Clinical trial results:
An open Phase I trial to investigate the maximum tolerated dose, safety, efficacy and pharmacokinetics of BI 811283 in combination with cytarabine in patients with previously untreated or relapsed/refractory acute myeloid leukaemia ineligible for intensive treatment

Due to a system error, the data reported in v1 is not correct and has been removed from public view.

Summary

EudraCT number	2007-005684-10
Trial protocol	ES AT
Global end of trial date	05 March 2014

Results information

Result version number	v2 (current)
This version publication date	02 July 2016
First version publication date	01 August 2015
Version creation reason	• Correction of full data set Data correction due to a system error in EudraCT- Results

Trial information

Trial identification

Sponsor protocol code	1247.3

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00632749
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Boehringer Ingelheim
Sponsor organisation address	Binger Strasse 173 , Ingelheim am Rhein, Germany, 55216
Public contact	QRPE Processes and Systems Coordination Clinical Trial Information Disclosure, Boehringer Ingelheim Pharma GmbH & Co. KG, +1 800 243 0127, clintriage.rdg@boehringer-ingelheim.com
Scientific contact	QRPE Processes and Systems Coordination Clinical Trial Information Disclosure, Boehringer Ingelheim Pharma GmbH & Co. KG, +1 800 243 0127, clintriage.rdg@boehringer-ingelheim.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	No

1901/2006 apply to this trial?	

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	12 May 2014
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	05 March 2014
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

In this phase I trial, two schedules of BI 811283 in combination with LD-Ara-C will be investigated. The dose of BI 811283 will be escalated to determine the maximum tolerated dose (MTD) of the two dosing schedules of BI 811283 in combination with LDAra-C.

Protection of trial subjects:

Only subjects that met all study inclusion and none of the exclusion criteria were to be entered in the study. All subjects were free to withdraw from the clinical trial at any time for any reason given.
Close monitoring of all subjects was adhered to throughout the trial conduct.

Background therapy: -	
Evidence for comparator: -	
Actual start date of recruitment	20 June 2008
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Germany: 72
Worldwide total number of subjects	72
EEA total number of subjects	72

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)	8
From 65 to 84 years	63
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

Out of 72 patients enrolled, 68 entered the study, and 64 were treated with the study treatment. One patient was on trial receiving medication for 2.5 years after the primary database lock date due to benefit.

Pre-assignment

Screening details:

All subjects were screened for eligibility to participate in the trial. Subjects attended specialist sites which would then ensure that they (the subjects) met all inclusion/exclusion criteria.
Subjects were not to be entered into the trial to receive trial medication if any one of the specific entry criteria were violated.

Period 1

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

Blinding implementation details:

Non-randomized, uncontrolled design.

Arms

Are arms mutually exclusive?	Yes
Arm title	5mg BI 811283+ 20mg Cytarabine- Treatment Schedule A

Arm description:

5 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment Schedule A: BI 811283 on Days 1 + 15 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion
Cytarabine: subcutaneous injection

Arm type	Experimental
Investigational medicinal product name	BI 811283
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

5 mg of BI 811283 administered on days 1+15 via 24-hour continuous intravenous infusion

Investigational medicinal product name	Cytarabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

20 mg of cytarabine was administered via subcutaneous injection twice daily on Days 1-10 (28-day cycle)

Arm title	15mg BI 811283 +20mg Cytarabine - Treatment Schedule A

Arm description:

15 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment Schedule A: BI 811283 on Days 1 + 15 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion
cytarabine: subcutaneous injection.

Two patients were entered in the 15mg BI 811283+ 20mg cytarabine- Treatment Schedule A cohort, however those two patients were not treated. Consequently, even though the actual number of subjects

that started is 5, only 3 were reported to ensure consistent reporting with baseline characteristics that includes only treated patients.

Arm type	Experimental
Investigational medicinal product name	BI 811283
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

15 mg of BI 811283 administered on days 1+15 via 24-hour continuous intravenous infusion

Investigational medicinal product name	Cytarabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

20 mg of cytarabine was administered via subcutaneous injection twice daily on Days 1-10 (28-day cycle)

Arm title	30mg BI 811283+ 20mg Cytarabine- Treatment Schedule A

Arm description:

30 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment Schedule A: BI 811283 on Days 1 + 15 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion Cytarabine: subcutaneous injection

Arm type	Experimental
Investigational medicinal product name	BI 811283
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

30 mg of BI 811283 administered on days 1+15 via 24-hour continuous intravenous infusion

Investigational medicinal product name	Cytarabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

20 mg of cytarabine was administered via subcutaneous injection twice daily on Days 1-10 (28-day cycle)

Arm title	60mg BI 811283+ 20mg Cytarabine - Treatment Schedule A

Arm description:

60 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment Schedule A: BI 811283 on Days 1 + 15 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion Cytarabine: subcutaneous injection

Arm type	Experimental
Investigational medicinal product name	BI 811283
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

60 mg of BI 811283 administered on days 1+15 via 24-hour continuous intravenous infusion

Investigational medicinal product name	Cytarabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

20 mg of cytarabine was administered via subcutaneous injection twice daily on Days 1-10 (28-day cycle)

Arm title	100mg BI 811283+ 20mg Cytarabine - Treatment Schedule A

Arm description:

100 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment Schedule A: BI 811283 on Days 1 + 15 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion Cytarabine: subcutaneous injection

Arm type	Experimental
Investigational medicinal product name	BI 811283
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

100 mg of BI 811283 administered on days 1+15 via 24-hour continuous intravenous infusion

Investigational medicinal product name	Cytarabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

20 mg of cytarabine was administered via subcutaneous injection twice daily on Days 1-10 (28-day cycle)

Arm title	120mg BI 811283+ 20mg Cytarabine - Treatment Schedule A

Arm description:

120 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment Schedule A: BI 811283 on Days 1 + 15 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion cytarabine: subcutaneous injection.

One patient was entered in the 120mg BI 811283+ 20 mg cytarabine- Treatment Schedule A cohort, however this patient was not treated. Consequently, even though the actual number of subjects that started is 8, only 7 were reported to ensure consistent reporting with baseline characteristics that includes only treated patients.

Arm type	Experimental
Investigational medicinal product name	BI 811283
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

120 mg of BI 811283 administered on days 1+15 via 24-hour continuous intravenous infusion

Investigational medicinal product name	Cytarabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

20 mg of cytarabine was administered via subcutaneous injection twice daily on Days 1-10 (28-day cycle)

Arm title	5mg BI 811283+ 20mg Cytarabine - Treatment Schedule B

Arm description:

5 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment schedule B: BI 811283 on Day 1 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion cytarabine: subcutaneous injection.

One patient was entered in the 5mg BI 811283+ 20mg cytarabine- Treatment Schedule B cohort, however this patient was not treated. Consequently, even though the actual number of subjects that started is 5, only 4 were reported to ensure consistent reporting with baseline characteristics that includes only treated patients.

Arm type	Experimental
Investigational medicinal product name	BI 811283
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

5 mg of BI 811283 administered on days 1 via 24-hour continuous intravenous infusion

Investigational medicinal product name	Cytarabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

20 mg of cytarabine was administered via subcutaneous injection twice daily on Days 1-10 (28-day cycle)

Arm title	40mg BI 811283+ 20mg Cytarabine- Treatment Schedule B

Arm description:

40 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment schedule B: BI 811283 on Day 1 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion Cytarabine: subcutaneous injection

Arm type	Experimental
Investigational medicinal product name	BI 811283
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

40 mg of BI 811283 administered on days 1 via 24-hour continuous intravenous infusion

Investigational medicinal product name	Cytarabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

20 mg of cytarabine was administered via subcutaneous injection twice daily on Days 1-10 (28-day cycle)

Arm title	80mg BI 811283+ 20mg Cytarabine- Treatment Schedule B

Arm description:

80 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment schedule B: BI 811283 on Day 1 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion Cytarabine: subcutaneous injection

Arm type	Experimental
Investigational medicinal product name	BI 811283
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

80 mg of BI 811283 administered on days 1 via 24-hour continuous intravenous infusion

Investigational medicinal product name	Cytarabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

20 mg of cytarabine was administered via subcutaneous injection twice daily on Days 1-10 (28-day cycle)

Arm title	160mg BI 811283+ 20mg Cytarabine- Treatment Schedule B

Arm description:

160 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment schedule B: BI 811283 on Day 1 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion Cytarabine: subcutaneous injection

Arm type	Experimental
Investigational medicinal product name	BI 811283
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

160 mg of BI 811283 administered on days 1 via 24-hour continuous intravenous infusion

Investigational medicinal product name	Cytarabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

20 mg of cytarabine was administered via subcutaneous injection twice daily on Days 1-10 (28-day cycle)

Arm title	240mg BI 811283+ 20mg Cytarabine - Treatment Schedule B

Arm description:

240 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment schedule B: BI 811283 on Day 1 in combination with cytarabine 20 mg twice

daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion Cytarabine: subcutaneous injection

Arm type	Experimental
Investigational medicinal product name	BI 811283
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

240 mg of BI 811283 administered on days 1 via 24-hour continuous intravenous infusion

Investigational medicinal product name	Cytarabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

20 mg of cytarabine was administered via subcutaneous injection twice daily on Days 1-10 (28-day cycle)

Arm title	300mg BI 811283+ 20mg Cytarabine - Treatment Schedule B

Arm description:

300 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment schedule B: BI 811283 on Day 1 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion Cytarabine: subcutaneous injection

Arm type	Experimental
Investigational medicinal product name	BI 811283
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

300 mg of BI 811283 administered on days 1 via 24-hour continuous intravenous infusion

Investigational medicinal product name	Cytarabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

20 mg of cytarabine was administered via subcutaneous injection twice daily on Days 1-10 (28-day cycle)

Arm title	360mg BI 811283+ 20mg Cytarabine - Treatment Schedule B

Arm description:

360 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment schedule B: BI 811283 on Day 1 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion Cytarabine: subcutaneous injection

Arm type	Experimental
Investigational medicinal product name	BI 811283
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

360 mg of BI 811283 administered on days 1 via 24-hour continuous intravenous infusion

Investigational medicinal product name	Cytarabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

20 mg of cytarabine was administered via subcutaneous injection twice daily on Days 1-10 (28-day cycle)

Arm title	420mg BI 811283+ 20mg Cytarabine- Treatment Schedule B

Arm description:

420 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment schedule B: BI 811283 on Day 1 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion Cytarabine: subcutaneous injection.

Arm type	Experimental
Investigational medicinal product name	BI 811283
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

420 mg of BI 811283 administered on days 1 via 24-hour continuous intravenous infusion

Investigational medicinal product name	Cytarabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

20 mg of cytarabine was administered via subcutaneous injection twice daily on Days 1-10 (28-day cycle)

Number of subjects in period 1[1]	5mg BI 811283+ 20mg Cytarabine- Treatment Schedule A	15mg BI 811283 +20mg Cytarabine - Treatment Schedule A	30mg BI 811283+ 20mg Cytarabine- Treatment Schedule A
Started	4	3	3
Completed	0	0	0
Not completed	4	3	3
Adverse event, serious fatal	-	-	-
Other reason not specified	-	1	-
Adverse event, non-fatal	1	-	1
Refuse to continue medication	-	-	-
Progressive disease	3	2	2

Number of subjects in period 1[1]	60mg BI 811283+ 20mg Cytarabine - Treatment Schedule A	100mg BI 811283+ 20mg Cytarabine - Treatment Schedule A	120mg BI 811283+ 20mg Cytarabine - Treatment Schedule A
Started	4	7	7

Completed	0	0	0
Not completed	4	7	7
Adverse event, serious fatal	1	1	2
Other reason not specified	-	1	-
Adverse event, non-fatal	-	1	1
Refuse to continue medication	1	-	-
Progressive disease	2	4	4

Number of subjects in period 1[1]	5mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	40mg BI 811283+ 20mg Cytarabine- Treatment Schedule B	80mg BI 811283+ 20mg Cytarabine- Treatment Schedule B
Started	4	4	5
Completed	0	0	0
Not completed	4	4	5
Adverse event, serious fatal	-	2	1
Other reason not specified	1	-	-
Adverse event, non-fatal	-	-	1
Refuse to continue medication	-	-	-
Progressive disease	3	2	3

Number of subjects in period 1[1]	160mg BI 811283+ 20mg Cytarabine- Treatment Schedule B	240mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	300mg BI 811283+ 20mg Cytarabine - Treatment Schedule B
Started	3	7	4
Completed	0	0	0
Not completed	3	7	4
Adverse event, serious fatal	-	-	-
Other reason not specified	-	2	1
Adverse event, non-fatal	-	1	-
Refuse to continue medication	1	-	-
Progressive disease	2	4	3

Number of subjects in period 1[1]	360mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	420mg BI 811283+ 20mg Cytarabine- Treatment Schedule B
Started	3	6
Completed	0	0
Not completed	3	6
Adverse event, serious fatal	-	-
Other reason not specified	-	2
Adverse event, non-fatal	1	-
Refuse to continue medication	-	-
Progressive disease	2	4

Notes:

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

Justification: Baseline characteristics are based on patients who were entered after successfully completing the screening period and received at least one of the trial medications.

Reporting groups

Reporting group title	5mg BI 811283+ 20mg Cytarabine- Treatment Schedule A

Reporting group description:

5 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment Schedule A: BI 811283 on Days 1 + 15 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion Cytarabine: subcutaneous injection

Reporting group title	15mg BI 811283 +20mg Cytarabine - Treatment Schedule A

Reporting group description:

15 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment Schedule A: BI 811283 on Days 1 + 15 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion cytarabine: subcutaneous injection.

Two patients were entered in the 15mg BI 811283+ 20mg cytarabine- Treatment Schedule A cohort, however those two patients were not treated. Consequently, even though the actual number of subjects that started is 5, only 3 were reported to ensure consistent reporting with baseline characteristics that includes only treated patients.

Reporting group title	30mg BI 811283+ 20mg Cytarabine- Treatment Schedule A

Reporting group description:

30 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment Schedule A: BI 811283 on Days 1 + 15 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion Cytarabine: subcutaneous injection

Reporting group title	60mg BI 811283+ 20mg Cytarabine - Treatment Schedule A

Reporting group description:

60 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment Schedule A: BI 811283 on Days 1 + 15 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion Cytarabine: subcutaneous injection

Reporting group title	100mg BI 811283+ 20mg Cytarabine - Treatment Schedule A

Reporting group description:

100 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment Schedule A: BI 811283 on Days 1 + 15 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion Cytarabine: subcutaneous injection

Reporting group title	120mg BI 811283+ 20mg Cytarabine - Treatment Schedule A

Reporting group description:

120 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment Schedule A: BI 811283 on Days 1 + 15 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion cytarabine: subcutaneous injection.

One patient was entered in the 120mg BI 811283+ 20 mg cytarabine- Treatment Schedule A cohort, however this patient was not treated. Consequently, even though the actual number of subjects that started is 8, only 7 were reported to ensure consistent reporting with baseline characteristics that includes only treated patients.

Reporting group title	5mg BI 811283+ 20mg Cytarabine - Treatment Schedule B

Reporting group description:

5 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment schedule B: BI 811283 on Day 1 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion cytarabine: subcutaneous injection.

One patient was entered in the 5mg BI 811283+ 20mg cytarabine- Treatment Schedule B cohort,

however this patient was not treated. Consequently, even though the actual number of subjects that started is 5, only 4 were reported to ensure consistent reporting with baseline characteristics that includes only treated patients.

Reporting group title	40mg BI 811283+ 20mg Cytarabine- Treatment Schedule B
Reporting group description:	
40 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment schedule B: BI 811283 on Day 1 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion Cytarabine: subcutaneous injection	
Reporting group title	80mg BI 811283+ 20mg Cytarabine- Treatment Schedule B
Reporting group description:	
80 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment schedule B: BI 811283 on Day 1 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion Cytarabine: subcutaneous injection	
Reporting group title	160mg BI 811283+ 20mg Cytarabine- Treatment Schedule B
Reporting group description:	
160 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment schedule B: BI 811283 on Day 1 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion Cytarabine: subcutaneous injection	
Reporting group title	240mg BI 811283+ 20mg Cytarabine - Treatment Schedule B
Reporting group description:	
240 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment schedule B: BI 811283 on Day 1 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion Cytarabine: subcutaneous injection	
Reporting group title	300mg BI 811283+ 20mg Cytarabine - Treatment Schedule B
Reporting group description:	
300 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment schedule B: BI 811283 on Day 1 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion Cytarabine: subcutaneous injection	
Reporting group title	360mg BI 811283+ 20mg Cytarabine - Treatment Schedule B
Reporting group description:	
360 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment schedule B: BI 811283 on Day 1 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion Cytarabine: subcutaneous injection	
Reporting group title	420mg BI 811283+ 20mg Cytarabine- Treatment Schedule B
Reporting group description:	
420 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment schedule B: BI 811283 on Day 1 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion Cytarabine: subcutaneous injection.	

