucleated cells), no blasts with auer rods, no extramedullary disease, absolute neutrophil count (ANC) greater than or equal to (>=) 1000/µL, platelet count >=100,000/µL and transfusion independence. CRc is defined as CR with no residual cytogenetic abnormalities. CRm is defined as CR with undetectable IDH1m minimal residual disease (MRD) and CRh is defined as bone marrow blasts and

partial recovery of peripheral blood counts (platelet count >50*10^9/L and ANC > 0.5*10^9/L). Efficacy evaluable analysis set included all subjects in Phase 2, Cohort 1 with confirmed IDH1-R132 who have received the first dose of FT-2102 180 days or more prior to the analysis cutoff date. This endpoint is applicable only for Cohort 1.

End point type	Primary

End point timeframe:

Phase 2: up to 3 weeks post last dose of study drug or until the introduction of new anticancer therapy, whichever is earlier (up to 82 months)

Notes:

[9] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The primary endpoint was analysed using descriptive statistics, and thus no statistical analysis was performed.
[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint applicable for the reported arms only.

End point values	Phase 2: Cohort 1; FT-2102 (Single Agent)			
Subject group type	Reporting group			
Number of subjects analysed	147			
Units: Percentage of Subjects				
number (confidence interval 95%)	35 (27.0 to 43.0)			

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2, Cohort 3, 4, 5, 6, 7, 8: Percentage of Subjects with CR Plus CRh for Acute Myeloid Leukemia Assessed by Investigator Based on IWG Response Criteria

End point title	Phase 2, Cohort 3, 4, 5, 6, 7, 8: Percentage of Subjects with CR Plus CRh for Acute Myeloid Leukemia Assessed by Investigator Based on IWG Response Criteria[11][12]

End point description:

Percentage of subjects with CR plus CRh (CR, Molecular CR [CRm]), Cytogenetic CR [CRc], CRh) is reported. CR is defined as bone marrow blasts <5 % (in aspirate with spicules and 200 nucleated cells), no blasts with auer rods, no extramedullary disease, ANC >=1000/µL, platelet count >=100,000/µL and transfusion independence. CRc is defined as CR with no residual cytogenetic abnormalities. CRm is defined as CR with undetectable IDH1m MRD and CRh is defined as bone marrow blasts and partial recovery of peripheral blood counts (platelet count >50 × 10^9/L and ANC >0.5 × 10^9/L). Full analysis set included all the subjects who were enrolled in the study and have received at least one dose of FT-2102. This endpoint is applicable for Cohort 3, 4, 5, 6, 7 and 8. Here, N= subjects with available data for this endpoint.

End point type	Primary

End point timeframe:

Phase 2: up to 3 weeks post last dose of study drug or until the introduction of new anticancer therapy, whichever is earlier (up to 82 months)

Notes:

[11] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The primary endpoint was analysed using descriptive statistics, and thus no statistical analysis was performed.

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint applicable for the reported arms only.

End point values	Phase 2: Cohort 3; FT-2102 (Single Agent)	Phase 2: Cohort 4; FT-2102+azacitidine (Combination Therapy)	Phase 2: Cohort 5; FT-2102+azacitidine (Combination Therapy)	Phase 2: Cohort 6; FT-2102+azacitidine (Combination Therapy)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	19	13	20
Units: Percentage of subjects				
number (confidence interval 95%)	0 (0.0 to 52.2)	47 (24.4 to 71.1)	38 (13.9 to 68.4)	30 (11.9 to 54.3)

End point values	Phase 2: Cohort 7; FT-2102 (Single Agent)	Phase 2: Cohort 8; FT-2102+azacitidine (Combination Therapy)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	11		
Units: Percentage of subjects				
number (confidence interval 95%)	40 (12.2 to 73.8)	45 (16.7 to 76.6)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2: Four-month Relapse Free survival (RFS) Rate (Cohort 2)

End point title	Phase 2: Four-month Relapse Free survival (RFS) Rate (Cohort 2)[13][14]

End point description:

RFS is defined as the time between the date of first dose until relapse or death from any cause, whichever occurs first. RFS is calculated for all subjects in Phase 2 Cohort 2. 4-Month RFS rate is defined as the proportion of subjects in Phase 2 Cohort 2 who have not relapsed or died on or before their 4-month response evaluation. Full analysis set included all the subjects who were enrolled in the study and have received at least one dose of FT-2102.

End point type	Primary

End point timeframe:

Phase 2: From the date of first dose until relapse or death from any cause, whichever occurs first (up to 82 months)

Notes:

[13] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The primary endpoint was analysed using descriptive statistics, and thus no statistical analysis was performed.
[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline

period.

Justification: This endpoint applicable for the reported arms only.

End point values	Phase 2: Cohort 2; FT-2102 (Single Agent)			
Subject group type	Reporting group			
Number of subjects analysed	18			
Units: Percentage of subjects				
number (confidence interval 95%)	83 (58.6 to 96.4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1: Area Under the Curve (AUClast) for FT-2102

End point title	Phase 1: Area Under the Curve (AUClast) for FT-2102

End point description:

Area under the plasma concentration-time curve from zero time until the last measurable concentration is presented. The pharmacokinetic (PK) analysis set included those subjects for whom it was possible to calculate at least 1 primary PK parameter and who had no major protocol deviations thought to influence the absorption, distribution, metabolism, and excretion of the FT-2102. Here, number anaylsed (n) = subjects with available data for specific timepoints.

End point type	Secondary

End point timeframe:

Phase 1: Cycle 1 Day 1 and Cycle 2 Day 1 (Cycle length= 28 days)

End point values	Phase 1: FT-2102 100 mg QD (Single Agent)	Phase 1: FT-2102 150 mg QD (Single Agent)	Phase 1: FT-2102 300 mg QD (Single Agent)	Phase 1: FT-2102 150 mg BID (Single Agent
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	3	8	4	6
Units: Hour*nanograms per millilitre (h*ng/mL)				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (n=3, 8, 4, 6, 7, 8)	5505 (± 146.9)	8955 (± 63.7)	12100 (± 75.4)	2538 (± 34.2)
Cycle 2 Day 1 (n= 3, 5, 4, 6, 6, 5)	13080 (± 63.5)	14130 (± 124.0)	19140 (± 24.0)	26360 (± 22.3)

End point values	Phase 1: FT-2102 150 mg QD+azacitidine (Combination Therapy)	Phase 1: FT-2102 150 mg BID+azacitidine(Combination Therapy)		

Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	7	8		
Units: Hour*nanograms per millilitre (h*ng/mL)				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (n=3, 8, 4, 6, 7, 8)	8529 (± 51.1)	2288 (± 71.7)		
Cycle 2 Day 1 (n= 3, 5, 4, 6, 6, 5)	7468 (± 92.6)	20640 (± 71.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1: Maximum Plasma Concentration (Cmax) for FT-2102

End point title	Phase 1: Maximum Plasma Concentration (Cmax) for FT-2102

End point description:

Maximum plasma concentration (Cmax) for FT-2102 is presented. The PK analysis set included those subjects for whom it was possible to calculate at least 1 primary PK parameter and who had no major protocol deviations thought to influence the absorption, distribution, metabolism, and excretion of the FT-2102. Here, number anaylsed (n) = subjects with available data for specific timepoints.

End point type	Secondary

End point timeframe:

Phase 1: Cycle 1 Day 1 and Cycle 2 Day 1 (Cycle length= 28 days)

End point values	Phase 1: FT-2102 100 mg QD (Single Agent)	Phase 1: FT-2102 150 mg QD (Single Agent)	Phase 1: FT-2102 300 mg QD (Single Agent)	Phase 1: FT-2102 150 mg QD+azacitidine (Combination Therapy)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	3	8	4	7
Units: Nanograms per millilitre (ng/mL)				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (n=3, 8, 4, 6, 7, 8)	571.5 (± 53.1)	535.0 (± 58.7)	708.0 (± 58.2)	543.3 (± 39.8)
Cycle 2 Day 1 (n=3, 5, 4, 6, 6, 5)	1913 (± 47.9)	1998 (± 112.9)	2907 (± 36.1)	1101 (± 75.4)

End point values	Phase: FT-2102 150 mg BID (Single Agent)	Phase 1: FT-2102 150 mg BID+azacitidine(Combination Therapy)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	6	8		
Units: Nanograms per millilitre (ng/mL)				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (n=3, 8, 4, 6, 7, 8)	495.5 (± 37.4)	439.9 (± 56.2)		

Cycle 2 Day 1 (n=3, 5, 4, 6, 6, 5)	3703 (± 20.8)	3183 (± 51.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1: Time to Maximum Plasma Concentration (Tmax) for FT-2102

End point title	Phase 1: Time to Maximum Plasma Concentration (Tmax) for FT-2102

End point description:

Time to reach the maximum plasma concentration (Tmax) is presented. The PK analysis set included those subjects for whom it was possible to calculate at least 1 primary PK parameter and who had no major protocol deviations thought to influence the absorption, distribution, metabolism, and excretion of the FT-2102. Here, number anaylsed (n) = subjects with available data for specific timepoints.

End point type	Secondary

End point timeframe:

Phase 1: Cycle 1 Day 1 and Cycle 2 Day 1 (Cycle length= 28 days)

End point values	Phase 1: FT-2102 100 mg QD (Single Agent)	Phase 1: FT-2102 150 mg QD (Single Agent)	Phase 1: FT-2102 300 mg QD (Single Agent)	Phase 1: FT-2102 150 mg QD+azacitidine (Combination Therapy)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	3	8	4	7
Units: hour				
median (full range (min-max))				
Cycle 1 Day 1 (n=3, 8, 4, 6, 7, 8)	4.05 (2.22 to 4.12)	4.00 (2.02 to 24.00)	23.83 (4.00 to 24.00)	4.02 (2.00 to 22.55)
Cycle 2 Day 1 (n=3, 5, 4, 6, 6, 5)	2.23 (2.13 to 4.00)	2.00 (1.00 to 2.12)	1.00 (0.00 to 1.08)	2.29 (2.00 to 4.00)

End point values	Phase 1: FT-2102 150 mg BID+azacitidine(Combination Therapy)	Phase 1: FT-2102 150 mg BID (Single Agent)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	8	6		
Units: hour				
median (full range (min-max))				
Cycle 1 Day 1 (n=3, 8, 4, 6, 7, 8)	3.13 (2.03 to 4.12)	5.79 (1.00 to 7.83)		
Cycle 2 Day 1 (n=3, 5, 4, 6, 6, 5)	1.18 (0.00 to 2.07)	3.00 (0.00 to 7.50)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1: Time to Response (TTR) for AML

End point title	Phase 1: Time to Response (TTR) for AML[15]

End point description:

TTR is the time in months between the first dose of study drug and documentation of the first overall response for subjects who achieve a PR or better. This analysis was performed only on subjects who have achieved PR or better as a best overall response. FAS included all the subjects who were enrolled in the study and have received at least one dose of FT-2102. Here, N= subjects with PR or better as a best overall response.

End point type	Secondary

End point timeframe:

Phase 1: Time from first dose of study drug until documentation of the first overall response (up to 82 months)

Notes:

[15] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint applicable for the reported arms only.

End point values	Phase1:TotalFT-2102;FT-2102+azacitidine(Combination Therapy)	Phase 1: FT-2102 (Single Agent)	Phase 1: Total FT-2102 (Single Agent)	Phase 1: FT-2102+azacitidine (Combination Therapy)
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	22	5	10	18
Units: Months				
median (full range (min-max))	1.90 (1.0 to 5.6)	1.90 (1.0 to 2.9)	1.90 (1.0 to 4.7)	1.90 (1.0 to 5.6)

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1: Duration of Overall Response for AML

End point title	Phase 1: Duration of Overall Response for AML[16]

End point description:

Duration of response is defined as the time from the date of the first response to the date of the relapse or death. FAS included all the subjects who were enrolled in the study and have received at least one dose of FT-2102. Here, N = subjects with available data for this endpoint. Here 99999 signifies that since the upper confidence limits for the survivor function lies above 0.5, it is not possible to estimate the upper confidence limit for the median.

End point type	Secondary

End point timeframe:

Phase 1: From date of the first response to the date of the relapse or death (up to 82 months)

Notes:

[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint applicable for the reported arms only.

End point values	Phase1:TotalFT-2102;FT-2102+azacitidine(Combination Therapy)	Phase 1: FT-2102 (Single Agent)	Phase 1: Total FT-2102 (Single Agent)	Phase 1: FT-2102+azacitidine (Combination Therapy)
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	22	5	10	18
Units: Months				
median (confidence interval 95%)	22.00 (3.20 to 99999)	3.60 (1.70 to 99999)	2.90 (0.90 to 6.40)	22.00 (3.20 to 99999)

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1: Time to Response (TTR) for MDS

End point title	Phase 1: Time to Response (TTR) for MDS[17]

End point description:

TTR is the time in months between the first dose of study drug and documentation of the first overall response for subjects who achieve a PR or better. This analysis was performed only on subjects who have achieved PR or better as a best overall response. FAS included all the subjects who were enrolled in the study and have received at least one dose of FT-2102. Here, N= subjects with PR or better as a best overall response.

End point type	Secondary

End point timeframe:

Phase 1: Time from first dose of study drug until documentation of the first overall response (up to 82 months)

Notes:

[17] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint applicable for the reported arms only.

End point values	Phase1:TotalFT-2102;FT-2102+azacitidine(Combination Therapy)	Phase 1: FT-2102 (Single Agent)	Phase 1: Total FT-2102 (Single Agent)	Phase 1: FT-2102+azacitidine (Combination Therapy)
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	6	2	2	6
Units: Months				
median (full range (min-max))	2.20 (1.0 to 8.5)	4.65 (1.0 to 8.3)	4.65 (1.0 to 8.3)	2.20 (1.0 to 8.5)

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Time to Response (TTR) for Acute Myeloid Leukemia (AML)

End point title	Phase 2: Time to Response (TTR) for Acute Myeloid Leukemia (AML)[18]

End point description:

TTR is the time in months between the first dose of study drug and documentation of the first overall response for subjects who achieve a PR or better. This analysis was performed only on subjects who have achieved PR or better as a best overall response. FAS included all the subjects who were enrolled in the study and have received at least one dose of FT-2102. Here, N= subjects with PR or better as a best overall response. Data is reported only for Cohort 1, 3, 4, 5, 6, 7 and 8.

End point type	Secondary

End point timeframe:

Phase 2: Time from first dose of study drug until documentation of the first overall response (up to 82 months)

Notes:

[18] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint applicable for the reported arms only.

End point values	Phase 2: Cohort 1; FT-2102 (Single Agent)	Phase 2: Cohort 3; FT-2102 (Single Agent)	Phase 2: Cohort 4; FT-2102+azacitidine (Combination Therapy)	Phase 2: Cohort 5; FT-2102+azacitidine (Combination Therapy)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	75	0[19]	13	6
Units: Months				
median (full range (min-max))	1.90 (0.9 to 10.2)	(to)	1.80 (0.9 to 3.8)	2.50 (1.0 to 4.2)

Notes:

[19] - Subjects were not evaluated

End point values	Phase 2: Cohort 6; FT-2102+azacitidine (Combination Therapy)	Phase 2: Cohort 7; FT-2102 (Single Agent)	Phase 2: Cohort 8; FT-2102+azacitidine (Combination Therapy)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	8	5	7	
Units: Months				
median (full range (min-max))	2.50 (1.0 to 7.6)	1.90 (1.8 to 3.9)	2.80 (1.1 to 5.6)	

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Duration of Overall Response for Acute Myeloid Leukemia (AML)

End point title	Phase 2: Duration of Overall Response for Acute Myeloid Leukemia (AML)[20]

End point description:

Duration of overall response is defined as the time from the date of the first response to the date of the relapse or death. FAS included all the subjects who were enrolled in the study and have received at least one dose of FT-2102. Data is reported only for Cohort 1, 4, 5, 6, 7 and 8. No subjects achieved an overall response in Phase 2 Cohort 3. Duration of Response is not calculated for Phase 2 Cohort 2. Here, N = subjects with overall response for this endpoint. Here 99999 signifies that since the upper confidence limits for the survivor function lies above 0.5, it is not possible to estimate the upper confidence limit for the median.

End point type	Secondary

End point timeframe:

Phase 2: From the date of the first response to the date of the relapse or death (up to 82 months)

Notes:

[20] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint applicable for the reported arms only.

End point values	Phase 2: Cohort 1; FT-2102 (Single Agent)	Phase 2: Cohort 4; FT-2102+azacitidine (Combination Therapy)	Phase 2: Cohort 5; FT-2102+azacitidine (Combination Therapy)	Phase 2: Cohort 6; FT-2102+azacitidine (Combination Therapy)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	75	13	6	8
Units: Months				
median (confidence interval 95%)	14.80 (7.40 to 19.40)	20.00 (1.90 to 28.80)	7.25 (4.90 to 99999)	4.65 (2.80 to 99999)

End point values	Phase 2: Cohort 7; FT-2102 (Single Agent)	Phase 2: Cohort 8; FT-2102+azacitidine (Combination Therapy)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	7		
Units: Months				
median (confidence interval 95%)	10.60 (3.5 to 39.6)	20.90 (5.60 to 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Time to Response (TTR) for Myelodysplastic Syndrome (MDS)

End point title	Phase 2: Time to Response (TTR) for Myelodysplastic Syndrome (MDS)[21]

End point description:

TTR is the time in months between the first dose of study drug and documentation of the first overall response for subjects who achieve a PR or better. This analysis was performed only on subjects who have achieved PR or better as a best overall response. FAS included all the subjects who were enrolled in the study and have received at least one dose of FT-2102. This endpoint is applicable for Cohort 4 and 5. Here, N= participants with PR or better as a best overall response.

End point type	Secondary

End point timeframe:

Phase 2: Time from first dose of study drug until documentation of the first overall response (up to 82 months)

Notes:

[21] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint applicable for the reported arms only.

End point values	Phase 2: Cohort 4; FT-2102+azacitidine (Combination Therapy)	Phase 2: Cohort 5; FT-2102+azacitidine (Combination Therapy)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	4		
Units: Months				
median (full range (min-max))	3.30 (3.3 to 3.3)	1.50 (1.0 to 13.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Overall Survival (OS)

End point title	Phase 2: Overall Survival (OS)[22]

End point description:

OS is defined as the time in months from the first dose of study drug until death from any cause. For the subjects who are not known to have died by the end of study follow-up, OS will be censored on the date the subjects was last known to be alive. OS is calculated using Kaplan-Meier method. FAS included all the subjects who were enrolled in the study and have received at least one dose of FT-2102. Here, 99999 signifies since the upper confidence limits for the survivor function lies above 0.5, it is not possible to estimate the upper confidence limit for the median and the median was not reached, since

more than half of the subjects in the study had not experienced the event of death at the time of analysis.

End point type	Secondary

End point timeframe:

Phase 2: From first dose of study drug until death from any cause (up to 82 months)

Notes:

[22] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint applicable for the reported arms only.

End point values	Phase 2: Cohort 1; FT-2102 (Single Agent)	Phase 2: Cohort 2; FT-2102 (Single Agent)	Phase 2: Cohort 3; FT-2102 (Single Agent)	Phase 2: Cohort 4; FT-2102+azacitidine (Combination Therapy)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	153	18	5	20
Units: Months				
median (confidence interval 95%)	11.60 (8.90 to 15.50)	99999 (27.30 to 99999)	1.20 (1.10 to 99999)	25.20 (13.60 to 99999)

End point values	Phase 2: Cohort 5; FT-2102+azacitidine (Combination Therapy)	Phase 2: Cohort 6; FT-2102+azacitidine (Combination Therapy)	Phase 2: Cohort 7; FT-2102 (Single Agent)	Phase 2: Cohort 8; FT-2102+azacitidine (Combination Therapy)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	20	10	11
Units: Months				
median (confidence interval 95%)	11.60 (5.00 to 27.50)	10.20 (4.40 to 17.90)	14.00 (1.00 to 19.10)	18.70 (1.60 to 99999)

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Duration of Overall Response for Myelodysplastic Syndrome (MDS)

End point title	Phase 2: Duration of Overall Response for Myelodysplastic Syndrome (MDS)[23]

End point description:

Duration of overall response is defined as the time from the date of the first response to the date of the relapse or death. FAS included all the subjects who were enrolled in the study and have received at least one dose of FT-2102. This endpoint is applicable for Cohort 4 and 5. Here, N = subjects with overall response for this endpoint. Here 99999 signifies that median, upper and lower limit of 95% CI could not be calculated since there is only one subject for Cohort 4 and since the upper confidence limits for the survivor function lies above 0.5, it is not possible to estimate the upper confidence limit for the median for Cohort 5.

End point type	Secondary

End point timeframe:

Phase 2: From the documentation of the first response of PR or better until the date of relapse, death, whichever is earlier (up to 82 months)

Notes:

[23] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint applicable for the reported arms only.

End point values	Phase 2: Cohort 4; FT-2102+azacitidine (Combination Therapy)	Phase 2: Cohort 5; FT-2102+azacitidine (Combination Therapy)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	4		
Units: Months				
median (confidence interval 95%)	99999 (99999 to 99999)	11.90 (2.8 to 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2 Cohort 2: Time to Relapse-Free Survival (RFS)

End point title	Phase 2 Cohort 2: Time to Relapse-Free Survival (RFS)[24]

End point description:

RFS was calculated for all subjects in Phase 2 Cohort 2. RFS is defined as the time (in months) between the date of first dose until relapse or death from any cause, whichever occurs first. Relapse free survival time to event is reported for all subjects in Cohort 2. FAS included all the subjects who were enrolled in the study and have received at least one dose of FT-2102. Here 99999 signifies that since the upper confidence limits for the survivor function lies above 0.5, it is not possible to estimate the upper confidence limit for the median.

End point type	Secondary

End point timeframe:

Phase 2: From the date of first dose until relapse or death from any cause, whichever occurs first (up to 82 months)

Notes:

[24] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint applicable for the reported arms only.

End point values	Phase 2: Cohort 2; FT-2102 (Single Agent)			
Subject group type	Reporting group			
Number of subjects analysed	18			
Units: Months				
median (confidence interval 95%)	18.40 (9.50 to 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Transfusion Independence

End point title	Phase 2: Transfusion Independence[25]

End point description:

Transfusion independence is defined as the number of subjects who experience at least a 56-day period during any point on treatment without requiring a transfusion of RBC and/or platelet transfusion. Subjects are classified as either "dependent" or "independent" at baseline based on their transfusion history. Those who received either platelets or pRBC or both within 8 weeks prior to the first dose of FT-2102 are considered "dependent. FAS included all the subjects who were enrolled in the study and have received at least one dose of FT-2102. Number of subjects with transfusion independent is reported here.

End point type	Secondary

End point timeframe:

Phase 2: From baseline (8 weeks prior to first dose) up to treatment period (up to 82 months)

Notes:

[25] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint applicable for the reported arms only.

End point values	Phase 2: Cohort 1; FT-2102 (Single Agent)	Phase 2: Cohort 2; FT-2102 (Single Agent)	Phase 2: Cohort 3; FT-2102 (Single Agent)	Phase 2: Cohort 4; FT-2102+azacitidine (Combination Therapy)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	153	18	5	20
Units: Subjects	72	15	0	12

End point values	Phase 2: Cohort 5; FT-2102+azacitidine (Combination Therapy)	Phase 2: Cohort 6; FT-2102+azacitidine (Combination Therapy)	Phase 2: Cohort 7; FT-2102 (Single Agent)	Phase 2: Cohort 8; FT-2102+azacitidine (Combination Therapy)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	20	10	11
Units: Subjects	13	14	3	8

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Event-free survival (EFS)

End point title	Phase 2: Event-free survival (EFS)[26]

End point description:

EFS is defined as the time in months between first dose of study drug and disease progression, relapse, death from any cause, treatment failure, or start of other (non-protocol study drug) new antileukemia therapy, whichever occurs first. FAS included all the subjects who were enrolled in the study and have received at least one dose of FT-2102. Here 99999 signifies that since the upper confidence limits for the survivor function lies above 0.5, it is not possible to estimate the upper confidence limit for the median.

End point type	Secondary

End point timeframe:

Phase 2: From first dose of study drug to disease progression, relapse, death from any cause, treatment failure, or start of other (non-protocol study drug) new antileukemia therapy (up to 82 months)

Notes:

[26] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint applicable for the reported arms only.

End point values	Phase 2: Cohort 1; FT-2102 (Single Agent)	Phase 2: Cohort 2; FT-2102 (Single Agent)	Phase 2: Cohort 3; FT-2102 (Single Agent)	Phase 2: Cohort 4; FT-2102+azacitidine (Combination Therapy)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	153	18	5	20
Units: Months				
median (confidence interval 95%)	5.50 (4.30 to 7.40)	18.40 (9.50 to 99999)	1.05 (0.80 to 99999)	5.70 (1.90 to 16.40)

End point values	Phase 2: Cohort 5; FT-2102+azacitidine (Combination Therapy)	Phase 2: Cohort 6; FT-2102+azacitidine (Combination Therapy)	Phase 2: Cohort 7; FT-2102 (Single Agent)	Phase 2: Cohort 8; FT-2102+azacitidine (Combination Therapy)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	20	10	11
Units: Months				
median (confidence interval 95%)	7.80 (2.10 to 10.20)	4.80 (2.50 to 9.70)	5.50 (0.30 to 99999)	8.10 (1.60 to 33.00)

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Number of Subjects With Treatment-emergent Adverse Events (TEAEs) and Serious Adverse Events (SAEs)

End point title	Phase 2: Number of Subjects With Treatment-emergent

	Adverse Events (TEAEs) and Serious Adverse Events (SAEs)[27]

End point description:

A TEAE was defined as an AE with onset on or after the start of study drug, or any worsen-ing of a pre-existing medical condition/AE with onset on or after the start of study drug and until 28 days after the last dose. An AE was defined as any unfavourable and unintended sign (including an abnormal laboratory finding), symptom or disease temporally associated with the use of a product, whether or not considered related to the product. A SAE is defined as any untoward medical occur-rence that at any dose results in death, or is life-threatening, or requires inpatient hospitalisation or causes prolongation of existing hospitalisation results in persistent or significant disability/incapacity, or may have caused a congenital anomaly/birth defect, or requires intervention to prevent permanent impairment or damage. Number of subjects with TEAEs and SAEs is reported. SAS included all the subjects who have received at least one dose of study drug (FT-2102, azacitidine, or cytarabine).

End point type	Secondary

End point timeframe:

Phase 2: From start of drug administration (Day 1) up to 28 days after last dose of study drug (up to 82 months)

Notes:

[27] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint applicable for the reported arms only.