Reporting group values	5mg BI 811283+ 20mg Cytarabine- Treatment Schedule A	15mg BI 811283 +20mg Cytarabine - Treatment Schedule A	30mg BI 811283+ 20mg Cytarabine- Treatment Schedule A
Number of subjects	4	3	3
Age categorical Units: Subjects			
Age Continuous | Units: years arithmetic mean	76	71.3	79.3

standard deviation	± 5.8	± 2.5	± 8.4

Gender, Male/Female Units: participants			
Female	3	2	2
Male	1	1	1

Reporting group values	60mg BI 811283+ 20mg Cytarabine - Treatment Schedule A	100mg BI 811283+ 20mg Cytarabine - Treatment Schedule A	120mg BI 811283+ 20mg Cytarabine - Treatment Schedule A
Number of subjects	4	7	7
Age categorical Units: Subjects			

Age Continuous | Units: years			
arithmetic mean	77.5	67.4	72.3
standard deviation	± 4	± 9.3	± 5.1
Gender, Male/Female Units: participants			
Female	2	4	3
Male	2	3	4

Reporting group values	5mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	40mg BI 811283+ 20mg Cytarabine- Treatment Schedule B	80mg BI 811283+ 20mg Cytarabine- Treatment Schedule B
Number of subjects	4	4	5
Age categorical Units: Subjects			

Age Continuous | Units: years			
arithmetic mean	74.3	73.5	79
standard deviation	± 4.1	± 6.6	± 4.4
Gender, Male/Female Units: participants			
Female	1	3	2
Male	3	1	3

Reporting group values	160mg BI 811283+ 20mg Cytarabine- Treatment Schedule B	240mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	300mg BI 811283+ 20mg Cytarabine - Treatment Schedule B
Number of subjects	3	7	4
Age categorical Units: Subjects			

Age Continuous | Units: years			
arithmetic mean	78.3	72.3	69.5
standard deviation	± 4	± 4.4	± 11.8

Gender, Male/Female Units: participants			
Female	2	2	2
Male	1	5	2

Reporting group values	360mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	420mg BI 811283+ 20mg Cytarabine- Treatment Schedule B	Total
Number of subjects	3	6	64
Age categorical Units: Subjects			

Age Continuous | Units: years			
arithmetic mean	63.3	63.3	
standard deviation	± 5.1	± 5.6	-
Gender, Male/Female Units: participants			
Female	0	2	30
Male	3	4	34

Subject analysis sets

Subject analysis set title	Treatment Schedule A
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Subjects received BI 811283 on Days 1 + 15 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle). BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection).The starting dose for BI 811283 was 5 mg, with dose levels of 5, 15, 30, 60, 100 and 120 mg used in Schedule A.BI 811283: 24-hour continuous intravenous infusion Cytarabine: subcutaneous injection

Subject analysis set title	Treatment schedule B
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Subjects received BI 811283 on Day 1 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle).BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection).The starting dose for BI 811283 was 5 mg, with dose levels of 5, 40, 80, 160, 240, 300, 360 and 420 mg being used in Schedule B.BI 811283: 24-hour continuous intravenous infusion Cytarabine: subcutaneous injection.

Reporting group values	Treatment Schedule A	Treatment schedule B	
Number of subjects	28	36	
Age categorical Units: Subjects			

Age Continuous | Units: years			
arithmetic mean	73	71.5	
standard deviation	± 7.3	± 7.8	
Gender, Male/Female Units: participants			
Female	16	14	

Male	12	22	

End points

End points reporting groups

Reporting group title	5mg BI 811283+ 20mg Cytarabine- Treatment Schedule A

Reporting group description:

5 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment Schedule A: BI 811283 on Days 1 + 15 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion Cytarabine: subcutaneous injection

Reporting group title	15mg BI 811283 +20mg Cytarabine - Treatment Schedule A

Reporting group description:

15 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment Schedule A: BI 811283 on Days 1 + 15 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion cytarabine: subcutaneous injection.

Two patients were entered in the 15mg BI 811283+ 20mg cytarabine- Treatment Schedule A cohort, however those two patients were not treated. Consequently, even though the actual number of subjects that started is 5, only 3 were reported to ensure consistent reporting with baseline characteristics that includes only treated patients.

Reporting group title	30mg BI 811283+ 20mg Cytarabine- Treatment Schedule A

Reporting group description:

30 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment Schedule A: BI 811283 on Days 1 + 15 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion Cytarabine: subcutaneous injection

Reporting group title	60mg BI 811283+ 20mg Cytarabine - Treatment Schedule A

Reporting group description:

60 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment Schedule A: BI 811283 on Days 1 + 15 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion Cytarabine: subcutaneous injection

Reporting group title	100mg BI 811283+ 20mg Cytarabine - Treatment Schedule A

Reporting group description:

100 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment Schedule A: BI 811283 on Days 1 + 15 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion Cytarabine: subcutaneous injection

Reporting group title	120mg BI 811283+ 20mg Cytarabine - Treatment Schedule A

Reporting group description:

120 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment Schedule A: BI 811283 on Days 1 + 15 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion cytarabine: subcutaneous injection.

One patient was entered in the 120mg BI 811283+ 20 mg cytarabine- Treatment Schedule A cohort, however this patient was not treated. Consequently, even though the actual number of subjects that started is 8, only 7 were reported to ensure consistent reporting with baseline characteristics that includes only treated patients.

Reporting group title	5mg BI 811283+ 20mg Cytarabine - Treatment Schedule B

Reporting group description:

5 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment schedule B: BI 811283 on Day 1 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion cytarabine: subcutaneous injection.

One patient was entered in the 5mg BI 811283+ 20mg cytarabine- Treatment Schedule B cohort,

however this patient was not treated. Consequently, even though the actual number of subjects that started is 5, only 4 were reported to ensure consistent reporting with baseline characteristics that includes only treated patients.

Reporting group title	40mg BI 811283+ 20mg Cytarabine- Treatment Schedule B

Reporting group description:

40 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment schedule B: BI 811283 on Day 1 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion Cytarabine: subcutaneous injection

Reporting group title	80mg BI 811283+ 20mg Cytarabine- Treatment Schedule B

Reporting group description:

80 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment schedule B: BI 811283 on Day 1 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion Cytarabine: subcutaneous injection

Reporting group title	160mg BI 811283+ 20mg Cytarabine- Treatment Schedule B

Reporting group description:

160 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment schedule B: BI 811283 on Day 1 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion Cytarabine: subcutaneous injection

Reporting group title	240mg BI 811283+ 20mg Cytarabine - Treatment Schedule B

Reporting group description:

240 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment schedule B: BI 811283 on Day 1 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion Cytarabine: subcutaneous injection

Reporting group title	300mg BI 811283+ 20mg Cytarabine - Treatment Schedule B

Reporting group description:

300 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment schedule B: BI 811283 on Day 1 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion Cytarabine: subcutaneous injection

Reporting group title	360mg BI 811283+ 20mg Cytarabine - Treatment Schedule B

Reporting group description:

360 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment schedule B: BI 811283 on Day 1 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion Cytarabine: subcutaneous injection

Reporting group title	420mg BI 811283+ 20mg Cytarabine- Treatment Schedule B

Reporting group description:

420 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment schedule B: BI 811283 on Day 1 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion Cytarabine: subcutaneous injection.

Subject analysis set title	Treatment Schedule A
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Subjects received BI 811283 on Days 1 + 15 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle). BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection).The starting dose for BI 811283 was 5 mg, with dose levels of 5, 15, 30, 60, 100 and 120 mg used in Schedule A.BI 811283: 24-hour continuous intravenous infusion Cytarabine: subcutaneous injection

Subject analysis set title	Treatment schedule B
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Subjects received BI 811283 on Day 1 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle).BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection).The starting dose for BI 811283 was 5 mg, with dose levels of 5, 40, 80, 160,

240, 300, 360 and 420 mg being used in Schedule B.BI 811283: 24-hour continuous intravenous infusion Cytarabine: subcutaneous injection.

Primary: The maximum tolerated dose (MTD) of 2 schedules of BI 811283 in combination with cytarabine.

End point title	The maximum tolerated dose (MTD) of 2 schedules of BI 811283 in combination with cytarabine.[1]

End point description:

The MTD was defined as the highest dose at which 6 patients were treated and less than 2 patients who experienced a dose limiting toxicities (DLT) within the first cycle of treatment.The MTD was defined based on safety data from the first cycle only. It was determined using a standard "3 + 3 design with de-escalation".

Treated set (TS): All patients who received at least one single dose of trial medication (BI 811283 or cytarabine) were considered for evaluation.

99999= Due to the early termination of study for strategic reasons, the MDT was not reached in schedule B

End point type	Primary

End point timeframe:

up to 28 days of treatment

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: All analyses in this study are descriptive and exploratory by nature,thus no statistical analyses for this primary endpoint are specified.

End point values	Treatment Schedule A	Treatment schedule B		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	28[2]	36[3]		
Units: mg	100	99999		

Notes:

[2] - TS

[3] - TS

Statistical analyses

No statistical analyses for this end point

Secondary: Response (complete remission [CR], complete remission with incomplete blood count recovery [CRi])

End point title	Response (complete remission [CR], complete remission with incomplete blood count recovery [CRi])

End point description:

Response to treatment was evaluated according to the following criteria (modified from the National Cancer Institute/Cancer and Leukemia Group B criteria): The best overall response was defined as the best overall response recorded during the time period from the start of the treatment until the end of the treatment period, progression or death (whichever was earlier). Possible categories for best overall response were CR, CRi, Partial remission (PR), no change (NC), Progressive disease (PD) and no assessment.Complete remission (CR): morphologically leukaemia free state (i.e. bone marrow with < 5% blasts by morphologic criteria and no Auer rods, no evidence of extramedullary leukaemia) and absolute neutrophil count ≥ 1,000/µL and platelets > 100,000/µL.Complete remission with incomplete blood count recovery ("incomplete" CR, CRi).All of the above criteria for CR had to be met, except that neutrophils < 1,000/µL or platelets < 100,000/µL in the blood. Patients in TS were considered.

End point type	Secondary

End point timeframe:

Data collected up to cut-off date 20Oct2011, Up to 1239 days

End point values	5mg BI 811283+ 20mg Cytarabine- Treatment Schedule A	15mg BI 811283 +20mg Cytarabine - Treatment Schedule A	30mg BI 811283+ 20mg Cytarabine- Treatment Schedule A	60mg BI 811283+ 20mg Cytarabine - Treatment Schedule A
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	3	4
Units: participants				
CR	0	0	0	1
CRi	0	0	0	0

End point values	100mg BI 811283+ 20mg Cytarabine - Treatment Schedule A	120mg BI 811283+ 20mg Cytarabine - Treatment Schedule A	5mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	40mg BI 811283+ 20mg Cytarabine- Treatment Schedule B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	7	4	4
Units: participants				
CR	0	1	1	0
CRi	0	0	0	0

End point values	80mg BI 811283+ 20mg Cytarabine- Treatment Schedule B	160mg BI 811283+ 20mg Cytarabine- Treatment Schedule B	240mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	300mg BI 811283+ 20mg Cytarabine - Treatment Schedule B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	3	7	4
Units: participants				
CR	1	1	1	0
CRi	0	0	0	0

End point values	360mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	420mg BI 811283+ 20mg Cytarabine- Treatment Schedule B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	6		
Units: participants				
CR	1	0		
CRi	1	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Incidence and intensity of AEs graded according to CTCAE (version 3.0)

End point title	Incidence and intensity of AEs graded according to CTCAE (version 3.0)

End point description:

The severity and timing of AEs indicates how well the treatment regimen was tolerated. Toxicities were evaluated using the common terminology criteria for adverse events (CTCAE) grading scheme.

Only patients included in treated set (TS) were considered for evaluation.

End point type	Secondary

End point timeframe:

Data from first treatment administration until cut-off date of 20 October 2011; up to 1239 days

End point values	5mg BI 811283+ 20mg Cytarabine- Treatment Schedule A	15mg BI 811283 +20mg Cytarabine - Treatment Schedule A	30mg BI 811283+ 20mg Cytarabine- Treatment Schedule A	60mg BI 811283+ 20mg Cytarabine - Treatment Schedule A
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	3	4
Units: participants				
CTCAE Grade 1	0	0	0	0
CTCAE Grade 2	0	0	1	0
CTCAE Grade 3	1	1	0	1
CTCAE Grade 4	0	2	2	2
CTCAE Grade 5	3	0	0	1

End point values	100mg BI 811283+ 20mg Cytarabine - Treatment Schedule A	120mg BI 811283+ 20mg Cytarabine - Treatment Schedule A	5mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	40mg BI 811283+ 20mg Cytarabine- Treatment Schedule B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	7	4	4
Units: participants				
CTCAE Grade 1	0	0	0	0
CTCAE Grade 2	0	0	0	0
CTCAE Grade 3	1	0	1	0
CTCAE Grade 4	4	3	1	2
CTCAE Grade 5	2	4	2	2

End point values	80mg BI 811283+ 20mg Cytarabine- Treatment Schedule B	160mg BI 811283+ 20mg Cytarabine- Treatment Schedule B	240mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	300mg BI 811283+ 20mg Cytarabine - Treatment Schedule B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	3	7	4
Units: participants				
CTCAE Grade 1	0	0	0	0
CTCAE Grade 2	0	0	0	0
CTCAE Grade 3	0	1	2	1
CTCAE Grade 4	3	1	3	1
CTCAE Grade 5	2	1	2	2

End point values	360mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	420mg BI 811283+ 20mg Cytarabine- Treatment Schedule B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	6		
Units: participants				
CTCAE Grade 1	0	0		
CTCAE Grade 2	0	0		
CTCAE Grade 3	0	0		
CTCAE Grade 4	2	2		
CTCAE Grade 5	1	4		

Statistical analyses

No statistical analyses for this end point

Secondary: Incidence of dose limiting toxicity (DLT)

End point title	Incidence of dose limiting toxicity (DLT)

End point description:

Number of participants with DLT in the first cycle (28 days) for the determination of the maximum tolerated dose (MTD).

Only patients included in treated set (TS) were considered for evaluation.

End point type	Secondary

End point timeframe:

up to 28 days of treatment

End point values	5mg BI 811283+ 20mg Cytarabine- Treatment Schedule A	15mg BI 811283 +20mg Cytarabine - Treatment Schedule A	30mg BI 811283+ 20mg Cytarabine- Treatment Schedule A	60mg BI 811283+ 20mg Cytarabine - Treatment Schedule A
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	3	4
Units: participants	0	0	0	0

End point values	100mg BI 811283+ 20mg Cytarabine - Treatment Schedule A	120mg BI 811283+ 20mg Cytarabine - Treatment Schedule A	5mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	40mg BI 811283+ 20mg Cytarabine- Treatment Schedule B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	7	4	4
Units: participants	0	2	1	0

End point values	80mg BI 811283+ 20mg Cytarabine- Treatment Schedule B	160mg BI 811283+ 20mg Cytarabine- Treatment Schedule B	240mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	300mg BI 811283+ 20mg Cytarabine - Treatment Schedule B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	3	7	4
Units: participants	0	0	1	0

End point values	360mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	420mg BI 811283+ 20mg Cytarabine- Treatment Schedule B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	6		
Units: participants	1	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Partial Remission

End point title	Partial Remission

End point description:

Response to treatment was evaluated according to the following criteria (modified from the National Cancer Institute/Cancer and Leukemia Group B criteria); The best overall response was defined as the best overall response recorded during the time period from the start of the treatment until the end of the treatment period, progression or death (whichever was earlier). Possible categories for best overall response were CR, CRi, Partial remission (PR), no change (NC), Progressive disease (PD) and no assessment. Partial remission (PR). All of the criteria for CR had to be met, except that the bone marrow had to contain ≥ 5% but less than 25% blasts (or ≤ 50% of initial blast count), or < 5% blasts in the presence of Auer rods or abnormal morphology.

Only patients included in treated set (TS) were considered for evaluation.

End point type	Secondary

End point timeframe:

Data collected up to cut-off date 20 Oct 2011, Up to 1239 days

End point values	5mg BI 811283+ 20mg Cytarabine- Treatment Schedule A	15mg BI 811283 +20mg Cytarabine - Treatment Schedule A	30mg BI 811283+ 20mg Cytarabine- Treatment Schedule A	60mg BI 811283+ 20mg Cytarabine - Treatment Schedule A
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	3	4
Units: participants	0	0	0	0

End point values	100mg BI 811283+ 20mg Cytarabine - Treatment Schedule A	120mg BI 811283+ 20mg Cytarabine - Treatment Schedule A	5mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	40mg BI 811283+ 20mg Cytarabine- Treatment Schedule B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	7	4	4
Units: participants	0	0	0	1

End point values	80mg BI 811283+ 20mg Cytarabine- Treatment Schedule B	160mg BI 811283+ 20mg Cytarabine- Treatment Schedule B	240mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	300mg BI 811283+ 20mg Cytarabine - Treatment Schedule B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	3	7	4
Units: participants	0	0	0	0

End point values	360mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	420mg BI 811283+ 20mg Cytarabine- Treatment Schedule B		

Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	6		
Units: participants	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Event free survival (EFS)

End point title	Event free survival (EFS)

End point description:

EFS was defined as the duration of time from randomisation to time of treatment failure (i.e. PD), relapse from CR, or death from any cause, whichever came first.

Only patients included in treated set (TS) were considered for evaluation.

End point type	Secondary

End point timeframe:

Data collected up to cut-off date 20 Oct 2011, Up to 1239 days

End point values	5mg BI 811283+ 20mg Cytarabine-Treatment Schedule A	15mg BI 811283 +20mg Cytarabine - Treatment Schedule A	30mg BI 811283+ 20mg Cytarabine-Treatment Schedule A	60mg BI 811283+ 20mg Cytarabine - Treatment Schedule A
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	3	4
Units: days				
arithmetic mean (standard deviation)	35 (± 15.6)	122.3 (± 120)	32 (± 1)	117.5 (± 102.4)

End point values	100mg BI 811283+ 20mg Cytarabine - Treatment Schedule A	120mg BI 811283+ 20mg Cytarabine - Treatment Schedule A	5mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	40mg BI 811283+ 20mg Cytarabine-Treatment Schedule B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	7	4	4
Units: days				
arithmetic mean (standard deviation)	60.4 (± 52.6)	62 (± 54.1)	209 (± 315.8)	65 (± 41.5)

End point values	80mg BI 811283+ 20mg Cytarabine-Treatment Schedule B	160mg BI 811283+ 20mg Cytarabine-Treatment Schedule B	240mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	300mg BI 811283+ 20mg Cytarabine - Treatment Schedule B

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	3	7	4
Units: days				
arithmetic mean (standard deviation)	168.8 (± 219.3)	62.7 (± 53.9)	138.7 (± 183.2)	48.5 (± 36.9)

End point values	360mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	420mg BI 811283+ 20mg Cytarabine- Treatment Schedule B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	6		
Units: days				
arithmetic mean (standard deviation)	174 (± 67.2)	30 (± 7.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Relapse free survival

End point title	Relapse free survival

End point description:

Relapse-free survival was defined only for patients who achieved CR/CRi and was measured from the date of attaining CR/CRi until the date of recurrence or death from any cause, whichever occurred first. Number of patients having relapse free survival are presented.

Only patients included in treated set with observed cases values were considered for evaluation.

End point type	Secondary

End point timeframe:

Data collected up to cut-off date 20 Oct 2011, Up to 1239 days

End point values	5mg BI 811283+ 20mg Cytarabine- Treatment Schedule A	15mg BI 811283 +20mg Cytarabine - Treatment Schedule A	30mg BI 811283+ 20mg Cytarabine- Treatment Schedule A	60mg BI 811283+ 20mg Cytarabine - Treatment Schedule A
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[4]	0[5]	0[6]	1
Units: participants				1

Notes:

[4] - No patients in this treatment arm had CR/CRi to qualify for evaluation of this endpoint

[5] - No patients in this treatment arm had CR/CRi to qualify for evaluation of this endpoint

[6] - No patients in this treatment arm had CR/CRi to qualify for evaluation of this endpoint

End point values	100mg BI 811283+ 20mg	120mg BI 811283+ 20mg	5mg BI 811283+ 20mg	40mg BI 811283+ 20mg

	Cytarabine - Treatment Schedule A	Cytarabine - Treatment Schedule A	Cytarabine - Treatment Schedule B	Cytarabine- Treatment Schedule B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[7]	1	1	0[8]
Units: participants		1	1	

Notes:

[7] - No patients in this treatment arm had CR/CRi to qualify for evaluation of this endpoint

[8] - No patients in this treatment arm had CR/CRi to qualify for evaluation of this endpoint

End point values	80mg BI 811283+ 20mg Cytarabine- Treatment Schedule B	160mg BI 811283+ 20mg Cytarabine- Treatment Schedule B	240mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	300mg BI 811283+ 20mg Cytarabine - Treatment Schedule B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	1	0[9]
Units: participants	1	1	1	

Notes:

[9] - No patients in this treatment arm had CR/CRi to qualify for evaluation of this endpoint

End point values	360mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	420mg BI 811283+ 20mg Cytarabine- Treatment Schedule B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	0[10]		
Units: participants	2			

Notes:

[10] - No patients in this treatment arm had CR/CRi to qualify for evaluation of this endpoint

Statistical analyses

No statistical analyses for this end point

Secondary: Remission duration

End point title	Remission duration

End point description:

Remission duration analysis was defined only for patients who achieved CR, and was measured from the date of attaining CR until the date of disease recurrence (relapse). For patients who died without report of relapse, remission duration was censored on the date of death, regardless of the cause.

Only patients included in treated set with observed cases values were considered for evaluation.

99999: As only one participant is analysed, SD is not calculable

End point type	Secondary

End point timeframe:

Data collected up to cut-off date 20 Oct 2011, Up to 1239 days

End point values	5mg BI 811283+ 20mg Cytarabine- Treatment Schedule A	15mg BI 811283 +20mg Cytarabine - Treatment Schedule A	30mg BI 811283+ 20mg Cytarabine- Treatment Schedule A	60mg BI 811283+ 20mg Cytarabine - Treatment Schedule A
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[11]	0[12]	0[13]	1
Units: days				
arithmetic mean (standard deviation)	()	()	()	263 (± 99999)

Notes:

[11] - No patients in this treatment arm had observed cases values

[12] - No patients in this treatment arm had observed cases values

[13] - No patients in this treatment arm had observed cases values

End point values	100mg BI 811283+ 20mg Cytarabine - Treatment Schedule A	120mg BI 811283+ 20mg Cytarabine - Treatment Schedule A	5mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	40mg BI 811283+ 20mg Cytarabine- Treatment Schedule B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[14]	1	1	0[15]
Units: days				
arithmetic mean (standard deviation)	()	28 (± 99999)	337 (± 99999)	()

Notes:

[14] - No patients in this treatment arm had observed cases values

[15] - No patients in this treatment arm had observed cases values

End point values	80mg BI 811283+ 20mg Cytarabine- Treatment Schedule B	160mg BI 811283+ 20mg Cytarabine- Treatment Schedule B	240mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	300mg BI 811283+ 20mg Cytarabine - Treatment Schedule B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	0[16]	1	0[17]
Units: days				
arithmetic mean (standard deviation)	455 (± 99999)	()	128 (± 99999)	()

Notes:

[16] - No patients in this treatment arm had observed cases values

[17] - No patients in this treatment arm had observed cases values

End point values	360mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	420mg BI 811283+ 20mg Cytarabine- Treatment Schedule B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	0[18]		
Units: days				
arithmetic mean (standard deviation)	15 (± 99999)	()		

Notes:

[18] - No patients in this treatment arm had observed cases values

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival (OS)

End point title	Overall Survival (OS)

End point description:

OS was defined for all patients that entered the trial, and measured from the date of randomization until death from any cause.

Only patients included in treated set (TS) were considered for evaluation.

End point type	Secondary

End point timeframe:

Data collected up to cut-off date 20 Oct 2011, Up to 1239 days

End point values	5mg BI 811283+ 20mg Cytarabine- Treatment Schedule A	15mg BI 811283 +20mg Cytarabine - Treatment Schedule A	30mg BI 811283+ 20mg Cytarabine- Treatment Schedule A	60mg BI 811283+ 20mg Cytarabine - Treatment Schedule A
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	3	4
Units: days				
arithmetic mean (standard deviation)	122.8 (± 166.2)	212 (± 55.1)	71.3 (± 40.5)	236.8 (± 225.5)

End point values	100mg BI 811283+ 20mg Cytarabine - Treatment Schedule A	120mg BI 811283+ 20mg Cytarabine - Treatment Schedule A	5mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	40mg BI 811283+ 20mg Cytarabine- Treatment Schedule B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	7	4	4
Units: days				
arithmetic mean (standard deviation)	148.7 (± 125.5)	86.6 (± 58.1)	236.8 (± 322.9)	137.3 (± 121.7)

End point values	80mg BI 811283+ 20mg Cytarabine- Treatment Schedule B	160mg BI 811283+ 20mg Cytarabine- Treatment Schedule B	240mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	300mg BI 811283+ 20mg Cytarabine - Treatment Schedule B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	3	7	4
Units: days				
arithmetic mean (standard deviation)	198.2 (± 260.1)	339.7 (± 364.8)	175.7 (± 175.4)	73 (± 31.3)

End point values	360mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	420mg BI 811283+ 20mg Cytarabine- Treatment Schedule B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	6		
Units: days				
arithmetic mean (standard deviation)	294.7 (± 101.5)	48.7 (± 17.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax (maximum measured concentration of BI 811283 in plasma)

End point title	Cmax (maximum measured concentration of BI 811283 in plasma)

End point description:

Cmax (maximum measured concentration of BI 811283 in plasma) during Cycle 1.

Only patients included in treated set with observed cases values were considered for evaluation.

End point type	Secondary

End point timeframe:

-0.05 hours before and 1:00, 4:00, 6:00, 24:00, 25:00, 26:00, 28:00, 32:00, 36:00, 48:00 hours after administration of BI 811283

End point values	5mg BI 811283+ 20mg Cytarabine- Treatment Schedule A	15mg BI 811283 +20mg Cytarabine - Treatment Schedule A	30mg BI 811283+ 20mg Cytarabine- Treatment Schedule A	60mg BI 811283+ 20mg Cytarabine - Treatment Schedule A
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	3	4
Units: nmol/L				
geometric mean (geometric coefficient of variation)	8.03 (± 32.3)	64.1 (± 686)	104 (± 321)	153 (± 108)

End point values	100mg BI 811283+ 20mg Cytarabine - Treatment Schedule A	120mg BI 811283+ 20mg Cytarabine - Treatment Schedule A	5mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	40mg BI 811283+ 20mg Cytarabine- Treatment Schedule B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	7	4	4
Units: nmol/L				
geometric mean (geometric coefficient of variation)	214 (± 38.8)	272 (± 30)	7.06 (± 10)	66.1 (± 85.3)

End point values	80mg BI 811283+ 20mg Cytarabine-Treatment Schedule B	160mg BI 811283+ 20mg Cytarabine-Treatment Schedule B	240mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	300mg BI 811283+ 20mg Cytarabine - Treatment Schedule B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	3	7	3
Units: nmol/L				
geometric mean (geometric coefficient of variation)	139 (± 33.8)	499 (± 101)	445 (± 71)	631 (± 31)

End point values	360mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	420mg BI 811283+ 20mg Cytarabine-Treatment Schedule B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	6		
Units: nmol/L				
geometric mean (geometric coefficient of variation)	528 (± 40.5)	1130 (± 53.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: AUC(0-inf) (area under the concentration-time curve of BI 811283 in plasma over the time interval from 0 extrapolated to infinity)

End point title	AUC(0-inf) (area under the concentration-time curve of BI 811283 in plasma over the time interval from 0 extrapolated to infinity)

End point description:

AUC(0-inf) (area under the concentration-time curve of BI 811283 in plasma over the time interval from 0 extrapolated to infinity) during Cycle 1.
Treated set (Only patients with observed cases (OC) values were analysed).

End point type	Secondary

End point timeframe:

-0.05 hours before and 1:00, 4:00, 6:00, 24:00, 25:00, 26:00, 28:00, 32:00, 36:00, 48:00 hours after administration of BI 811283

End point values	5mg BI 811283+ 20mg Cytarabine- Treatment Schedule A	15mg BI 811283 +20mg Cytarabine - Treatment Schedule A	30mg BI 811283+ 20mg Cytarabine- Treatment Schedule A	60mg BI 811283+ 20mg Cytarabine - Treatment Schedule A
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	2	3
Units: nmol·h/L				
geometric mean (geometric coefficient of variation)	177 (± 28.2)	985 (± 311)	1000 (± 40.7)	2790 (± 130)

End point values	100mg BI 811283+ 20mg Cytarabine - Treatment Schedule A	120mg BI 811283+ 20mg Cytarabine - Treatment Schedule A	5mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	40mg BI 811283+ 20mg Cytarabine- Treatment Schedule B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	7	4	4
Units: nmol·h/L				
geometric mean (geometric coefficient of variation)	4400 (± 62.9)	5620 (± 27.9)	192 (± 47.7)	1490 (± 98.1)

End point values	80mg BI 811283+ 20mg Cytarabine- Treatment Schedule B	160mg BI 811283+ 20mg Cytarabine- Treatment Schedule B	240mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	300mg BI 811283+ 20mg Cytarabine - Treatment Schedule B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	3	7	3
Units: nmol·h/L				
geometric mean (geometric coefficient of variation)	2840 (± 29.6)	8870 (± 59.9)	9770 (± 63)	14100 (± 32.6)

End point values	360mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	420mg BI 811283+ 20mg Cytarabine- Treatment Schedule B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	6		
Units: nmol·h/L				
geometric mean (geometric coefficient of variation)	12800 (± 64.3)	23200 (± 57.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: AUC0-tz (area under the concentration-time curve of BI 811283 in plasma over the time interval from 0 to the time of the last quantifiable data point)

End point title	AUC0-tz (area under the concentration-time curve of BI 811283 in plasma over the time interval from 0 to the time of the last quantifiable data point)

End point description:

AUC0-tz (area under the concentration-time curve of BI 811283 in plasma over the time interval from 0 to the time of the last quantifiable data point) during Cycle 1.

Only patients included in treated set with observed cases values were considered for evaluation.

End point type	Secondary

End point timeframe:

-0.05 hours before and 1:00, 4:00, 6:00, 24:00, 25:00, 26:00, 28:00, 32:00, 36:00, 48:00 hours after administration of BI 811283

End point values	5mg BI 811283+ 20mg Cytarabine- Treatment Schedule A	15mg BI 811283 +20mg Cytarabine - Treatment Schedule A	30mg BI 811283+ 20mg Cytarabine- Treatment Schedule A	60mg BI 811283+ 20mg Cytarabine - Treatment Schedule A
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	3	4
Units: nmol·h/L				
geometric mean (geometric coefficient of variation)	169 (± 30.5)	939 (± 328)	2010 (± 207)	2350 (± 105)

End point values	100mg BI 811283+ 20mg Cytarabine - Treatment Schedule A	120mg BI 811283+ 20mg Cytarabine - Treatment Schedule A	5mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	40mg BI 811283+ 20mg Cytarabine- Treatment Schedule B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	7	4	4
Units: nmol·h/L				
geometric mean (geometric coefficient of variation)	2810 (± 135)	5340 (± 27.2)	156 (± 17.5)	1450 (± 97.3)

End point values	80mg BI 811283+ 20mg Cytarabine- Treatment Schedule B	160mg BI 811283+ 20mg Cytarabine- Treatment Schedule B	240mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	300mg BI 811283+ 20mg Cytarabine - Treatment Schedule B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	3	7	3
Units: nmol·h/L				
geometric mean (geometric coefficient of variation)	2730 (± 29.1)	8680 (± 60.4)	9260 (± 63.6)	13700 (± 31.7)

End point values	360mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	420mg BI 811283+ 20mg Cytarabine- Treatment Schedule B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	6		
Units: nmol·h/L				
geometric mean (geometric coefficient of variation)	12100 (± 63.1)	21700 (± 55.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax,ss (maximum measured concentration of BI 811283 in plasma at steady state)

End point title	Cmax,ss (maximum measured concentration of BI 811283 in plasma at steady state)[19]

End point description:

Cmax (maximum measured concentration of BI 811283 in plasma at steady state) during Cycle 1.

Only patients included in treated set with observed cases values were considered for evaluation. Steady state analyses is not applicable for Treatment schedule B, since pharmacokinetic analyses was performed after a single dose for Treatment schedule B.

End point type	Secondary

End point timeframe:

-0.05 hours before and 1:00, 4:00, 6:00, 24:00, 25:00, 26:00, 28:00, 32:00, 36:00, 48:00 hours after administration of BI 811283

Notes:

[19] - 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: Only those arms for which the statistics are presented in the clinical trial report thus, those that would yield meaningful results were reported.

End point values	5mg BI 811283+ 20mg Cytarabine- Treatment Schedule A	15mg BI 811283 +20mg Cytarabine - Treatment Schedule A	30mg BI 811283+ 20mg Cytarabine- Treatment Schedule A	60mg BI 811283+ 20mg Cytarabine - Treatment Schedule A
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	3
Units: nmol/L				
geometric mean (geometric coefficient of variation)	8.02 (± 4.59)	24.7 (± 18.5)	43.3 (± 5.58)	141 (± 52.2)

End point values	100mg BI 811283+ 20mg	120mg BI 811283+ 20mg		

	Cytarabine - Treatment Schedule A	Cytarabine - Treatment Schedule A		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	7		
Units: nmol/L				
geometric mean (geometric coefficient of variation)	213 (± 96.1)	229 (± 67.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: AUC (0-inf, ss)(area under the concentration-time curve of BI 811283 in plasma over the time interval from 0 extrapolated to infinity) at steady state

End point title	AUC (0-inf, ss)(area under the concentration-time curve of BI 811283 in plasma over the time interval from 0 extrapolated to infinity) at steady state[20]

End point description:

AUC (0-inf, ss)(area under the concentration-time curve of BI 811283 in plasma over the time interval from 0 extrapolated to infinity) at steady state during Cycle 1.

Only patients included in treated set with observed cases values were considered for evaluation.Steady state analyses is not applicable for Treatment schedule B, since pharmacokinetic analyses was performed after a single dose for Treatment schedule B.

99999: Not calculated as estimates of summary statistical values are not considered reliable if data from fever than 2/3 of tested subjects are available, according to Boehringer-Ingelheim Clinical PK SOP.

End point type	Secondary

End point timeframe:

-0.05 hours before and 1:00, 4:00, 6:00, 24:00, 25:00, 26:00, 28:00, 32:00, 36:00, 48:00 hours after administration of BI 811283

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: Only those arms for which the statistics are presented in the clinical trial report thus, those that would yield meaningful results were reported.

End point values	5mg BI 811283+ 20mg Cytarabine- Treatment Schedule A	15mg BI 811283 +20mg Cytarabine - Treatment Schedule A	30mg BI 811283+ 20mg Cytarabine- Treatment Schedule A	60mg BI 811283+ 20mg Cytarabine - Treatment Schedule A
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	1	3
Units: nmol·h/L				
geometric mean (geometric coefficient of variation)	188 (± 12.7)	615 (± 15.3)	99999 (± 99999)	4460 (± 41.8)

End point values	100mg BI 811283+ 20mg Cytarabine - Treatment	120mg BI 811283+ 20mg Cytarabine - Treatment		

	Schedule A	Schedule A		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	7		
Units: nmol·h/L				
geometric mean (geometric coefficient of variation)	5140 (± 105)	4750 (± 58.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: AUC (0-tz,ss) (area under the concentration-time curve of BI 811283 in plasma over the time interval from 0 to the time of the last quantifiable data point) at steady state

End point title	AUC (0-tz,ss) (area under the concentration-time curve of BI 811283 in plasma over the time interval from 0 to the time of the last quantifiable data point) at steady state[21]

End point description:

AUC (0-tz,ss) (area under the concentration-time curve of BI 811283 in plasma over the time interval from 0 to the time of the last quantifiable data point) at steady state during Cycle 1.