End point values	Phase 2: Cohort 1; FT-2102 (Single Agent)	Phase 2: Cohort 2; FT-2102 (Single Agent)	Phase 2: Cohort 3; FT-2102 (Single Agent)	Phase 2: Cohort 4; FT-2102+azacitidine (Combination Therapy)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	153	18	5	20
Units: Subjects				
TEAEs	153	18	5	19
SAEs	115	6	4	12

End point values	Phase 2: Cohort 5; FT-2102+azacitidine (Combination Therapy)	Phase 2: Cohort 6; FT-2102+azacitidine (Combination Therapy)	Phase 2: Cohort 7; FT-2102 (Single Agent)	Phase 2: Cohort 8; FT-2102+azacitidine (Combination Therapy)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	20	10	11
Units: Subjects				
TEAEs	21	19	10	11
SAEs	18	13	8	9

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Number of Subjects With Change From Baseline in Clinically Significant Abnormal Laboratory Values

End point title	Phase 2: Number of Subjects With Change From Baseline in

	Clinically Significant Abnormal Laboratory Values[28]

End point description:

Number of subjects with change from baseline in clinically significant abnormal laboratory values for hematology, chemistry and coagulation with Grade <1 to 4 is reported. National Cancer Institute - Common Terminology Criteria for Adverse Events (NCI-CTCAE) version 4.03 toxicity grade used to determine severity of AE. Grade 1: mild;asymptomatic/mild symptoms; Grade 2: moderate; minimal; Grade 3: severe/medically significant; Grade 4: life-threatening consequences, Grade 5: death. Safety analysis set included all the subjects who have received at least one dose of study drug (FT-2102, azacitidine, or cytarabine).

End point type	Secondary

End point timeframe:

Phase 2: From Baseline up to 28 days after last dose of study drug (up to 82 months)

Notes:

[28] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint applicable for the reported arms only.

End point values	Phase 2: Cohort 1; FT-2102 (Single Agent)	Phase 2: Cohort 2; FT-2102 (Single Agent)	Phase 2: Cohort 3; FT-2102 (Single Agent)	Phase 2: Cohort 4; FT-2102+azacitidine (Combination Therapy)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	153	18	5	20
Units: Subjects				
Hematology: Hemoglobin; Increase (Grade <1)	146	18	5	19
Hematology: Hemoglobin; Increase (Grade 1)	1	0	0	0
Hematology: Hemoglobin; Increase (Grade 2)	0	0	0	0
Hematology: Hemoglobin; Increase (Grade 3)	5	0	0	0
Hematology: Hemoglobin; Increase (Grade 4)	0	0	0	0
Hematology: Hemoglobin; Increase (Grade 3 or 4)	5	0	0	0
Hematology: Hemoglobin; Decrease (Grade <1)	3	3	0	0
Hematology: Hemoglobin; Decrease (Grade 1)	17	8	0	1
Hematology: Hemoglobin; Decrease (Grade 2)	46	3	1	7
Hematology: Hemoglobin; Decrease (Grade 3)	86	4	4	11
Hematology: Hemoglobin; Decrease (Grade 4)	0	0	0	0
Hematology: Hemoglobin; Decrease (Grade 3 or 4)	86	4	4	11
Hematology: Platelets; Decrease (Grade <1)	3	3	0	0
Hematology: Platelets; Decrease (Grade 1)	19	8	0	1
Hematology: Platelets; Decrease (Grade 2)	14	3	0	2
Hematology: Platelets; Decrease (Grade 3)	25	3	1	3
Hematology: Platelets; Decrease (Grade 4)	91	1	4	13

Hematology: Platelets; Decrease (Grade 3 or 4)	116	4	5	16
Hematology: Leukocytes; Increase (Grade <1)	150	18	5	18
Hematology: Leukocytes; Increase (Grade 1)	0	0	0	0
Hematology: Leukocytes; Increase (Grade 2)	0	0	0	0
Hematology: Leukocytes; Increase (Grade 3)	2	0	0	1
Hematology: Leukocytes; Increase (Grade 4)	0	0	0	0
Hematology: Leukocytes; Increase (Grade 3 or 4)	2	0	0	1
Hematology: Leukocytes; Decrease (Grade <1)	17	1	2	0
Hematology: Leukocytes; Decrease (Grade 1)	8	2	0	0
Hematology: Leukocytes; Decrease (Grade 2)	20	7	0	3
Hematology: Leukocytes; Decrease (Grade 3)	50	6	1	4
Hematology: Leukocytes; Decrease (Grade 4)	57	2	2	12
Hematology: Leukocytes; Decrease (Grade 3 or 4)	107	8	3	16
Hematology: Neutrophils; Decrease (Grade <1)	1	2	0	1
Hematology: Neutrophils; Decrease (Grade 1)	2	1	0	0
Hematology: Neutrophils; Decrease (Grade 2)	6	5	0	0
Hematology: Neutrophils; Decrease (Grade 3)	21	4	0	1
Hematology: Neutrophils; Decrease (Grade 4)	117	6	5	17
Hematology: Neutrophils; Decrease (Grade 3 or 4)	138	10	5	18
Hematology: Lymphocytes; Increase (Grade <1)	103	17	2	14
Hematology: Lymphocytes; Increase (Grade 1)	0	0	0	0
Hematology: Lymphocytes; Increase (Grade 2)	36	1	3	5
Hematology: Lymphocytes; Increase (Grade 3)	4	0	0	0
Hematology: Lymphocytes; Increase (Grade 4)	0	0	0	0
Hematology: Lymphocytes; Increase (Grade 3 or 4)	4	0	0	0
Hematology: Lymphocytes; Decrease (Grade <1)	18	2	1	1
Hematology: Lymphocytes; Decrease (Grade 1)	18	1	0	0
Hematology: Lymphocytes; Decrease (Grade 2)	36	7	0	7
Hematology: Lymphocytes; Decrease (Grade 3)	44	7	4	7
Hematology: Lymphocytes; Decrease (Grade 4)	27	1	0	4
Hematology: Lymphocytes; Decrease (Grade 3 or 4)	71	8	4	11

Chemistry: Creatinine; Increase (Grade <1)	2	0	1	0
Chemistry: Creatinine; Increase (Grade 1)	92	13	3	13
Chemistry: Creatinine; Increase (Grade 2)	55	4	1	5
Chemistry: Creatinine; Increase (Grade 3)	3	0	0	1
Chemistry: Creatinine; Increase (Grade 4)	0	1	0	0
Chemistry: Creatinine; Increase (Grade 3 or 4)	3	1	0	1
Chemistry: Calcium; Increase (Grade <1)	126	16	4	14
Chemistry: Calcium; Increase (Grade 1)	14	1	1	3
Chemistry: Calcium; Increase (Grade 2)	2	0	0	0
Chemistry: Calcium; Increase (Grade 3)	0	0	0	0
Chemistry: Calcium; Increase (Grade 4)	4	0	0	1
Chemistry: Calcium; Increase (Grade 3 or 4)	4	0	0	1
Chemistry: Calcium; Decrease (Grade <1)	83	13	4	14
Chemistry: Calcium; Decrease (Grade 1)	50	4	0	3
Chemistry: Calcium; Decrease (Grade 2)	4	0	0	0
Chemistry: Calcium; Decrease (Grade 3)	2	0	1	0
Chemistry: Calcium; Decrease (Grade 4)	7	0	0	1
Chemistry: Calcium; Decrease (Grade 3 or 4)	9	0	1	1
Chemistry: Magnesium; Increase (Grade <1)	129	18	3	15
Chemistry: Magnesium; Increase (Grade 1)	13	0	2	1
Chemistry: Magnesium; Increase (Grade 2)	0	0	0	0
Chemistry: Magnesium; Increase (Grade 3)	9	0	0	2
Chemistry: Magnesium; Increase (Grade 4)	0	0	0	1
Chemistry: Magnesium; Increase (Grade 3 or 4)	9	0	0	3
Chemistry: Magnesium; Decrease (Grade <1)	103	14	2	11
Chemistry: Magnesium; Decrease (Grade 1)	39	4	3	8
Chemistry: Magnesium; Decrease (Grade 2)	8	0	0	0
Chemistry: Magnesium; Decrease (Grade 3)	1	0	0	0
Chemistry: Magnesium; Decrease (Grade 4)	0	0	0	0
Chemistry: Magnesium; Decrease (Grade 3 or 4)	1	0	0	0
Chemistry: Potassium; Increase (Grade <1)	120	12	5	17
Chemistry: Potassium; Increase (Grade 1)	28	4	0	2

Chemistry: Potassium; Increase (Grade 2)	4	2	0	0
Chemistry: Potassium; Increase (Grade 3)	0	0	0	0
Chemistry: Potassium; Increase (Grade 4)	0	0	0	0
Chemistry: Potassium; Increase (Grade 3 or 4)	0	0	0	0
Chemistry: Potassium; Decrease (Grade <1)	73	14	1	7
Chemistry: Potassium; Decrease (Grade 1)	64	4	3	8
Chemistry: Potassium; Decrease (Grade 2)	0	0	0	0
Chemistry: Potassium; Decrease (Grade 3)	9	0	0	4
Chemistry: Potassium; Decrease (Grade 4)	6	0	1	0
Chemistry: Potassium; Decrease (Grade 3 or 4)	15	0	1	4
Chemistry: Sodium; Increase (Grade <1)	139	17	4	18
Chemistry: Sodium; Increase (Grade 1)	13	0	0	1
Chemistry: Sodium; Increase (Grade 2)	0	1	1	0
Chemistry: Sodium; Increase (Grade 3)	0	0	0	0
Chemistry: Sodium; Increase (Grade 4)	0	0	0	0
Chemistry: Sodium; Increase (Grade 3 or 4)	0	0	0	0
Chemistry: Sodium; Decrease (Grade <1)	77	15	3	13
Chemistry: Sodium; Decrease (Grade 1)	62	2	2	5
Chemistry: Sodium; Decrease (Grade 2)	0	0	0	0
Chemistry: Sodium; Decrease (Grade 3)	12	0	0	0
Chemistry: Sodium; Decrease (Grade 4)	1	1	0	1
Chemistry: Sodium; Decrease (Grade 3 or 4)	13	1	0	1
Chemistry: Uric acid; Increase (Grade <1)	96	10	5	11
Chemistry: Uric acid; Increase (Grade 1)	49	8	0	6
Chemistry: Uric acid; Increase (Grade 2)	0	0	0	0
Chemistry: Uric acid; Increase (Grade 3)	0	0	0	0
Chemistry: Uric acid; Increase (Grade 4)	6	0	0	1
Chemistry: Uric acid; Increase (Grade 3 or 4)	6	0	0	1
Chemistry: Albumin; Decrease (Grade <1)	57	16	0	7
Chemistry: Albumin; Decrease (Grade 1)	41	1	2	6
Chemistry: Albumin; Decrease (Grade 2)	45	1	2	6
Chemistry: Albumin; Decrease (Grade 3)	8	0	1	0
Chemistry: Albumin; Decrease (Grade 4)	0	0	0	0
Chemistry: Albumin; Decrease (Grade 3 or 4)	8	0	1	0

Chemistry: Glucose; Increase (Grade <1)	134	18	5	17
Chemistry: Glucose; Increase (Grade 1)	0	0	0	0
Chemistry: Glucose; Increase (Grade 2)	0	0	0	0
Chemistry: Glucose; Increase (Grade 3)	16	0	0	2
Chemistry: Glucose; Increase (Grade 4)	1	0	0	0
Chemistry: Glucose; Increase (Grade 3 or 4)	17	0	0	2
Chemistry: Glucose; Decrease (Grade <1)	136	15	5	17
Chemistry: Glucose; Decrease (Grade 1)	13	3	0	1
Chemistry: Glucose; Decrease (Grade 2)	0	0	0	0
Chemistry: Glucose; Decrease (Grade 3)	0	0	0	0
Chemistry: Glucose; Decrease (Grade 4)	2	0	0	1
Chemistry: Glucose; Decrease (Grade 3 or 4)	2	0	0	1
Chemistry: Lipase; Increase (Grade <1)	108	8	5	12
Chemistry: Lipase; Increase (Grade 1)	13	4	0	3
Chemistry: Lipase; Increase (Grade 2)	12	3	0	2
Chemistry: Lipase; Increase (Grade 3)	11	1	0	0
Chemistry: Lipase; Increase (Grade 4)	1	0	0	0
Chemistry: Lipase; Increase (Grade 3 or 4)	12	1	0	0
Chemistry: Amylase; Decrease (Grade <1)	116	13	5	13
Chemistry: Amylase; Decrease (Grade 1)	24	3	0	3
Chemistry: Amylase; Decrease (Grade 2)	3	0	0	0
Chemistry: Amylase; Decrease (Grade 3)	4	0	0	0
Chemistry: Amylase; Decrease (Grade 4)	1	0	0	0
Chemistry: Amylase; Decrease (Grade 3 or 4)	5	0	0	0
Coagulation: APT Time; Increase (Grade <1)	82	14	0	13
Coagulation: APT Time; Increase (Grade 1)	15	0	1	0
Coagulation: APT Time; Increase (Grade 2)	1	0	0	1
Coagulation: APT Time; Increase (Grade 3)	1	0	0	0
Coagulation: APT Time; Increase (Grade 4)	0	0	0	0
Coagulation: APT Time; Increase (Grade 3 or 4)	1	0	0	0

End point values	Phase 2: Cohort 5; FT-2102+azacitidine (Combination Therapy)	Phase 2: Cohort 6; FT-2102+azacitidine (Combination Therapy)	Phase 2: Cohort 7; FT-2102 (Single Agent)	Phase 2: Cohort 8; FT-2102+azacitidine (Combination Therapy)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	20	10	11

Units: Subjects				
Hematology: Hemoglobin; Increase (Grade <1)	20	20	10	10
Hematology: Hemoglobin; Increase (Grade 1)	1	0	0	0
Hematology: Hemoglobin; Increase (Grade 2)	0	0	0	0
Hematology: Hemoglobin; Increase (Grade 3)	0	0	0	1
Hematology: Hemoglobin; Increase (Grade 4)	0	0	0	0
Hematology: Hemoglobin; Increase (Grade 3 or 4)	0	0	0	1
Hematology: Hemoglobin; Decrease (Grade <1)	0	1	0	0
Hematology: Hemoglobin; Decrease (Grade 1)	0	2	1	0
Hematology: Hemoglobin; Decrease (Grade 2)	3	5	2	2
Hematology: Hemoglobin; Decrease (Grade 3)	18	12	7	9
Hematology: Hemoglobin; Decrease (Grade 4)	0	0	0	0
Hematology: Hemoglobin; Decrease (Grade 3 or 4)	18	12	7	9
Hematology: Platelets; Decrease (Grade <1)	0	0	1	0
Hematology: Platelets; Decrease (Grade 1)	0	3	0	0
Hematology: Platelets; Decrease (Grade 2)	1	1	0	2
Hematology: Platelets; Decrease (Grade 3)	2	5	2	3
Hematology: Platelets; Decrease (Grade 4)	18	11	7	6
Hematology: Platelets; Decrease (Grade 3 or 4)	20	16	9	9
Hematology: Leukocytes; Increase (Grade <1)	20	19	10	11
Hematology: Leukocytes; Increase (Grade 1)	0	0	0	0
Hematology: Leukocytes; Increase (Grade 2)	0	0	0	0
Hematology: Leukocytes; Increase (Grade 3)	1	1	0	0
Hematology: Leukocytes; Increase (Grade 4)	0	0	0	0
Hematology: Leukocytes; Increase (Grade 3 or 4)	1	1	0	0
Hematology: Leukocytes; Decrease (Grade <1)	2	2	3	0
Hematology: Leukocytes; Decrease (Grade 1)	1	3	0	0
Hematology: Leukocytes; Decrease (Grade 2)	0	0	2	0
Hematology: Leukocytes; Decrease (Grade 3)	6	5	3	4
Hematology: Leukocytes; Decrease (Grade 4)	12	10	2	7
Hematology: Leukocytes; Decrease (Grade 3 or 4)	18	15	5	11

Hematology: Neutrophils; Decrease (Grade <1)	0	3	1	0
Hematology: Neutrophils; Decrease (Grade 1)	1	0	0	0
Hematology: Neutrophils; Decrease (Grade 2)	0	0	1	0
Hematology: Neutrophils; Decrease (Grade 3)	1	1	2	0
Hematology: Neutrophils; Decrease (Grade 4)	19	15	6	10
Hematology: Neutrophils; Decrease (Grade 3 or 4)	20	16	8	10
Hematology: Lymphocytes; Increase (Grade <1)	19	14	8	8
Hematology: Lymphocytes; Increase (Grade 1)	0	0	0	0
Hematology: Lymphocytes; Increase (Grade 2)	1	4	2	1
Hematology: Lymphocytes; Increase (Grade 3)	1	0	0	0
Hematology: Lymphocytes; Increase (Grade 4)	0	0	0	0
Hematology: Lymphocytes; Increase (Grade 3 or 4)	1	0	0	0
Hematology: Lymphocytes; Decrease (Grade <1)	1	1	1	1
Hematology: Lymphocytes; Decrease (Grade 1)	1	4	1	0
Hematology: Lymphocytes; Decrease (Grade 2)	4	4	3	3
Hematology: Lymphocytes; Decrease (Grade 3)	10	6	4	5
Hematology: Lymphocytes; Decrease (Grade 4)	5	3	1	0
Hematology: Lymphocytes; Decrease (Grade 3 or 4)	15	9	5	5
Chemistry: Creatinine; Increase (Grade <1)	0	0	1	0
Chemistry: Creatinine; Increase (Grade 1)	10	14	3	8
Chemistry: Creatinine; Increase (Grade 2)	10	6	6	3
Chemistry: Creatinine; Increase (Grade 3)	1	0	0	0
Chemistry: Creatinine; Increase (Grade 4)	0	0	0	0
Chemistry: Creatinine; Increase (Grade 3 or 4)	1	0	0	0
Chemistry: Calcium; Increase (Grade <1)	18	16	7	9
Chemistry: Calcium; Increase (Grade 1)	1	3	1	2
Chemistry: Calcium; Increase (Grade 2)	1	1	0	0
Chemistry: Calcium; Increase (Grade 3)	0	0	0	0
Chemistry: Calcium; Increase (Grade 4)	1	0	0	0
Chemistry: Calcium; Increase (Grade 3 or 4)	1	0	0	0
Chemistry: Calcium; Decrease (Grade <1)	13	16	4	6
Chemistry: Calcium; Decrease (Grade 1)	7	3	4	4

Chemistry: Calcium; Decrease (Grade 2)	1	0	0	0
Chemistry: Calcium; Decrease (Grade 3)	0	1	0	0
Chemistry: Calcium; Decrease (Grade 4)	0	0	0	1
Chemistry: Calcium; Decrease (Grade 3 or 4)	0	1	0	1
Chemistry: Magnesium; Increase (Grade <1)	18	19	9	10
Chemistry: Magnesium; Increase (Grade 1)	3	1	0	1
Chemistry: Magnesium; Increase (Grade 2)	0	0	0	0
Chemistry: Magnesium; Increase (Grade 3)	0	0	1	0
Chemistry: Magnesium; Increase (Grade 4)	0	0	0	0
Chemistry: Magnesium; Increase (Grade 3 or 4)	0	0	1	0
Chemistry: Magnesium; Decrease (Grade <1)	17	10	7	6
Chemistry: Magnesium; Decrease (Grade 1)	4	8	3	5
Chemistry: Magnesium; Decrease (Grade 2)	0	2	0	0
Chemistry: Magnesium; Decrease (Grade 3)	0	0	0	0
Chemistry: Magnesium; Decrease (Grade 4)	0	0	0	0
Chemistry: Magnesium; Decrease (Grade 3 or 4)	0	0	0	0
Chemistry: Potassium; Increase (Grade <1)	16	16	7	9
Chemistry: Potassium; Increase (Grade 1)	4	2	3	2
Chemistry: Potassium; Increase (Grade 2)	1	2	0	0
Chemistry: Potassium; Increase (Grade 3)	0	0	0	0
Chemistry: Potassium; Increase (Grade 4)	0	0	0	0
Chemistry: Potassium; Increase (Grade 3 or 4)	0	0	0	0
Chemistry: Potassium; Decrease (Grade <1)	16	12	6	5
Chemistry: Potassium; Decrease (Grade 1)	4	6	3	5
Chemistry: Potassium; Decrease (Grade 2)	0	0	0	0
Chemistry: Potassium; Decrease (Grade 3)	1	2	1	1
Chemistry: Potassium; Decrease (Grade 4)	0	0	0	0
Chemistry: Potassium; Decrease (Grade 3 or 4)	1	2	1	1
Chemistry: Sodium; Increase (Grade <1)	19	20	9	8
Chemistry: Sodium; Increase (Grade 1)	2	0	1	3
Chemistry: Sodium; Increase (Grade 2)	0	0	0	0
Chemistry: Sodium; Increase (Grade 3)	0	0	0	0

Chemistry: Sodium; Increase (Grade 4)	0	0	0	0
Chemistry: Sodium; Increase (Grade 3 or 4)	0	0	0	0
Chemistry: Sodium; Decrease (Grade <1)	13	12	5	5
Chemistry: Sodium; Decrease (Grade 1)	8	7	4	6
Chemistry: Sodium; Decrease (Grade 2)	0	0	0	0
Chemistry: Sodium; Decrease (Grade 3)	0	1	1	0
Chemistry: Sodium; Decrease (Grade 4)	0	0	0	0
Chemistry: Sodium; Decrease (Grade 3 or 4)	0	1	1	0
Chemistry: Uric acid; Increase (Grade <1)	14	3	5	11
Chemistry: Uric acid; Increase (Grade 1)	5	6	4	0
Chemistry: Uric acid; Increase (Grade 2)	0	0	0	0
Chemistry: Uric acid; Increase (Grade 3)	0	0	0	0
Chemistry: Uric acid; Increase (Grade 4)	1	1	1	0
Chemistry: Uric acid; Increase (Grade 3 or 4)	1	1	1	0
Chemistry: Albumin; Decrease (Grade <1)	8	9	3	5
Chemistry: Albumin; Decrease (Grade 1)	7	6	2	2
Chemistry: Albumin; Decrease (Grade 2)	4	4	2	4
Chemistry: Albumin; Decrease (Grade 3)	2	1	3	0
Chemistry: Albumin; Decrease (Grade 4)	0	0	0	0
Chemistry: Albumin; Decrease (Grade 3 or 4)	2	1	3	0
Chemistry: Glucose; Increase (Grade <1)	19	18	9	10
Chemistry: Glucose; Increase (Grade 1)	0	0	0	0
Chemistry: Glucose; Increase (Grade 2)	0	0	0	0
Chemistry: Glucose; Increase (Grade 3)	1	2	1	1
Chemistry: Glucose; Increase (Grade 4)	0	0	0	0
Chemistry: Glucose; Increase (Grade 3 or 4)	1	2	1	1
Chemistry: Glucose; Decrease (Grade <1)	18	19	10	10
Chemistry: Glucose; Decrease (Grade 1)	0	1	0	1
Chemistry: Glucose; Decrease (Grade 2)	1	0	0	0
Chemistry: Glucose; Decrease (Grade 3)	0	0	0	0
Chemistry: Glucose; Decrease (Grade 4)	1	0	0	0
Chemistry: Glucose; Decrease (Grade 3 or 4)	1	0	0	0
Chemistry: Lipase; Increase (Grade <1)	16	17	8	7
Chemistry: Lipase; Increase (Grade 1)	5	1	0	3
Chemistry: Lipase; Increase (Grade 2)	0	1	1	0
Chemistry: Lipase; Increase (Grade 3)	0	1	1	0
Chemistry: Lipase; Increase (Grade 4)	0	0	0	1
Chemistry: Lipase; Increase (Grade 3 or 4)	0	1	0	1

Chemistry: Amylase; Decrease (Grade <1)	18	18	9	9
Chemistry: Amylase; Decrease (Grade 1)	2	0	1	1
Chemistry: Amylase; Decrease (Grade 2)	1	0	0	0
Chemistry: Amylase; Decrease (Grade 3)	0	0	0	1
Chemistry: Amylase; Decrease (Grade 4)	0	1	0	0
Chemistry: Amylase; Decrease (Grade 3 or 4)	0	1	0	1
Coagulation: APT Time; Increase (Grade <1)	13	8	4	5
Coagulation: APT Time; Increase (Grade 1)	3	2	0	3
Coagulation: APT Time; Increase (Grade 2)	0	0	0	0
Coagulation: APT Time; Increase (Grade 3)	0	0	0	0
Coagulation: APT Time; Increase (Grade 4)	0	0	0	0
Coagulation: APT Time; Increase (Grade 3 or 4)	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Number of Subjects With Change From Baseline in Clinically Significant Abnormal Electrocardiogram (ECG)

End point title	Phase 2: Number of Subjects With Change From Baseline in Clinically Significant Abnormal Electrocardiogram (ECG)[29]

End point description:

Number of subjects with change from baseline in clinically significant abnormal ECG parameter (QTcF) is reported. QT interval was the time between the start of the Q wave and the end of the T wave in the cardiac electrical cycle. QTcF was the QT interval corrected for heart rate using Fridericia's formula: QTcF = QT divided by cube root of 60/heart rate. Safety analysis set included all the subjects who have received at least one dose of study drug (FT-2102, azacitidine, or cytarabine). Here, N= participants with available data for this endpoint.

End point type	Secondary

End point timeframe:

Phase 2: From Baseline up to 28 days after last dose of study drug (up to 82 months)

Notes:

[29] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint applicable for the reported arms only.

End point values	Phase 2: Cohort 1; FT-2102 (Single Agent)	Phase 2: Cohort 2; FT-2102 (Single Agent)	Phase 2: Cohort 3; FT-2102 (Single Agent)	Phase 2: Cohort 4; FT-2102+azacitidine (Combination Therapy)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	151	17	5	18

Units: Subjects				
<=450 msec	90	11	1	9
>450 to <=480 msec	44	3	3	6
>480 to <=500 msec	12	1	1	1
>500 msec	5	2	0	2
>30 to <=60 msec	43	3	2	3
>60 msec	10	0	0	3

End point values	Phase 2: Cohort 5; FT-2102+azacitidine (Combination Therapy)	Phase 2: Cohort 6; FT-2102+azacitidine (Combination Therapy)	Phase 2: Cohort 7; FT-2102 (Single Agent)	Phase 2: Cohort 8; FT-2102+azacitidine (Combination Therapy)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	20	10	11
Units: Subjects				
<=450 msec	9	11	9	4
>450 to <=480 msec	7	5	0	4
>480 to <=500 msec	2	1	1	1
>500 msec	3	3	0	2
>30 to <=60 msec	4	7	3	1
>60 msec	1	2	0	5

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Area Under the Curve (AUClast) for FT-2102

End point title	Phase 2: Area Under the Curve (AUClast) for FT-2102[30]

End point description:

Area under the plasma concentration-time curve from zero time until the last measurable concentration is presented. The PK analysis set included those subjects for whom it was possible to calculate at least 1 primary PK parameter and who had no major protocol deviations thought to influence the absorption, distribution, metabolism, and excretion of the FT-2102. Here, N and number analysed (n) = subjects with available data for specific timepoints. Here, 99999 signifies geometric coefficient of variation could not be calculated due to small number of subjects.