Only patients included in treated set with observed cases values were considered for evaluation. Steady state analyses is not applicable for Treatment schedule B, since pharmacokinetic analyses was performed after a single dose for Treatment schedule B.

End point type	Secondary

End point timeframe:

-0.05 hours before and 1:00, 4:00, 6:00, 24:00, 25:00, 26:00, 28:00, 32:00, 36:00, 48:00 hours after administration of BI 811283

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: Only those arms for which the statistics are presented in the clinical trial report thus, those that would yield meaningful results were reported.

End point values	5mg BI 811283+ 20mg Cytarabine- Treatment Schedule A	15mg BI 811283 +20mg Cytarabine - Treatment Schedule A	30mg BI 811283+ 20mg Cytarabine- Treatment Schedule A	60mg BI 811283+ 20mg Cytarabine - Treatment Schedule A
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	3
Units: nmol·h/L				
geometric mean (geometric coefficient of variation)	183 (± 14.3)	597 (± 15)	1620 (± 58.2)	4330 (± 40.5)

End point values	100mg BI 811283+ 20mg Cytarabine - Treatment Schedule A	120mg BI 811283+ 20mg Cytarabine - Treatment Schedule A		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	7		

Units: nmol·h/L				
geometric mean (geometric coefficient of variation)	4340 (± 83.6)	4820 (± 55.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: tmax (time from dosing to maximum measured concentration of BI 811283 in plasma)

End point title	tmax (time from dosing to maximum measured concentration of BI 811283 in plasma)

End point description:

tmax (time from dosing to maximum measured concentration of BI 811283 in plasma) during Cycle 1.

Only patients included in treated set with observed cases values were considered for evaluation.

End point type	Secondary

End point timeframe:

-0.05 hours before and 1:00, 4:00, 6:00, 24:00, 25:00, 26:00, 28:00, 32:00, 36:00, 48:00 hours after administration of BI 811283

End point values	5mg BI 811283+ 20mg Cytarabine- Treatment Schedule A	15mg BI 811283 +20mg Cytarabine - Treatment Schedule A	30mg BI 811283+ 20mg Cytarabine- Treatment Schedule A	60mg BI 811283+ 20mg Cytarabine - Treatment Schedule A
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	3	4
Units: hours				
median (full range (min-max))	24 (6 to 24.1)	26 (6 to 48)	25 (24 to 32)	22.7 (6 to 24.1)

End point values	100mg BI 811283+ 20mg Cytarabine - Treatment Schedule A	120mg BI 811283+ 20mg Cytarabine - Treatment Schedule A	5mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	40mg BI 811283+ 20mg Cytarabine- Treatment Schedule B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	7	4	4
Units: hours				
median (full range (min-max))	6 (4.1 to 24.3)	23.6 (5.9 to 24.5)	23.9 (4 to 24.2)	6 (6 to 6)

End point values	80mg BI 811283+ 20mg Cytarabine-	160mg BI 811283+ 20mg Cytarabine-	240mg BI 811283+ 20mg Cytarabine -	300mg BI 811283+ 20mg Cytarabine -

	Treatment Schedule B	Treatment Schedule B	Treatment Schedule B	Treatment Schedule B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	3	7	3
Units: hours				
median (full range (min-max))	24.1 (6 to 26.8)	24.9 (23.6 to 32)	6 (6 to 25)	23.9 (23.9 to 24.1)

End point values	360mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	420mg BI 811283+ 20mg Cytarabine- Treatment Schedule B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	6		
Units: hours				
median (full range (min-max))	5.9 (4.8 to 6)	14.8 (3.9 to 26.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: tmax,ss (time from dosing to maximum measured concentration of BI 811283 in plasma at steady state)

End point title	tmax,ss (time from dosing to maximum measured concentration of BI 811283 in plasma at steady state)[22]

End point description:

tmax,ss (time from dosing to maximum measured concentration of BI 811283 in plasma at steady state) during Cycle 1

Only patients included in treated set with observed cases values were considered for evaluation. Steady state analyses is not applicable for Treatment schedule B, since pharmacokinetic analyses was performed after a single dose for Treatment schedule B.

End point type	Secondary

End point timeframe:

-0.05 hours before and 1:00, 4:00, 6:00, 24:00, 25:00, 26:00, 28:00, 32:00, 36:00, 48:00 hours after administration of BI 811283

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: Only those arms for which the statistics are presented in the clinical trial report thus, those that would yield meaningful results were reported.

End point values	5mg BI 811283+ 20mg Cytarabine- Treatment Schedule A	15mg BI 811283 +20mg Cytarabine - Treatment Schedule A	30mg BI 811283+ 20mg Cytarabine- Treatment Schedule A	60mg BI 811283+ 20mg Cytarabine - Treatment Schedule A
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	3
Units: hours				

median (full range (min-max))	23.9 (4.1 to 23.9)	24 (4 to 24)	6 (4 to 24)	6 (4.1 to 24)

End point values	100mg BI 811283+ 20mg Cytarabine - Treatment Schedule A	120mg BI 811283+ 20mg Cytarabine - Treatment Schedule A		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	7		
Units: hours				
median (full range (min-max))	6 (5.9 to 23.5)	6 (4 to 23.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax (maximum measured concentration of Cytarabine in plasma)

End point title	Cmax (maximum measured concentration of Cytarabine in plasma)

End point description:

Cmax of Cytarabine after a 20 mg Subcutaneous Dose on the First Day of BI 811283.

Only patients included in treated set with observed cases values were considered for evaluation.

End point type	Secondary

End point timeframe:

-0.05 hours before and 0:30, 1:00, 1:30, 2:00, 3:00, 4:00, 6:00 hours after administration of Cytarabine

End point values	5mg BI 811283+ 20mg Cytarabine- Treatment Schedule A	15mg BI 811283 +20mg Cytarabine - Treatment Schedule A	30mg BI 811283+ 20mg Cytarabine- Treatment Schedule A	60mg BI 811283+ 20mg Cytarabine - Treatment Schedule A
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	3	4
Units: ng/mL				
geometric mean (geometric coefficient of variation)	53.2 (± 65.4)	72.6 (± 31)	49 (± 80.6)	64.9 (± 49.5)

End point values	100mg BI 811283+ 20mg Cytarabine - Treatment Schedule A	120mg BI 811283+ 20mg Cytarabine - Treatment Schedule A	5mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	40mg BI 811283+ 20mg Cytarabine- Treatment Schedule B

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	7	4	3
Units: ng/mL				
geometric mean (geometric coefficient of variation)	61.9 (± 57.3)	46 (± 54.1)	46.3 (± 31.8)	49.8 (± 58.1)

End point values	80mg BI 811283+ 20mg Cytarabine-Treatment Schedule B	160mg BI 811283+ 20mg Cytarabine-Treatment Schedule B	240mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	300mg BI 811283+ 20mg Cytarabine - Treatment Schedule B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	3	7	3
Units: ng/mL				
geometric mean (geometric coefficient of variation)	55 (± 16.5)	65.1 (± 44.5)	49.4 (± 58.9)	48.6 (± 88.4)

End point values	360mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	420mg BI 811283+ 20mg Cytarabine-Treatment Schedule B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	6		
Units: ng/mL				
geometric mean (geometric coefficient of variation)	49 (± 77)	68.7 (± 33.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Tmax (time from dosing to maximum measured concentration of Cytarabine in plasma)

End point title	Tmax (time from dosing to maximum measured concentration of Cytarabine in plasma)

End point description:

Tmax of Cytarabine after a 20 mg Subcutaneous Dose on the First Day of BI 811283.

Only patients included in treated set with observed cases values were considered for evaluation.

End point type	Secondary

End point timeframe:

-0.05 hours before and 0:30, 1:00, 1:30, 2:00, 3:00, 4:00, 6:00 hours after administration of Cytarabine

End point values	5mg BI 811283+ 20mg Cytarabine- Treatment Schedule A	15mg BI 811283 +20mg Cytarabine - Treatment Schedule A	30mg BI 811283+ 20mg Cytarabine- Treatment Schedule A	60mg BI 811283+ 20mg Cytarabine - Treatment Schedule A
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	3	4
Units: hours				
median (full range (min-max))	0.5 (0.5 to 1)	0.5 (0.5 to 1)	0.92 (0.5 to 1)	0.83 (0.5 to 1.4)

End point values	100mg BI 811283+ 20mg Cytarabine - Treatment Schedule A	120mg BI 811283+ 20mg Cytarabine - Treatment Schedule A	5mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	40mg BI 811283+ 20mg Cytarabine- Treatment Schedule B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	7	4	3
Units: hours				
median (full range (min-max))	0.48 (0.42 to 0.53)	0.55 (0.5 to 1.5)	0.5 (0.4 to 0.7)	0.5 (0.5 to 0.5)

End point values	80mg BI 811283+ 20mg Cytarabine- Treatment Schedule B	160mg BI 811283+ 20mg Cytarabine- Treatment Schedule B	240mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	300mg BI 811283+ 20mg Cytarabine - Treatment Schedule B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	3	7	3
Units: hours				
median (full range (min-max))	0.58 (0.47 to 1)	0.5 (0.43 to 0.67)	0.5 (0.45 to 1)	0.5 (0.47 to 0.5)

End point values	360mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	420mg BI 811283+ 20mg Cytarabine- Treatment Schedule B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	6		
Units: hours				
median (full range (min-max))	0.48 (0.48 to 1)	0.49 (0.48 to 0.57)		

Statistical analyses

No statistical analyses for this end point

Secondary: AUC (0-inf) (area under the concentration-time curve of Cytarabine in plasma over the time interval from 0 extrapolated to infinity)

End point title	AUC (0-inf) (area under the concentration-time curve of Cytarabine in plasma over the time interval from 0 extrapolated to infinity)

End point description:

AUC (0-inf) of Cytarabine after a 20 mg Subcutaneous Dose on the First Day of BI 811283.

Only patients included in treated set with observed cases values were considered for evaluation.

99999: Not calculated as estimates of summary statistical values are not considered reliable if data from fever than 2/3 of tested subjects are available, according to Boehringer-Ingelheim Clinical PK SOP.

End point type	Secondary

End point timeframe:

-0.05 hours before and 0:30, 1:00, 1:30, 2:00, 3:00, 4:00, 6:00 hours after administration of Cytarabine

End point values	5mg BI 811283+ 20mg Cytarabine- Treatment Schedule A	15mg BI 811283 +20mg Cytarabine - Treatment Schedule A	30mg BI 811283+ 20mg Cytarabine- Treatment Schedule A	60mg BI 811283+ 20mg Cytarabine - Treatment Schedule A
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	2	3	3
Units: ng·h/mL				
geometric mean (geometric coefficient of variation)	104 (± 31.4)	122 (± 6.89)	102 (± 31.5)	85.4 (± 35.3)

End point values	100mg BI 811283+ 20mg Cytarabine - Treatment Schedule A	120mg BI 811283+ 20mg Cytarabine - Treatment Schedule A	5mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	40mg BI 811283+ 20mg Cytarabine- Treatment Schedule B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	5	4	2
Units: ng·h/mL				
geometric mean (geometric coefficient of variation)	65.9 (± 42.5)	68.1 (± 41.4)	62 (± 24.1)	99999 (± 99999)

End point values	80mg BI 811283+ 20mg Cytarabine- Treatment Schedule B	160mg BI 811283+ 20mg Cytarabine- Treatment Schedule B	240mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	300mg BI 811283+ 20mg Cytarabine - Treatment Schedule B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	7	3
Units: ng·h/mL				
geometric mean (geometric coefficient of variation)	99999 (± 99999)	71.2 (± 20.7)	72.7 (± 23.6)	75.5 (± 27.2)

End point values	360mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	420mg BI 811283+ 20mg Cytarabine- Treatment Schedule B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	5		
Units: ng·h/mL				
geometric mean (geometric coefficient of variation)	76.9 (± 19.5)	76.8 (± 42.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: AUC (0-tz) (area under the concentration-time curve of Cytarabine in plasma over the time interval from 0 to the time of the last quantifiable data point)

End point title	AUC (0-tz) (area under the concentration-time curve of Cytarabine in plasma over the time interval from 0 to the time of the last quantifiable data point)

End point description:

AUC (0-tz) of Cytarabine after a 20 mg Subcutaneous Dose on the First Day of BI 811283

Only patients included in treated set with observed cases values were considered for evaluation.

End point type	Secondary

End point timeframe:

-0.05 hours before and 0:30, 1:00, 1:30, 2:00, 3:00, 4:00, 6:00 hours after administration of Cytarabine

End point values	5mg BI 811283+ 20mg Cytarabine- Treatment Schedule A	15mg BI 811283 +20mg Cytarabine - Treatment Schedule A	30mg BI 811283+ 20mg Cytarabine- Treatment Schedule A	60mg BI 811283+ 20mg Cytarabine - Treatment Schedule A
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	3	4
Units: ng·h/L				
geometric mean (geometric coefficient of variation)	45 (± 156)	66.9 (± 73.8)	66.8 (± 57.6)	71.8 (± 26.4)

End point values	100mg BI 811283+ 20mg Cytarabine - Treatment Schedule A	120mg BI 811283+ 20mg Cytarabine - Treatment Schedule A	5mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	40mg BI 811283+ 20mg Cytarabine- Treatment Schedule B

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	7	4	3
Units: ng·h/L				
geometric mean (geometric coefficient of variation)	46.6 (± 51.2)	42.3 (± 64.3)	45.9 (± 20)	33.9 (± 245)

End point values	80mg BI 811283+ 20mg Cytarabine-Treatment Schedule B	160mg BI 811283+ 20mg Cytarabine-Treatment Schedule B	240mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	300mg BI 811283+ 20mg Cytarabine - Treatment Schedule B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	3	7	3
Units: ng·h/L				
geometric mean (geometric coefficient of variation)	57 (± 18.2)	60.2 (± 30.4)	52.5 (± 38.8)	52.1 (± 42.1)

End point values	360mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	420mg BI 811283+ 20mg Cytarabine-Treatment Schedule B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	6		
Units: ng·h/L				
geometric mean (geometric coefficient of variation)	41.3 (± 87.2)	51.6 (± 38.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacodynamic Monitoring

End point title	Pharmacodynamic Monitoring

End point description:

Pharmacodynamic monitoring: drug effect on leukaemia cells (e.g. polyploidy, histone H3 phosphorylation, morphologic changes).

An evaluation of this secondary endpoint is not possible due to missing samples/ samples of poor quality of the provided material.

Only patients included in treated set (TS) were considered for evaluation.

End point type	Secondary

End point timeframe:

On Day 5, i.e. 72 hours after the end of the first BI 811283 infusion, and on Day 28 in the first cycle only

End point values	5mg BI 811283+ 20mg Cytarabine- Treatment Schedule A	15mg BI 811283 +20mg Cytarabine - Treatment Schedule A	30mg BI 811283+ 20mg Cytarabine- Treatment Schedule A	60mg BI 811283+ 20mg Cytarabine - Treatment Schedule A
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[23]	0[24]	0[25]	0[26]
Units: NA				
number (not applicable)				

Notes:

[23] - Due to the premature termination of the trial, no subjects were analysed

[24] - Due to the premature termination of the trial, no subjects were analysed

[25] - Due to the premature termination of the trial, no subjects were analysed

[26] - Due to the premature termination of the trial, no subjects were analysed

End point values	100mg BI 811283+ 20mg Cytarabine - Treatment Schedule A	120mg BI 811283+ 20mg Cytarabine - Treatment Schedule A	5mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	40mg BI 811283+ 20mg Cytarabine- Treatment Schedule B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[27]	0[28]	0[29]	0[30]
Units: NA				
number (not applicable)				

Notes:

[27] - Due to the premature termination of the trial, no subjects were analysed

[28] - Due to the premature termination of the trial, no subjects were analysed

[29] - Due to the premature termination of the trial, no subjects were analysed

[30] - Due to the premature termination of the trial, no subjects were analysed

End point values	80mg BI 811283+ 20mg Cytarabine- Treatment Schedule B	160mg BI 811283+ 20mg Cytarabine- Treatment Schedule B	240mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	300mg BI 811283+ 20mg Cytarabine - Treatment Schedule B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[31]	0[32]	0[33]	0[34]
Units: NA				
number (not applicable)				

Notes:

[31] - Due to the premature termination of the trial, no subjects were analysed

[32] - Due to the premature termination of the trial, no subjects were analysed

[33] - Due to the premature termination of the trial, no subjects were analysed

[34] - Due to the premature termination of the trial, no subjects were analysed

End point values	360mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	420mg BI 811283+ 20mg Cytarabine- Treatment Schedule B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[35]	0[36]		
Units: NA				

number (not applicable)				

Notes:

[35] - Due to the premature termination of the trial, no subjects were analysed

[36] - Due to the premature termination of the trial, no subjects were analysed

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacokinetics of Cytarabine After a Single Dose and at Steady State When Given Alone

End point title	Pharmacokinetics of Cytarabine After a Single Dose and at Steady State When Given Alone

End point description:

The study protocol originally included a phase II part with a treatment arm in which Cytarabine was given alone, however the sponsor discontinued the clinical development of BI 811283, therefore the protocol was amended and the reference therapy arm was removed from the study protocol" -> (Protocol Amendment 5, version 19 -May-2010, approved 28-Jun-2010).
Since there was never a treatment arm in which Cytarabine was given alone; hence pharmacokinetics are not calculated.

Only patients included in treated set (TS) were considered for evaluation.