End point type	Secondary

End point timeframe:

Phase 2: Cycle 1 Day 1 and Cycle 2 Day 1 (Cycle length= 28 days)

Notes:

[30] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint applicable for the reported arms only.

End point values	Phase 2: Cohort 1; FT-2102 (Single Agent)	Phase 2: Cohort 2; FT-2102 (Single Agent)	Phase 2: Cohort 3; FT-2102 (Single Agent)	Phase 2: Cohort 4; FT-2102+azacitidine (Combination Therapy)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	117	14	2	12
Units: h*ng/mL				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (n=117, 14, 2, 12, 16, 3, 2 ,1)	2836 (± 59.5)	2657 (± 36.8)	1880 (± 77.4)	3051 (± 109.7)
Cycle 2 Day 1 (n=88, 12, 0, 11, 14, 4, 1, 1)	20610 (± 69.7)	27710 (± 14.9)	0 (± 0)	19820 (± 77.6)

End point values	Phase 2: Cohort 5; FT-2102+azacitidine (Combination Therapy)	Phase 2: Cohort 6; FT-2102+azacitidine (Combination Therapy)	Phase 2: Cohort 7; FT-2102 (Single Agent)	Phase 2: Cohort 8; FT-2102+azacitidine (Combination Therapy)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	4	2	1
Units: h*ng/mL				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (n=117, 14, 2, 12, 16, 3, 2 ,1)	2031 (± 69.4)	1701 (± 39.4)	4165 (± 116.5)	3898 (± 99999)
Cycle 2 Day 1 (n=88, 12, 0, 11, 14, 4, 1, 1)	19610 (± 62.1)	21810 (± 45.6)	25880 (± 99999)	19940 (± 99999)

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Maximum Plasma Concentration (Cmax) for FT-2102

End point title	Phase 2: Maximum Plasma Concentration (Cmax) for FT-

End point description:

Maximum Plasma Concentartion (Cmax) for FT-2102 is presented. The PK analysis set included those subjects for whom it was possible to calculate at least 1 primary PK parameter and who had no major protocol deviations thought to influence the absorption, distribution, metabolism, and excretion of the FT-2102. Here, N and number analysed (n) = subjects with available data for specific timepoints. Here, 99999 signifies geometric coefficient of variation could not be calculated due to small number of subjects.

End point type	Secondary

End point timeframe:

Phase 2: Cycle 1 Day 1 and Cycle 2 Day 1 (Cycle length= 28 days)

Notes:

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

Justification: This endpoint applicable for the reported arms only.

End point values	Phase 2: Cohort 1; FT-2102 (Single Agent)	Phase 2: Cohort 2; FT-2102 (Single Agent)	Phase 2: Cohort 3; FT-2102 (Single Agent)	Phase 2: Cohort 4; FT-2102+azacitidine (Combination Therapy)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	120	14	2	13
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (n=120, 14, 2, 13, 16, 4, 2 ,1)	534.5 (± 57.5)	492.4 (± 29.3)	388.8 (± 49.1)	623.2 (± 75.8)
Cycle 2 Day 1 (n=88, 12, 0, 11, 14, 4, 1, 1)	3136 (± 62.0)	3800 (± 14.7)	0 (± 0)	3239 (± 68.7)

End point values	Phase 2: Cohort 5; FT-2102+azacitidine (Combination Therapy)	Phase 2: Cohort 6; FT-2102+azacitidine (Combination Therapy)	Phase 2: Cohort 7; FT-2102 (Single Agent)	Phase 2: Cohort 8; FT-2102+azacitidine (Combination Therapy)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	4	2	1
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (n=120, 14, 2, 13, 16, 4, 2 ,1)	404.1 (± 58.5)	411.2 (± 9.0)	747.5 (± 107.6)	671 (± 99999)
Cycle 2 Day 1 (n=88, 12, 0, 11, 14, 4, 1, 1)	2934 (± 53.6)	3043 (± 39.3)	3500 (± 99999)	3080 (± 99999)

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Time to Maximum Plasma Concentration (Tmax) for FT-2102

End point title	Phase 2: Time to Maximum Plasma Concentration (Tmax) for FT-2102[32]

End point description:

Time to reach the maximum plasma concentration (Tmax) for FT-2102 is presented. The PK analysis set included those subjects for whom it was possible to calculate at least 1 primary PK parameter and who had no major protocol deviations thought to influence the absorption, distribution, metabolism, and excretion of the FT-2102. Here, N and number analysed (n) = subjects with available data for specific timepoints.

End point type	Secondary

End point timeframe:

Phase 2: Cycle 1 Day 1 and Cycle 2 Day 1 (Cycle length= 28 days)

Notes:

[32] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint applicable for the reported arms only.

End point values	Phase 2: Cohort 1; FT-2102 (Single Agent)	Phase 2: Cohort 2; FT-2102 (Single Agent)	Phase 2: Cohort 3; FT-2102 (Single Agent)	Phase 2: Cohort 4; FT-2102+azacitidine (Combination Therapy)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	120	14	2	13
Units: hour				
median (full range (min-max))				
Cycle 1 Day 1 (n=120, 14, 2, 13, 16, 4, 2 ,1)	4.00 (1.00 to 8.00)	4.00 (2.00 to 8.00)	5.00 (2.00 to 8.00)	4.00 (2.00 to 8.00)
Cycle 2 Day 1 (n=88, 12, 0, 11, 14, 4, 1, 1)	2.00 (0.00 to 8.00)	1.00 (0.00 to 2.00)	0 (0 to 0)	1.00 (0.00 to 8.00)

End point values	Phase 2: Cohort 5; FT-2102+azacitidine (Combination Therapy)	Phase 2: Cohort 6; FT-2102+azacitidine (Combination Therapy)	Phase 2: Cohort 7; FT-2102 (Single Agent)	Phase 2: Cohort 8; FT-2102+azacitidine (Combination Therapy)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	4	2	1
Units: hour				
median (full range (min-max))				
Cycle 1 Day 1 (n=120, 14, 2, 13, 16, 4, 2 ,1)	4.00 (2.00 to 8.00)	4.00 (2.00 to 8.00)	3.00 (2.00 to 4.00)	1.00 (1.00 to 1.00)
Cycle 2 Day 1 (n=88, 12, 0, 11, 14, 4, 1, 1)	1.00 (0.00 to 4.00)	4.00 (0.00 to 8.00)	0.00 (0 to 0)	1.00 (1.00 to 1.00)

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

From start of drug administration (Day 1) up to 28 days after last dose of study drug (up to 82 months)

Adverse event reporting additional description:

All presented AEs are treatment-emergent (i.e., TEAEs). A TEAE is an AE that emerges during treatment, having been absent pre-treatment, or worsens relative to the pre-treatment state. One subject received olutasidenib in combination with cytarabine. This subject is included in the Phase 1 Overall column.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	19

Reporting groups

Reporting group title	Phase 1:TotalFT-2102;FT-2102+azacitidine(Combination Therapy)

Reporting group description:

Subjects with AML or MDS received combination therapy azacitidine (administered at the dose of 75 mg/m^2 for 7 days IV/SC per every 28-day cycle) until treatment discontinuation.

Reporting group title	Phase 1: FT-2102+azacitidine(Combination Therapy)

Reporting group description:

Subjects with AML or MDS received combination therapy (FT-2102 + azacitidine 75 mg/m^2) orally BID in 28-day cycles at dose levels of 150 mg until MTD or MED achieved.

Reporting group title	Phase 1: Total FT-2102 (Single Agent)

Reporting group description:

Subjects with AML or MDS received single agent FT-2102 orally QD and BID in 28-day cycles at the different dose levels (150 mg and 300 mg) until MTD or MED achieved.

Reporting group title	Phase 1: FT-2102 (Single Agent)

Reporting group description:

Subjects with AML or MDS received single agent FT-2102 orally BID in 28-day cycles at dose levels of 150 mg until maximum MTD or maximum MED achieved.

Reporting group title	Phase 2: Cohort 7; FT-2102 (Single Agent)

Reporting group description:

Subjects who have not received any prior AML treatment but may have received a prior treatment for another hematologic malignancy be given single agent of FT-2102 150 mg BID in continuous 28-day cycles.

Reporting group title	Phase 2: Cohort 4; FT-2102+azacitidine (Combination Therapy)

Reporting group description:

Subjects with R/R AML that is naïve to prior hypomethylating therapy and IDH1 inhibitor therapy received combination therapy of azacitidine + FT-2102 150 mg BID in continuous 28-day cycles.

Reporting group title	Phase 2: Cohort 5; FT-2102+azacitidine (Combination Therapy)

Reporting group description:

Subjects with R/R AML/MDS that have inadequately responded to or have progressed on prior hypo-methylating therapy received combination therapy of azacitidine 75 mg/m^2 + FT-2102 150 mg BID in continuous 28-day cycles.

Reporting group title	Phase 2: Cohort 6; FT-2102+azacitidine (Combination Therapy)

Reporting group description:

Participants with R/R AML/MDS that have been previously treated with single agent FT-2102 as their last therapy prior to study enrolment received combination therapy of azacitidine + FT-2102 150 mg BID in continuous 28-day cycles. Participants from the FT-2102 single agent cohorts of this study allowed to be enrolled in Cohort 6 after their disease progression.

Reporting group title	Phase 2: Cohort 3; FT-2102 (Single Agent)

Reporting group description:

Subjects with R/R AML or MDS who were previously treated with FT-2102 and who underwent HSCT on-study then relapsed post-HSCT received single agent of FT-2102 150 mg BID in continuous 28-day cycles.

Reporting group title	Phase 2: Cohort 8; FT-2102+azacitidine (Combination Therapy)

Reporting group description:

Subjects who have not received any prior AML treatment but may have received a prior treatment for another hematologic malignancy be given combination therapy of azacitidine 75 mg/m^2 + FT-2102 150 mg BID in continuous 28-day cycles.

Reporting group title	Phase 2: Cohort 1; FT-2102 (Single Agent)

Reporting group description:

Subjects with R/R AML received single agent of FT-2102 150 mg BID in continuous 28-day cycles.

Reporting group title	Phase 1: Overall

Reporting group description:

Subjects with AML or MDS received single agent, combination therapy (FT-2102 azacitidine, FT-2102+LDAC) orally BID in 28-day cycles at dose levels of 150 mg until MTD or MED achieved.

Reporting group title	Phase 2: Cohort 2; FT-2102 (Single Agent)

Reporting group description:

Subjects with AML in morphologic CR/CRi after prior therapy with residual IDH1-R132 mutation were received single agent of FT-2102 150 mg BID in continuous 28-day cycles.

Serious adverse events	Phase 1:TotalFT-2102;FT-2102+azacitidine(Combination Therapy)	Phase 1: FT-2102+azacitidine(Combination Therapy)	Phase 1: Total FT-2102 (Single Agent)
Total subjects affected by serious adverse events			
subjects affected / exposed	36 / 46 (78.26%)	30 / 39 (76.92%)	23 / 31 (74.19%)
number of deaths (all causes)	10	9	11
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant pleural effusion			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant melanoma			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
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 stenosis			

subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial stenosis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
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			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (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
Hypotension			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	1 / 31 (3.23%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Death			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Disease progression			
subjects affected / exposed	5 / 46 (10.87%)	4 / 39 (10.26%)	3 / 31 (9.68%)
occurrences causally related to treatment / all	0 / 5	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 5	0 / 4	0 / 3
Fatigue			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	1 / 31 (3.23%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			

subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Non-cardiac chest pain			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (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
Oedema peripheral			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
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			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
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			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	3 / 31 (9.68%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Social circumstances			

Social stay hospitalisation			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
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			
Cystocele			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Female genital tract fistula			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
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			
Acute promyelocytic leukaemia differentiation syndrome			
subjects affected / exposed	4 / 46 (8.70%)	2 / 39 (5.13%)	2 / 31 (6.45%)
occurrences causally related to treatment / all	3 / 4	2 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory failure			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumopathy			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			

subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngeal oedema			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung disorder			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngeal haemorrhage			
subjects affected / exposed	1 / 46 (2.17%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (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
Pneumonitis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
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 embolism			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
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 haemorrhage			

subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
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 oedema			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
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 alkalosis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
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 failure			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Acute psychosis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Catatonia			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Confusional state			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			

subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (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
Mental status changes			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic enzyme increased			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipase increased			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test abnormal			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test increased			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutrophil count decreased			

subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	1 / 31 (3.23%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Red blood cell count decreased			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
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			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
White blood cell count increased			
subjects affected / exposed	5 / 46 (10.87%)	3 / 39 (7.69%)	5 / 31 (16.13%)
occurrences causally related to treatment / all	3 / 5	2 / 3	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (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
Fall			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral neck fracture			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			

subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laceration			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (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
Lower limb fracture			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (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
Lumbar vertebral fracture			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	1 / 31 (3.23%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
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			
Familial mediterranean fever			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
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 flutter			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
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 fibrillation			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	1 / 31 (3.23%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	1 / 31 (3.23%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cardiac failure			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery stenosis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
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 infarction			

subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (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
Pericardial effusion			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular extrasystoles			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (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
Nervous system disorders			
Cerebral haemorrhage			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cerebral infarction			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			

subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic stroke			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (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
Polyneuropathy			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	1 / 46 (2.17%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
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			
Bone marrow failure			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			

subjects affected / exposed	10 / 46 (21.74%)	8 / 39 (20.51%)	6 / 31 (19.35%)
occurrences causally related to treatment / all	1 / 15	1 / 12	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile bone marrow aplasia			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolytic anaemia			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal fistula			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis microscopic			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (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
Colitis ischaemic			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			

subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (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
Diarrhoea			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (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
Gastrointestinal angiectasia			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal fistula			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower gastrointestinal haemorrhage			

subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (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
Nausea			
subjects affected / exposed	2 / 46 (4.35%)	1 / 39 (2.56%)	0 / 31 (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
Rectal haemorrhage			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary tract disorder			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
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			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			

subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder obstruction			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder perforation			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
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 acute			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
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 and subcutaneous tissue disorders			
Acute febrile neutrophilic dermatosis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angioedema			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pruritus			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (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
Pyoderma gangrenosum			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
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 mass			

subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (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
Renal failure			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal colic			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthritis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (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
Bone pain			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flank pain			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Muscle haemorrhage			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal pain			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Anal abscess			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anorectal infection			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspergillus infection			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	1 / 46 (2.17%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial prostatitis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial sepsis			

subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	2 / 46 (4.35%)	2 / 39 (5.13%)	1 / 31 (3.23%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (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
Clostridial sepsis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Corona virus infection			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	1 / 31 (3.23%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Empyema			

subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterococcal bacteraemia			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia infection			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterococcal sepsis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia sepsis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (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
Human bocavirus infection			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (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
Infection			

subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella infection			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Labyrinthitis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngitis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver abscess			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection fungal			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucosal infection			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucormycosis			

subjects affected / exposed	1 / 46 (2.17%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metapneumovirus infection			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic sepsis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parotitis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital cellulitis			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (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
Pneumonia			
subjects affected / exposed	7 / 46 (15.22%)	5 / 39 (12.82%)	7 / 31 (22.58%)
occurrences causally related to treatment / all	1 / 8	1 / 6	0 / 10
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Pneumonia legionella			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
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 fungal			

subjects affected / exposed	2 / 46 (4.35%)	2 / 39 (5.13%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia mycoplasmal			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
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 pseudomonal			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
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			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonal sepsis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
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 mycosis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary sepsis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal abscess			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (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
Respiratory tract infection			

subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	2 / 31 (6.45%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Sepsis			
subjects affected / exposed	2 / 46 (4.35%)	2 / 39 (5.13%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin infection			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	1 / 46 (2.17%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal infection			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal skin infection			

subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
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			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
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 infection			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	1 / 31 (3.23%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			

subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (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
Gout			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (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
Hypokalaemia			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (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
Tumour lysis syndrome			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Phase 1: FT-2102 (Single Agent)	Phase 2: Cohort 7; FT-2102 (Single Agent)	Phase 2: Cohort 4; FT-2102+azacitidine (Combination Therapy)
Total subjects affected by serious adverse events			
subjects affected / exposed	10 / 16 (62.50%)	8 / 10 (80.00%)	12 / 20 (60.00%)
number of deaths (all causes)	4	4	3
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant pleural effusion			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant melanoma			

subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
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 stenosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial stenosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematoma			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
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			
subjects affected / exposed	0 / 16 (0.00%)	1 / 10 (10.00%)	0 / 20 (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
Hypotension			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Death			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disease progression			
subjects affected / exposed	0 / 16 (0.00%)	1 / 10 (10.00%)	3 / 20 (15.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1

Fatigue			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
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-cardiac chest pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
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			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
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			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			

Drug hypersensitivity			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Social circumstances			
Social stay hospitalisation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
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			
Cystocele			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Female genital tract fistula			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
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			
Acute promyelocytic leukaemia differentiation syndrome			
subjects affected / exposed	1 / 16 (6.25%)	2 / 10 (20.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 1	2 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory failure			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumopathy			

subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngeal oedema			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung disorder			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngeal haemorrhage			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
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 embolism			

subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
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 haemorrhage			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
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 oedema			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
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 alkalosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
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 failure			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Acute psychosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Catatonia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Confusional state			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			

subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
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			
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic enzyme increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipase increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test abnormal			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test increased			

subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutrophil count decreased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	0 / 16 (0.00%)	1 / 10 (10.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Red blood cell count decreased			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transaminases increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
White blood cell count increased			
subjects affected / exposed	2 / 16 (12.50%)	1 / 10 (10.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral neck fracture			

subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laceration			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar vertebral fracture			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (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
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
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			
Familial mediterranean fever			
subjects affected / exposed	0 / 16 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			

Acute coronary syndrome			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
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 flutter			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
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 fibrillation			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cardiac failure			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery stenosis			

subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
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 infarction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular extrasystoles			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebral haemorrhage			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
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 infarction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			

subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic stroke			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polyneuropathy			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
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			
Bone marrow failure			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated intravascular coagulation			

subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	3 / 16 (18.75%)	2 / 10 (20.00%)	2 / 20 (10.00%)
occurrences causally related to treatment / all	0 / 3	0 / 2	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile bone marrow aplasia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolytic anaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 16 (0.00%)	1 / 10 (10.00%)	0 / 20 (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
Anal fistula			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis microscopic			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ischaemic			

subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 10 (10.00%)	0 / 20 (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
Constipation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
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			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal angiectasia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal fistula			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			

subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary tract disorder			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
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			

subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
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 obstruction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder perforation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
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 acute			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
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 and subcutaneous tissue disorders			
Acute febrile neutrophilic dermatosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angioedema			
subjects affected / exposed	0 / 16 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pruritus			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyoderma gangrenosum			

subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
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 mass			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 16 (0.00%)	1 / 10 (10.00%)	0 / 20 (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
Renal failure			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal colic			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthritis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Flank pain			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle haemorrhage			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal pain			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
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			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Anal abscess			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anorectal infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspergillus infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (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
Bacterial prostatitis			

subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial sepsis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	2 / 20 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridial sepsis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Corona virus infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	2 / 20 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			

subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Empyema			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterococcal bacteraemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterococcal sepsis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Escherichia sepsis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 10 (10.00%)	0 / 20 (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
Gastroenteritis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Human bocavirus infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			

subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Labyrinthitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver abscess			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
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 fungal			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucosal infection			

subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucormycosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metapneumovirus infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic sepsis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parotitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital cellulitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	2 / 16 (12.50%)	1 / 10 (10.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pneumonia legionella			

subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
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 fungal			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia mycoplasmal			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
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 pseudomonal			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
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			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonal sepsis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
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 mycosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary sepsis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal abscess			

subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	2 / 16 (12.50%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
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			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
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 infection			

subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal skin infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
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			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
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 infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 16 (0.00%)	1 / 10 (10.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Viral infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			

subjects affected / exposed	0 / 16 (0.00%)	1 / 10 (10.00%)	0 / 20 (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
Dehydration			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gout			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour lysis syndrome			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Phase 2: Cohort 5; FT-2102+azacitidine (Combination Therapy)	Phase 2: Cohort 6; FT-2102+azacitidine (Combination Therapy)	Phase 2: Cohort 3; FT-2102 (Single Agent)
Total subjects affected by serious adverse events			
subjects affected / exposed	18 / 21 (85.71%)	13 / 20 (65.00%)	4 / 5 (80.00%)
number of deaths (all causes)	6	7	2
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant pleural effusion			

subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant melanoma			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
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 stenosis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial stenosis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
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			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
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			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (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
General disorders and administration site conditions			
Death			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Disease progression			
subjects affected / exposed	4 / 21 (19.05%)	3 / 20 (15.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 4	0 / 3	0 / 1
Fatigue			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
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-cardiac chest pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
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			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	1 / 21 (4.76%)	1 / 20 (5.00%)	0 / 5 (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
Systemic inflammatory response syndrome			

subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Social circumstances			
Social stay hospitalisation			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
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			
Cystocele			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Female genital tract fistula			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
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			
Acute promyelocytic leukaemia differentiation syndrome			
subjects affected / exposed	2 / 21 (9.52%)	0 / 20 (0.00%)	0 / 5 (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
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory failure			

subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumopathy			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngeal oedema			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung disorder			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngeal haemorrhage			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			

subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
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 embolism			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
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 haemorrhage			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
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 oedema			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
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 alkalosis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 5 (20.00%)
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			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Acute psychosis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Catatonia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Confusional state			

subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
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			
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (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
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic enzyme increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipase increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test abnormal			

subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutrophil count decreased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Red blood cell count decreased			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (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
Transaminases increased			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 5 (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
White blood cell count increased			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			

subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral neck fracture			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laceration			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar vertebral fracture			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
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			
Familial mediterranean fever			

subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
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 flutter			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (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
Atrial fibrillation			
subjects affected / exposed	1 / 21 (4.76%)	2 / 20 (10.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 5 (0.00%)
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 disease			

subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery stenosis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
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 infarction			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular extrasystoles			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebral haemorrhage			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
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 infarction			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			

subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 5 (20.00%)
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			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic stroke			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 5 (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
Polyneuropathy			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Bone marrow failure			

subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated intravascular coagulation			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 5 (0.00%)
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			
subjects affected / exposed	4 / 21 (19.05%)	2 / 20 (10.00%)	2 / 5 (40.00%)
occurrences causally related to treatment / all	1 / 8	1 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile bone marrow aplasia			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolytic anaemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal fistula			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis microscopic			

subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ischaemic			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (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
Diarrhoea			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal angiectasia			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 5 (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
Gastrointestinal fistula			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			

subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (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
Rectal haemorrhage			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (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
Hepatobiliary disorders			
Biliary tract disorder			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			

subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
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			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 5 (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
Cholelithiasis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder obstruction			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder perforation			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 5 (0.00%)
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 acute			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
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 and subcutaneous tissue disorders			
Acute febrile neutrophilic dermatosis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angioedema			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pruritus			

subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyoderma gangrenosum			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
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 mass			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal colic			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthritis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Bone pain			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flank pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle haemorrhage			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Anal abscess			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anorectal infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspergillus infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			

subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial prostatitis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (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
Bacterial sepsis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridial sepsis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Corona virus infection			
subjects affected / exposed	1 / 21 (4.76%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Device related infection			

subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Empyema			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterococcal bacteraemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Escherichia infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterococcal sepsis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia sepsis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Human bocavirus infection			

subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (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			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Labyrinthitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver abscess			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection fungal			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 5 (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
Lower respiratory tract infection			

subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucosal infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucormycosis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metapneumovirus infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic sepsis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parotitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital cellulitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			

subjects affected / exposed	4 / 21 (19.05%)	2 / 20 (10.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 5	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 2	0 / 0
Pneumonia legionella			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
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 fungal			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia mycoplasmal			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia pseudomonal			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia pneumococcal			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonal sepsis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (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
Pulmonary mycosis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary sepsis			

subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal abscess			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	3 / 21 (14.29%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin infection			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			

subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal skin infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
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			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
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 infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			

subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (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
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gout			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour lysis syndrome			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Phase 2: Cohort 8; FT-2102+azacitidine (Combination Therapy)	Phase 2: Cohort 1; FT-2102 (Single Agent)	Phase 1: Overall
Total subjects affected by serious adverse events			
subjects affected / exposed	9 / 11 (81.82%)	115 / 153 (75.16%)	60 / 78 (76.92%)
number of deaths (all causes)	2	50	21

number of deaths resulting from adverse events	0	2	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant pleural effusion			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant melanoma			
subjects affected / exposed	1 / 11 (9.09%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Aortic stenosis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Arterial stenosis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
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			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 11 (0.00%)	2 / 153 (1.31%)	2 / 78 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Death			

subjects affected / exposed	0 / 11 (0.00%)	3 / 153 (1.96%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 3	0 / 1
Disease progression			
subjects affected / exposed	3 / 11 (27.27%)	25 / 153 (16.34%)	8 / 78 (10.26%)
occurrences causally related to treatment / all	0 / 3	1 / 25	0 / 8
deaths causally related to treatment / all	0 / 2	1 / 22	0 / 8
Fatigue			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	2 / 78 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 11 (0.00%)	2 / 153 (1.31%)	0 / 78 (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 organ dysfunction syndrome			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Non-cardiac chest pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
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			

subjects affected / exposed	1 / 11 (9.09%)	3 / 153 (1.96%)	3 / 78 (3.85%)
occurrences causally related to treatment / all	0 / 1	0 / 6	2 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Social circumstances			
Social stay hospitalisation			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Reproductive system and breast disorders			
Cystocele			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Female genital tract fistula			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute promyelocytic leukaemia differentiation syndrome			
subjects affected / exposed	0 / 11 (0.00%)	14 / 153 (9.15%)	6 / 78 (7.69%)
occurrences causally related to treatment / all	0 / 0	12 / 16	3 / 6
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Acute respiratory distress syndrome			

subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Acute respiratory failure			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumopathy			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Hypoxia			
subjects affected / exposed	1 / 11 (9.09%)	1 / 153 (0.65%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngeal oedema			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Lung disorder			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Pharyngeal haemorrhage			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
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			

subjects affected / exposed	0 / 11 (0.00%)	2 / 153 (1.31%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Pulmonary embolism			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Pulmonary haemorrhage			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Pulmonary oedema			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory alkalosis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
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 failure			
subjects affected / exposed	0 / 11 (0.00%)	2 / 153 (1.31%)	0 / 78 (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
Psychiatric disorders			
Acute psychosis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Catatonia			

subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Confusional state			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Delirium			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Depression			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic enzyme increased			
subjects affected / exposed	0 / 11 (0.00%)	4 / 153 (2.61%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	5 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipase increased			

subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test abnormal			
subjects affected / exposed	2 / 11 (18.18%)	2 / 153 (1.31%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	1 / 3	2 / 3	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Liver function test increased			
subjects affected / exposed	0 / 11 (0.00%)	2 / 153 (1.31%)	0 / 78 (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
Neutrophil count decreased			
subjects affected / exposed	0 / 11 (0.00%)	2 / 153 (1.31%)	0 / 78 (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
Platelet count decreased			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	2 / 78 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Red blood cell count decreased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
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			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
White blood cell count increased			
subjects affected / exposed	1 / 11 (9.09%)	6 / 153 (3.92%)	10 / 78 (12.82%)
occurrences causally related to treatment / all	1 / 1	3 / 6	4 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Ankle fracture			

subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Infusion related reaction			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Laceration			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar vertebral fracture			
subjects affected / exposed	1 / 11 (9.09%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	2 / 78 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 2
Subarachnoid haemorrhage			

subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Congenital, familial and genetic disorders			
Familial mediterranean fever			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	1 / 11 (9.09%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Atrial fibrillation			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	2 / 78 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Cardiac arrest			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	2 / 78 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cardiac failure			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cardiac failure congestive			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Coronary artery disease			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Coronary artery stenosis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Myocardial infarction			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	1 / 11 (9.09%)	0 / 153 (0.00%)	0 / 78 (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
Supraventricular tachycardia			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular extrasystoles			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebral haemorrhage			
subjects affected / exposed	0 / 11 (0.00%)	3 / 153 (1.96%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 1
Cerebral infarction			

subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic stroke			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Haemorrhage intracranial			
subjects affected / exposed	0 / 11 (0.00%)	2 / 153 (1.31%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Polyneuropathy			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Seizure			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	2 / 78 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			

subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Blood and lymphatic system disorders			
Bone marrow failure			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	2 / 11 (18.18%)	23 / 153 (15.03%)	16 / 78 (20.51%)
occurrences causally related to treatment / all	0 / 2	2 / 28	1 / 22
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Febrile bone marrow aplasia			
subjects affected / exposed	1 / 11 (9.09%)	3 / 153 (1.96%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolytic anaemia			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Pancytopenia			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Anal fistula			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Colitis microscopic			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ischaemic			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Colitis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Constipation			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 11 (0.00%)	2 / 153 (1.31%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal angiectasia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal fistula			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Gastrointestinal haemorrhage			

subjects affected / exposed	0 / 11 (0.00%)	2 / 153 (1.31%)	0 / 78 (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
Large intestinal obstruction			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Large intestine perforation			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 11 (0.00%)	2 / 153 (1.31%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	2 / 78 (2.56%)
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 haemorrhage			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary tract disorder			

subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Cholangitis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Cholecystitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder obstruction			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Gallbladder perforation			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
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 acute			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Skin and subcutaneous tissue disorders			
Acute febrile neutrophilic dermatosis			
subjects affected / exposed	0 / 11 (0.00%)	2 / 153 (1.31%)	0 / 78 (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
Angioedema			

subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pruritus			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyoderma gangrenosum			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
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 mass			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 11 (0.00%)	2 / 153 (1.31%)	2 / 78 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Renal failure			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Renal colic			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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 and connective tissue disorders			
Arthritis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Back pain			
subjects affected / exposed	0 / 11 (0.00%)	2 / 153 (1.31%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Flank pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle haemorrhage			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Infections and infestations			
Anal abscess			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anorectal infection			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Aspergillus infection			

subjects affected / exposed	1 / 11 (9.09%)	2 / 153 (1.31%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	2 / 78 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial prostatitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial sepsis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Bronchopulmonary aspergillosis			
subjects affected / exposed	1 / 11 (9.09%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 11 (0.00%)	3 / 153 (1.96%)	3 / 78 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridial sepsis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Corona virus infection			

subjects affected / exposed	0 / 11 (0.00%)	3 / 153 (1.96%)	0 / 78 (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
Device related infection			
subjects affected / exposed	0 / 11 (0.00%)	2 / 153 (1.31%)	0 / 78 (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
Diverticulitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	2 / 78 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Empyema			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Enterococcal bacteraemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia infection			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Enterococcal sepsis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia sepsis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			

subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Human bocavirus infection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 11 (0.00%)	2 / 153 (1.31%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella infection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Labyrinthitis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Liver abscess			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection fungal			

subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Mucosal infection			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Mucormycosis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metapneumovirus infection			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Neutropenic sepsis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Parotitis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Periorbital cellulitis			

subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
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			
subjects affected / exposed	0 / 11 (0.00%)	14 / 153 (9.15%)	14 / 78 (17.95%)
occurrences causally related to treatment / all	0 / 0	0 / 14	1 / 18
deaths causally related to treatment / all	0 / 0	0 / 3	0 / 2
Pneumonia legionella			
subjects affected / exposed	1 / 11 (9.09%)	0 / 153 (0.00%)	0 / 78 (0.00%)
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 fungal			
subjects affected / exposed	0 / 11 (0.00%)	3 / 153 (1.96%)	2 / 78 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Pneumonia mycoplasmal			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
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 pseudomonal			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
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			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Pseudomonal sepsis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
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 mycosis			

subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Pulmonary sepsis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Rectal abscess			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
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 tract infection			
subjects affected / exposed	1 / 11 (9.09%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 11 (0.00%)	2 / 153 (1.31%)	3 / 78 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 2
Sepsis			
subjects affected / exposed	2 / 11 (18.18%)	6 / 153 (3.92%)	2 / 78 (2.56%)
occurrences causally related to treatment / all	0 / 2	0 / 7	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 2	0 / 0
Skin infection			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Soft tissue infection			

subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
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 infection			
subjects affected / exposed	0 / 11 (0.00%)	2 / 153 (1.31%)	0 / 78 (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
Staphylococcal skin infection			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Streptococcal sepsis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth infection			
subjects affected / exposed	0 / 11 (0.00%)	2 / 153 (1.31%)	0 / 78 (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
Upper respiratory tract infection			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Urinary tract infection			

subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	2 / 78 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Dehydration			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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
Failure to thrive			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gout			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour lysis syndrome			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (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

Serious adverse events	Phase 2: Cohort 2;		

	FT-2102 (Single Agent)		
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 18 (33.33%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant pleural effusion			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Malignant melanoma			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Aortic stenosis			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Arterial stenosis			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haematoma			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypertension			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypotension			

subjects affected / exposed	0 / 18 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Death			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Disease progression			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Fatigue			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General physical health deterioration			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Non-cardiac chest pain			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oedema peripheral			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pain			

subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyrexia				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Systemic inflammatory response syndrome				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Immune system disorders				
Drug hypersensitivity				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Social circumstances				
Social stay hospitalisation				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Reproductive system and breast disorders				
Cystocele				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Female genital tract fistula				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
Acute promyelocytic leukaemia differentiation syndrome				

subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Acute respiratory distress syndrome				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Acute respiratory failure				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchopneumopathy				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Epistaxis				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypoxia				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Laryngeal oedema				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung disorder				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pharyngeal haemorrhage				

subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pleural effusion				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonitis				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary embolism				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary haemorrhage				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary oedema				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory alkalosis				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory failure				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Psychiatric disorders				
Acute psychosis				

subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Catatonia				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Confusional state				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Delirium				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Depression				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mental status changes				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Investigations				
Electrocardiogram QT prolonged				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gamma-glutamyltransferase increased				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatic enzyme increased				

subjects affected / exposed	1 / 18 (5.56%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Lipase increased				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Liver function test abnormal				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Liver function test increased				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neutrophil count decreased				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Platelet count decreased				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Red blood cell count decreased				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Transaminases increased				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
White blood cell count increased				

subjects affected / exposed	0 / 18 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Fall			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Femoral neck fracture			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infusion related reaction			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Laceration			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lower limb fracture			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lumbar vertebral fracture			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Subdural haematoma			

subjects affected / exposed	1 / 18 (5.56%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Subarachnoid haemorrhage				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Congenital, familial and genetic disorders				
Familial mediterranean fever				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
Acute coronary syndrome				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atrial flutter				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atrial fibrillation				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atrioventricular block				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac arrest				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Cardiac failure				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac failure congestive				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Coronary artery disease				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Coronary artery stenosis				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myocardial infarction				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pericardial effusion				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Supraventricular tachycardia				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ventricular extrasystoles				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				

Cerebral haemorrhage				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebral infarction				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebrovascular accident				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dizziness				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Encephalopathy				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemorrhagic stroke				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemorrhage intracranial				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Polyneuropathy				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Seizure				

subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Syncope				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood and lymphatic system disorders				
Bone marrow failure				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Disseminated intravascular coagulation				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Febrile neutropenia				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Febrile bone marrow aplasia				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemolytic anaemia				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancytopenia				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				

Abdominal pain				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anal fistula				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colitis microscopic				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colitis ischaemic				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colitis				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Constipation				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diarrhoea				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal angiectasia				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal fistula				

subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal haemorrhage				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Large intestinal obstruction				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Large intestine perforation				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lower gastrointestinal haemorrhage				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nausea				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rectal haemorrhage				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Upper gastrointestinal haemorrhage				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vomiting				

subjects affected / exposed	0 / 18 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Biliary tract disorder			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholangitis			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholecystitis			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholelithiasis			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gallbladder obstruction			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gallbladder perforation			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatitis acute			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			

Acute febrile neutrophilic dermatosis			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Angioedema			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pruritus			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pyoderma gangrenosum			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Skin mass			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal failure			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal colic			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue			

disorders				
Arthritis				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Back pain				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bone pain				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Flank pain				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Muscle haemorrhage				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal pain				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Osteoarthritis				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Anal abscess				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Anorectal infection				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Aspergillus infection				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bacteraemia				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bacterial prostatitis				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bacterial sepsis				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchopulmonary aspergillosis				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cellulitis				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Clostridium difficile colitis				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Clostridial sepsis				

subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Corona virus infection				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Device related infection				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Diverticulitis				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Empyema				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Enterococcal bacteraemia				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Escherichia infection				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Enterococcal sepsis				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Escherichia sepsis				

subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Human bocavirus infection				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Influenza				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infection				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Klebsiella infection				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Labyrinthitis				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Laryngitis				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Liver abscess				

subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lower respiratory tract infection fungal				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lower respiratory tract infection				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mucosal infection				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mucormycosis				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metapneumovirus infection				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neutropenic sepsis				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Parotitis				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Parainfluenzae virus infection				

subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Periorbital cellulitis				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia legionella				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia fungal				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia mycoplasmal				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia pseudomonal				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia pneumococcal				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pseudomonal sepsis				

subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary mycosis				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary sepsis				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rectal abscess				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory tract infection				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rhinovirus infection				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Septic shock				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin infection				

subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Soft tissue infection				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Staphylococcal bacteraemia				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Staphylococcal infection				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Staphylococcal skin infection				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Streptococcal sepsis				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tooth infection				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Upper respiratory tract infection				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urosepsis				

subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Viral infection				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Decreased appetite				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dehydration				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Failure to thrive				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gout				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypokalaemia				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tumour lysis syndrome				

subjects affected / exposed	0 / 18 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Phase 1:TotalFT-2102;FT-2102+azacitidine(Combination Therapy)	Phase 1: FT-2102+azacitidine(Combination Therapy)	Phase 1: Total FT-2102 (Single Agent)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	46 / 46 (100.00%)	39 / 39 (100.00%)	29 / 31 (93.55%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adrenal adenoma			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Basal cell carcinoma			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Cancer pain			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Endotheliomatosis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Melanocytic naevus			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Squamous cell carcinoma of skin			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (0.00%)
occurrences (all)	2	2	0
Vascular disorders			
Aortic calcification			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Deep vein thrombosis			

subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Embolism			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Haematoma			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	3 / 31 (9.68%)
occurrences (all)	1	1	4
Hypertension			
subjects affected / exposed	9 / 46 (19.57%)	7 / 39 (17.95%)	5 / 31 (16.13%)
occurrences (all)	15	9	5
Hypertensive crisis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	5 / 46 (10.87%)	5 / 39 (12.82%)	4 / 31 (12.90%)
occurrences (all)	5	5	5
Orthostatic hypotension			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Thrombophlebitis superficial			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Thrombosis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Venous thrombosis limb			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Administration site pain			

subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	11 / 46 (23.91%)	10 / 39 (25.64%)	1 / 31 (3.23%)
occurrences (all)	15	14	1
Catheter site bruise			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Catheter site rash			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (0.00%)
occurrences (all)	1	1	0
Catheter site pain			
subjects affected / exposed	2 / 46 (4.35%)	2 / 39 (5.13%)	0 / 31 (0.00%)
occurrences (all)	2	2	0
Catheter site haemorrhage			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Chills			
subjects affected / exposed	6 / 46 (13.04%)	6 / 39 (15.38%)	1 / 31 (3.23%)
occurrences (all)	10	10	1
Device related thrombosis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Drug intolerance			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Early satiety			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Fatigue			
subjects affected / exposed	19 / 46 (41.30%)	16 / 39 (41.03%)	13 / 31 (41.94%)
occurrences (all)	28	25	16
Facial pain			

subjects affected / exposed	1 / 46 (2.17%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	2	0	0
Generalised oedema			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	1 / 31 (3.23%)
occurrences (all)	1	1	1
General physical health deterioration			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (0.00%)
occurrences (all)	1	1	0
Influenza like illness			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	2 / 46 (4.35%)	2 / 39 (5.13%)	0 / 31 (0.00%)
occurrences (all)	2	2	0
Injection site reaction			
subjects affected / exposed	3 / 46 (6.52%)	3 / 39 (7.69%)	0 / 31 (0.00%)
occurrences (all)	4	4	0
Malaise			
subjects affected / exposed	2 / 46 (4.35%)	2 / 39 (5.13%)	1 / 31 (3.23%)
occurrences (all)	2	2	1
Mucosal dryness			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	10 / 46 (21.74%)	8 / 39 (20.51%)	1 / 31 (3.23%)
occurrences (all)	12	10	1
Non-cardiac chest pain			
subjects affected / exposed	2 / 46 (4.35%)	2 / 39 (5.13%)	0 / 31 (0.00%)
occurrences (all)	2	2	0
Pain			
subjects affected / exposed	4 / 46 (8.70%)	3 / 39 (7.69%)	2 / 31 (6.45%)
occurrences (all)	4	3	3
Peripheral swelling			

subjects affected / exposed	7 / 46 (15.22%)	7 / 39 (17.95%)	1 / 31 (3.23%)
occurrences (all)	9	9	1
Pyrexia			
subjects affected / exposed	11 / 46 (23.91%)	9 / 39 (23.08%)	9 / 31 (29.03%)
occurrences (all)	16	14	12
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Temperature intolerance			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site bruise			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Hypogammaglobulinaemia			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	1 / 31 (3.23%)
occurrences (all)	1	1	1
Reproductive system and breast disorders			
Breast haemorrhage			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Breast mass			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Genital erythema			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			

subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (0.00%)
occurrences (all)	1	1	0
Vulvovaginal pain			
subjects affected / exposed	2 / 46 (4.35%)	2 / 39 (5.13%)	0 / 31 (0.00%)
occurrences (all)	2	2	0
Vulvovaginal dryness			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Acute promyelocytic leukaemia differentiation syndrome			
subjects affected / exposed	4 / 46 (8.70%)	4 / 39 (10.26%)	2 / 31 (6.45%)
occurrences (all)	5	5	2
Catarrh			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	18 / 46 (39.13%)	15 / 39 (38.46%)	5 / 31 (16.13%)
occurrences (all)	19	16	5
Dyspnoea			
subjects affected / exposed	13 / 46 (28.26%)	12 / 39 (30.77%)	7 / 31 (22.58%)
occurrences (all)	23	22	8
Dyspnoea exertional			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	1 / 31 (3.23%)
occurrences (all)	1	1	1
Dyspnoea paroxysmal nocturnal			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (0.00%)
occurrences (all)	1	1	0
Epistaxis			
subjects affected / exposed	7 / 46 (15.22%)	7 / 39 (17.95%)	5 / 31 (16.13%)
occurrences (all)	8	8	6
Haemoptysis			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (0.00%)
occurrences (all)	1	1	0
Hiccups			

subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	2 / 46 (4.35%)	1 / 39 (2.56%)	2 / 31 (6.45%)
occurrences (all)	2	1	2
Nasal septum perforation			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Nasal dryness			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	1 / 31 (3.23%)
occurrences (all)	1	1	1
Nasal congestion			
subjects affected / exposed	4 / 46 (8.70%)	3 / 39 (7.69%)	2 / 31 (6.45%)
occurrences (all)	4	3	2
Oropharyngeal pain			
subjects affected / exposed	7 / 46 (15.22%)	5 / 39 (12.82%)	0 / 31 (0.00%)
occurrences (all)	8	6	0
Pleural effusion			
subjects affected / exposed	2 / 46 (4.35%)	2 / 39 (5.13%)	3 / 31 (9.68%)
occurrences (all)	2	2	3
Pleuritic pain			
subjects affected / exposed	2 / 46 (4.35%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	2	0	0
Pneumonitis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	2 / 46 (4.35%)	1 / 39 (2.56%)	0 / 31 (0.00%)
occurrences (all)	2	1	0
Pulmonary oedema			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Pulmonary embolism			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Rales			

subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (0.00%)
occurrences (all)	1	1	0
Rhinorrhoea			
subjects affected / exposed	5 / 46 (10.87%)	5 / 39 (12.82%)	3 / 31 (9.68%)
occurrences (all)	6	6	3
Sinus pain			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (0.00%)
occurrences (all)	1	1	0
Sneezing			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Sputum discoloured			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Tachypnoea			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	3 / 46 (6.52%)	3 / 39 (7.69%)	1 / 31 (3.23%)
occurrences (all)	4	4	1
Wheezing			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Psychiatric disorders			
Affective disorder			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Agitation			
subjects affected / exposed	2 / 46 (4.35%)	2 / 39 (5.13%)	0 / 31 (0.00%)
occurrences (all)	2	2	0
Anxiety			
subjects affected / exposed	6 / 46 (13.04%)	5 / 39 (12.82%)	2 / 31 (6.45%)
occurrences (all)	6	5	2
Confusional state			
subjects affected / exposed	3 / 46 (6.52%)	3 / 39 (7.69%)	2 / 31 (6.45%)
occurrences (all)	3	3	3

Delirium			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (0.00%)
occurrences (all)	1	1	0
Depression			
subjects affected / exposed	4 / 46 (8.70%)	4 / 39 (10.26%)	0 / 31 (0.00%)
occurrences (all)	5	5	0
Flat affect			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	7 / 46 (15.22%)	5 / 39 (12.82%)	6 / 31 (19.35%)
occurrences (all)	8	6	6
Mental disorder			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Mental status changes			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	3 / 31 (9.68%)
occurrences (all)	1	1	3
Restlessness			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	7 / 46 (15.22%)	6 / 39 (15.38%)	3 / 31 (9.68%)
occurrences (all)	7	6	9
Amylase increased			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	1 / 31 (3.23%)
occurrences (all)	1	1	1
Aspartate aminotransferase increased			
subjects affected / exposed	5 / 46 (10.87%)	5 / 39 (12.82%)	5 / 31 (16.13%)
occurrences (all)	8	8	9
Blood alkaline phosphatase increased			
subjects affected / exposed	6 / 46 (13.04%)	5 / 39 (12.82%)	3 / 31 (9.68%)
occurrences (all)	9	8	6
Blood bicarbonate decreased			

subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	3 / 46 (6.52%)	2 / 39 (5.13%)	4 / 31 (12.90%)
occurrences (all)	3	2	8
Blood creatine increased			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (0.00%)
occurrences (all)	1	1	0
Blood creatinine increased			
subjects affected / exposed	6 / 46 (13.04%)	5 / 39 (12.82%)	1 / 31 (3.23%)
occurrences (all)	7	6	1
Blood fibrinogen decreased			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus decreased			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Blood urea increased			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Blood uric acid increased			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Brain natriuretic peptide increased			
subjects affected / exposed	1 / 46 (2.17%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Chest X-ray abnormal			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Coronavirus test positive			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0

Electrocardiogram QT prolonged			
subjects affected / exposed	3 / 46 (6.52%)	3 / 39 (7.69%)	0 / 31 (0.00%)
occurrences (all)	4	4	0
Ejection fraction decreased			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	2 / 31 (6.45%)
occurrences (all)	0	0	2
Enterococcus test positive			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (0.00%)
occurrences (all)	1	1	0
Heart rate increased			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	4 / 46 (8.70%)	4 / 39 (10.26%)	1 / 31 (3.23%)
occurrences (all)	6	6	1
Liver function test abnormal			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Liver function test increased			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	5 / 46 (10.87%)	4 / 39 (10.26%)	3 / 31 (9.68%)
occurrences (all)	11	5	3
Neutrophil count decreased			
subjects affected / exposed	14 / 46 (30.43%)	12 / 39 (30.77%)	3 / 31 (9.68%)
occurrences (all)	41	35	5
Platelet count decreased			

subjects affected / exposed	20 / 46 (43.48%)	18 / 39 (46.15%)	8 / 31 (25.81%)
occurrences (all)	81	67	16
Platelet count increased			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Red blood cell count decreased			
subjects affected / exposed	11 / 46 (23.91%)	8 / 39 (20.51%)	6 / 31 (19.35%)
occurrences (all)	29	26	10
Staphylococcus test positive			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	2 / 46 (4.35%)	2 / 39 (5.13%)	0 / 31 (0.00%)
occurrences (all)	2	2	0
Weight decreased			
subjects affected / exposed	5 / 46 (10.87%)	4 / 39 (10.26%)	0 / 31 (0.00%)
occurrences (all)	5	4	0
White blood cell count decreased			
subjects affected / exposed	8 / 46 (17.39%)	6 / 39 (15.38%)	2 / 31 (6.45%)
occurrences (all)	13	9	2
White blood cell count increased			
subjects affected / exposed	10 / 46 (21.74%)	8 / 39 (20.51%)	3 / 31 (9.68%)
occurrences (all)	12	10	4
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	5 / 46 (10.87%)	4 / 39 (10.26%)	4 / 31 (12.90%)
occurrences (all)	5	4	4
Eye contusion			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Fall			
subjects affected / exposed	5 / 46 (10.87%)	4 / 39 (10.26%)	3 / 31 (9.68%)
occurrences (all)	8	7	4
Hand fracture			

subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	2 / 46 (4.35%)	1 / 39 (2.56%)	1 / 31 (3.23%)
occurrences (all)	4	1	1
Laceration			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	1 / 31 (3.23%)
occurrences (all)	2	2	1
Limb injury			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Medication error			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Periorbital haematoma			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Post procedural haemorrhage			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Skin wound			
subjects affected / exposed	2 / 46 (4.35%)	2 / 39 (5.13%)	0 / 31 (0.00%)
occurrences (all)	2	2	0
Subdural haematoma			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Transfusion reaction			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (0.00%)
occurrences (all)	1	1	0
Wound secretion			

subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	1 / 31 (3.23%)
occurrences (all)	1	1	1
Arrhythmia			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	2 / 31 (6.45%)
occurrences (all)	0	0	2
Atrial fibrillation			
subjects affected / exposed	5 / 46 (10.87%)	5 / 39 (12.82%)	1 / 31 (3.23%)
occurrences (all)	5	5	1
Atrioventricular block first degree			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Atrial tachycardia			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Atrial flutter			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed	3 / 46 (6.52%)	3 / 39 (7.69%)	0 / 31 (0.00%)
occurrences (all)	3	3	0
Cardiac failure			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Coronary artery disease			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Left ventricular dysfunction			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Myocardial ischaemia			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0

Palpitations			
subjects affected / exposed	5 / 46 (10.87%)	5 / 39 (12.82%)	0 / 31 (0.00%)
occurrences (all)	5	5	0
Pericardial effusion			
subjects affected / exposed	2 / 46 (4.35%)	2 / 39 (5.13%)	2 / 31 (6.45%)
occurrences (all)	2	2	2
Sinus bradycardia			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Sinus tachycardia			
subjects affected / exposed	2 / 46 (4.35%)	2 / 39 (5.13%)	0 / 31 (0.00%)
occurrences (all)	3	3	0
Supraventricular tachycardia			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	3 / 46 (6.52%)	3 / 39 (7.69%)	5 / 31 (16.13%)
occurrences (all)	4	4	6
Ventricular tachycardia			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Ageusia			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Amnesia			
subjects affected / exposed	2 / 46 (4.35%)	2 / 39 (5.13%)	0 / 31 (0.00%)
occurrences (all)	2	2	0
Disturbance in attention			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Dizziness			
subjects affected / exposed	11 / 46 (23.91%)	11 / 39 (28.21%)	7 / 31 (22.58%)
occurrences (all)	16	16	10
Dysgeusia			

subjects affected / exposed	6 / 46 (13.04%)	5 / 39 (12.82%)	1 / 31 (3.23%)
occurrences (all)	6	5	1
Essential tremor			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	15 / 46 (32.61%)	13 / 39 (33.33%)	6 / 31 (19.35%)
occurrences (all)	22	20	7
Hyperaesthesia			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Hypersomnia			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	3 / 46 (6.52%)	3 / 39 (7.69%)	1 / 31 (3.23%)
occurrences (all)	3	3	1
Lethargy			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	1 / 31 (3.23%)
occurrences (all)	1	1	1
Memory impairment			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (0.00%)
occurrences (all)	1	1	0
Motor dysfunction			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	1 / 31 (3.23%)
occurrences (all)	1	1	1
Paraesthesia			
subjects affected / exposed	2 / 46 (4.35%)	1 / 39 (2.56%)	0 / 31 (0.00%)
occurrences (all)	2	1	0
Peripheral sensory neuropathy			

subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Restless legs syndrome			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	3 / 46 (6.52%)	3 / 39 (7.69%)	2 / 31 (6.45%)
occurrences (all)	3	3	2
Syncope			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	2 / 31 (6.45%)
occurrences (all)	1	1	3
Visual field defect			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Bone marrow failure			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Coagulopathy			
subjects affected / exposed	2 / 46 (4.35%)	2 / 39 (5.13%)	0 / 31 (0.00%)
occurrences (all)	2	2	0
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Eosinophilia			

subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Febrile neutropenia			
subjects affected / exposed	5 / 46 (10.87%)	5 / 39 (12.82%)	1 / 31 (3.23%)
occurrences (all)	7	7	1
Febrile bone marrow aplasia			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Haemorrhagic diathesis			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (0.00%)
occurrences (all)	1	1	0
Lymphadenopathy			
subjects affected / exposed	3 / 46 (6.52%)	3 / 39 (7.69%)	0 / 31 (0.00%)
occurrences (all)	3	3	0
Splenomegaly			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (0.00%)
occurrences (all)	1	1	0
Thrombotic thrombocytopenic purpura			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Tinnitus			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (0.00%)
occurrences (all)	1	1	0
Vertigo			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (0.00%)
occurrences (all)	1	1	0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	2 / 31 (6.45%)
occurrences (all)	0	0	2
Chalazion			

subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage			
subjects affected / exposed	2 / 46 (4.35%)	2 / 39 (5.13%)	0 / 31 (0.00%)
occurrences (all)	2	2	0
Dry eye			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	2 / 31 (6.45%)
occurrences (all)	0	0	2
Eye haemorrhage			
subjects affected / exposed	1 / 46 (2.17%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences (all)	1	0	1
Eyelid ptosis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Eye oedema			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Macular fibrosis			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (0.00%)
occurrences (all)	1	1	0
Ocular hyperaemia			
subjects affected / exposed	2 / 46 (4.35%)	2 / 39 (5.13%)	0 / 31 (0.00%)
occurrences (all)	2	2	0
Vision blurred			
subjects affected / exposed	3 / 46 (6.52%)	2 / 39 (5.13%)	1 / 31 (3.23%)
occurrences (all)	3	2	1
Visual acuity reduced			
subjects affected / exposed	1 / 46 (2.17%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences (all)	1	0	1
Visual impairment			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	4 / 46 (8.70%)	3 / 39 (7.69%)	5 / 31 (16.13%)
occurrences (all)	5	3	5