End point type	Secondary

End point timeframe:

-0.05, 0:30, 1:00, 1:30, 2:00, 3:00, 4:00, 6:00 hours

End point values	5mg BI 811283+ 20mg Cytarabine- Treatment Schedule A	15mg BI 811283 +20mg Cytarabine - Treatment Schedule A	30mg BI 811283+ 20mg Cytarabine- Treatment Schedule A	60mg BI 811283+ 20mg Cytarabine - Treatment Schedule A
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[37]	0[38]	0[39]	0[40]
Units: NA				
number (not applicable)				

Notes:

[37] - There was never a treatment arm in which Cytarabine was given alone, thus no subjects were analysed.

[38] - There was never a treatment arm in which Cytarabine was given alone, thus no subjects were analysed.

[39] - There was never a treatment arm in which Cytarabine was given alone, thus no subjects were analysed.

[40] - There was never a treatment arm in which Cytarabine was given alone, thus no subjects were analysed.

End point values	100mg BI 811283+ 20mg Cytarabine - Treatment Schedule A	120mg BI 811283+ 20mg Cytarabine - Treatment Schedule A	5mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	40mg BI 811283+ 20mg Cytarabine- Treatment Schedule B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[41]	0[42]	0[43]	0[44]
Units: NA				

number (not applicable)				

Notes:

[41] - There was never a treatment arm in which Cytarabine was given alone, thus no subjects were analysed.
[42] - There was never a treatment arm in which Cytarabine was given alone, thus no subjects were analysed.
[43] - There was never a treatment arm in which Cytarabine was given alone, thus no subjects were analysed.
[44] - There was never a treatment arm in which Cytarabine was given alone, thus no subjects were analysed.

End point values	80mg BI 811283+ 20mg Cytarabine- Treatment Schedule B	160mg BI 811283+ 20mg Cytarabine- Treatment Schedule B	240mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	300mg BI 811283+ 20mg Cytarabine - Treatment Schedule B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[45]	0[46]	0[47]	0[48]
Units: NA				
number (not applicable)				

Notes:

[45] - There was never a treatment arm in which Cytarabine was given alone, thus no subjects were analysed.
[46] - There was never a treatment arm in which Cytarabine was given alone, thus no subjects were analysed.
[47] - There was never a treatment arm in which Cytarabine was given alone, thus no subjects were analysed.
[48] - There was never a treatment arm in which Cytarabine was given alone, thus no subjects were analysed.

End point values	360mg BI 811283+ 20mg Cytarabine - Treatment Schedule B	420mg BI 811283+ 20mg Cytarabine- Treatment Schedule B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[49]	0[50]		
Units: NA				
number (not applicable)				

Notes:

[49] - There was never a treatment arm in which Cytarabine was given alone, thus no subjects were analysed.
[50] - There was never a treatment arm in which Cytarabine was given alone, thus no subjects were analysed.

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

Data from first treatment administration until cut-off date of 20 October 2011; up to 1239 days

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	14.1

Reporting groups

Reporting group title	5mg BI 811283 + 20mg Cytarabine - Treatment Schedule A

Reporting group description:

5 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment Schedule A: BI 811283 on Days 1 + 15 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion Cytarabine: subcutaneous injection

Reporting group title	15mg BI 811283 + 20mg Cytarabine - Treatment Schedule A

Reporting group description:

15 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment Schedule A: BI 811283 on Days 1 + 15 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion Cytarabine: subcutaneous injection

Reporting group title	30mg BI 811283 + 20mg Cytarabine - Treatment Schedule A

Reporting group description:

30 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment Schedule A: BI 811283 on Days 1 + 15 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion Cytarabine: subcutaneous injection

Reporting group title	60mg BI 811283 + 20mg Cytarabine - Treatment Schedule A

Reporting group description:

60 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment Schedule A: BI 811283 on Days 1 + 15 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion Cytarabine: subcutaneous injection

Reporting group title	100mg BI 811283 + 20mg Cytarabine - Treatment Schedule A

Reporting group description:

100 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment Schedule A: BI 811283 on Days 1 + 15 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion Cytarabine: subcutaneous injection

Reporting group title	120mg BI 811283 + 20mg Cytarabine - Treatment Schedule A

Reporting group description:

120 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment Schedule A: BI 811283 on Days 1 + 15 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion Cytarabine: subcutaneous injection

Reporting group title	5mg BI 811283 + 20mg Cytarabine - Treatment Schedule B

Reporting group description:

5 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment schedule B: BI 811283 on Day 1 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion Cytarabine: subcutaneous injection

Reporting group title	40mg BI 811283 + 20mg Cytarabine - Treatment Schedule B

Reporting group description:

40 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment schedule B: BI 811283 on Day 1 in combination with cytarabine 20 mg twice

daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion
Cytarabine: subcutaneous injection

Reporting group title	80mg BI 811283 + 20mg Cytarabine - Treatment Schedule B

Reporting group description:

80 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment schedule B: BI 811283 on Day 1 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion
Cytarabine: subcutaneous injection

Reporting group title	160mg BI 811283 + 20mg Cytarabine - Treatment Schedule B

Reporting group description:

160 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment schedule B: BI 811283 on Day 1 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion
Cytarabine: subcutaneous injection

Reporting group title	240mg BI 811283 + 20mg Cytarabine - Treatment Schedule B

Reporting group description:

240 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment schedule B: BI 811283 on Day 1 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion
Cytarabine: subcutaneous injection

Reporting group title	300mg BI 811283 + 20mg Cytarabine - Treatment Schedule B

Reporting group description:

300 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment schedule B: BI 811283 on Day 1 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion
Cytarabine: subcutaneous injection

Reporting group title	360mg BI 811283 + 20mg Cytarabine - Treatment Schedule B

Reporting group description:

360 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment schedule B: BI 811283 on Day 1 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion
Cytarabine: subcutaneous injection

Reporting group title	420mg BI 811283 + 20mg Cytarabine - Treatment Schedule B

Reporting group description:

420 mg of BI 811283 (preconcentrate for infusion after dilution) in combination with cytarabine (solution for injection); Treatment schedule B: BI 811283 on Day 1 in combination with cytarabine 20 mg twice daily on Days 1-10 (28-day cycle); BI 811283: 24-hour continuous intravenous infusion
Cytarabine: subcutaneous injection

Serious adverse events	5mg BI 811283 + 20mg Cytarabine - Treatment Schedule A	15mg BI 811283 + 20mg Cytarabine - Treatment Schedule A	30mg BI 811283 + 20mg Cytarabine - Treatment Schedule A
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 4 (75.00%)	2 / 3 (66.67%)	3 / 3 (100.00%)
number of deaths (all causes)	4	3	2
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
Hypotension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
Asthenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 3 (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
General physical health deterioration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multi-organ failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 / 4 (25.00%)	2 / 3 (66.67%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 infiltration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
Confusional state			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood uric acid increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
C-reactive protein increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transaminases increased			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 / 4 (25.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urostomy complication			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
Aplasia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 3 (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
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 fibrillation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral ischaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Convulsion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Eye haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blindness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
Diarrhoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
Cholecystitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
Renal failure			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 3 (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
Renal failure acute			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
Abscess			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis infective			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocarditis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Folliculitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gingivitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Groin abscess			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
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 infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 / 4 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic sepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 / 4 (50.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pneumonia fungal			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 3 (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
Sepsis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 3 (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
Skin infection			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 / 4 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
Hyperuricaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fasciitis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 3 (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

Serious adverse events	60mg BI 811283 + 20mg Cytarabine - Treatment Schedule A	100mg BI 811283 + 20mg Cytarabine - Treatment Schedule A	120mg BI 811283 + 20mg Cytarabine - Treatment Schedule A
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 4 (100.00%)	6 / 7 (85.71%)	6 / 7 (85.71%)
number of deaths (all causes)	3	6	7
number of deaths resulting from adverse events	0	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
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			
Asthenia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 7 (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
Death			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
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	1 / 4 (25.00%)	0 / 7 (0.00%)	2 / 7 (28.57%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Multi-organ failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pyrexia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 7 (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
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			

subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 7 (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
Epistaxis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
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 infiltration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
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	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 7 (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
Pulmonary embolism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
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 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
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			
Confusional state			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 7 (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
Investigations			
Blood uric acid increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
C-reactive protein increased			

subjects affected / exposed	1 / 4 (25.00%)	1 / 7 (14.29%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transaminases increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
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	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urostomy complication			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 7 (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			
Aplasia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
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 myocardial infarction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
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	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
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	1 / 4 (25.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac fibrillation			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 7 (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
Tachycardia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 7 (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
Nervous system disorders			
Cerebral haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 7 (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
Cerebral ischaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Convulsion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
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 / 4 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			

Disseminated intravascular coagulation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
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 / 4 (50.00%)	2 / 7 (28.57%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 7 (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
Eye disorders			
Eye haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blindness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
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			
Diarrhoea			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 7 (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 haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
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	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 7 (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

Rectal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
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 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
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			
Cholecystitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
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			
Renal failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
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 acute			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abscess			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis infective			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
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 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
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 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
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 / 4 (0.00%)	1 / 7 (14.29%)	0 / 7 (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
Diverticulitis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 7 (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
Endocarditis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
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 / 4 (0.00%)	1 / 7 (14.29%)	0 / 7 (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
Folliculitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gingivitis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Groin abscess			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
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 infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
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 / 4 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Osteomyelitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
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 / 4 (50.00%)	2 / 7 (28.57%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pneumonia fungal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
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 / 4 (0.00%)	1 / 7 (14.29%)	0 / 7 (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 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
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			
Hyperuricaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
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 / 4 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fasciitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
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	5mg BI 811283 + 20mg Cytarabine - Treatment Schedule B	40mg BI 811283 + 20mg Cytarabine - Treatment Schedule B	80mg BI 811283 + 20mg Cytarabine - Treatment Schedule B
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 4 (100.00%)	3 / 4 (75.00%)	5 / 5 (100.00%)
number of deaths (all causes)	4	3	5

number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (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 / 1	0 / 0	0 / 1
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Death			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 / 4 (0.00%)	0 / 4 (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
Multi-organ failure			
subjects affected / exposed	0 / 4 (0.00%)	2 / 4 (50.00%)	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 / 1	0 / 0
Pyrexia			
subjects affected / exposed	2 / 4 (50.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	2 / 3	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			

Dyspnoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 / 4 (0.00%)	0 / 4 (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 infiltration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 / 4 (0.00%)	0 / 4 (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 / 4 (0.00%)	0 / 4 (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 failure			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	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 / 1	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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			
Blood uric acid increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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

C-reactive protein increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Transaminases increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (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
Subdural haematoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Urostomy complication			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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			
Aplasia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 myocardial infarction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 fibrillation			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 / 4 (0.00%)	0 / 4 (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 / 1	0 / 0	0 / 0
Cardiac fibrillation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 / 4 (0.00%)	0 / 4 (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 ischaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Convulsion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Dizziness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Blood and lymphatic system disorders			

Disseminated intravascular coagulation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Febrile neutropenia			
subjects affected / exposed	3 / 4 (75.00%)	1 / 4 (25.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	1 / 3	1 / 2	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Eye disorders			
Eye haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Blindness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 / 4 (0.00%)	0 / 4 (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 / 4 (0.00%)	0 / 4 (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 haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 / 4 (0.00%)	0 / 4 (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
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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			
Renal failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 acute			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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			
Abscess			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (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
Arthritis infective			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 sepsis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 / 4 (0.00%)	0 / 4 (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
Clostridium difficile infection			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	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
Device related infection			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	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
Diverticulitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Endocarditis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	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
Escherichia sepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Folliculitis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (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
Gingivitis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Groin abscess			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 / 4 (0.00%)	0 / 4 (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 / 4 (0.00%)	0 / 4 (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
Osteomyelitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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
Pneumonia			
subjects affected / exposed	1 / 4 (25.00%)	2 / 4 (50.00%)	2 / 5 (40.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	1 / 2
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Pneumonia fungal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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	0 / 4 (0.00%)	0 / 4 (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 infection			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	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
Staphylococcal infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 / 4 (0.00%)	0 / 4 (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
Metabolism and nutrition disorders			
Hyperuricaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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 / 4 (0.00%)	0 / 4 (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
Fasciitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (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	160mg BI 811283 + 20mg Cytarabine - Treatment Schedule B	240mg BI 811283 + 20mg Cytarabine - Treatment Schedule B	300mg BI 811283 + 20mg Cytarabine - Treatment Schedule B
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	7 / 7 (100.00%)	3 / 4 (75.00%)
number of deaths (all causes)	2	6	3

number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 4 (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
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 4 (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			
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
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	2 / 3 (66.67%)	3 / 7 (42.86%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Multi-organ failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
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 / 3 (33.33%)	0 / 7 (0.00%)	0 / 4 (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
Respiratory, thoracic and mediastinal disorders			

Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
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 / 3 (0.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infiltration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
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			
Confusional state			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood uric acid increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

C-reactive protein increased			
subjects affected / exposed	2 / 3 (66.67%)	1 / 7 (14.29%)	0 / 4 (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
Transaminases increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 4 (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
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
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	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urostomy complication			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
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			
Aplasia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
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 myocardial infarction			
subjects affected / exposed	1 / 3 (33.33%)	1 / 7 (14.29%)	0 / 4 (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
Atrial fibrillation			

subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 4 (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
Cardiac failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
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 fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral ischaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Convulsion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
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			

Disseminated intravascular coagulation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
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	1 / 3 (33.33%)	2 / 7 (28.57%)	2 / 4 (50.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 4 (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
Eye disorders			
Eye haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blindness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
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			
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 4 (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 haemorrhage			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 4 (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
Nausea			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 4 (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	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 4 (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 and urinary disorders			
Renal failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
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 acute			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
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			
Abscess			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis infective			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 4 (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
Bacterial sepsis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocarditis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Folliculitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gingivitis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Groin abscess			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
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 infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
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 / 3 (0.00%)	1 / 7 (14.29%)	0 / 4 (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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
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	0 / 3 (0.00%)	2 / 7 (28.57%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia fungal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
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	1 / 3 (33.33%)	1 / 7 (14.29%)	2 / 4 (50.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 2
Skin infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hyperuricaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fasciitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
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	360mg BI 811283 + 20mg Cytarabine - Treatment Schedule B	420mg BI 811283 + 20mg Cytarabine - Treatment Schedule B	
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	5 / 6 (83.33%)	
number of deaths (all causes)	2	6	

number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	0 / 3 (0.00%)	2 / 6 (33.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General physical health deterioration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multi-organ failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			

Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epistaxis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung infiltration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory failure			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Blood uric acid increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

C-reactive protein increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transaminases increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdural haematoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urostomy complication			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Aplasia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Cerebral haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral ischaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Convulsion			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dizziness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			

Disseminated intravascular coagulation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile neutropenia			
subjects affected / exposed	2 / 3 (66.67%)	2 / 6 (33.33%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukocytosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Eye haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blindness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Rectal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Renal failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure acute			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Abscess			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis infective			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial sepsis			

subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocarditis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Folliculitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gingivitis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Groin abscess			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematoma infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenic sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 6 (16.67%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pneumonia fungal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tooth infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Hyperuricaemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tumour lysis syndrome			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fasciitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	5mg BI 811283 + 20mg Cytarabine - Treatment Schedule A	15mg BI 811283 + 20mg Cytarabine - Treatment Schedule A	30mg BI 811283 + 20mg Cytarabine - Treatment Schedule A
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 4 (100.00%)	3 / 3 (100.00%)	3 / 3 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Osteoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Metastases to bone			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Circulatory collapse			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypertensive crisis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Intra-abdominal haematoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Lymphoedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Jugular vein thrombosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Phlebitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis			
subjects affected / exposed	1 / 4 (25.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Orthostatic hypotension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thrombosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vasculitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Central venous catheterisation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Catheterisation venous			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Adverse drug reaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Catheter site erythema			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Catheter site inflammation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Catheter site haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Facial pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Feeling cold			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	2 / 3 (66.67%)
occurrences (all)	0	1	2
General physical health deterioration			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Gait disturbance			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Inflammation			

subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Injection site inflammation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Localised oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Local swelling			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mass			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	1 / 4 (25.00%)	2 / 3 (66.67%)	0 / 3 (0.00%)
occurrences (all)	1	2	0
Oedema			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1
Oedema peripheral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Vessel puncture site pain			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Social circumstances			
Bedridden			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Breast pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vaginal inflammation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Atelectasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bronchial secretion retention			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Epistaxis			
subjects affected / exposed	1 / 4 (25.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	1	1	0

Dyspnoea			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences (all)	0	2	3
Hiccups			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemothorax			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Increased upper airway secretion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lung infiltration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lung disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Obstructive airways disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pharyngeal erythema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Pharyngeal oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Productive cough			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pulmonary mass			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pulmonary oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory acidosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rales			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhonchi			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Stridor			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tachypnoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Agitation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Confusional state			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Depression			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Catatonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Disorientation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Illusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Panic attack			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mood altered			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Sleep disorder			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Restlessness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Psychotic disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Investigations			

Activated partial thromboplastin time			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Antithrombin III decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Basophil count increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood calcium decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood chloride increased			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood chloride decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood calcium increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood cholinesterase decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood creatinine decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood glucose increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood fibrinogen increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood magnesium decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Blood phosphorus increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood potassium decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood potassium increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood sodium decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood urea increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood triglycerides increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood uric acid increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood urine present			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eosinophil count increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fibrin D dimer increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Heart rate increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mean cell haemoglobin concentration increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mean cell volume decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oxygen saturation decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Protein total decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Prothrombin time prolonged			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Protein total increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Prothrombin time shortened			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
pH urine decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Angina pectoris			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Bradycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pericardial effusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Myocardial ischaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cardiovascular insufficiency			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Right ventricular failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Supraventricular tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ventricular tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ventricular extrasystoles			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Ageusia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Aphasia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Cerebral ischaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Balance disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dementia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Convulsion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dizziness			

subjects affected / exposed	1 / 4 (25.00%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences (all)	1	2	1
Disturbance in attention			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hemiparesis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Headache			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Dysgeusia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypotonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Spinal haematoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Transient ischaemic attack			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 4 (25.00%)	2 / 3 (66.67%)	1 / 3 (33.33%)
occurrences (all)	1	5	1
Disseminated intravascular coagulation			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Febrile neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences (all)	0	2	2
Leukocytosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Leukopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Lymphadenopathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 4 (0.00%)	2 / 3 (66.67%)	1 / 3 (33.33%)
occurrences (all)	0	3	1
Neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Cerumen impaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ear haemorrhage			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eyelid oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eyelid bleeding			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Photopsia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Visual impairment			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal discomfort			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Abdominal pain upper			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Anal fissure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Anal ulcer			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Anal haemorrhage			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Ascites			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Aphthous stomatitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	1 / 4 (25.00%)	2 / 3 (66.67%)	0 / 3 (0.00%)
occurrences (all)	2	2	0
Diarrhoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry mouth			

subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Faecal incontinence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Faecaloma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gingival bleeding			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Gingival swelling			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haematemesis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Lip ulceration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mouth haemorrhage			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Melaena			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	2 / 4 (50.00%)	2 / 3 (66.67%)	0 / 3 (0.00%)
occurrences (all)	2	2	0
Oral disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral mucosal erythema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Palatal disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Parotid gland enlargement			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Periodontal disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rectal tenesmus			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Retching			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Salivary gland pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Tongue coated			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tongue discolouration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Vomiting			
subjects affected / exposed	1 / 4 (25.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Hepatobiliary disorders			
Hepatic cyst			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hepatic lesion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hepatic vein occlusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cold sweat			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Decubitus ulcer			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Drug eruption			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Erythema nodosum			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Milia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Pain of skin			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Palmar erythema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	4	0
Papule			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Petechiae			
subjects affected / exposed	2 / 4 (50.00%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences (all)	3	2	1
Pruritus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Psoriasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Pruritus generalised			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin hyperpigmentation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Swelling face			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin mass			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Bladder spasm			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemoglobinuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Incontinence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Micturition urgency			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Micturition disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Renal disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Renal cyst			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Renal failure acute			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Arthralgia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1
Bone lesion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Bursitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fistula			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Groin pain			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fracture pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemarthrosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mobility decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Muscle disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	2
Muscular weakness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Pain in extremity			

subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Pain in jaw			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Spinal osteoarthritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Spinal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tendon pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bacterial disease carrier			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bronchiolitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Clostridial infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Device related infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Enterobacter infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Enterococcal infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Erysipelas			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Herpes simplex			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Localised infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Infectious disease carrier			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Oral herpes			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Periodontitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Pneumonia fungal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pseudomonas infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Postoperative wound infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Puncture site infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection fungal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Skin infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin candida			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Soft tissue infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Staphylococcal infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Urinary tract infection staphylococcal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Allergic transfusion reaction			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Bone contusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Excoriation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Drug administration error			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Fall			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Head injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Laceration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Post procedural haematoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Lumbar vertebral fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Post procedural inflammation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Post procedural haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Procedural dizziness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pubis fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rib fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Transfusion reaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tracheal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Traumatic haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Wrist fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Metabolism and nutrition disorders			
Acidosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Alkalosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dehydration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperlipidaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			

subjects affected / exposed	1 / 4 (25.00%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences (all)	1	1	1
Iron overload			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Metabolic disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tumour lysis syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	60mg BI 811283 + 20mg Cytarabine - Treatment Schedule A	100mg BI 811283 + 20mg Cytarabine - Treatment Schedule A	120mg BI 811283 + 20mg Cytarabine - Treatment Schedule A
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 4 (100.00%)	7 / 7 (100.00%)	7 / 7 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Osteoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Metastases to bone			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Circulatory collapse			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	3 / 4 (75.00%)	2 / 7 (28.57%)	2 / 7 (28.57%)
occurrences (all)	3	2	2
Hypertension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Hypertensive crisis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Hot flush			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	1 / 4 (25.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	2	1	0
Intra-abdominal haematoma			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Lymphoedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Jugular vein thrombosis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Phlebitis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Thrombophlebitis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Orthostatic hypotension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Thrombosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vasculitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Central venous catheterisation			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Catheterisation venous			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Adverse drug reaction			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Asthenia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Catheter site erythema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Catheter site inflammation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Catheter site haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Chills			
subjects affected / exposed	3 / 4 (75.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	3	0	1
Discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Facial pain			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Feeling cold			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	1 / 4 (25.00%)	3 / 7 (42.86%)	2 / 7 (28.57%)
occurrences (all)	2	3	2
General physical health deterioration			
subjects affected / exposed	0 / 4 (0.00%)	4 / 7 (57.14%)	2 / 7 (28.57%)
occurrences (all)	0	4	6
Gait disturbance			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Inflammation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Injection site inflammation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Injection site reaction			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Localised oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Local swelling			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Mass			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Oedema			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Oedema peripheral			
subjects affected / exposed	1 / 4 (25.00%)	2 / 7 (28.57%)	1 / 7 (14.29%)
occurrences (all)	1	3	1
Pyrexia			
subjects affected / exposed	1 / 4 (25.00%)	3 / 7 (42.86%)	3 / 7 (42.86%)
occurrences (all)	1	3	4
Pain			
subjects affected / exposed	3 / 4 (75.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	4	0	0
Vessel puncture site pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Social circumstances			
Bedridden			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Reproductive system and breast disorders			
Breast pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vaginal inflammation			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			

Atelectasis			
subjects affected / exposed	1 / 4 (25.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Bronchial secretion retention			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	2 / 4 (50.00%)	2 / 7 (28.57%)	3 / 7 (42.86%)
occurrences (all)	4	2	4
Epistaxis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	2 / 7 (28.57%)
occurrences (all)	0	1	3
Dyspnoea			
subjects affected / exposed	0 / 4 (0.00%)	2 / 7 (28.57%)	4 / 7 (57.14%)
occurrences (all)	0	3	7
Hiccups			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Haemoptysis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Haemothorax			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Increased upper airway secretion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lung infiltration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lung disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Obstructive airways disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Pharyngeal erythema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 4 (25.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	2	1	0
Pharyngeal oedema			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Pleural effusion			
subjects affected / exposed	1 / 4 (25.00%)	2 / 7 (28.57%)	0 / 7 (0.00%)
occurrences (all)	1	2	0
Productive cough			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Pulmonary mass			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Pulmonary oedema			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Respiratory acidosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Rales			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Rhonchi			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	1 / 7 (14.29%)
occurrences (all)	0	1	2
Stridor			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0

Respiratory failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	2
Tachypnoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Agitation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	1 / 4 (25.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Depression			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Catatonia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Disorientation			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	3	0	0
Hallucination			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Insomnia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Illusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Panic attack			

subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Mood altered			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Restlessness			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Psychotic disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Antithrombin III decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Amylase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase decreased			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Basophil count increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Blood calcium decreased			
subjects affected / exposed	0 / 4 (0.00%)	3 / 7 (42.86%)	1 / 7 (14.29%)
occurrences (all)	0	11	1
Blood chloride increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood chloride decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood calcium increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood cholinesterase decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood creatinine decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	1 / 7 (14.29%)
occurrences (all)	0	2	3

Blood glucose increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood fibrinogen increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood magnesium decreased			
subjects affected / exposed	0 / 4 (0.00%)	2 / 7 (28.57%)	1 / 7 (14.29%)
occurrences (all)	0	2	1
Blood phosphorus decreased			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	2 / 7 (28.57%)
occurrences (all)	0	1	2
Blood phosphorus increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood potassium decreased			
subjects affected / exposed	1 / 4 (25.00%)	5 / 7 (71.43%)	4 / 7 (57.14%)
occurrences (all)	3	13	8
Blood potassium increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood sodium decreased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Blood urea increased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	1 / 7 (14.29%)
occurrences (all)	0	2	2
Blood triglycerides increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood uric acid increased			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Blood urine present			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	2 / 4 (50.00%)	4 / 7 (57.14%)	2 / 7 (28.57%)
occurrences (all)	3	4	2
Eosinophil count increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fibrin D dimer increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Heart rate increased			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Lipase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Mean cell haemoglobin concentration increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Mean cell volume decreased			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oxygen saturation decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Protein total decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Prothrombin time prolonged			
subjects affected / exposed	1 / 4 (25.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Protein total increased			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Prothrombin time shortened			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Weight decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	2
Weight increased			
subjects affected / exposed	1 / 4 (25.00%)	1 / 7 (14.29%)	1 / 7 (14.29%)
occurrences (all)	1	1	1
pH urine decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Angina pectoris			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1

Bradycardia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Atrial fibrillation			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Pericardial effusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Myocardial ischaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cardiovascular insufficiency			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Right ventricular failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Supraventricular tachycardia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Ventricular tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Ventricular extrasystoles			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Ageusia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Aphasia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cerebral ischaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Balance disorder			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Dementia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Convulsion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	1 / 4 (25.00%)	2 / 7 (28.57%)	2 / 7 (28.57%)
occurrences (all)	1	2	2
Disturbance in attention			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hemiparesis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	1 / 4 (25.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Dysgeusia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypotonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Spinal haematoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Tremor			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Transient ischaemic attack			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 4 (25.00%)	5 / 7 (71.43%)	5 / 7 (71.43%)
occurrences (all)	5	7	7
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Febrile neutropenia			
subjects affected / exposed	1 / 4 (25.00%)	2 / 7 (28.57%)	2 / 7 (28.57%)
occurrences (all)	1	2	3
Leukocytosis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	2 / 7 (28.57%)
occurrences (all)	0	3	3
Lymph node pain			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	1 / 4 (25.00%)	4 / 7 (57.14%)	5 / 7 (71.43%)
occurrences (all)	3	8	8
Lymphadenopathy			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Thrombocytopenia			
subjects affected / exposed	2 / 4 (50.00%)	2 / 7 (28.57%)	2 / 7 (28.57%)
occurrences (all)	4	3	11
Neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	1 / 7 (14.29%)
occurrences (all)	0	2	2
Ear and labyrinth disorders			
Cerumen impaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ear haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Eye disorders			
Cataract			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye pain			

subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Eyelid oedema			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Eyelid bleeding			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Photopsia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	2 / 4 (50.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	3	1	0
Abdominal discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	1 / 4 (25.00%)	1 / 7 (14.29%)	2 / 7 (28.57%)
occurrences (all)	1	2	2
Abdominal pain lower			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Anal fissure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Anal ulcer			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Anal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Aphthous stomatitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Constipation			
subjects affected / exposed	2 / 4 (50.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	3	1	0
Diarrhoea			
subjects affected / exposed	2 / 4 (50.00%)	3 / 7 (42.86%)	1 / 7 (14.29%)
occurrences (all)	4	5	1
Dry mouth			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Faecal incontinence			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Dyspepsia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Dysphagia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Faecaloma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Gingival pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gingival bleeding			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gingival swelling			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haematemesis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lip ulceration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Mouth haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	2 / 4 (50.00%)	3 / 7 (42.86%)	4 / 7 (57.14%)
occurrences (all)	4	5	7
Oral disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Oral mucosal erythema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Palatal disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Parotid gland enlargement			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Periodontal disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rectal tenesmus			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Retching			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Salivary gland pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	1 / 4 (25.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	2	1	0
Tongue coated			
subjects affected / exposed	1 / 4 (25.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Tongue discolouration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Toothache			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Vomiting			
subjects affected / exposed	1 / 4 (25.00%)	4 / 7 (57.14%)	3 / 7 (42.86%)
occurrences (all)	2	5	7
Hepatobiliary disorders			
Hepatic cyst			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hepatic lesion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hepatic vein occlusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	1 / 4 (25.00%)	1 / 7 (14.29%)	2 / 7 (28.57%)
occurrences (all)	1	1	2
Cold sweat			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Decubitus ulcer			
subjects affected / exposed	1 / 4 (25.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Dermatitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Drug eruption			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Dry skin			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Erythema			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Erythema nodosum			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Milia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hyperhidrosis			
subjects affected / exposed	1 / 4 (25.00%)	1 / 7 (14.29%)	1 / 7 (14.29%)
occurrences (all)	1	2	1
Pain of skin			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Palmar erythema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Night sweats			
subjects affected / exposed	2 / 4 (50.00%)	2 / 7 (28.57%)	1 / 7 (14.29%)
occurrences (all)	2	2	1
Papule			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	1 / 4 (25.00%)	1 / 7 (14.29%)	1 / 7 (14.29%)
occurrences (all)	1	1	2
Pruritus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Psoriasis			

subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Pruritus generalised			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin hyperpigmentation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Swelling face			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin mass			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Bladder spasm			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haemoglobinuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	2

Incontinence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Micturition urgency			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Micturition disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Renal disorder			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Renal cyst			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Renal failure acute			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Renal failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Urinary incontinence			
subjects affected / exposed	1 / 4 (25.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Musculoskeletal and connective tissue disorders			

Back pain			
subjects affected / exposed	1 / 4 (25.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	1	2	0
Arthralgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Bone lesion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Bursitis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Fistula			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Groin pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fracture pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Haemarthrosis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Mobility decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Muscle disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 4 (0.00%)	2 / 7 (28.57%)	1 / 7 (14.29%)
occurrences (all)	0	2	1
Pain in jaw			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Spinal osteoarthritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Spinal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tendon pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bacterial disease carrier			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	2
Bronchiolitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Clostridial infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Clostridium difficile infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Device related infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Enterobacter infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Enterococcal infection			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Erysipelas			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Fungal skin infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Infection			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Localised infection			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Infectious disease carrier			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Nasopharyngitis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Oral herpes			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Periodontitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Pneumonia fungal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pseudomonas infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Postoperative wound infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Puncture site infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection fungal			

subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Sinusitis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Rhinitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	1 / 7 (14.29%)
occurrences (all)	0	2	1
Skin candida			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Soft tissue infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Staphylococcal infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Urinary tract infection staphylococcal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Allergic transfusion reaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Bone contusion			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Contusion			

subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Excoriation			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Drug administration error			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Fall			
subjects affected / exposed	2 / 4 (50.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	4	1	0
Head injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Laceration			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Post procedural haematoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lumbar vertebral fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Post procedural inflammation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Post procedural haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Procedural dizziness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Pubis fracture			

subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rib fracture			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Transfusion reaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tracheal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Traumatic haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 4 (0.00%)	2 / 7 (28.57%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Wrist fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Acidosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	0 / 4 (0.00%)	4 / 7 (57.14%)	4 / 7 (57.14%)
occurrences (all)	0	5	5
Alkalosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dehydration			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hyperglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	1 / 7 (14.29%)
occurrences (all)	0	2	1

Hyperkalaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Hyperlipidaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hypoglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hyponatraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	2 / 4 (50.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Iron overload			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Metabolic disorder			
subjects affected / exposed	1 / 4 (25.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Tumour lysis syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 7 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	2

Non-serious adverse events	5mg BI 811283 + 20mg Cytarabine - Treatment Schedule B	40mg BI 811283 + 20mg Cytarabine - Treatment Schedule B	80mg BI 811283 + 20mg Cytarabine - Treatment Schedule B
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 4 (100.00%)	4 / 4 (100.00%)	5 / 5 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Osteoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Metastases to bone			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Circulatory collapse			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Flushing			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	2 / 5 (40.00%)
occurrences (all)	2	0	3
Hypertension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypertensive crisis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	1 / 4 (25.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Intra-abdominal haematoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	2 / 5 (40.00%)
occurrences (all)	0	0	2
Lymphoedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Jugular vein thrombosis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Phlebitis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	1
Thrombophlebitis			
subjects affected / exposed	1 / 4 (25.00%)	1 / 4 (25.00%)	1 / 5 (20.00%)
occurrences (all)	2	1	2
Orthostatic hypotension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Thrombosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vasculitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Surgical and medical procedures			
Central venous catheterisation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	2
Catheterisation venous			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Adverse drug reaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Catheter site erythema			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Catheter site inflammation			

subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0
Catheter site haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Catheter site pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	2
Chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	2 / 5 (40.00%)
occurrences (all)	1	0	2
Discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Facial pain			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Feeling cold			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	1 / 4 (25.00%)	2 / 4 (50.00%)	1 / 5 (20.00%)
occurrences (all)	2	2	5
General physical health deterioration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Inflammation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Injection site inflammation			

subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Injection site pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	2 / 5 (40.00%)
occurrences (all)	0	0	3
Localised oedema			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Local swelling			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	2 / 5 (40.00%)
occurrences (all)	1	0	2
Mass			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Mucosal inflammation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	2 / 5 (40.00%)
occurrences (all)	0	0	2
Oedema			
subjects affected / exposed	2 / 4 (50.00%)	1 / 4 (25.00%)	2 / 5 (40.00%)
occurrences (all)	3	1	3
Oedema peripheral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	3
Pyrexia			
subjects affected / exposed	2 / 4 (50.00%)	1 / 4 (25.00%)	3 / 5 (60.00%)
occurrences (all)	5	2	6
Pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Vessel puncture site pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			