Abdominal tenderness			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Abdominal rigidity			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	3 / 31 (9.68%)
occurrences (all)	1	1	3
Abdominal pain			
subjects affected / exposed	9 / 46 (19.57%)	7 / 39 (17.95%)	1 / 31 (3.23%)
occurrences (all)	11	9	1
Anal fissure			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (0.00%)
occurrences (all)	1	1	0
Anal incontinence			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Anal ulcer			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Angina bullosa haemorrhagica			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	2 / 31 (6.45%)
occurrences (all)	1	1	3
Colitis			
subjects affected / exposed	2 / 46 (4.35%)	2 / 39 (5.13%)	0 / 31 (0.00%)
occurrences (all)	2	2	0
Constipation			
subjects affected / exposed	27 / 46 (58.70%)	24 / 39 (61.54%)	7 / 31 (22.58%)
occurrences (all)	41	35	7
Diarrhoea			
subjects affected / exposed	21 / 46 (45.65%)	16 / 39 (41.03%)	7 / 31 (22.58%)
occurrences (all)	29	21	8
Dry mouth			
subjects affected / exposed	4 / 46 (8.70%)	2 / 39 (5.13%)	1 / 31 (3.23%)
occurrences (all)	4	2	1

Dyspepsia			
subjects affected / exposed	4 / 46 (8.70%)	4 / 39 (10.26%)	2 / 31 (6.45%)
occurrences (all)	5	5	2
Dysphagia			
subjects affected / exposed	3 / 46 (6.52%)	2 / 39 (5.13%)	1 / 31 (3.23%)
occurrences (all)	3	2	1
Eosinophilic colitis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Faeces discoloured			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	2 / 31 (6.45%)
occurrences (all)	0	0	3
Flatulence			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	1 / 31 (3.23%)
occurrences (all)	1	1	1
Frequent bowel movements			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Food poisoning			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Gastritis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Gingival bleeding			
subjects affected / exposed	2 / 46 (4.35%)	2 / 39 (5.13%)	2 / 31 (6.45%)
occurrences (all)	3	3	3
Gastrooesophageal reflux disease			
subjects affected / exposed	4 / 46 (8.70%)	4 / 39 (10.26%)	1 / 31 (3.23%)
occurrences (all)	4	4	1
Haematemesis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0

Gingival swelling			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Gingival pain			
subjects affected / exposed	2 / 46 (4.35%)	2 / 39 (5.13%)	2 / 31 (6.45%)
occurrences (all)	2	2	2
Gingival hypertrophy			
subjects affected / exposed	3 / 46 (6.52%)	3 / 39 (7.69%)	0 / 31 (0.00%)
occurrences (all)	3	3	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	2 / 46 (4.35%)	2 / 39 (5.13%)	0 / 31 (0.00%)
occurrences (all)	2	2	0
Mouth haemorrhage			
subjects affected / exposed	3 / 46 (6.52%)	3 / 39 (7.69%)	0 / 31 (0.00%)
occurrences (all)	3	3	0
Mouth ulceration			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Nausea			
subjects affected / exposed	32 / 46 (69.57%)	26 / 39 (66.67%)	14 / 31 (45.16%)
occurrences (all)	43	37	23
Odynophagia			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	3 / 46 (6.52%)	2 / 39 (5.13%)	0 / 31 (0.00%)
occurrences (all)	3	2	0
Oral disorder			
subjects affected / exposed	2 / 46 (4.35%)	2 / 39 (5.13%)	1 / 31 (3.23%)
occurrences (all)	2	2	1
Pancreatitis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0

Proctalgia			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	1 / 31 (3.23%)
occurrences (all)	2	2	2
Proctitis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (0.00%)
occurrences (all)	1	1	0
Stomatitis haemorrhagic			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	5 / 46 (10.87%)	3 / 39 (7.69%)	2 / 31 (6.45%)
occurrences (all)	5	3	2
Toothache			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	2 / 31 (6.45%)
occurrences (all)	0	0	2
Tongue dysplasia			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Varices oesophageal			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	17 / 46 (36.96%)	14 / 39 (35.90%)	8 / 31 (25.81%)
occurrences (all)	23	20	12
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (0.00%)
occurrences (all)	1	1	0
Cholestasis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Hepatic steatosis			

subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Jaundice			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Actinic keratosis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	2 / 31 (6.45%)
occurrences (all)	1	1	2
Angioedema			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Blister			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Blood blister			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Dermatitis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	3 / 46 (6.52%)	3 / 39 (7.69%)	1 / 31 (3.23%)
occurrences (all)	3	3	1
Ecchymosis			
subjects affected / exposed	3 / 46 (6.52%)	3 / 39 (7.69%)	3 / 31 (9.68%)
occurrences (all)	4	4	3
Erythema			
subjects affected / exposed	3 / 46 (6.52%)	3 / 39 (7.69%)	2 / 31 (6.45%)
occurrences (all)	5	5	2

Hidradenitis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	3 / 31 (9.68%)
occurrences (all)	1	1	3
Hyperkeratosis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Miliaria			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (0.00%)
occurrences (all)	1	1	0
Onychoclasis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Onycholysis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Papule			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	2 / 31 (6.45%)
occurrences (all)	1	1	3
Pruritus generalised			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	8 / 46 (17.39%)	7 / 39 (17.95%)	4 / 31 (12.90%)
occurrences (all)	9	8	4
Psoriasis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0

Purpura			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (0.00%)
occurrences (all)	1	1	0
Pyoderma gangrenosum			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (0.00%)
occurrences (all)	1	1	0
Rash erythematous			
subjects affected / exposed	2 / 46 (4.35%)	2 / 39 (5.13%)	0 / 31 (0.00%)
occurrences (all)	2	2	0
Rash			
subjects affected / exposed	4 / 46 (8.70%)	4 / 39 (10.26%)	0 / 31 (0.00%)
occurrences (all)	4	4	0
Rash papular			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Scab			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Skin hyperpigmentation			
subjects affected / exposed	2 / 46 (4.35%)	2 / 39 (5.13%)	1 / 31 (3.23%)
occurrences (all)	2	2	1
Skin lesion			
subjects affected / exposed	2 / 46 (4.35%)	1 / 39 (2.56%)	0 / 31 (0.00%)
occurrences (all)	3	2	0
Skin ulcer			
subjects affected / exposed	2 / 46 (4.35%)	2 / 39 (5.13%)	0 / 31 (0.00%)
occurrences (all)	3	3	0
Skin reaction			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Skin mass			
subjects affected / exposed	4 / 46 (8.70%)	4 / 39 (10.26%)	0 / 31 (0.00%)
occurrences (all)	4	4	0

Toxic skin eruption			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	4 / 46 (8.70%)	4 / 39 (10.26%)	1 / 31 (3.23%)
occurrences (all)	5	5	1
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	3 / 46 (6.52%)	2 / 39 (5.13%)	3 / 31 (9.68%)
occurrences (all)	3	2	3
Calculus urinary			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Dysuria			
subjects affected / exposed	3 / 46 (6.52%)	3 / 39 (7.69%)	1 / 31 (3.23%)
occurrences (all)	5	5	1
Haematuria			
subjects affected / exposed	5 / 46 (10.87%)	5 / 39 (12.82%)	4 / 31 (12.90%)
occurrences (all)	5	5	4
Hydronephrosis			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	1 / 31 (3.23%)
occurrences (all)	1	1	1
Pollakiuria			
subjects affected / exposed	5 / 46 (10.87%)	5 / 39 (12.82%)	2 / 31 (6.45%)
occurrences (all)	9	9	3
Renal failure			
subjects affected / exposed	2 / 46 (4.35%)	2 / 39 (5.13%)	1 / 31 (3.23%)
occurrences (all)	2	2	1
Renal colic			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Urinary hesitation			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			

subjects affected / exposed	3 / 46 (6.52%)	3 / 39 (7.69%)	1 / 31 (3.23%)
occurrences (all)	3	3	1
Urinary retention			
subjects affected / exposed	3 / 46 (6.52%)	3 / 39 (7.69%)	1 / 31 (3.23%)
occurrences (all)	4	4	1
Urinary tract pain			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	2 / 46 (4.35%)	2 / 39 (5.13%)	0 / 31 (0.00%)
occurrences (all)	2	2	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	8 / 46 (17.39%)	8 / 39 (20.51%)	5 / 31 (16.13%)
occurrences (all)	14	14	9
Articular calcification			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	5 / 46 (10.87%)	5 / 39 (12.82%)	4 / 31 (12.90%)
occurrences (all)	10	10	5
Bone pain			
subjects affected / exposed	2 / 46 (4.35%)	1 / 39 (2.56%)	1 / 31 (3.23%)
occurrences (all)	2	1	1
Bone swelling			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	2 / 46 (4.35%)	2 / 39 (5.13%)	2 / 31 (6.45%)
occurrences (all)	2	2	3
Joint swelling			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	1 / 31 (3.23%)
occurrences (all)	1	1	2
Joint effusion			

subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	4 / 46 (8.70%)	4 / 39 (10.26%)	3 / 31 (9.68%)
occurrences (all)	4	4	5
Musculoskeletal chest pain			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	1 / 31 (3.23%)
occurrences (all)	1	1	1
Muscular weakness			
subjects affected / exposed	2 / 46 (4.35%)	2 / 39 (5.13%)	2 / 31 (6.45%)
occurrences (all)	2	2	2
Muscle twitching			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Muscle tightness			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Muscle spasms			
subjects affected / exposed	1 / 46 (2.17%)	0 / 39 (0.00%)	2 / 31 (6.45%)
occurrences (all)	1	0	3
Myalgia			
subjects affected / exposed	3 / 46 (6.52%)	2 / 39 (5.13%)	3 / 31 (9.68%)
occurrences (all)	3	2	3
Neck pain			
subjects affected / exposed	2 / 46 (4.35%)	2 / 39 (5.13%)	1 / 31 (3.23%)
occurrences (all)	2	2	1
Pain in extremity			
subjects affected / exposed	8 / 46 (17.39%)	8 / 39 (20.51%)	4 / 31 (12.90%)
occurrences (all)	13	13	4
Osteoporosis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Osteoarthritis			
subjects affected / exposed	2 / 46 (4.35%)	2 / 39 (5.13%)	0 / 31 (0.00%)
occurrences (all)	2	2	0
Pain in jaw			

subjects affected / exposed	3 / 46 (6.52%)	2 / 39 (5.13%)	0 / 31 (0.00%)
occurrences (all)	3	2	0
Periarthritis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Rheumatoid arthritis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Seronegative arthritis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Aspergillus infection			
subjects affected / exposed	1 / 46 (2.17%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Bacteraemia			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (0.00%)
occurrences (all)	1	1	0
Cellulitis			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (0.00%)
occurrences (all)	2	2	0
Chronic sinusitis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile colitis			
subjects affected / exposed	1 / 46 (2.17%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	2	0	0

Conjunctivitis			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (0.00%)
occurrences (all)	1	1	0
Corona virus infection			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (0.00%)
occurrences (all)	1	1	0
Cystitis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Device related infection			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (0.00%)
occurrences (all)	1	1	0
Enterococcal bacteraemia			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (0.00%)
occurrences (all)	1	1	0
Enterobacter bacteraemia			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Escherichia bacteraemia			
subjects affected / exposed	2 / 46 (4.35%)	2 / 39 (5.13%)	0 / 31 (0.00%)
occurrences (all)	2	2	0
Erysipelas			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Fungal rhinitis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	2 / 46 (4.35%)	2 / 39 (5.13%)	0 / 31 (0.00%)
occurrences (all)	2	2	0
Genital infection fungal			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0

Herpes zoster			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Herpes virus infection			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Klebsiella infection			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (0.00%)
occurrences (all)	1	1	0
Lower respiratory tract infection fungal			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Lung infection			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Nail infection			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	3 / 46 (6.52%)	3 / 39 (7.69%)	2 / 31 (6.45%)
occurrences (all)	4	4	2
Ophthalmic herpes zoster			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Oral fungal infection			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			

subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Orchitis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	1 / 46 (2.17%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Peritonsillar abscess			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	2 / 46 (4.35%)	2 / 39 (5.13%)	0 / 31 (0.00%)
occurrences (all)	2	2	0
Pneumonia pseudomonal			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	5 / 46 (10.87%)	4 / 39 (10.26%)	1 / 31 (3.23%)
occurrences (all)	5	4	1
Pseudomonal sepsis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Rhinitis			

subjects affected / exposed	4 / 46 (8.70%)	4 / 39 (10.26%)	0 / 31 (0.00%)
occurrences (all)	5	5	0
Sinusitis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Staphylococcal sepsis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Staphylococcal infection			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	0 / 31 (0.00%)
occurrences (all)	1	1	0
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	1 / 46 (2.17%)	1 / 39 (2.56%)	1 / 31 (3.23%)
occurrences (all)	1	1	1
Tooth abscess			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	5 / 46 (10.87%)	4 / 39 (10.26%)	0 / 31 (0.00%)
occurrences (all)	5	4	0
Urinary tract infection			
subjects affected / exposed	3 / 46 (6.52%)	3 / 39 (7.69%)	1 / 31 (3.23%)
occurrences (all)	4	4	1
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Abnormal loss of weight			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	10 / 46 (21.74%)	8 / 39 (20.51%)	7 / 31 (22.58%)
occurrences (all)	14	12	7

Dehydration			
subjects affected / exposed	4 / 46 (8.70%)	3 / 39 (7.69%)	2 / 31 (6.45%)
occurrences (all)	7	6	2
Diabetes mellitus			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Fluid overload			
subjects affected / exposed	4 / 46 (8.70%)	2 / 39 (5.13%)	1 / 31 (3.23%)
occurrences (all)	4	2	1
Hyperkalaemia			
subjects affected / exposed	2 / 46 (4.35%)	1 / 39 (2.56%)	1 / 31 (3.23%)
occurrences (all)	2	1	1
Hypercalcaemia			
subjects affected / exposed	1 / 46 (2.17%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Hyperferritinaemia			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	3 / 46 (6.52%)	3 / 39 (7.69%)	3 / 31 (9.68%)
occurrences (all)	3	3	3
Hypernatraemia			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Hyperphosphataemia			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	2 / 31 (6.45%)
occurrences (all)	0	0	2
Hyperuricaemia			
subjects affected / exposed	4 / 46 (8.70%)	3 / 39 (7.69%)	4 / 31 (12.90%)
occurrences (all)	4	3	4
Hypervolaemia			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	5 / 46 (10.87%)	3 / 39 (7.69%)	2 / 31 (6.45%)
occurrences (all)	5	3	2

Hypocalcaemia			
subjects affected / exposed	5 / 46 (10.87%)	3 / 39 (7.69%)	3 / 31 (9.68%)
occurrences (all)	8	6	3
Hypokalaemia			
subjects affected / exposed	16 / 46 (34.78%)	13 / 39 (33.33%)	7 / 31 (22.58%)
occurrences (all)	21	18	8
Hypomagnesaemia			
subjects affected / exposed	5 / 46 (10.87%)	5 / 39 (12.82%)	3 / 31 (9.68%)
occurrences (all)	5	5	3
Hyponatraemia			
subjects affected / exposed	5 / 46 (10.87%)	5 / 39 (12.82%)	3 / 31 (9.68%)
occurrences (all)	5	5	3
Hypophosphataemia			
subjects affected / exposed	4 / 46 (8.70%)	2 / 39 (5.13%)	0 / 31 (0.00%)
occurrences (all)	4	2	0
Hypovolaemia			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Increased appetite			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Iron deficiency			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Lactic acidosis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Malnutrition			
subjects affected / exposed	4 / 46 (8.70%)	4 / 39 (10.26%)	0 / 31 (0.00%)
occurrences (all)	4	4	0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Tumour lysis syndrome			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	4 / 31 (12.90%)
occurrences (all)	0	0	5

Vitamin D deficiency			
subjects affected / exposed	0 / 46 (0.00%)	0 / 39 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Phase 1: FT-2102 (Single Agent)	Phase 2: Cohort 7; FT-2102 (Single Agent)	Phase 2: Cohort 4; FT-2102+azacitidine (Combination Therapy)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	15 / 16 (93.75%)	10 / 10 (100.00%)	18 / 20 (90.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adrenal adenoma			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Basal cell carcinoma			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Cancer pain			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Endotheliomatosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Melanocytic naevus			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Vascular disorders			
Aortic calcification			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Deep vein thrombosis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
Embolism			

subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Haematoma			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	3 / 16 (18.75%)	2 / 10 (20.00%)	4 / 20 (20.00%)
occurrences (all)	3	2	6
Hypertensive crisis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Hypotension			
subjects affected / exposed	2 / 16 (12.50%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	2	0	1
Orthostatic hypotension			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis superficial			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Thrombosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Venous thrombosis limb			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Administration site pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Asthenia			

subjects affected / exposed	0 / 16 (0.00%)	1 / 10 (10.00%)	2 / 20 (10.00%)
occurrences (all)	0	2	2
Catheter site bruise			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Catheter site rash			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Catheter site haemorrhage			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Chest discomfort			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Chills			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	2
Device related thrombosis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Drug intolerance			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Early satiety			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	6 / 16 (37.50%)	2 / 10 (20.00%)	6 / 20 (30.00%)
occurrences (all)	9	2	6
Facial pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Generalised oedema			

subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
General physical health deterioration			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	2
Influenza like illness			
subjects affected / exposed	0 / 16 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Injection site pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Injection site reaction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	2
Malaise			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	3 / 20 (15.00%)
occurrences (all)	0	0	3
Mucosal dryness			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Oedema peripheral			
subjects affected / exposed	0 / 16 (0.00%)	5 / 10 (50.00%)	3 / 20 (15.00%)
occurrences (all)	0	5	3
Non-cardiac chest pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	1 / 16 (6.25%)	2 / 10 (20.00%)	0 / 20 (0.00%)
occurrences (all)	2	2	0
Peripheral swelling			
subjects affected / exposed	0 / 16 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Pyrexia			

subjects affected / exposed	4 / 16 (25.00%)	3 / 10 (30.00%)	5 / 20 (25.00%)
occurrences (all)	5	5	9
Systemic inflammatory response syndrome			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Temperature intolerance			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Vessel puncture site bruise			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 16 (0.00%)	1 / 10 (10.00%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
Hypogammaglobulinaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Breast haemorrhage			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Breast mass			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Genital erythema			
subjects affected / exposed	0 / 16 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Pelvic pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal pain			

subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal dryness			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Acute promyelocytic leukaemia differentiation syndrome			
subjects affected / exposed	2 / 16 (12.50%)	0 / 10 (0.00%)	2 / 20 (10.00%)
occurrences (all)	2	0	2
Catarrh			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	3 / 16 (18.75%)	4 / 10 (40.00%)	4 / 20 (20.00%)
occurrences (all)	3	5	5
Dyspnoea			
subjects affected / exposed	4 / 16 (25.00%)	2 / 10 (20.00%)	2 / 20 (10.00%)
occurrences (all)	5	3	2
Dyspnoea exertional			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Dyspnoea paroxysmal nocturnal			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	2 / 16 (12.50%)	1 / 10 (10.00%)	4 / 20 (20.00%)
occurrences (all)	3	1	4
Haemoptysis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hypoxia			

subjects affected / exposed	1 / 16 (6.25%)	1 / 10 (10.00%)	1 / 20 (5.00%)
occurrences (all)	1	1	1
Nasal septum perforation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Nasal dryness			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Nasal congestion			
subjects affected / exposed	2 / 16 (12.50%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Pleural effusion			
subjects affected / exposed	2 / 16 (12.50%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	2	0	1
Pleuritic pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Pulmonary oedema			
subjects affected / exposed	0 / 16 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Pulmonary embolism			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Rales			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			

subjects affected / exposed	3 / 16 (18.75%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	3	0	0
Sinus pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Sneezing			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Sputum discoloured			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Tachypnoea			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Affective disorder			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Agitation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	1 / 16 (6.25%)	1 / 10 (10.00%)	2 / 20 (10.00%)
occurrences (all)	1	2	2
Confusional state			
subjects affected / exposed	0 / 16 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Delirium			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	2

Depression			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	2
Flat affect			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	4 / 16 (25.00%)	0 / 10 (0.00%)	4 / 20 (20.00%)
occurrences (all)	4	0	5
Mental disorder			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Mental status changes			
subjects affected / exposed	2 / 16 (12.50%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
Restlessness			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	3 / 16 (18.75%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	9	0	0
Amylase increased			
subjects affected / exposed	1 / 16 (6.25%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
Aspartate aminotransferase increased			
subjects affected / exposed	4 / 16 (25.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	8	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	2 / 16 (12.50%)	1 / 10 (10.00%)	1 / 20 (5.00%)
occurrences (all)	5	3	1
Blood bicarbonate decreased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Blood bilirubin increased			

subjects affected / exposed	4 / 16 (25.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	8	1	0
Blood creatine increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Blood creatinine increased			
subjects affected / exposed	1 / 16 (6.25%)	2 / 10 (20.00%)	2 / 20 (10.00%)
occurrences (all)	1	2	3
Blood fibrinogen decreased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus decreased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Blood urea increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Blood uric acid increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Brain natriuretic peptide increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Chest X-ray abnormal			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Coronavirus test positive			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	2

Ejection fraction decreased			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Enterococcus test positive			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Heart rate increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
Liver function test abnormal			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Liver function test increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Lymphocyte count decreased			
subjects affected / exposed	2 / 16 (12.50%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 16 (0.00%)	2 / 10 (20.00%)	6 / 20 (30.00%)
occurrences (all)	0	6	7
Platelet count decreased			
subjects affected / exposed	4 / 16 (25.00%)	1 / 10 (10.00%)	6 / 20 (30.00%)
occurrences (all)	7	7	34
Platelet count increased			

subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Red blood cell count decreased			
subjects affected / exposed	4 / 16 (25.00%)	2 / 10 (20.00%)	7 / 20 (35.00%)
occurrences (all)	6	5	27
Staphylococcus test positive			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Transaminases increased			
subjects affected / exposed	0 / 16 (0.00%)	1 / 10 (10.00%)	1 / 20 (5.00%)
occurrences (all)	0	2	3
Weight decreased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	4
White blood cell count decreased			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	2 / 20 (10.00%)
occurrences (all)	1	0	2
White blood cell count increased			
subjects affected / exposed	2 / 16 (12.50%)	0 / 10 (0.00%)	3 / 20 (15.00%)
occurrences (all)	3	0	6
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	2 / 16 (12.50%)	1 / 10 (10.00%)	2 / 20 (10.00%)
occurrences (all)	2	1	2
Eye contusion			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Fall			
subjects affected / exposed	2 / 16 (12.50%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	2	0	1
Hand fracture			
subjects affected / exposed	0 / 16 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Infusion related reaction			

subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Laceration			
subjects affected / exposed	0 / 16 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Limb injury			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Medication error			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Periorbital haematoma			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Procedural pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Post procedural haemorrhage			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Skin wound			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Subdural haematoma			
subjects affected / exposed	0 / 16 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Transfusion reaction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Wound secretion			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			

Angina pectoris			
subjects affected / exposed	1 / 16 (6.25%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
Arrhythmia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Atrioventricular block first degree			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Atrial tachycardia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Atrial flutter			
subjects affected / exposed	0 / 16 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Bradycardia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Cardiac failure			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Coronary artery disease			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Left ventricular dysfunction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Myocardial ischaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1

Pericardial effusion			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Sinus bradycardia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Supraventricular tachycardia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	3 / 16 (18.75%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	3	0	2
Ventricular tachycardia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Ageusia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Amnesia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Dizziness			
subjects affected / exposed	3 / 16 (18.75%)	2 / 10 (20.00%)	1 / 20 (5.00%)
occurrences (all)	5	2	1
Dysgeusia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	2 / 20 (10.00%)
occurrences (all)	1	0	5
Essential tremor			

subjects affected / exposed	0 / 16 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Headache			
subjects affected / exposed	1 / 16 (6.25%)	3 / 10 (30.00%)	6 / 20 (30.00%)
occurrences (all)	1	3	9
Hyperaesthesia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hypersomnia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Lethargy			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Motor dysfunction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Neuropathy peripheral			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Paraesthesia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Presyncope			

subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
Syncope			
subjects affected / exposed	0 / 16 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Tremor			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Visual field defect			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Bone marrow failure			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Coagulopathy			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 16 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Eosinophilia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Febrile neutropenia			

subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Febrile bone marrow aplasia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Haemorrhagic diathesis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Splenomegaly			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Thrombotic thrombocytopenic purpura			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Tinnitus			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Cataract			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Chalazion			
subjects affected / exposed	0 / 16 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Conjunctival haemorrhage			

subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Eye haemorrhage			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Eyelid ptosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Eye oedema			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Macular fibrosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Visual acuity reduced			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Abdominal tenderness			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1

Abdominal rigidity			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 16 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Abdominal pain			
subjects affected / exposed	0 / 16 (0.00%)	2 / 10 (20.00%)	2 / 20 (10.00%)
occurrences (all)	0	3	3
Anal fissure			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Anal incontinence			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Anal ulcer			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Angina bullosa haemorrhagica			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
Colitis			
subjects affected / exposed	0 / 16 (0.00%)	2 / 10 (20.00%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
Constipation			
subjects affected / exposed	4 / 16 (25.00%)	2 / 10 (20.00%)	5 / 20 (25.00%)
occurrences (all)	4	2	9
Diarrhoea			
subjects affected / exposed	5 / 16 (31.25%)	2 / 10 (20.00%)	5 / 20 (25.00%)
occurrences (all)	6	3	11
Dry mouth			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Dyspepsia			
subjects affected / exposed	1 / 16 (6.25%)	1 / 10 (10.00%)	1 / 20 (5.00%)
occurrences (all)	1	1	1