Hypersensitivity			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Social circumstances			
Bedridden			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Breast pain			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vaginal inflammation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Atelectasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Bronchial secretion retention			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Cough			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	2 / 5 (40.00%)
occurrences (all)	0	1	3
Epistaxis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	8	0	1
Dyspnoea			
subjects affected / exposed	1 / 4 (25.00%)	2 / 4 (50.00%)	1 / 5 (20.00%)
occurrences (all)	1	3	1

Hiccups			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Haemothorax			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Increased upper airway secretion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lung infiltration			
subjects affected / exposed	1 / 4 (25.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Lung disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Obstructive airways disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pharyngeal erythema			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pharyngeal oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	1 / 4 (25.00%)	1 / 4 (25.00%)	1 / 5 (20.00%)
occurrences (all)	1	1	1
Productive cough			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0

Pulmonary mass			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pulmonary oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Respiratory acidosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rales			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Rhonchi			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Stridor			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Respiratory failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tachypnoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Agitation			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Confusional state			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	1 / 5 (20.00%)
occurrences (all)	0	1	1
Depression			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Catatonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Disorientation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Illusion			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Panic attack			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Mood altered			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	1
Restlessness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Psychotic disorder			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Investigations			
Activated partial thromboplastin time			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Alanine aminotransferase decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	6
Activated partial thromboplastin time prolonged			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	5	0	1
Antithrombin III decreased			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	1
Alanine aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Aspartate aminotransferase decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	2
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Basophil count increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Blood bilirubin increased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	1 / 5 (20.00%)
occurrences (all)	0	1	2
Blood calcium decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	3
Blood chloride increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	2
Blood chloride decreased			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	3
Blood calcium increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	2
Blood cholinesterase decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood creatinine decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	2 / 5 (40.00%)
occurrences (all)	0	0	6
Blood glucose increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	3
Blood fibrinogen increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood magnesium decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	2
Blood phosphorus increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	2

Blood potassium decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood potassium increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood sodium decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood urea increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	2
Blood triglycerides increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood uric acid increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood urine present			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
C-reactive protein increased			
subjects affected / exposed	2 / 4 (50.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	3	0	0
Eosinophil count increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Fibrin D dimer increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Haemoglobin decreased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	2 / 5 (40.00%)
occurrences (all)	0	5	3
Gamma-glutamyltransferase increased			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	2
Heart rate increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	2
Lymphocyte count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Mean cell haemoglobin concentration increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Mean cell volume decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	2
Oxygen saturation decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Protein total decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Prothrombin time prolonged			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Protein total increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Prothrombin time shortened			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Weight decreased			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	1
Weight increased			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
pH urine decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Angina pectoris			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Bradycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pericardial effusion			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Myocardial ischaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cardiovascular insufficiency			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Right ventricular failure			

subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Supraventricular tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ventricular tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ventricular extrasystoles			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Ageusia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Aphasia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cerebral ischaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Balance disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dementia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Convulsion			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Dizziness			
subjects affected / exposed	1 / 4 (25.00%)	1 / 4 (25.00%)	3 / 5 (60.00%)
occurrences (all)	2	1	5

Disturbance in attention			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hemiparesis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	1 / 4 (25.00%)	1 / 4 (25.00%)	1 / 5 (20.00%)
occurrences (all)	1	1	1
Dysgeusia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypotonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Syncope			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Spinal haematoma			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Somnolence			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Tremor			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Transient ischaemic attack			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 4 (25.00%)	2 / 4 (50.00%)	1 / 5 (20.00%)
occurrences (all)	2	7	2
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Febrile neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Leukocytosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Lymph node pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	1 / 4 (25.00%)	1 / 4 (25.00%)	1 / 5 (20.00%)
occurrences (all)	1	1	3
Lymphadenopathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	2 / 4 (50.00%)	3 / 4 (75.00%)	3 / 5 (60.00%)
occurrences (all)	5	9	3
Neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	2
Ear and labyrinth disorders			
Cerumen impaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ear haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tinnitus			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Eye haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eyelid oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eyelid bleeding			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Photopsia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Abdominal discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Abdominal pain			

subjects affected / exposed	3 / 4 (75.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	4	0	1
Abdominal pain lower			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	1 / 4 (25.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Anal fissure			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Anal ulcer			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Anal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Aphthous stomatitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Diarrhoea			
subjects affected / exposed	3 / 4 (75.00%)	1 / 4 (25.00%)	2 / 5 (40.00%)
occurrences (all)	3	4	4
Dry mouth			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	1 / 5 (20.00%)
occurrences (all)	0	1	1
Faecal incontinence			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0
Flatulence			
subjects affected / exposed	1 / 4 (25.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Faecaloma			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Gingival pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Gingival bleeding			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Gingival swelling			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Haematemesis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Lip ulceration			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Mouth haemorrhage			
subjects affected / exposed	1 / 4 (25.00%)	1 / 4 (25.00%)	1 / 5 (20.00%)
occurrences (all)	1	1	1
Melaena			
subjects affected / exposed	1 / 4 (25.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Nausea			
subjects affected / exposed	1 / 4 (25.00%)	1 / 4 (25.00%)	3 / 5 (60.00%)
occurrences (all)	1	3	11
Oral disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oral mucosal erythema			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Oral pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Palatal disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Parotid gland enlargement			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Rectal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Periodontal disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rectal tenesmus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Retching			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Salivary gland pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Stomatitis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	1
Tongue coated			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tongue discolouration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	2	0	1
Vomiting			
subjects affected / exposed	2 / 4 (50.00%)	1 / 4 (25.00%)	2 / 5 (40.00%)
occurrences (all)	3	3	5
Hepatobiliary disorders			
Hepatic cyst			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hepatic lesion			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Hepatic vein occlusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Alopecia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cold sweat			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Decubitus ulcer			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Drug eruption			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Eczema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	2 / 5 (40.00%)
occurrences (all)	0	0	2
Erythema nodosum			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Milia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	2
Pain of skin			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Palmar erythema			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	1 / 5 (20.00%)
occurrences (all)	0	2	1
Papule			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	1 / 4 (25.00%)	1 / 4 (25.00%)	1 / 5 (20.00%)
occurrences (all)	2	1	1
Pruritus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	2 / 5 (40.00%)
occurrences (all)	0	0	6
Psoriasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Pruritus generalised			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Skin hyperpigmentation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Swelling face			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Skin ulcer			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin mass			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Bladder spasm			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haemoglobinuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Haematuria			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Incontinence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Micturition urgency			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Micturition disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Nocturia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Renal disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Renal cyst			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0

Renal failure acute			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Urinary retention			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	1
Arthralgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Bone lesion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Bursitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Fistula			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Flank pain			

subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Fracture pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haemarthrosis			
subjects affected / exposed	1 / 4 (25.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	2	1	0
Mobility decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Muscle disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	2
Muscular weakness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Musculoskeletal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	2 / 5 (40.00%)
occurrences (all)	0	0	2
Pain in extremity			
subjects affected / exposed	2 / 4 (50.00%)	1 / 4 (25.00%)	1 / 5 (20.00%)
occurrences (all)	3	1	2
Pain in jaw			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Spinal osteoarthritis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Spinal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tendon pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Infections and infestations			
Bacterial disease carrier			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Bronchiolitis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Candida infection			
subjects affected / exposed	0 / 4 (0.00%)	2 / 4 (50.00%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Clostridial infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile infection			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Conjunctivitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Device related infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Enterobacter infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Enterococcal infection			
subjects affected / exposed	1 / 4 (25.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Erysipelas			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Localised infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Infectious disease carrier			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Oral herpes			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Periodontitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Pneumonia fungal			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Pseudomonas infection			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Postoperative wound infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Puncture site infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection fungal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin candida			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Soft tissue infection			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Staphylococcal infection			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Urinary tract infection staphylococcal			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0

Urinary tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Allergic transfusion reaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Bone contusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Excoriation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Drug administration error			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	2 / 5 (40.00%)
occurrences (all)	0	2	5
Fall			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	2 / 5 (40.00%)
occurrences (all)	1	0	2
Head injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Laceration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Post procedural haematoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Lumbar vertebral fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Post procedural inflammation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Post procedural haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Procedural dizziness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Pubis fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rib fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Transfusion reaction			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Tracheal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Traumatic haemorrhage			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Wound			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Wrist fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Acidosis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0
Alkalosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Dehydration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Hyperlipidaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Hyperuricaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	2 / 5 (40.00%)
occurrences (all)	0	0	6
Hypoglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Hypocalcaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	2 / 4 (50.00%)	1 / 4 (25.00%)	2 / 5 (40.00%)
occurrences (all)	2	3	7
Iron overload			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Metabolic disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tumour lysis syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	160mg BI 811283 + 20mg Cytarabine - Treatment Schedule B	240mg BI 811283 + 20mg Cytarabine - Treatment Schedule B	300mg BI 811283 + 20mg Cytarabine - Treatment Schedule B
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	6 / 7 (85.71%)	4 / 4 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Osteoma			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Metastases to bone			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
Circulatory collapse			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Haematoma			
subjects affected / exposed	1 / 3 (33.33%)	2 / 7 (28.57%)	2 / 4 (50.00%)
occurrences (all)	2	2	2
Hypertension			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hypertensive crisis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Hot flush			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	1 / 4 (25.00%)
occurrences (all)	2	0	1
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Intra-abdominal haematoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lymphoedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Jugular vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Phlebitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	2
Orthostatic hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vasculitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Central venous catheterisation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Catheterisation venous			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Adverse drug reaction			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Asthenia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	3	1	0
Catheter site erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Catheter site inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Catheter site haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Chest pain			
subjects affected / exposed	2 / 3 (66.67%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	4	0	0
Chills			
subjects affected / exposed	2 / 3 (66.67%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	3	0	0
Discomfort			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Facial pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Feeling cold			

subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Fatigue			
subjects affected / exposed	3 / 3 (100.00%)	4 / 7 (57.14%)	2 / 4 (50.00%)
occurrences (all)	9	4	3
General physical health deterioration			
subjects affected / exposed	1 / 3 (33.33%)	3 / 7 (42.86%)	1 / 4 (25.00%)
occurrences (all)	1	4	1
Gait disturbance			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injection site inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Local swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mass			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 3 (0.00%)	3 / 7 (42.86%)	1 / 4 (25.00%)
occurrences (all)	0	3	1
Oedema			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	2 / 3 (66.67%)	2 / 7 (28.57%)	0 / 4 (0.00%)
occurrences (all)	3	3	0
Pyrexia			
subjects affected / exposed	3 / 3 (100.00%)	4 / 7 (57.14%)	1 / 4 (25.00%)
occurrences (all)	4	7	1
Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Vessel puncture site pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Social circumstances			
Bedridden			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Breast pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Vaginal inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Atelectasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Bronchial secretion retention			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	3	0	0
Epistaxis			
subjects affected / exposed	1 / 3 (33.33%)	4 / 7 (57.14%)	0 / 4 (0.00%)
occurrences (all)	2	6	0
Dyspnoea			
subjects affected / exposed	3 / 3 (100.00%)	5 / 7 (71.43%)	0 / 4 (0.00%)
occurrences (all)	6	5	0
Hiccups			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haemothorax			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Increased upper airway secretion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lung infiltration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lung disorder			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Obstructive airways disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Pharyngeal erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 3 (33.33%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	1	2	0
Pharyngeal oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pulmonary mass			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pulmonary oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory acidosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rales			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rhonchi			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Stridor			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Tachypnoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Agitation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Depression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Catatonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Disorientation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hallucination			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Insomnia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Illusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Panic attack			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mood altered			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Restlessness			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Psychotic disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Antithrombin III decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Basophil count increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood calcium decreased			
subjects affected / exposed	2 / 3 (66.67%)	0 / 7 (0.00%)	1 / 4 (25.00%)
occurrences (all)	3	0	1
Blood chloride increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood chloride decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood calcium increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood cholinesterase decreased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Blood cholesterol increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood creatinine decreased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Blood glucose increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Blood fibrinogen increased			

subjects affected / exposed	1 / 3 (33.33%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Blood magnesium decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	1 / 3 (33.33%)	1 / 7 (14.29%)	1 / 4 (25.00%)
occurrences (all)	1	1	1
Blood phosphorus increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood potassium decreased			
subjects affected / exposed	1 / 3 (33.33%)	3 / 7 (42.86%)	1 / 4 (25.00%)
occurrences (all)	2	4	2
Blood potassium increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood sodium decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood urea increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood triglycerides increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood uric acid increased			
subjects affected / exposed	1 / 3 (33.33%)	1 / 7 (14.29%)	1 / 4 (25.00%)
occurrences (all)	1	2	1
Blood urine present			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

C-reactive protein increased			
subjects affected / exposed	1 / 3 (33.33%)	4 / 7 (57.14%)	1 / 4 (25.00%)
occurrences (all)	1	7	2
Eosinophil count increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fibrin D dimer increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Heart rate increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mean cell haemoglobin concentration increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mean cell volume decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oxygen saturation decreased			
subjects affected / exposed	0 / 3 (0.00%)	2 / 7 (28.57%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Protein total decreased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Prothrombin time prolonged			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Protein total increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Prothrombin time shortened			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
pH urine decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Angina pectoris			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0

Pericardial effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Myocardial ischaemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Cardiovascular insufficiency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Right ventricular failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Supraventricular tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ventricular tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ventricular extrasystoles			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Ageusia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Aphasia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cerebral ischaemia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Balance disorder			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Dementia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Convulsion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	2 / 3 (66.67%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	2	1	0
Disturbance in attention			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hemiparesis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Headache			
subjects affected / exposed	0 / 3 (0.00%)	3 / 7 (42.86%)	2 / 4 (50.00%)
occurrences (all)	0	6	2
Dysgeusia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Hypotonia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Paraesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Syncope			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Spinal haematoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	1 / 3 (33.33%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Tremor			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Transient ischaemic attack			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 3 (100.00%)	3 / 7 (42.86%)	1 / 4 (25.00%)
occurrences (all)	8	4	1
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Febrile neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
Lymph node pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	1 / 3 (33.33%)	3 / 7 (42.86%)	2 / 4 (50.00%)
occurrences (all)	1	5	3
Lymphadenopathy			

subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Thrombocytopenia			
subjects affected / exposed	2 / 3 (66.67%)	2 / 7 (28.57%)	2 / 4 (50.00%)
occurrences (all)	7	7	2
Neutropenia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	1	4	0
Ear and labyrinth disorders			
Cerumen impaction			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Ear haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Tinnitus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eyelid oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eyelid bleeding			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Photopsia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal discomfort			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Abdominal pain			
subjects affected / exposed	1 / 3 (33.33%)	3 / 7 (42.86%)	0 / 4 (0.00%)
occurrences (all)	3	4	0
Abdominal pain lower			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Anal fissure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Anal ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Anal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Aphthous stomatitis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Colitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	2 / 3 (66.67%)	0 / 7 (0.00%)	1 / 4 (25.00%)
occurrences (all)	2	0	2
Diarrhoea			
subjects affected / exposed	1 / 3 (33.33%)	2 / 7 (28.57%)	0 / 4 (0.00%)
occurrences (all)	1	3	0
Dry mouth			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Faecal incontinence			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Dyspepsia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Flatulence			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Faecaloma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gingival bleeding			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1

Gingival swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haematemesis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Haematochezia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Haemorrhoids			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lip ulceration			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Mouth haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Nausea			
subjects affected / exposed	2 / 3 (66.67%)	1 / 7 (14.29%)	3 / 4 (75.00%)
occurrences (all)	7	2	3
Oral disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral mucosal erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0

Palatal disorder			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Parotid gland enlargement			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Periodontal disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Rectal tenesmus			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Retching			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Salivary gland pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tongue coated			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tongue discolouration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	1 / 3 (33.33%)	2 / 7 (28.57%)	1 / 4 (25.00%)
occurrences (all)	4	2	1

Hepatobiliary disorders			
Hepatic cyst			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hepatic lesion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hepatic vein occlusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	1 / 3 (33.33%)	2 / 7 (28.57%)	1 / 4 (25.00%)
occurrences (all)	1	2	1
Cold sweat			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Decubitus ulcer			
subjects affected / exposed	0 / 3 (0.00%)	2 / 7 (28.57%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Dermatitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Drug eruption			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	1 / 3 (33.33%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Eczema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Erythema			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Erythema nodosum			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Milia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Pain of skin			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Palmar erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	2 / 3 (66.67%)	0 / 7 (0.00%)	1 / 4 (25.00%)
occurrences (all)	4	0	1
Papule			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	2 / 3 (66.67%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	3	1	0
Pruritus			
subjects affected / exposed	0 / 3 (0.00%)	2 / 7 (28.57%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
Psoriasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 3 (0.00%)	2 / 7 (28.57%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
Pruritus generalised			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin hyperpigmentation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Swelling face			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Skin mass			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Renal and urinary disorders			
Bladder spasm			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Dysuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haemoglobinuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	1 / 3 (33.33%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Incontinence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Micturition urgency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Micturition disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Pollakiuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Renal disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal cyst			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal failure acute			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 3 (0.00%)	2 / 7 (28.57%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Urinary incontinence			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	2 / 3 (66.67%)	0 / 7 (0.00%)	1 / 4 (25.00%)
occurrences (all)	3	0	1
Arthralgia			
subjects affected / exposed	2 / 3 (66.67%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	2	1	0
Bone lesion			

subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Bone pain			
subjects affected / exposed	1 / 3 (33.33%)	1 / 7 (14.29%)	1 / 4 (25.00%)
occurrences (all)	1	2	1
Bursitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fistula			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fracture pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Joint swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haemarthrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mobility decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscle disorder			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Muscle spasms			
subjects affected / exposed	1 / 3 (33.33%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Muscular weakness			

subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal chest pain			
subjects affected / exposed	2 / 3 (66.67%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	3	0	0
Myalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	2 / 3 (66.67%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	4	1	0
Pain in extremity			
subjects affected / exposed	2 / 3 (66.67%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	2	1	0
Pain in jaw			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Spinal osteoarthritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Spinal pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Tendon pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bacterial disease carrier			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Bronchiolitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Clostridial infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Device related infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Enterobacter infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Enterococcal infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Erysipelas			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Localised infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Infectious disease carrier			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Periodontitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Pneumonia fungal			
subjects affected / exposed	1 / 3 (33.33%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Pseudomonas infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Postoperative wound infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Puncture site infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection fungal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0

Skin infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin candida			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Soft tissue infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Staphylococcal infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection staphylococcal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	1 / 3 (33.33%)	1 / 7 (14.29%)	1 / 4 (25.00%)
occurrences (all)	1	1	1
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Allergic transfusion reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Bone contusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Excoriation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Drug administration error			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Fall			
subjects affected / exposed	3 / 3 (100.00%)	2 / 7 (28.57%)	0 / 4 (0.00%)
occurrences (all)	3	2	0
Head injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Laceration			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Post procedural haematoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lumbar vertebral fracture			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Post procedural inflammation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Post procedural haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Procedural dizziness			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Procedural pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Pubis fracture			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Rib fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Transfusion reaction			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0

Tracheal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Traumatic haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Wrist fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Acidosis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Decreased appetite			
subjects affected / exposed	2 / 3 (66.67%)	3 / 7 (42.86%)	0 / 4 (0.00%)
occurrences (all)	5	3	0
Alkalosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dehydration			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperlipidaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Hypokalaemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
Iron overload			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metabolic disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tumour lysis syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	360mg BI 811283 + 20mg Cytarabine - Treatment Schedule B	420mg BI 811283 + 20mg Cytarabine - Treatment Schedule B	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	6 / 6 (100.00%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Osteoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Metastases to bone			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Vascular disorders			

Circulatory collapse			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Flushing			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	2	0	
Haematoma			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Hypertension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hypertensive crisis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hot flush			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Intra-abdominal haematoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Lymphoedema			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Jugular vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Phlebitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Thrombophlebitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	

Orthostatic hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Thrombosis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Vasculitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Surgical and medical procedures			
Central venous catheterisation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Catheterisation venous			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
General disorders and administration site conditions			
Adverse drug reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Catheter site erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Catheter site inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Catheter site haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Catheter site pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Chest pain			

subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	2	
Chills			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Facial pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Feeling cold			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Fatigue			
subjects affected / exposed	1 / 3 (33.33%)	2 / 6 (33.33%)	
occurrences (all)	1	2	
General physical health deterioration			
subjects affected / exposed	1 / 3 (33.33%)	3 / 6 (50.00%)	
occurrences (all)	1	3	
Gait disturbance			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Injection site inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Injection site pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Injection site reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Localised oedema			

subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	
Local swelling subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	
Mass subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	
Mucosal inflammation subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 6 (16.67%) 1	
Oedema subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 6 (16.67%) 1	
Oedema peripheral subjects affected / exposed occurrences (all)	2 / 3 (66.67%) 5	0 / 6 (0.00%) 0	
Pyrexia subjects affected / exposed occurrences (all)	2 / 3 (66.67%) 4	1 / 6 (16.67%) 2	
Pain subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	2 / 6 (33.33%) 2	
Vessel puncture site pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	
Immune system disorders Hypersensitivity subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	
Social circumstances Bedridden subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	
Reproductive system and breast disorders			

Breast pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Vaginal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Vaginal inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
Atelectasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Bronchial secretion retention			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Dysphonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Cough			
subjects affected / exposed	1 / 3 (33.33%)	2 / 6 (33.33%)	
occurrences (all)	2	2	
Epistaxis			
subjects affected / exposed	2 / 3 (66.67%)	3 / 6 (50.00%)	
occurrences (all)	2	3	
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	2 / 6 (33.33%)	
occurrences (all)	0	4	
Hiccups			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Haemoptysis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Haemothorax			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Increased upper airway secretion			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Lung infiltration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Lung disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Obstructive airways disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Pharyngeal erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Oropharyngeal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Pharyngeal oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Productive cough			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Pulmonary mass			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Pulmonary oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Respiratory acidosis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Rales			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Rhonchi			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Stridor			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Respiratory failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Tachypnoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Agitation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Confusional state			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Depression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Catatonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Disorientation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	

Hallucination			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Insomnia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	2	
Illusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Panic attack			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Mood altered			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Sleep disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Restlessness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Psychotic disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Investigations			
Activated partial thromboplastin time			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Alanine aminotransferase decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Antithrombin III decreased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Alanine aminotransferase increased			
subjects affected / exposed	1 / 3 (33.33%)	1 / 6 (16.67%)	
occurrences (all)	3	1	
Amylase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Aspartate aminotransferase decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 3 (33.33%)	1 / 6 (16.67%)	
occurrences (all)	2	1	
Basophil count increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Blood bilirubin increased			
subjects affected / exposed	0 / 3 (0.00%)	2 / 6 (33.33%)	
occurrences (all)	0	5	
Blood calcium decreased			
subjects affected / exposed	2 / 3 (66.67%)	1 / 6 (16.67%)	
occurrences (all)	4	2	
Blood chloride increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Blood chloride decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Blood calcium increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Blood cholinesterase decreased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Blood cholesterol increased				
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)		
occurrences (all)	3	0		
Blood creatinine decreased				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Blood creatinine increased				
subjects affected / exposed	1 / 3 (33.33%)	2 / 6 (33.33%)		
occurrences (all)	1	2		
Blood glucose increased				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Blood fibrinogen increased				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Blood magnesium decreased				
subjects affected / exposed	1 / 3 (33.33%)	3 / 6 (50.00%)		
occurrences (all)	1	4		
Blood phosphorus decreased				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Blood lactate dehydrogenase increased				
subjects affected / exposed	0 / 3 (0.00%)	2 / 6 (33.33%)		
occurrences (all)	0	3		
Blood phosphorus increased				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Blood potassium decreased				
subjects affected / exposed	3 / 3 (100.00%)	1 / 6 (16.67%)		
occurrences (all)	12	2		
Blood potassium increased				
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)		
occurrences (all)	3	0		

Blood sodium decreased				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Blood urea increased				
subjects affected / exposed	2 / 3 (66.67%)	2 / 6 (33.33%)		
occurrences (all)	7	4		
Blood triglycerides increased				
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)		
occurrences (all)	0	1		
Blood uric acid increased				
subjects affected / exposed	2 / 3 (66.67%)	1 / 6 (16.67%)		
occurrences (all)	3	1		
Blood urine present				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
C-reactive protein increased				
subjects affected / exposed	2 / 3 (66.67%)	1 / 6 (16.67%)		
occurrences (all)	4	1		
Eosinophil count increased				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Fibrin D dimer increased				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Haemoglobin decreased				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Gamma-glutamyltransferase increased				
subjects affected / exposed	1 / 3 (33.33%)	1 / 6 (16.67%)		
occurrences (all)	1	1		
Heart rate increased				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Lipase increased				

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Lymphocyte count decreased				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Mean cell haemoglobin concentration increased				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Mean cell volume decreased				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Oxygen saturation decreased				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Protein total decreased				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Prothrombin time prolonged				
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)		
occurrences (all)	0	1		
Protein total increased				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Prothrombin time shortened				
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)		
occurrences (all)	0	2		
Transaminases increased				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Weight decreased				
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)		
occurrences (all)	1	0		
Weight increased				
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)		
occurrences (all)	1	0		

pH urine decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Angina pectoris			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Bradycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Pericardial effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Myocardial ischaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Cardiovascular insufficiency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Sinus tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Right ventricular failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Supraventricular tachycardia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Ventricular tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Ventricular extrasystoles			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
Ageusia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Aphasia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Cerebral ischaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Balance disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Dementia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Convulsion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Dizziness			
subjects affected / exposed	1 / 3 (33.33%)	1 / 6 (16.67%)	
occurrences (all)	1	1	
Disturbance in attention			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hemiparesis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	

Headache			
subjects affected / exposed	0 / 3 (0.00%)	2 / 6 (33.33%)	
occurrences (all)	0	2	
Dysgeusia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hypotonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Paraesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Syncope			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	2	0	
Spinal haematoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Somnolence			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Tremor			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Transient ischaemic attack			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 3 (100.00%)	3 / 6 (50.00%)	
occurrences (all)	3	4	
Disseminated intravascular coagulation			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Febrile neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Leukocytosis			
subjects affected / exposed	1 / 3 (33.33%)	2 / 6 (33.33%)	
occurrences (all)	1	2	
Lymph node pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Leukopenia			
subjects affected / exposed	3 / 3 (100.00%)	2 / 6 (33.33%)	
occurrences (all)	11	2	
Lymphadenopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Thrombocytopenia			
subjects affected / exposed	2 / 3 (66.67%)	2 / 6 (33.33%)	
occurrences (all)	5	2	
Neutropenia			
subjects affected / exposed	3 / 3 (100.00%)	2 / 6 (33.33%)	
occurrences (all)	8	2	
Ear and labyrinth disorders			
Cerumen impaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Ear haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Tinnitus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
Cataract			

subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Eye haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Eye pruritus			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Eye pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Eyelid oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Eyelid bleeding			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Photopsia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Visual impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Abdominal discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Abdominal pain			
subjects affected / exposed	1 / 3 (33.33%)	1 / 6 (16.67%)	
occurrences (all)	1	1	
Abdominal pain lower			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	

Abdominal pain upper			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Anal fissure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Anal ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Anal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Ascites			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Aphthous stomatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Colitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Constipation			
subjects affected / exposed	2 / 3 (66.67%)	0 / 6 (0.00%)	
occurrences (all)	3	0	
Diarrhoea			
subjects affected / exposed	2 / 3 (66.67%)	2 / 6 (33.33%)	
occurrences (all)	2	2	
Dry mouth			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Faecal incontinence			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Dyspepsia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	

Dysphagia				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Flatulence				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Faecaloma				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Gingival pain				
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)		
occurrences (all)	0	1		
Gingival bleeding				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Gingival swelling				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Haematemesis				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Haematochezia				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Haemorrhoidal haemorrhage				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Haemorrhoids				
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)		
occurrences (all)	0	1		
Lip ulceration				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Mouth haemorrhage				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		

Melaena				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Nausea				
subjects affected / exposed	3 / 3 (100.00%)	2 / 6 (33.33%)		
occurrences (all)	4	3		
Oral disorder				
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)		
occurrences (all)	1	0		
Oral mucosal erythema				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Oral pain				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Palatal disorder				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Parotid gland enlargement				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Rectal haemorrhage				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Periodontal disease				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Rectal tenesmus				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Retching				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Salivary gland pain				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		

Stomatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Tongue coated			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Tongue discolouration			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Toothache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Hepatobiliary disorders			
Hepatic cyst			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hepatic lesion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hepatic vein occlusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Alopecia			
subjects affected / exposed	2 / 3 (66.67%)	2 / 6 (33.33%)	
occurrences (all)	2	2	
Cold sweat			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Decubitus ulcer			

subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)		
occurrences (all)	1	0		
Dermatitis				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Drug eruption				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Dry skin				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Eczema				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Erythema				
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)		
occurrences (all)	1	0		
Erythema nodosum				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Milia				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Hyperhidrosis				
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)		
occurrences (all)	0	1		
Pain of skin				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Palmar erythema				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Night sweats				
subjects affected / exposed	1 / 3 (33.33%)	2 / 6 (33.33%)		
occurrences (all)	1	2		
Papule				

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Petechiae			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Pruritus			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Psoriasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Rash			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Pruritus generalised			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Skin hyperpigmentation			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Skin lesion			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Swelling face			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Skin ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Skin mass			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Renal and urinary disorders			
Bladder spasm			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	

Dysuria			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Haemoglobinuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Haematuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Incontinence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Micturition urgency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Micturition disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Pollakiuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Nocturia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Renal disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Renal cyst			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Renal failure acute			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Renal failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	

Urinary retention			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Urinary incontinence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Arthralgia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	2	0	
Bone lesion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Bone pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Bursitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Fistula			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Groin pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Flank pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Fracture pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Joint swelling			

subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)		
occurrences (all)	0	1		
Haemarthrosis				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Mobility decreased				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Muscle disorder				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Muscle spasms				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Muscular weakness				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Musculoskeletal chest pain				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Myalgia				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Musculoskeletal pain				
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)		
occurrences (all)	1	0		
Pain in extremity				
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)		
occurrences (all)	0	1		
Pain in jaw				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Spinal osteoarthritis				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Spinal pain				

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Tendon pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
Bacterial disease carrier			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Bronchiolitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Candida infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Clostridial infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Clostridium difficile infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Conjunctivitis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Device related infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Enterobacter infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Enterococcal infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	

Erysipelas			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Fungal skin infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Herpes simplex			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Localised infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Infectious disease carrier			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Nasopharyngitis			
subjects affected / exposed	1 / 3 (33.33%)	1 / 6 (16.67%)	
occurrences (all)	1	1	
Oral herpes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Periodontitis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Pneumonia fungal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Pseudomonas infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	

Postoperative wound infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Puncture site infection			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Respiratory tract infection fungal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Rhinitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Skin infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Skin candida			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Soft tissue infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Staphylococcal infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Urinary tract infection staphylococcal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	

Allergic transfusion reaction				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Bone contusion				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Contusion				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Excoriation				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Drug administration error				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Fall				
subjects affected / exposed	1 / 3 (33.33%)	1 / 6 (16.67%)		
occurrences (all)	1	1		
Head injury				
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)		
occurrences (all)	0	1		
Laceration				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Post procedural haematoma				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Lumbar vertebral fracture				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Post procedural inflammation				
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Post procedural haemorrhage				
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)		
occurrences (all)	0	1		

Procedural dizziness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Procedural pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Pubis fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Rib fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Transfusion reaction			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Tracheal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Traumatic haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Wound			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Wrist fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Metabolism and nutrition disorders			
Acidosis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Decreased appetite			
subjects affected / exposed	0 / 3 (0.00%)	2 / 6 (33.33%)	
occurrences (all)	0	3	
Alkalosis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hyperglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hyperkalaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hyperlipidaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hyperuricaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hypoglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hypocalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hypokalaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Iron overload			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Metabolic disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Tumour lysis syndrome			

subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
04 March 2008	•More detail was provided on the criteria used to assess patients ineligible for intensive treatment. •Additional procedures (cytogenetics and molecular genetics) were amended to allow for the most up-to-date AML diagnostics. •The time specification 72 hours after BI 811283 treatment was defined more precisely as 72 hours after the end of the first 24 hours continuous infusion of the trial drug. •The instructions for pharmcodynamic sampling were changed to be consistent between the text and the flowcharts. •PK sampling numbers were revised to make the numbering consecutive.
16 September 2008	•The dose escalation levels were amended based on data available from trial 1247.1, so that the next cohort started at a dose level proven safe in trial 1247.1. However, since BI 811283 was investigated as monotherapy in trial 1247.1, whereas in this trial BI 811283 is combined with low-dose cytarabine (with overlapping haematological toxicity expected), the BI 811283 dose for the next cohort was approximately half the highest BI 811823 dose that was considered safe in the first cycle of the ongoing monotherapy trial 1247.1. •PK sampling 36 hours after start of administration of the trial drug was changed from mandatory to optional since this sampling occurred at nighttime. •Up to 7 days hydroxyurea treatment for peripheral blast control was allowed, up until 1 day before the first administration of the trial drugs.
11 February 2009	•A formal safety analysis after the Phase I part of the trial, and if necessary an updated risk-benefit assessment, was implemented. •To get more comprehensive survival data, the follow-up rules were changed to allow longer follow-up. •Details were added regarding the vial size of cytarabine used in the trial. •Rules for pharmacodynamic investigations were changed so that analysis in Phase IIa of the study was optional. •Planned dates of the trial were adjusted.

21 December 2009	•Handling instructions of BI 811283 ready-for-use infusion were adapted based on new analytical data and the need for an adjustment of the infusion concentration. •Photostability testing of the diluted drug product revealed a photosensitivity, so changes were made in the storage conditions. •AE and SAE reporting criteria were modified. •Screening for additional mutations/deregulated expression of genes was added to the planned cytogenetic and molecular genetic testing to allow the most up to date exploratory diagnostics. Sample volume was adapted accordingly. •Wording for replacement of patients was unclear for the Phase II part of the trial so this was clarified. •The address of the coordinating investigator was revised. •Inclusion and exclusion criteria were modified to allow inclusion of patients with relapsed and refractory AML in the Phase I part of the trial.
19 May 2010	•The number of patients in Phase I was adapted because more dose escalation cohorts than previously expected were needed to determine the MTD. •Details on Phase IIa of the study were deleted since BI decided not to develop BI 811283 in a Phase II program. •Trial timelines were adapted. •An additional safety laboratory test was added to Day 2 (after the first administration of BI 811283 and cytarabine) in the first treatment cycle to allow for early detection of laboratory changes after the first administration of the trial drugs. •Further instructions were provided on the allowed timelines for pre-treatment of patients with relapsed/refractory AML. •Details were provided on how many omitted doses of cytarabine were acceptable inthe first cycle without the requirement to replace the patient for correct determination of the MTD. •The trial objective was reduced to determine the MTD