Dysphagia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
Eosinophilic colitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Faeces discoloured			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Flatulence			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Frequent bowel movements			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Food poisoning			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal haemorrhage			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Gastritis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Gingival bleeding			
subjects affected / exposed	2 / 16 (12.50%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	3	0	1
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
Haematemesis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Gingival swelling			
subjects affected / exposed	0 / 16 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0

Gingival pain			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Gingival hypertrophy			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Haemorrhoids			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Mouth haemorrhage			
subjects affected / exposed	0 / 16 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Mouth ulceration			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
Nausea			
subjects affected / exposed	6 / 16 (37.50%)	2 / 10 (20.00%)	11 / 20 (55.00%)
occurrences (all)	11	6	14
Odynophagia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	2
Oral disorder			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Pancreatitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Proctalgia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Proctitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Stomatitis haemorrhagic			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	1 / 16 (6.25%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
Toothache			
subjects affected / exposed	0 / 16 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Tongue dysplasia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Varices oesophageal			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	3 / 16 (18.75%)	2 / 10 (20.00%)	10 / 20 (50.00%)
occurrences (all)	3	3	15
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Cholestasis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hepatic steatosis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Jaundice			

subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Actinic keratosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Angioedema			
subjects affected / exposed	0 / 16 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
Blister			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Blood blister			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Dermatitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Dry skin			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Ecchymosis			
subjects affected / exposed	2 / 16 (12.50%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
Erythema			
subjects affected / exposed	1 / 16 (6.25%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
Hidradenitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1

Hyperhidrosis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Hyperkeratosis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Miliaria			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Onychoclasis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Onycholysis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Papule			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	2 / 20 (10.00%)
occurrences (all)	1	0	2
Pruritus generalised			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	3 / 16 (18.75%)	1 / 10 (10.00%)	1 / 20 (5.00%)
occurrences (all)	3	2	1
Psoriasis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Purpura			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1

Pyoderma gangrenosum			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	2
Rash erythematous			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	2
Rash papular			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Scab			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Skin hyperpigmentation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Skin lesion			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Skin ulcer			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Skin reaction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	3
Skin mass			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Toxic skin eruption			
subjects affected / exposed	0 / 16 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0

Urticaria			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	2 / 16 (12.50%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
Calculus urinary			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Dysuria			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	3 / 16 (18.75%)	2 / 10 (20.00%)	3 / 20 (15.00%)
occurrences (all)	3	2	3
Hydronephrosis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Pollakiuria			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
Renal failure			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Renal colic			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Urinary hesitation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Urinary retention			

subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Urinary tract pain			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 16 (12.50%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
Articular calcification			
subjects affected / exposed	0 / 16 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Back pain			
subjects affected / exposed	3 / 16 (18.75%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	4	0	0
Bone pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Bone swelling			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
Joint swelling			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Joint effusion			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Musculoskeletal pain			

subjects affected / exposed	2 / 16 (12.50%)	1 / 10 (10.00%)	1 / 20 (5.00%)
occurrences (all)	3	1	1
Musculoskeletal chest pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Muscular weakness			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	2
Muscle twitching			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Muscle tightness			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Muscle spasms			
subjects affected / exposed	2 / 16 (12.50%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	3	0	0
Myalgia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
Neck pain			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
Pain in extremity			
subjects affected / exposed	2 / 16 (12.50%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
Osteoporosis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Osteoarthritis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Periarthritis			

subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Rheumatoid arthritis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Seronegative arthritis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Aspergillus infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Bacteraemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Chronic sinusitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Clostridium difficile colitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Corona virus infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Device related infection			
subjects affected / exposed	0 / 16 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Enterococcal bacteraemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	2
Enterobacter bacteraemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Escherichia bacteraemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Erysipelas			
subjects affected / exposed	0 / 16 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Fungal rhinitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Genital infection fungal			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Herpes virus infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Klebsiella infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 16 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Lower respiratory tract infection fungal			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Lung infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Nail infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Ophthalmic herpes zoster			
subjects affected / exposed	0 / 16 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Oral herpes			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Oral fungal infection			
subjects affected / exposed	0 / 16 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Oral candidiasis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	2 / 20 (10.00%)
occurrences (all)	1	0	3
Orchitis			

subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Peritonsillar abscess			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Pharyngitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Pneumonia pseudomonal			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
Pseudomonal sepsis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Rhinitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Sinusitis			

subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	2
Staphylococcal sepsis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Staphylococcal infection			
subjects affected / exposed	0 / 16 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	1 / 16 (6.25%)	1 / 10 (10.00%)	2 / 20 (10.00%)
occurrences (all)	1	1	3
Tooth abscess			
subjects affected / exposed	0 / 16 (0.00%)	2 / 10 (20.00%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 16 (0.00%)	1 / 10 (10.00%)	2 / 20 (10.00%)
occurrences (all)	0	1	2
Urinary tract infection			
subjects affected / exposed	0 / 16 (0.00%)	2 / 10 (20.00%)	1 / 20 (5.00%)
occurrences (all)	0	3	1
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Abnormal loss of weight			
subjects affected / exposed	0 / 16 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Decreased appetite			
subjects affected / exposed	3 / 16 (18.75%)	3 / 10 (30.00%)	4 / 20 (20.00%)
occurrences (all)	3	5	5
Dehydration			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0

Diabetes mellitus			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Fluid overload			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hyperferritinaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Hyperglycaemia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Hypernatraemia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Hyperphosphataemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	2 / 16 (12.50%)	0 / 10 (0.00%)	2 / 20 (10.00%)
occurrences (all)	2	0	2
Hypervolaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Hypocalcaemia			
subjects affected / exposed	1 / 16 (6.25%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	1	1	0

Hypokalaemia			
subjects affected / exposed	2 / 16 (12.50%)	1 / 10 (10.00%)	6 / 20 (30.00%)
occurrences (all)	2	1	11
Hypomagnesaemia			
subjects affected / exposed	2 / 16 (12.50%)	1 / 10 (10.00%)	1 / 20 (5.00%)
occurrences (all)	2	1	2
Hyponatraemia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Hypovolaemia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Increased appetite			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Iron deficiency			
subjects affected / exposed	0 / 16 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Lactic acidosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Malnutrition			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 16 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Tumour lysis syndrome			
subjects affected / exposed	1 / 16 (6.25%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
Vitamin D deficiency			
subjects affected / exposed	0 / 16 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	Phase 2: Cohort 5; FT-2102+azacitidine (Combination Therapy)	Phase 2: Cohort 6; FT-2102+azacitidine (Combination Therapy)	Phase 2: Cohort 3; FT-2102 (Single Agent)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	20 / 21 (95.24%)	19 / 20 (95.00%)	5 / 5 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adrenal adenoma			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Basal cell carcinoma			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cancer pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Endotheliomatosis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Melanocytic naevus			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Aortic calcification			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Deep vein thrombosis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	1 / 5 (20.00%)
occurrences (all)	0	1	1
Embolism			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Flushing			

subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	1 / 21 (4.76%)	2 / 20 (10.00%)	0 / 5 (0.00%)
occurrences (all)	1	4	0
Hypertensive crisis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	2 / 5 (40.00%)
occurrences (all)	1	0	2
Orthostatic hypotension			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Thrombophlebitis superficial			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Thrombosis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Venous thrombosis limb			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Administration site pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	3 / 21 (14.29%)	3 / 20 (15.00%)	1 / 5 (20.00%)
occurrences (all)	13	4	3
Catheter site bruise			

subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Catheter site rash			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Catheter site haemorrhage			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Chest discomfort			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	2 / 21 (9.52%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0
Device related thrombosis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Drug intolerance			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Early satiety			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Fatigue			
subjects affected / exposed	6 / 21 (28.57%)	7 / 20 (35.00%)	2 / 5 (40.00%)
occurrences (all)	7	11	2
Facial pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Generalised oedema			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
General physical health deterioration			

subjects affected / exposed	0 / 21 (0.00%)	2 / 20 (10.00%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Injection site erythema			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 21 (0.00%)	2 / 20 (10.00%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Injection site reaction			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Malaise			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Mucosal dryness			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	4 / 21 (19.05%)	4 / 20 (20.00%)	0 / 5 (0.00%)
occurrences (all)	4	5	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	1 / 21 (4.76%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	1	2	0
Peripheral swelling			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Pyrexia			
subjects affected / exposed	1 / 21 (4.76%)	2 / 20 (10.00%)	1 / 5 (20.00%)
occurrences (all)	2	3	1
Systemic inflammatory response			

syndrome			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Temperature intolerance			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site bruise			
subjects affected / exposed	1 / 21 (4.76%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypogammaglobulinaemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Reproductive system and breast disorders			
Breast haemorrhage			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Breast mass			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Genital erythema			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Vulvovaginal pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal dryness			

subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Acute promyelocytic leukaemia differentiation syndrome			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	2 / 5 (40.00%)
occurrences (all)	0	0	2
Catarrh			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	4 / 21 (19.05%)	3 / 20 (15.00%)	1 / 5 (20.00%)
occurrences (all)	5	3	1
Dyspnoea			
subjects affected / exposed	1 / 21 (4.76%)	3 / 20 (15.00%)	2 / 5 (40.00%)
occurrences (all)	1	4	2
Dyspnoea exertional			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	1
Dyspnoea paroxysmal nocturnal			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	4 / 21 (19.05%)	1 / 20 (5.00%)	1 / 5 (20.00%)
occurrences (all)	4	1	1
Haemoptysis			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	1
Hiccups			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Hypoxia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nasal septum perforation			

subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nasal dryness			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 21 (4.76%)	2 / 20 (10.00%)	1 / 5 (20.00%)
occurrences (all)	1	2	1
Pleural effusion			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Pleuritic pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Productive cough			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pulmonary oedema			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rales			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Sinus pain			

subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sneezing			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sputum discoloured			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Tachypnoea			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Upper-airway cough syndrome			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Affective disorder			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Agitation			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	1 / 21 (4.76%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Confusional state			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Delirium			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0

Flat affect			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Insomnia			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Mental disorder			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Mental status changes			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	2 / 5 (40.00%)
occurrences (all)	0	0	3
Restlessness			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	2 / 21 (9.52%)	2 / 20 (10.00%)	1 / 5 (20.00%)
occurrences (all)	3	3	1
Amylase increased			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Aspartate aminotransferase increased			
subjects affected / exposed	2 / 21 (9.52%)	1 / 20 (5.00%)	1 / 5 (20.00%)
occurrences (all)	2	2	1
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 21 (4.76%)	2 / 20 (10.00%)	2 / 5 (40.00%)
occurrences (all)	1	2	2
Blood bicarbonate decreased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	3 / 21 (14.29%)	1 / 20 (5.00%)	1 / 5 (20.00%)
occurrences (all)	13	1	3
Blood creatine increased			

subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	1 / 5 (20.00%)
occurrences (all)	0	1	2
Blood fibrinogen decreased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus decreased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood urea increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Blood uric acid increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Brain natriuretic peptide increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Chest X-ray abnormal			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Coronavirus test positive			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	1 / 5 (20.00%)
occurrences (all)	0	2	2
Ejection fraction decreased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Enterococcus test positive			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	2 / 21 (9.52%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	3	1	0
Heart rate increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Hepatic enzyme increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Liver function test abnormal			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Liver function test increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	5	0
Neutrophil count decreased			
subjects affected / exposed	5 / 21 (23.81%)	5 / 20 (25.00%)	0 / 5 (0.00%)
occurrences (all)	16	14	0
Platelet count decreased			
subjects affected / exposed	9 / 21 (42.86%)	4 / 20 (20.00%)	1 / 5 (20.00%)
occurrences (all)	38	32	1
Platelet count increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Red blood cell count decreased			

subjects affected / exposed	5 / 21 (23.81%)	5 / 20 (25.00%)	1 / 5 (20.00%)
occurrences (all)	22	26	1
Staphylococcus test positive			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Weight decreased			
subjects affected / exposed	1 / 21 (4.76%)	5 / 20 (25.00%)	0 / 5 (0.00%)
occurrences (all)	1	6	0
White blood cell count decreased			
subjects affected / exposed	1 / 21 (4.76%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
White blood cell count increased			
subjects affected / exposed	3 / 21 (14.29%)	4 / 20 (20.00%)	2 / 5 (40.00%)
occurrences (all)	3	6	6
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	1 / 21 (4.76%)	2 / 20 (10.00%)	0 / 5 (0.00%)
occurrences (all)	1	3	0
Eye contusion			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Hand fracture			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Laceration			

subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Medication error			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Periorbital haematoma			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0
Post procedural haemorrhage			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin wound			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Subdural haematoma			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Transfusion reaction			
subjects affected / exposed	2 / 21 (9.52%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	3	0	0
Wound secretion			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Arrhythmia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0
Atrioventricular block first degree			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Atrial tachycardia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Atrial flutter			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Bradycardia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cardiac failure			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Coronary artery disease			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Left ventricular dysfunction			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Myocardial ischaemia			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Palpitations			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pericardial effusion			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Sinus bradycardia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Supraventricular tachycardia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Tachycardia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ventricular tachycardia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Nervous system disorders			
Ageusia			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Amnesia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	4 / 21 (19.05%)	2 / 20 (10.00%)	0 / 5 (0.00%)
occurrences (all)	4	2	0
Dysgeusia			
subjects affected / exposed	2 / 21 (9.52%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences (all)	3	0	1
Essential tremor			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Headache			

subjects affected / exposed	3 / 21 (14.29%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	3	1	0
Hyperaesthesia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypersomnia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Hypoaesthesia			
subjects affected / exposed	1 / 21 (4.76%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Lethargy			
subjects affected / exposed	1 / 21 (4.76%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Memory impairment			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Motor dysfunction			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	2 / 21 (9.52%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	2	1	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	2
Restless legs syndrome			

subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	1 / 21 (4.76%)	1 / 20 (5.00%)	1 / 5 (20.00%)
occurrences (all)	1	1	1
Tremor			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Visual field defect			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Bone marrow failure			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Coagulopathy			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Disseminated intravascular coagulation			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Eosinophilia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Febrile neutropenia			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Febrile bone marrow aplasia			

subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Haemorrhagic diathesis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Splenomegaly			
subjects affected / exposed	2 / 21 (9.52%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0
Thrombotic thrombocytopenic purpura			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Tinnitus			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Chalazion			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Conjunctival haemorrhage			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Dry eye			

subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eye haemorrhage			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Eyelid ptosis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Eye oedema			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Macular fibrosis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Vision blurred			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Visual acuity reduced			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Visual impairment			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	1 / 21 (4.76%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Abdominal tenderness			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Abdominal rigidity			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1

Abdominal pain upper			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Abdominal pain			
subjects affected / exposed	1 / 21 (4.76%)	2 / 20 (10.00%)	2 / 5 (40.00%)
occurrences (all)	1	2	2
Anal fissure			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Anal incontinence			
subjects affected / exposed	1 / 21 (4.76%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Anal ulcer			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Angina bullosa haemorrhagica			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	1
Colitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	7 / 21 (33.33%)	10 / 20 (50.00%)	0 / 5 (0.00%)
occurrences (all)	9	11	0
Diarrhoea			
subjects affected / exposed	7 / 21 (33.33%)	5 / 20 (25.00%)	1 / 5 (20.00%)
occurrences (all)	8	5	1
Dry mouth			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	1 / 21 (4.76%)	1 / 20 (5.00%)	1 / 5 (20.00%)
occurrences (all)	1	1	1

Eosinophilic colitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Faeces discoloured			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Frequent bowel movements			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Food poisoning			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Gastritis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gingival bleeding			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Haematemesis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gingival swelling			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Gingival hypertrophy			
subjects affected / exposed	3 / 21 (14.29%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	4	0	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 21 (0.00%)	3 / 20 (15.00%)	0 / 5 (0.00%)
occurrences (all)	0	3	0
Mouth haemorrhage			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Mouth ulceration			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	9 / 21 (42.86%)	8 / 20 (40.00%)	3 / 5 (60.00%)
occurrences (all)	14	11	4
Odynophagia			
subjects affected / exposed	0 / 21 (0.00%)	2 / 20 (10.00%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Oral pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oral disorder			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pancreatitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Proctitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Rectal haemorrhage			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Stomatitis haemorrhagic			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 21 (0.00%)	2 / 20 (10.00%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Toothache			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tongue dysplasia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Varices oesophageal			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	6 / 21 (28.57%)	6 / 20 (30.00%)	0 / 5 (0.00%)
occurrences (all)	6	7	0
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cholestasis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hepatic steatosis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Jaundice			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			

Actinic keratosis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Angioedema			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blister			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Blood blister			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Ecchymosis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Erythema			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Hidradenitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Hyperkeratosis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Miliaria			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Night sweats			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Onychoclasis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Onycholysis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Papule			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Petechiae			
subjects affected / exposed	2 / 21 (9.52%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0
Pruritus generalised			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Pruritus			
subjects affected / exposed	2 / 21 (9.52%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	3	0	0
Psoriasis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Purpura			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pyoderma gangrenosum			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Rash maculo-papular			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Rash erythematous			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	2
Rash			
subjects affected / exposed	2 / 21 (9.52%)	3 / 20 (15.00%)	0 / 5 (0.00%)
occurrences (all)	2	4	0
Rash papular			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Scab			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin hyperpigmentation			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Skin reaction			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin mass			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Toxic skin eruption			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0

Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Calculus urinary			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Haematuria			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Hydronephrosis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	1 / 21 (4.76%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Renal colic			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Urinary hesitation			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Urinary retention			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Urinary tract pain			

subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 21 (9.52%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	2	1	0
Articular calcification			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	2 / 21 (9.52%)	2 / 20 (10.00%)	0 / 5 (0.00%)
occurrences (all)	3	2	0
Bone pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Bone swelling			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Flank pain			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Joint swelling			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Joint effusion			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			

subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	1 / 5 (20.00%)
occurrences (all)	0	2	1
Muscular weakness			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Muscle twitching			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Muscle tightness			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	1
Myalgia			
subjects affected / exposed	1 / 21 (4.76%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Neck pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	2 / 21 (9.52%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0
Osteoporosis			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Osteoarthritis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Periarthritis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rheumatoid arthritis			

subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Seronegative arthritis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Aspergillus infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Bacteraemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Candida infection			
subjects affected / exposed	2 / 21 (9.52%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	3	0	0
Cellulitis			
subjects affected / exposed	1 / 21 (4.76%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Chronic sinusitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile colitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Conjunctivitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Corona virus infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Cystitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Device related infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Enterococcal bacteraemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Enterobacter bacteraemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Escherichia bacteraemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Erysipelas			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Fungal rhinitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Genital infection fungal			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Herpes virus infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Klebsiella infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Lower respiratory tract infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection fungal			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lung infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Nail infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ophthalmic herpes zoster			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oral fungal infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Orchitis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Parainfluenzae virus infection			

subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Paronychia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Peritonsillar abscess			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pneumonia pseudomonal			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Pneumonia			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	2
Pseudomonal sepsis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Rash pustular			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Respiratory tract infection			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0
Rhinitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Staphylococcal sepsis			

subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Staphylococcal infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Tooth infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	2 / 21 (9.52%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	4	0	0
Urinary tract infection			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Abnormal loss of weight			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	4 / 21 (19.05%)	5 / 20 (25.00%)	0 / 5 (0.00%)
occurrences (all)	5	7	0
Dehydration			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Diabetes mellitus			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Fluid overload			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Hypercalcaemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyperferritinaemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	1 / 21 (4.76%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Hypernatraemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyperphosphataemia			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	2
Hyperuricaemia			
subjects affected / exposed	1 / 21 (4.76%)	2 / 20 (10.00%)	0 / 5 (0.00%)
occurrences (all)	1	4	0
Hypervolaemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Hypoalbuminaemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Hypocalcaemia			
subjects affected / exposed	2 / 21 (9.52%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences (all)	2	0	2
Hypokalaemia			
subjects affected / exposed	1 / 21 (4.76%)	4 / 20 (20.00%)	3 / 5 (60.00%)
occurrences (all)	1	4	8

Hypomagnesaemia			
subjects affected / exposed	1 / 21 (4.76%)	3 / 20 (15.00%)	1 / 5 (20.00%)
occurrences (all)	1	3	2
Hyponatraemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	1 / 21 (4.76%)	3 / 20 (15.00%)	2 / 5 (40.00%)
occurrences (all)	1	4	3
Hypovolaemia			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Increased appetite			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lactic acidosis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Malnutrition			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tumour lysis syndrome			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences (all)	2	0	1
Vitamin D deficiency			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Phase 2: Cohort 8; FT-2102+azacitidine (Combination Therapy)	Phase 2: Cohort 1; FT-2102 (Single Agent)	Phase 1: Overall

Total subjects affected by non-serious adverse events subjects affected / exposed	11 / 11 (100.00%)	152 / 153 (99.35%)	76 / 78 (97.44%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adrenal adenoma			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Basal cell carcinoma			
subjects affected / exposed	0 / 11 (0.00%)	2 / 153 (1.31%)	1 / 78 (1.28%)
occurrences (all)	0	4	1
Cancer pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences (all)	0	0	1
Endotheliomatosis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Melanocytic naevus			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences (all)	0	0	2
Vascular disorders			
Aortic calcification			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Deep vein thrombosis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	1 / 78 (1.28%)
occurrences (all)	0	1	1
Embolism			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences (all)	0	0	1
Haematoma			

subjects affected / exposed	3 / 11 (27.27%)	2 / 153 (1.31%)	4 / 78 (5.13%)
occurrences (all)	3	4	5
Hypertension			
subjects affected / exposed	2 / 11 (18.18%)	17 / 153 (11.11%)	14 / 78 (17.95%)
occurrences (all)	3	31	20
Hypertensive crisis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	2 / 11 (18.18%)	7 / 153 (4.58%)	9 / 78 (11.54%)
occurrences (all)	3	8	10
Orthostatic hypotension			
subjects affected / exposed	1 / 11 (9.09%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences (all)	1	0	1
Thrombophlebitis superficial			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (0.00%)
occurrences (all)	0	1	0
Thrombosis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Venous thrombosis limb			
subjects affected / exposed	1 / 11 (9.09%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Administration site pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	4 / 11 (36.36%)	30 / 153 (19.61%)	12 / 78 (15.38%)
occurrences (all)	11	49	16
Catheter site bruise			
subjects affected / exposed	1 / 11 (9.09%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	1	0	0
Catheter site rash			

subjects affected / exposed	1 / 11 (9.09%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences (all)	1	0	1
Catheter site pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	3 / 78 (3.85%)
occurrences (all)	0	0	3
Catheter site haemorrhage			
subjects affected / exposed	1 / 11 (9.09%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	3	0	0
Chest discomfort			
subjects affected / exposed	0 / 11 (0.00%)	2 / 153 (1.31%)	1 / 78 (1.28%)
occurrences (all)	0	2	1
Chills			
subjects affected / exposed	1 / 11 (9.09%)	6 / 153 (3.92%)	7 / 78 (8.97%)
occurrences (all)	1	6	11
Device related thrombosis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences (all)	0	0	1
Drug intolerance			
subjects affected / exposed	1 / 11 (9.09%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	1	0	0
Early satiety			
subjects affected / exposed	1 / 11 (9.09%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences (all)	1	0	1
Fatigue			
subjects affected / exposed	0 / 11 (0.00%)	35 / 153 (22.88%)	32 / 78 (41.03%)
occurrences (all)	0	47	44
Facial pain			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	1 / 78 (1.28%)
occurrences (all)	0	1	2
Generalised oedema			
subjects affected / exposed	1 / 11 (9.09%)	2 / 153 (1.31%)	2 / 78 (2.56%)
occurrences (all)	1	2	2
General physical health deterioration			
subjects affected / exposed	1 / 11 (9.09%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	1	0	0
Injection site erythema			

subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences (all)	0	0	1
Influenza like illness			
subjects affected / exposed	0 / 11 (0.00%)	2 / 153 (1.31%)	0 / 78 (0.00%)
occurrences (all)	0	3	0
Injection site pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	2 / 78 (2.56%)
occurrences (all)	0	0	2
Injection site reaction			
subjects affected / exposed	2 / 11 (18.18%)	0 / 153 (0.00%)	3 / 78 (3.85%)
occurrences (all)	2	0	4
Malaise			
subjects affected / exposed	0 / 11 (0.00%)	4 / 153 (2.61%)	3 / 78 (3.85%)
occurrences (all)	0	5	3
Mucosal dryness			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	1 / 11 (9.09%)	23 / 153 (15.03%)	12 / 78 (15.38%)
occurrences (all)	3	36	14
Non-cardiac chest pain			
subjects affected / exposed	1 / 11 (9.09%)	7 / 153 (4.58%)	2 / 78 (2.56%)
occurrences (all)	1	10	2
Pain			
subjects affected / exposed	0 / 11 (0.00%)	6 / 153 (3.92%)	6 / 78 (7.69%)
occurrences (all)	0	9	7
Peripheral swelling			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	9 / 78 (11.54%)
occurrences (all)	0	0	12
Pyrexia			
subjects affected / exposed	3 / 11 (27.27%)	35 / 153 (22.88%)	20 / 78 (25.64%)
occurrences (all)	3	53	28
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences (all)	0	0	1

Temperature intolerance			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site bruise			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (0.00%)
occurrences (all)	0	1	0
Hypogammaglobulinaemia			
subjects affected / exposed	1 / 11 (9.09%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	1	0	0
Seasonal allergy			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	2 / 78 (2.56%)
occurrences (all)	0	0	2
Reproductive system and breast disorders			
Breast haemorrhage			
subjects affected / exposed	1 / 11 (9.09%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	1	0	0
Breast mass			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Genital erythema			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences (all)	0	0	1
Vulvovaginal pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	2 / 78 (2.56%)
occurrences (all)	0	0	2
Vulvovaginal dryness			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			

Acute promyelocytic leukaemia differentiation syndrome			
subjects affected / exposed	1 / 11 (9.09%)	11 / 153 (7.19%)	6 / 78 (7.69%)
occurrences (all)	1	11	7
Catarrh			
subjects affected / exposed	1 / 11 (9.09%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	1	0	0
Cough			
subjects affected / exposed	3 / 11 (27.27%)	25 / 153 (16.34%)	23 / 78 (29.49%)
occurrences (all)	3	33	24
Dyspnoea			
subjects affected / exposed	2 / 11 (18.18%)	31 / 153 (20.26%)	20 / 78 (25.64%)
occurrences (all)	2	50	31
Dyspnoea exertional			
subjects affected / exposed	1 / 11 (9.09%)	1 / 153 (0.65%)	2 / 78 (2.56%)
occurrences (all)	1	1	2
Dyspnoea paroxysmal nocturnal			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences (all)	0	0	1
Epistaxis			
subjects affected / exposed	3 / 11 (27.27%)	17 / 153 (11.11%)	12 / 78 (15.38%)
occurrences (all)	8	32	14
Haemoptysis			
subjects affected / exposed	1 / 11 (9.09%)	4 / 153 (2.61%)	1 / 78 (1.28%)
occurrences (all)	1	4	1
Hiccups			
subjects affected / exposed	1 / 11 (9.09%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	2	0	0
Hypoxia			
subjects affected / exposed	0 / 11 (0.00%)	4 / 153 (2.61%)	4 / 78 (5.13%)
occurrences (all)	0	7	4
Nasal septum perforation			
subjects affected / exposed	1 / 11 (9.09%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	1	0	0
Nasal dryness			

subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	2 / 78 (2.56%)
occurrences (all)	0	0	2
Nasal congestion			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	6 / 78 (7.69%)
occurrences (all)	0	1	6
Oropharyngeal pain			
subjects affected / exposed	0 / 11 (0.00%)	5 / 153 (3.27%)	7 / 78 (8.97%)
occurrences (all)	0	5	8
Pleural effusion			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	5 / 78 (6.41%)
occurrences (all)	0	1	5
Pleuritic pain			
subjects affected / exposed	1 / 11 (9.09%)	2 / 153 (1.31%)	2 / 78 (2.56%)
occurrences (all)	1	2	2
Pneumonitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 11 (0.00%)	5 / 153 (3.27%)	2 / 78 (2.56%)
occurrences (all)	0	5	2
Pulmonary oedema			
subjects affected / exposed	0 / 11 (0.00%)	4 / 153 (2.61%)	1 / 78 (1.28%)
occurrences (all)	0	4	1
Pulmonary embolism			
subjects affected / exposed	0 / 11 (0.00%)	2 / 153 (1.31%)	0 / 78 (0.00%)
occurrences (all)	0	2	0
Rales			
subjects affected / exposed	1 / 11 (9.09%)	1 / 153 (0.65%)	1 / 78 (1.28%)
occurrences (all)	1	1	1
Rhinorrhoea			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	8 / 78 (10.26%)
occurrences (all)	0	2	9
Sinus pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences (all)	0	0	1
Sneezing			

subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences (all)	0	0	1
Sputum discoloured			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Tachypnoea			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (0.00%)
occurrences (all)	0	1	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	4 / 78 (5.13%)
occurrences (all)	0	0	5
Wheezing			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences (all)	0	0	1
Psychiatric disorders			
Affective disorder			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Agitation			
subjects affected / exposed	1 / 11 (9.09%)	3 / 153 (1.96%)	2 / 78 (2.56%)
occurrences (all)	1	3	2
Anxiety			
subjects affected / exposed	2 / 11 (18.18%)	7 / 153 (4.58%)	9 / 78 (11.54%)
occurrences (all)	4	7	9
Confusional state			
subjects affected / exposed	0 / 11 (0.00%)	6 / 153 (3.92%)	5 / 78 (6.41%)
occurrences (all)	0	7	6
Delirium			
subjects affected / exposed	0 / 11 (0.00%)	3 / 153 (1.96%)	1 / 78 (1.28%)
occurrences (all)	0	3	1
Depression			
subjects affected / exposed	0 / 11 (0.00%)	6 / 153 (3.92%)	4 / 78 (5.13%)
occurrences (all)	0	8	5
Flat affect			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0

Insomnia			
subjects affected / exposed	2 / 11 (18.18%)	12 / 153 (7.84%)	13 / 78 (16.67%)
occurrences (all)	6	13	14
Mental disorder			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Mental status changes			
subjects affected / exposed	0 / 11 (0.00%)	2 / 153 (1.31%)	4 / 78 (5.13%)
occurrences (all)	0	2	4
Restlessness			
subjects affected / exposed	1 / 11 (9.09%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	1	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 11 (0.00%)	18 / 153 (11.76%)	11 / 78 (14.10%)
occurrences (all)	0	38	17
Amylase increased			
subjects affected / exposed	1 / 11 (9.09%)	7 / 153 (4.58%)	2 / 78 (2.56%)
occurrences (all)	1	8	2
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 11 (0.00%)	14 / 153 (9.15%)	11 / 78 (14.10%)
occurrences (all)	0	27	18
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 11 (0.00%)	9 / 153 (5.88%)	10 / 78 (12.82%)
occurrences (all)	0	19	16
Blood bicarbonate decreased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	1 / 11 (9.09%)	8 / 153 (5.23%)	8 / 78 (10.26%)
occurrences (all)	6	10	12
Blood creatine increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences (all)	0	0	1
Blood creatinine increased			

subjects affected / exposed	2 / 11 (18.18%)	14 / 153 (9.15%)	7 / 78 (8.97%)
occurrences (all)	9	15	8
Blood fibrinogen decreased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 11 (0.00%)	4 / 153 (2.61%)	0 / 78 (0.00%)
occurrences (all)	0	5	0
Blood phosphorus decreased			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (0.00%)
occurrences (all)	0	1	0
Blood urea increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Blood uric acid increased			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (0.00%)
occurrences (all)	0	1	0
Brain natriuretic peptide increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences (all)	0	0	1
Chest X-ray abnormal			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	1 / 78 (1.28%)
occurrences (all)	0	1	1
Coronavirus test positive			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	1 / 11 (9.09%)	12 / 153 (7.84%)	3 / 78 (3.85%)
occurrences (all)	1	18	4
Ejection fraction decreased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	2 / 78 (2.56%)
occurrences (all)	0	0	2
Enterococcus test positive			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0

Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 11 (0.00%)	11 / 153 (7.19%)	1 / 78 (1.28%)
occurrences (all)	0	24	1
Heart rate increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 11 (0.00%)	5 / 153 (3.27%)	0 / 78 (0.00%)
occurrences (all)	0	11	0
Lipase increased			
subjects affected / exposed	1 / 11 (9.09%)	10 / 153 (6.54%)	5 / 78 (6.41%)
occurrences (all)	1	20	7
Liver function test abnormal			
subjects affected / exposed	0 / 11 (0.00%)	2 / 153 (1.31%)	0 / 78 (0.00%)
occurrences (all)	0	3	0
Liver function test increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	8 / 78 (10.26%)
occurrences (all)	0	1	14
Neutrophil count decreased			
subjects affected / exposed	3 / 11 (27.27%)	21 / 153 (13.73%)	18 / 78 (23.08%)
occurrences (all)	11	65	47
Platelet count decreased			
subjects affected / exposed	3 / 11 (27.27%)	31 / 153 (20.26%)	28 / 78 (35.90%)
occurrences (all)	20	152	97
Platelet count increased			
subjects affected / exposed	0 / 11 (0.00%)	3 / 153 (1.96%)	0 / 78 (0.00%)
occurrences (all)	0	3	0
Red blood cell count decreased			
subjects affected / exposed	1 / 11 (9.09%)	40 / 153 (26.14%)	17 / 78 (21.79%)
occurrences (all)	5	123	39
Staphylococcus test positive			

subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 11 (0.00%)	2 / 153 (1.31%)	2 / 78 (2.56%)
occurrences (all)	0	2	2
Weight decreased			
subjects affected / exposed	1 / 11 (9.09%)	7 / 153 (4.58%)	5 / 78 (6.41%)
occurrences (all)	1	9	5
White blood cell count decreased			
subjects affected / exposed	1 / 11 (9.09%)	4 / 153 (2.61%)	10 / 78 (12.82%)
occurrences (all)	1	13	15
White blood cell count increased			
subjects affected / exposed	1 / 11 (9.09%)	36 / 153 (23.53%)	13 / 78 (16.67%)
occurrences (all)	1	56	16
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 11 (0.00%)	6 / 153 (3.92%)	9 / 78 (11.54%)
occurrences (all)	0	8	9
Eye contusion			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences (all)	0	0	1
Fall			
subjects affected / exposed	1 / 11 (9.09%)	14 / 153 (9.15%)	8 / 78 (10.26%)
occurrences (all)	1	14	12
Hand fracture			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	3 / 78 (3.85%)
occurrences (all)	0	1	5
Laceration			
subjects affected / exposed	1 / 11 (9.09%)	2 / 153 (1.31%)	2 / 78 (2.56%)
occurrences (all)	1	2	3
Limb injury			

subjects affected / exposed	1 / 11 (9.09%)	2 / 153 (1.31%)	0 / 78 (0.00%)
occurrences (all)	1	2	0
Medication error			
subjects affected / exposed	0 / 11 (0.00%)	3 / 153 (1.96%)	0 / 78 (0.00%)
occurrences (all)	0	3	0
Periorbital haematoma			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (0.00%)
occurrences (all)	0	1	0
Post procedural haemorrhage			
subjects affected / exposed	1 / 11 (9.09%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	1	0	0
Skin abrasion			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences (all)	0	0	1
Skin wound			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	2 / 78 (2.56%)
occurrences (all)	0	2	2
Subdural haematoma			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Transfusion reaction			
subjects affected / exposed	0 / 11 (0.00%)	3 / 153 (1.96%)	2 / 78 (2.56%)
occurrences (all)	0	3	2
Wound secretion			
subjects affected / exposed	1 / 11 (9.09%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 11 (0.00%)	2 / 153 (1.31%)	2 / 78 (2.56%)
occurrences (all)	0	2	2
Arrhythmia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	2 / 78 (2.56%)
occurrences (all)	0	0	2

Atrial fibrillation			
subjects affected / exposed	1 / 11 (9.09%)	5 / 153 (3.27%)	6 / 78 (7.69%)
occurrences (all)	1	7	6
Atrioventricular block first degree			
subjects affected / exposed	1 / 11 (9.09%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	2	0	0
Atrial tachycardia			
subjects affected / exposed	1 / 11 (9.09%)	1 / 153 (0.65%)	0 / 78 (0.00%)
occurrences (all)	1	1	0
Atrial flutter			
subjects affected / exposed	1 / 11 (9.09%)	3 / 153 (1.96%)	0 / 78 (0.00%)
occurrences (all)	1	4	0
Bradycardia			
subjects affected / exposed	1 / 11 (9.09%)	2 / 153 (1.31%)	4 / 78 (5.13%)
occurrences (all)	1	2	4
Cardiac failure			
subjects affected / exposed	1 / 11 (9.09%)	1 / 153 (0.65%)	1 / 78 (1.28%)
occurrences (all)	2	1	1
Coronary artery disease			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Left ventricular dysfunction			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Myocardial ischaemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 11 (0.00%)	5 / 153 (3.27%)	5 / 78 (6.41%)
occurrences (all)	0	6	5
Pericardial effusion			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	4 / 78 (5.13%)
occurrences (all)	0	0	4
Sinus bradycardia			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	1 / 78 (1.28%)
occurrences (all)	0	1	1

Sinus tachycardia			
subjects affected / exposed	1 / 11 (9.09%)	2 / 153 (1.31%)	2 / 78 (2.56%)
occurrences (all)	1	2	3
Supraventricular tachycardia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 11 (0.00%)	5 / 153 (3.27%)	8 / 78 (10.26%)
occurrences (all)	0	6	10
Ventricular tachycardia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Ageusia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Amnesia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	2 / 78 (2.56%)
occurrences (all)	0	0	2
Disturbance in attention			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences (all)	0	0	1
Dizziness			
subjects affected / exposed	1 / 11 (9.09%)	10 / 153 (6.54%)	18 / 78 (23.08%)
occurrences (all)	2	11	26
Dysgeusia			
subjects affected / exposed	0 / 11 (0.00%)	7 / 153 (4.58%)	7 / 78 (8.97%)
occurrences (all)	0	7	7
Essential tremor			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	2 / 11 (18.18%)	20 / 153 (13.07%)	21 / 78 (26.92%)
occurrences (all)	3	27	29
Hyperaesthesia			

subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Hypersomnia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	4 / 78 (5.13%)
occurrences (all)	0	0	4
Lethargy			
subjects affected / exposed	2 / 11 (18.18%)	0 / 153 (0.00%)	2 / 78 (2.56%)
occurrences (all)	2	0	2
Memory impairment			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	1 / 78 (1.28%)
occurrences (all)	0	1	1
Motor dysfunction			
subjects affected / exposed	1 / 11 (9.09%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	3	0	0
Neuralgia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	1 / 11 (9.09%)	0 / 153 (0.00%)	2 / 78 (2.56%)
occurrences (all)	1	0	2
Paraesthesia			
subjects affected / exposed	1 / 11 (9.09%)	3 / 153 (1.96%)	2 / 78 (2.56%)
occurrences (all)	1	3	2
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 11 (0.00%)	3 / 153 (1.96%)	0 / 78 (0.00%)
occurrences (all)	0	3	0
Presyncope			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences (all)	0	0	1
Restless legs syndrome			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (0.00%)
occurrences (all)	0	1	0
Somnolence			

subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	5 / 78 (6.41%)
occurrences (all)	0	1	5
Syncope			
subjects affected / exposed	1 / 11 (9.09%)	2 / 153 (1.31%)	0 / 78 (0.00%)
occurrences (all)	1	2	0
Tremor			
subjects affected / exposed	1 / 11 (9.09%)	0 / 153 (0.00%)	3 / 78 (3.85%)
occurrences (all)	1	0	4
Visual field defect			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Bone marrow failure			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Coagulopathy			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	2 / 78 (2.56%)
occurrences (all)	0	0	2
Disseminated intravascular coagulation			
subjects affected / exposed	1 / 11 (9.09%)	3 / 153 (1.96%)	0 / 78 (0.00%)
occurrences (all)	1	3	0
Eosinophilia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Febrile neutropenia			
subjects affected / exposed	1 / 11 (9.09%)	12 / 153 (7.84%)	6 / 78 (7.69%)
occurrences (all)	1	13	8
Febrile bone marrow aplasia			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (0.00%)
occurrences (all)	0	1	0
Haemorrhagic diathesis			

subjects affected / exposed	1 / 11 (9.09%)	1 / 153 (0.65%)	1 / 78 (1.28%)
occurrences (all)	3	1	1
Lymphadenopathy			
subjects affected / exposed	0 / 11 (0.00%)	2 / 153 (1.31%)	3 / 78 (3.85%)
occurrences (all)	0	2	3
Splenomegaly			
subjects affected / exposed	0 / 11 (0.00%)	2 / 153 (1.31%)	1 / 78 (1.28%)
occurrences (all)	0	2	1
Thrombotic thrombocytopenic purpura			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 11 (0.00%)	4 / 153 (2.61%)	1 / 78 (1.28%)
occurrences (all)	0	4	1
Tinnitus			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences (all)	0	0	1
Vertigo			
subjects affected / exposed	0 / 11 (0.00%)	4 / 153 (2.61%)	1 / 78 (1.28%)
occurrences (all)	0	5	1
Eye disorders			
Cataract			
subjects affected / exposed	0 / 11 (0.00%)	3 / 153 (1.96%)	2 / 78 (2.56%)
occurrences (all)	0	3	2
Chalazion			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage			
subjects affected / exposed	1 / 11 (9.09%)	1 / 153 (0.65%)	2 / 78 (2.56%)
occurrences (all)	1	1	2
Dry eye			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	2 / 78 (2.56%)
occurrences (all)	0	0	2
Eye haemorrhage			

subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	2 / 78 (2.56%)
occurrences (all)	0	0	2
Eyelid ptosis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Eye oedema			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Macular fibrosis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences (all)	0	0	1
Ocular hyperaemia			
subjects affected / exposed	0 / 11 (0.00%)	2 / 153 (1.31%)	2 / 78 (2.56%)
occurrences (all)	0	3	2
Vision blurred			
subjects affected / exposed	0 / 11 (0.00%)	2 / 153 (1.31%)	4 / 78 (5.13%)
occurrences (all)	0	2	4
Visual acuity reduced			
subjects affected / exposed	0 / 11 (0.00%)	2 / 153 (1.31%)	2 / 78 (2.56%)
occurrences (all)	0	2	2
Visual impairment			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	1 / 11 (9.09%)	2 / 153 (1.31%)	9 / 78 (11.54%)
occurrences (all)	1	3	10
Abdominal tenderness			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (0.00%)
occurrences (all)	0	1	0
Abdominal rigidity			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	1 / 11 (9.09%)	7 / 153 (4.58%)	4 / 78 (5.13%)
occurrences (all)	1	9	4

Abdominal pain			
subjects affected / exposed	2 / 11 (18.18%)	15 / 153 (9.80%)	10 / 78 (12.82%)
occurrences (all)	3	17	12
Anal fissure			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	1 / 78 (1.28%)
occurrences (all)	0	1	1
Anal incontinence			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences (all)	0	0	1
Anal ulcer			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Angina bullosa haemorrhagica			
subjects affected / exposed	0 / 11 (0.00%)	2 / 153 (1.31%)	3 / 78 (3.85%)
occurrences (all)	0	2	4
Colitis			
subjects affected / exposed	1 / 11 (9.09%)	1 / 153 (0.65%)	2 / 78 (2.56%)
occurrences (all)	1	1	2
Constipation			
subjects affected / exposed	7 / 11 (63.64%)	41 / 153 (26.80%)	34 / 78 (43.59%)
occurrences (all)	21	51	48
Diarrhoea			
subjects affected / exposed	4 / 11 (36.36%)	31 / 153 (20.26%)	29 / 78 (37.18%)
occurrences (all)	8	36	38
Dry mouth			
subjects affected / exposed	0 / 11 (0.00%)	4 / 153 (2.61%)	5 / 78 (6.41%)
occurrences (all)	0	4	5
Dyspepsia			
subjects affected / exposed	1 / 11 (9.09%)	11 / 153 (7.19%)	6 / 78 (7.69%)
occurrences (all)	1	11	7
Dysphagia			
subjects affected / exposed	0 / 11 (0.00%)	3 / 153 (1.96%)	4 / 78 (5.13%)
occurrences (all)	0	3	4
Eosinophilic colitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0

Faeces discoloured			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	2 / 78 (2.56%)
occurrences (all)	0	0	3
Flatulence			
subjects affected / exposed	1 / 11 (9.09%)	2 / 153 (1.31%)	2 / 78 (2.56%)
occurrences (all)	1	2	2
Frequent bowel movements			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Food poisoning			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences (all)	0	0	1
Gastritis			
subjects affected / exposed	1 / 11 (9.09%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	1	0	0
Gingival bleeding			
subjects affected / exposed	1 / 11 (9.09%)	4 / 153 (2.61%)	4 / 78 (5.13%)
occurrences (all)	1	9	6
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 11 (9.09%)	6 / 153 (3.92%)	5 / 78 (6.41%)
occurrences (all)	1	6	5
Haematemesis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Gingival swelling			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences (all)	0	0	1
Gingival pain			
subjects affected / exposed	1 / 11 (9.09%)	0 / 153 (0.00%)	4 / 78 (5.13%)
occurrences (all)	1	0	4
Gingival hypertrophy			
subjects affected / exposed	0 / 11 (0.00%)	5 / 153 (3.27%)	3 / 78 (3.85%)
occurrences (all)	0	6	3

Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	1 / 11 (9.09%)	5 / 153 (3.27%)	2 / 78 (2.56%)
occurrences (all)	1	5	2
Mouth haemorrhage			
subjects affected / exposed	0 / 11 (0.00%)	4 / 153 (2.61%)	3 / 78 (3.85%)
occurrences (all)	0	5	3
Mouth ulceration			
subjects affected / exposed	0 / 11 (0.00%)	5 / 153 (3.27%)	1 / 78 (1.28%)
occurrences (all)	0	5	1
Nausea			
subjects affected / exposed	8 / 11 (72.73%)	59 / 153 (38.56%)	47 / 78 (60.26%)
occurrences (all)	12	78	68
Odynophagia			
subjects affected / exposed	0 / 11 (0.00%)	3 / 153 (1.96%)	0 / 78 (0.00%)
occurrences (all)	0	3	0
Oral pain			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	3 / 78 (3.85%)
occurrences (all)	0	1	3
Oral disorder			
subjects affected / exposed	0 / 11 (0.00%)	3 / 153 (1.96%)	3 / 78 (3.85%)
occurrences (all)	0	3	3
Pancreatitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 11 (0.00%)	3 / 153 (1.96%)	2 / 78 (2.56%)
occurrences (all)	0	3	4
Proctitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences (all)	0	0	1

Stomatitis haemorrhagic			
subjects affected / exposed	1 / 11 (9.09%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	1	0	0
Stomatitis			
subjects affected / exposed	1 / 11 (9.09%)	12 / 153 (7.84%)	7 / 78 (8.97%)
occurrences (all)	1	16	7
Toothache			
subjects affected / exposed	0 / 11 (0.00%)	7 / 153 (4.58%)	2 / 78 (2.56%)
occurrences (all)	0	7	2
Tongue dysplasia			
subjects affected / exposed	1 / 11 (9.09%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	1	0	0
Varices oesophageal			
subjects affected / exposed	1 / 11 (9.09%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	1	0	0
Vomiting			
subjects affected / exposed	4 / 11 (36.36%)	27 / 153 (17.65%)	25 / 78 (32.05%)
occurrences (all)	11	35	35
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	2 / 78 (2.56%)
occurrences (all)	0	0	2
Cholestasis			
subjects affected / exposed	0 / 11 (0.00%)	2 / 153 (1.31%)	0 / 78 (0.00%)
occurrences (all)	0	2	0
Hepatic steatosis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	1 / 78 (1.28%)
occurrences (all)	0	1	1
Jaundice			
subjects affected / exposed	1 / 11 (9.09%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Actinic keratosis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (0.00%)
occurrences (all)	0	2	0
Alopecia			

subjects affected / exposed	0 / 11 (0.00%)	5 / 153 (3.27%)	3 / 78 (3.85%)
occurrences (all)	0	6	3
Angioedema			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Blister			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Blood blister			
subjects affected / exposed	0 / 11 (0.00%)	2 / 153 (1.31%)	1 / 78 (1.28%)
occurrences (all)	0	2	1
Dermatitis			
subjects affected / exposed	1 / 11 (9.09%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	1	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	4 / 78 (5.13%)
occurrences (all)	0	1	4
Ecchymosis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	6 / 78 (7.69%)
occurrences (all)	0	1	7
Erythema			
subjects affected / exposed	1 / 11 (9.09%)	1 / 153 (0.65%)	5 / 78 (6.41%)
occurrences (all)	1	1	7
Hidradenitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	1 / 11 (9.09%)	1 / 153 (0.65%)	4 / 78 (5.13%)
occurrences (all)	1	1	4
Hyperkeratosis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Miliaria			

subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	1 / 11 (9.09%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences (all)	1	0	1
Onychoclasis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences (all)	0	0	1
Onycholysis			
subjects affected / exposed	1 / 11 (9.09%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	1	0	0
Papule			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	2 / 11 (18.18%)	7 / 153 (4.58%)	3 / 78 (3.85%)
occurrences (all)	2	8	4
Pruritus generalised			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (0.00%)
occurrences (all)	0	1	0
Pruritus			
subjects affected / exposed	2 / 11 (18.18%)	8 / 153 (5.23%)	12 / 78 (15.38%)
occurrences (all)	3	10	13
Psoriasis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (0.00%)
occurrences (all)	0	1	0
Purpura			
subjects affected / exposed	0 / 11 (0.00%)	2 / 153 (1.31%)	1 / 78 (1.28%)
occurrences (all)	0	2	1
Pyoderma gangrenosum			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 11 (0.00%)	8 / 153 (5.23%)	1 / 78 (1.28%)
occurrences (all)	0	11	1
Rash erythematous			

subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	2 / 78 (2.56%)
occurrences (all)	0	1	2
Rash			
subjects affected / exposed	2 / 11 (18.18%)	12 / 153 (7.84%)	4 / 78 (5.13%)
occurrences (all)	6	12	4
Rash papular			
subjects affected / exposed	1 / 11 (9.09%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	2	0	0
Scab			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Skin hyperpigmentation			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	3 / 78 (3.85%)
occurrences (all)	0	0	3
Skin lesion			
subjects affected / exposed	0 / 11 (0.00%)	7 / 153 (4.58%)	2 / 78 (2.56%)
occurrences (all)	0	7	3
Skin ulcer			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	2 / 78 (2.56%)
occurrences (all)	0	1	3
Skin reaction			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Skin mass			
subjects affected / exposed	1 / 11 (9.09%)	3 / 153 (1.96%)	4 / 78 (5.13%)
occurrences (all)	1	6	4
Toxic skin eruption			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 11 (0.00%)	2 / 153 (1.31%)	5 / 78 (6.41%)
occurrences (all)	0	2	6
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 11 (9.09%)	7 / 153 (4.58%)	6 / 78 (7.69%)
occurrences (all)	1	15	6

Calculus urinary			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences (all)	0	0	1
Dysuria			
subjects affected / exposed	1 / 11 (9.09%)	1 / 153 (0.65%)	4 / 78 (5.13%)
occurrences (all)	1	2	6
Haematuria			
subjects affected / exposed	1 / 11 (9.09%)	5 / 153 (3.27%)	9 / 78 (11.54%)
occurrences (all)	2	5	9
Hydronephrosis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	2 / 78 (2.56%)
occurrences (all)	0	0	2
Pollakiuria			
subjects affected / exposed	1 / 11 (9.09%)	2 / 153 (1.31%)	7 / 78 (8.97%)
occurrences (all)	1	2	12
Renal failure			
subjects affected / exposed	0 / 11 (0.00%)	2 / 153 (1.31%)	3 / 78 (3.85%)
occurrences (all)	0	2	3
Renal colic			
subjects affected / exposed	1 / 11 (9.09%)	1 / 153 (0.65%)	0 / 78 (0.00%)
occurrences (all)	1	1	0
Urinary hesitation			
subjects affected / exposed	1 / 11 (9.09%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	1	0	0
Urinary incontinence			
subjects affected / exposed	2 / 11 (18.18%)	2 / 153 (1.31%)	4 / 78 (5.13%)
occurrences (all)	2	2	4
Urinary retention			
subjects affected / exposed	0 / 11 (0.00%)	3 / 153 (1.96%)	4 / 78 (5.13%)
occurrences (all)	0	3	5
Urinary tract pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences (all)	0	0	1
Endocrine disorders			
Hypothyroidism			

subjects affected / exposed	0 / 11 (0.00%)	2 / 153 (1.31%)	2 / 78 (2.56%)
occurrences (all)	0	2	2
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 11 (9.09%)	10 / 153 (6.54%)	13 / 78 (16.67%)
occurrences (all)	1	14	23
Articular calcification			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	2 / 11 (18.18%)	21 / 153 (13.73%)	9 / 78 (11.54%)
occurrences (all)	4	29	15
Bone pain			
subjects affected / exposed	2 / 11 (18.18%)	4 / 153 (2.61%)	3 / 78 (3.85%)
occurrences (all)	2	4	3
Bone swelling			
subjects affected / exposed	0 / 11 (0.00%)	2 / 153 (1.31%)	0 / 78 (0.00%)
occurrences (all)	0	2	0
Flank pain			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	4 / 78 (5.13%)
occurrences (all)	0	1	5
Joint swelling			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	3 / 78 (3.85%)
occurrences (all)	0	1	4
Joint effusion			
subjects affected / exposed	0 / 11 (0.00%)	2 / 153 (1.31%)	0 / 78 (0.00%)
occurrences (all)	0	2	0
Musculoskeletal pain			
subjects affected / exposed	0 / 11 (0.00%)	6 / 153 (3.92%)	7 / 78 (8.97%)
occurrences (all)	0	7	9
Musculoskeletal chest pain			
subjects affected / exposed	0 / 11 (0.00%)	5 / 153 (3.27%)	2 / 78 (2.56%)
occurrences (all)	0	5	2
Muscular weakness			

subjects affected / exposed	1 / 11 (9.09%)	6 / 153 (3.92%)	4 / 78 (5.13%)
occurrences (all)	1	6	4
Muscle twitching			
subjects affected / exposed	1 / 11 (9.09%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	1	0	0
Muscle tightness			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences (all)	0	0	1
Muscle spasms			
subjects affected / exposed	0 / 11 (0.00%)	3 / 153 (1.96%)	3 / 78 (3.85%)
occurrences (all)	0	3	4
Myalgia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	6 / 78 (7.69%)
occurrences (all)	0	0	6
Neck pain			
subjects affected / exposed	0 / 11 (0.00%)	2 / 153 (1.31%)	3 / 78 (3.85%)
occurrences (all)	0	3	3
Pain in extremity			
subjects affected / exposed	3 / 11 (27.27%)	13 / 153 (8.50%)	12 / 78 (15.38%)
occurrences (all)	4	18	17
Osteoporosis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences (all)	0	0	1
Osteoarthritis			
subjects affected / exposed	1 / 11 (9.09%)	3 / 153 (1.96%)	2 / 78 (2.56%)
occurrences (all)	1	3	2
Pain in jaw			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	3 / 78 (3.85%)
occurrences (all)	0	0	3
Periarthritis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (0.00%)
occurrences (all)	0	1	0
Rheumatoid arthritis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Seronegative arthritis			

subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Aspergillus infection			
subjects affected / exposed	0 / 11 (0.00%)	3 / 153 (1.96%)	1 / 78 (1.28%)
occurrences (all)	0	3	1
Bacteraemia			
subjects affected / exposed	1 / 11 (9.09%)	1 / 153 (0.65%)	0 / 78 (0.00%)
occurrences (all)	1	1	0
Bronchopulmonary aspergillosis			
subjects affected / exposed	1 / 11 (9.09%)	1 / 153 (0.65%)	0 / 78 (0.00%)
occurrences (all)	1	1	0
Bronchitis			
subjects affected / exposed	1 / 11 (9.09%)	6 / 153 (3.92%)	0 / 78 (0.00%)
occurrences (all)	1	6	0
Candida infection			
subjects affected / exposed	0 / 11 (0.00%)	2 / 153 (1.31%)	1 / 78 (1.28%)
occurrences (all)	0	3	1
Cellulitis			
subjects affected / exposed	0 / 11 (0.00%)	5 / 153 (3.27%)	1 / 78 (1.28%)
occurrences (all)	0	6	2
Chronic sinusitis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (0.00%)
occurrences (all)	0	1	0
Clostridium difficile colitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences (all)	0	0	2
Conjunctivitis			
subjects affected / exposed	0 / 11 (0.00%)	3 / 153 (1.96%)	1 / 78 (1.28%)
occurrences (all)	0	3	1
Corona virus infection			
subjects affected / exposed	0 / 11 (0.00%)	2 / 153 (1.31%)	1 / 78 (1.28%)
occurrences (all)	0	2	1
Cystitis			
subjects affected / exposed	0 / 11 (0.00%)	4 / 153 (2.61%)	0 / 78 (0.00%)
occurrences (all)	0	4	0

Device related infection			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	1 / 78 (1.28%)
occurrences (all)	0	1	1
Enterococcal bacteraemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences (all)	0	0	1
Enterobacter bacteraemia			
subjects affected / exposed	1 / 11 (9.09%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	1	0	0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (0.00%)
occurrences (all)	0	1	0
Escherichia bacteraemia			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	2 / 78 (2.56%)
occurrences (all)	0	1	2
Erysipelas			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Fungal rhinitis			
subjects affected / exposed	1 / 11 (9.09%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis			
subjects affected / exposed	0 / 11 (0.00%)	3 / 153 (1.96%)	2 / 78 (2.56%)
occurrences (all)	0	5	2
Genital infection fungal			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (0.00%)
occurrences (all)	0	1	0
Herpes zoster			
subjects affected / exposed	0 / 11 (0.00%)	4 / 153 (2.61%)	0 / 78 (0.00%)
occurrences (all)	0	4	0
Herpes virus infection			
subjects affected / exposed	1 / 11 (9.09%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	1	0	0
Klebsiella infection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0

Lower respiratory tract infection			
subjects affected / exposed	1 / 11 (9.09%)	3 / 153 (1.96%)	1 / 78 (1.28%)
occurrences (all)	1	3	1
Lower respiratory tract infection fungal			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Lung infection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Nail infection			
subjects affected / exposed	1 / 11 (9.09%)	1 / 153 (0.65%)	0 / 78 (0.00%)
occurrences (all)	1	1	0
Nasopharyngitis			
subjects affected / exposed	1 / 11 (9.09%)	2 / 153 (1.31%)	5 / 78 (6.41%)
occurrences (all)	1	2	6
Ophthalmic herpes zoster			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	1 / 11 (9.09%)	3 / 153 (1.96%)	0 / 78 (0.00%)
occurrences (all)	1	3	0
Oral fungal infection			
subjects affected / exposed	1 / 11 (9.09%)	3 / 153 (1.96%)	0 / 78 (0.00%)
occurrences (all)	1	3	0
Oral candidiasis			
subjects affected / exposed	0 / 11 (0.00%)	3 / 153 (1.96%)	1 / 78 (1.28%)
occurrences (all)	0	3	1
Orchitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Paronychia			

subjects affected / exposed	1 / 11 (9.09%)	1 / 153 (0.65%)	1 / 78 (1.28%)
occurrences (all)	1	1	1
Peritonsillar abscess			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 11 (0.00%)	2 / 153 (1.31%)	2 / 78 (2.56%)
occurrences (all)	0	2	2
Pneumonia pseudomonal			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 11 (0.00%)	8 / 153 (5.23%)	6 / 78 (7.69%)
occurrences (all)	0	8	6
Pseudomonal sepsis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (0.00%)
occurrences (all)	0	1	0
Rash pustular			
subjects affected / exposed	0 / 11 (0.00%)	2 / 153 (1.31%)	0 / 78 (0.00%)
occurrences (all)	0	2	0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (0.00%)
occurrences (all)	0	1	0
Rhinitis			
subjects affected / exposed	1 / 11 (9.09%)	3 / 153 (1.96%)	4 / 78 (5.13%)
occurrences (all)	1	3	5
Sinusitis			
subjects affected / exposed	0 / 11 (0.00%)	2 / 153 (1.31%)	1 / 78 (1.28%)
occurrences (all)	0	2	1
Staphylococcal sepsis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Staphylococcal infection			

subjects affected / exposed	0 / 11 (0.00%)	3 / 153 (1.96%)	1 / 78 (1.28%)
occurrences (all)	0	3	1
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	1 / 11 (9.09%)	1 / 153 (0.65%)	2 / 78 (2.56%)
occurrences (all)	2	1	2
Tooth abscess			
subjects affected / exposed	0 / 11 (0.00%)	3 / 153 (1.96%)	0 / 78 (0.00%)
occurrences (all)	0	3	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 11 (9.09%)	10 / 153 (6.54%)	5 / 78 (6.41%)
occurrences (all)	1	10	5
Urinary tract infection			
subjects affected / exposed	0 / 11 (0.00%)	14 / 153 (9.15%)	4 / 78 (5.13%)
occurrences (all)	0	20	5
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 11 (0.00%)	2 / 153 (1.31%)	0 / 78 (0.00%)
occurrences (all)	0	2	0
Metabolism and nutrition disorders			
Abnormal loss of weight			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	3 / 11 (27.27%)	26 / 153 (16.99%)	17 / 78 (21.79%)
occurrences (all)	3	39	21
Dehydration			
subjects affected / exposed	0 / 11 (0.00%)	3 / 153 (1.96%)	6 / 78 (7.69%)
occurrences (all)	0	4	9
Diabetes mellitus			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (0.00%)
occurrences (all)	0	1	0
Fluid overload			
subjects affected / exposed	0 / 11 (0.00%)	2 / 153 (1.31%)	5 / 78 (6.41%)
occurrences (all)	0	2	5

Hyperkalaemia			
subjects affected / exposed	0 / 11 (0.00%)	3 / 153 (1.96%)	3 / 78 (3.85%)
occurrences (all)	0	3	3
Hypercalcaemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences (all)	0	0	1
Hyperferritinaemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 11 (0.00%)	7 / 153 (4.58%)	6 / 78 (7.69%)
occurrences (all)	0	7	6
Hypernatraemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences (all)	0	0	1
Hyperphosphataemia			
subjects affected / exposed	0 / 11 (0.00%)	2 / 153 (1.31%)	2 / 78 (2.56%)
occurrences (all)	0	2	2
Hyperuricaemia			
subjects affected / exposed	1 / 11 (9.09%)	6 / 153 (3.92%)	8 / 78 (10.26%)
occurrences (all)	1	9	8
Hypervolaemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 11 (0.00%)	2 / 153 (1.31%)	7 / 78 (8.97%)
occurrences (all)	0	2	7
Hypocalcaemia			
subjects affected / exposed	0 / 11 (0.00%)	2 / 153 (1.31%)	8 / 78 (10.26%)
occurrences (all)	0	2	11
Hypokalaemia			
subjects affected / exposed	4 / 11 (36.36%)	33 / 153 (21.57%)	23 / 78 (29.49%)
occurrences (all)	4	56	29
Hypomagnesaemia			
subjects affected / exposed	0 / 11 (0.00%)	8 / 153 (5.23%)	8 / 78 (10.26%)
occurrences (all)	0	9	8

Hyponatraemia			
subjects affected / exposed	0 / 11 (0.00%)	6 / 153 (3.92%)	8 / 78 (10.26%)
occurrences (all)	0	10	8
Hypophosphataemia			
subjects affected / exposed	1 / 11 (9.09%)	6 / 153 (3.92%)	4 / 78 (5.13%)
occurrences (all)	1	7	4
Hypovolaemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences (all)	0	0	1
Increased appetite			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	1 / 78 (1.28%)
occurrences (all)	0	0	1
Iron deficiency			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Lactic acidosis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Malnutrition			
subjects affected / exposed	0 / 11 (0.00%)	0 / 153 (0.00%)	4 / 78 (5.13%)
occurrences (all)	0	0	4
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 11 (0.00%)	1 / 153 (0.65%)	0 / 78 (0.00%)
occurrences (all)	0	1	0
Tumour lysis syndrome			
subjects affected / exposed	1 / 11 (9.09%)	3 / 153 (1.96%)	4 / 78 (5.13%)
occurrences (all)	1	3	5
Vitamin D deficiency			
subjects affected / exposed	0 / 11 (0.00%)	2 / 153 (1.31%)	0 / 78 (0.00%)
occurrences (all)	0	2	0

Non-serious adverse events	Phase 2: Cohort 2; FT-2102 (Single Agent)		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	18 / 18 (100.00%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Adrenal adenoma				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Basal cell carcinoma				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Cancer pain				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Endotheliomatosis				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Melanocytic naevus				
subjects affected / exposed	2 / 18 (11.11%)			
occurrences (all)	2			
Squamous cell carcinoma of skin				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences (all)	1			
Vascular disorders				
Aortic calcification				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Deep vein thrombosis				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Embolism				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Flushing				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Haematoma				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Hypertension				

subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Hypertensive crisis			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Hypotension			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Orthostatic hypotension			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Thrombophlebitis superficial			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Thrombosis			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Venous thrombosis limb			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Administration site pain			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Asthenia			
subjects affected / exposed	2 / 18 (11.11%)		
occurrences (all)	2		
Catheter site bruise			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Catheter site rash			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Catheter site pain			

subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Catheter site haemorrhage				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Chest discomfort				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Chills				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Device related thrombosis				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Drug intolerance				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Early satiety				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Fatigue				
subjects affected / exposed	6 / 18 (33.33%)			
occurrences (all)	8			
Facial pain				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Generalised oedema				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
General physical health deterioration				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Injection site erythema				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Influenza like illness				

subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Injection site pain				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Injection site reaction				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Malaise				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences (all)	1			
Mucosal dryness				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Oedema peripheral				
subjects affected / exposed	2 / 18 (11.11%)			
occurrences (all)	2			
Non-cardiac chest pain				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Pain				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences (all)	1			
Peripheral swelling				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Pyrexia				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Systemic inflammatory response syndrome				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Temperature intolerance				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			

Vessel puncture site bruise subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0		
Immune system disorders Drug hypersensitivity subjects affected / exposed occurrences (all) Hypogammaglobulinaemia subjects affected / exposed occurrences (all) Seasonal allergy subjects affected / exposed occurrences (all)	 0 / 18 (0.00%) 0 0 / 18 (0.00%) 0 0 / 18 (0.00%) 0		
Reproductive system and breast disorders Breast haemorrhage subjects affected / exposed occurrences (all) Breast mass subjects affected / exposed occurrences (all) Genital erythema subjects affected / exposed occurrences (all) Pelvic pain subjects affected / exposed occurrences (all) Vulvovaginal pain subjects affected / exposed occurrences (all) Vulvovaginal dryness subjects affected / exposed occurrences (all)	 0 / 18 (0.00%) 0 1 / 18 (5.56%) 1 0 / 18 (0.00%) 0 0 / 18 (0.00%) 0 0 / 18 (0.00%) 0 0 / 18 (0.00%) 0		
Respiratory, thoracic and mediastinal disorders Acute promyelocytic leukaemia differentiation syndrome			

subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Catarrh				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Cough				
subjects affected / exposed	3 / 18 (16.67%)			
occurrences (all)	3			
Dyspnoea				
subjects affected / exposed	2 / 18 (11.11%)			
occurrences (all)	3			
Dyspnoea exertional				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Dyspnoea paroxysmal nocturnal				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences (all)	1			
Epistaxis				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Haemoptysis				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Hiccups				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Hypoxia				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Nasal septum perforation				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Nasal dryness				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Nasal congestion				

subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Oropharyngeal pain				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences (all)	1			
Pleural effusion				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Pleuritic pain				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Pneumonitis				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Productive cough				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Pulmonary oedema				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Pulmonary embolism				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences (all)	1			
Rales				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Rhinorrhoea				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences (all)	1			
Sinus pain				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences (all)	1			
Sneezing				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Sputum discoloured				

subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Tachypnoea			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Upper-airway cough syndrome			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Wheezing			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Affective disorder			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Agitation			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Anxiety			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Confusional state			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Delirium			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Depression			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Flat affect			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Insomnia			
subjects affected / exposed	3 / 18 (16.67%)		
occurrences (all)	3		

Mental disorder			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Mental status changes			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Restlessness			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	2 / 18 (11.11%)		
occurrences (all)	5		
Amylase increased			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Aspartate aminotransferase increased			
subjects affected / exposed	2 / 18 (11.11%)		
occurrences (all)	3		
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Blood bicarbonate decreased			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Blood bilirubin increased			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Blood creatine increased			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Blood creatinine increased			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Blood fibrinogen decreased			

subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Blood lactate dehydrogenase increased				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences (all)	1			
Blood phosphorus decreased				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences (all)	1			
Blood urea increased				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Blood uric acid increased				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences (all)	1			
Brain natriuretic peptide increased				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Chest X-ray abnormal				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Coronavirus test positive				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences (all)	1			
Electrocardiogram QT prolonged				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Ejection fraction decreased				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Enterococcus test positive				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Gamma-glutamyltransferase increased				

subjects affected / exposed	2 / 18 (11.11%)			
occurrences (all)	7			
Heart rate increased				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Hepatic enzyme increased				
subjects affected / exposed	2 / 18 (11.11%)			
occurrences (all)	6			
Lipase increased				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Liver function test abnormal				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Liver function test increased				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Lymphocyte count decreased				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences (all)	1			
Neutrophil count decreased				
subjects affected / exposed	4 / 18 (22.22%)			
occurrences (all)	10			
Platelet count decreased				
subjects affected / exposed	3 / 18 (16.67%)			
occurrences (all)	4			
Platelet count increased				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences (all)	1			
Red blood cell count decreased				
subjects affected / exposed	3 / 18 (16.67%)			
occurrences (all)	7			
Staphylococcus test positive				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Transaminases increased				

subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Weight decreased				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
White blood cell count decreased				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences (all)	1			
White blood cell count increased				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences (all)	1			
Injury, poisoning and procedural complications				
Contusion				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Eye contusion				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Fall				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences (all)	1			
Hand fracture				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Infusion related reaction				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Laceration				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Limb injury				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Medication error				

subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Periorbital haematoma			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Procedural pain			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Post procedural haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Skin abrasion			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Skin wound			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Subdural haematoma			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Transfusion reaction			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Wound secretion			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Arrhythmia			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Atrial fibrillation			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		

Atrioventricular block first degree				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences (all)	1			
Atrial tachycardia				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Atrial flutter				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Bradycardia				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Cardiac failure				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Coronary artery disease				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Left ventricular dysfunction				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Myocardial ischaemia				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Palpitations				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences (all)	1			
Pericardial effusion				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Sinus bradycardia				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Sinus tachycardia				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			

Supraventricular tachycardia			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Tachycardia			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Ventricular tachycardia			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Ageusia			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Amnesia			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Disturbance in attention			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Dizziness			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Dysgeusia			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Essential tremor			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Headache			
subjects affected / exposed	6 / 18 (33.33%)		
occurrences (all)	6		
Hyperaesthesia			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Hypersomnia			

subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Hypoaesthesia				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Lethargy				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences (all)	1			
Memory impairment				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences (all)	1			
Motor dysfunction				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Neuralgia				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Neuropathy peripheral				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Paraesthesia				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences (all)	1			
Peripheral sensory neuropathy				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences (all)	1			
Presyncope				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Restless legs syndrome				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences (all)	1			
Somnolence				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Syncope				

subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Tremor			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Visual field defect			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	2		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Bone marrow failure			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Coagulopathy			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Eosinophilia			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	2		
Febrile neutropenia			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Febrile bone marrow aplasia			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Haemorrhagic diathesis			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Lymphadenopathy			

subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Splenomegaly			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Thrombotic thrombocytopenic purpura			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Tinnitus			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Vertigo			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Eye disorders			
Cataract			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Chalazion			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Conjunctival haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Dry eye			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Eye haemorrhage			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Eyelid ptosis			

subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Eye oedema			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Macular fibrosis			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	3		
Ocular hyperaemia			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Vision blurred			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Visual acuity reduced			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Visual impairment			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Abdominal tenderness			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Abdominal rigidity			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Abdominal pain upper			
subjects affected / exposed	2 / 18 (11.11%)		
occurrences (all)	2		
Abdominal pain			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		

Anal fissure				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Anal incontinence				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Anal ulcer				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Angina bullosa haemorrhagica				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Colitis				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Constipation				
subjects affected / exposed	4 / 18 (22.22%)			
occurrences (all)	4			
Diarrhoea				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences (all)	2			
Dry mouth				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences (all)	1			
Dyspepsia				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Dysphagia				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Eosinophilic colitis				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences (all)	1			
Faeces discoloured				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			

Flatulence				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Frequent bowel movements				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Food poisoning				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences (all)	1			
Gastrointestinal haemorrhage				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Gastritis				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences (all)	1			
Gingival bleeding				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Gastrooesophageal reflux disease				
subjects affected / exposed	2 / 18 (11.11%)			
occurrences (all)	2			
Haematemesis				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Gingival swelling				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Gingival pain				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Gingival hypertrophy				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Haemorrhoidal haemorrhage				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			

Haemorrhoids				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Mouth haemorrhage				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Mouth ulceration				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Nausea				
subjects affected / exposed	5 / 18 (27.78%)			
occurrences (all)	7			
Odynophagia				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Oral pain				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Oral disorder				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Pancreatitis				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Proctalgia				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Proctitis				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences (all)	1			
Rectal haemorrhage				
subjects affected / exposed	2 / 18 (11.11%)			
occurrences (all)	2			
Stomatitis haemorrhagic				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			

Stomatitis			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Toothache			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Tongue dysplasia			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Varices oesophageal			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Vomiting			
subjects affected / exposed	2 / 18 (11.11%)		
occurrences (all)	4		
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Cholestasis			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Hepatic steatosis			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Jaundice			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Actinic keratosis			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Alopecia			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Angioedema			

subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Blister				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Blood blister				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Dermatitis				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Dermatitis acneiform				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Dry skin				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences (all)	1			
Ecchymosis				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Erythema				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences (all)	1			
Hidradenitis				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Hyperhidrosis				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Hyperkeratosis				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Miliaria				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Night sweats				

subjects affected / exposed	1 / 18 (5.56%)			
occurrences (all)	1			
Onychoclasis				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Onycholysis				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Papule				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Petechiae				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Pruritus generalised				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences (all)	1			
Pruritus				
subjects affected / exposed	2 / 18 (11.11%)			
occurrences (all)	3			
Psoriasis				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences (all)	1			
Purpura				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Pyoderma gangrenosum				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences (all)	2			
Rash maculo-papular				
subjects affected / exposed	2 / 18 (11.11%)			
occurrences (all)	2			
Rash erythematous				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Rash				

subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Rash papular			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Scab			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	2		
Skin hyperpigmentation			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Skin lesion			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	2		
Skin ulcer			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Skin reaction			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Skin mass			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Toxic skin eruption			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Urticaria			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Calculus urinary			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		

Dysuria subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1		
Haematuria subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0		
Hydronephrosis subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0		
Pollakiuria subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1		
Renal failure subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0		
Renal colic subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0		
Urinary hesitation subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0		
Urinary incontinence subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0		
Urinary retention subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0		
Urinary tract pain subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0		
Endocrine disorders Hypothyroidism subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0		
Musculoskeletal and connective tissue disorders			

Arthralgia				
subjects affected / exposed	2 / 18 (11.11%)			
occurrences (all)	2			
Articular calcification				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Back pain				
subjects affected / exposed	4 / 18 (22.22%)			
occurrences (all)	4			
Bone pain				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Bone swelling				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Flank pain				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Joint swelling				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Joint effusion				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Musculoskeletal pain				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Musculoskeletal chest pain				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Muscular weakness				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Muscle twitching				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			

Muscle tightness subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0		
Muscle spasms subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1		
Myalgia subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1		
Neck pain subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0		
Pain in extremity subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0		
Osteoporosis subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0		
Osteoarthritis subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0		
Pain in jaw subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1		
Periarthritis subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0		
Rheumatoid arthritis subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1		
Seronegative arthritis subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1		
Infections and infestations Aspergillus infection			

subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Bacteraemia				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Bronchopulmonary aspergillosis				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Bronchitis				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences (all)	1			
Candida infection				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Cellulitis				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences (all)	1			
Chronic sinusitis				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Clostridium difficile colitis				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Conjunctivitis				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences (all)	1			
Corona virus infection				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences (all)	1			
Cystitis				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences (all)	1			
Device related infection				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences (all)	1			
Enterococcal bacteraemia				

subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Enterobacter bacteraemia				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Escherichia urinary tract infection				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences (all)	1			
Escherichia bacteraemia				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Erysipelas				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Fungal rhinitis				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Gastroenteritis				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Genital infection fungal				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences (all)	1			
Herpes zoster				
subjects affected / exposed	2 / 18 (11.11%)			
occurrences (all)	3			
Herpes virus infection				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Klebsiella infection				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Lower respiratory tract infection				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences (all)	1			
Lower respiratory tract infection				

fungal				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Lung infection				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Nail infection				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Nasopharyngitis				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences (all)	1			
Ophthalmic herpes zoster				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Oral herpes				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Oral fungal infection				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Oral candidiasis				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences (all)	1			
Orchitis				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Parainfluenzae virus infection				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Paronychia				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Peritonsillar abscess				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			

Pharyngitis				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Pneumonia pseudomonal				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Pneumonia				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Pseudomonal sepsis				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Rash pustular				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences (all)	1			
Respiratory syncytial virus infection				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Respiratory tract infection				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Rhinitis				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Sinusitis				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences (all)	1			
Staphylococcal sepsis				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Staphylococcal infection				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Staphylococcal bacteraemia				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			

Tooth infection subjects affected / exposed occurrences (all)	2 / 18 (11.11%) 2			
Tooth abscess subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0			
Upper respiratory tract infection subjects affected / exposed occurrences (all)	2 / 18 (11.11%) 4			
Urinary tract infection subjects affected / exposed occurrences (all)	2 / 18 (11.11%) 2			
Vulvovaginal mycotic infection subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1			
Metabolism and nutrition disorders Abnormal loss of weight subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0			
Decreased appetite subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1			
Dehydration subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0			
Diabetes mellitus subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0			
Fluid overload subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0			
Hyperkalaemia subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0			
Hypercalcaemia				

subjects affected / exposed	1 / 18 (5.56%)			
occurrences (all)	1			
Hyperferritinaemia				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Hyperglycaemia				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Hypernatraemia				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Hyperphosphataemia				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Hyperuricaemia				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Hypervolaemia				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Hypoalbuminaemia				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Hypocalcaemia				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Hypokalaemia				
subjects affected / exposed	1 / 18 (5.56%)			
occurrences (all)	1			
Hypomagnesaemia				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Hyponatraemia				
subjects affected / exposed	0 / 18 (0.00%)			
occurrences (all)	0			
Hypophosphataemia				

subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Hypovolaemia			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Increased appetite			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Iron deficiency			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Lactic acidosis			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Malnutrition			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Tumour lysis syndrome			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Vitamin D deficiency			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
20 August 2020	Protocol Amendment 6: Focused on safety follow-up with scheduled assessments performed every 2 cycles, to begin with Cycle 5 for ongoing subjects. Removal of continued assessment of PK, PD, mutational analyses, and QOL parameters. Reduction of frequency of efficacy response assessments to every 6 cycles except in case of suspicion of relapse/progression (subjects with AML) or as clinically indicated (subjects with MDS).

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported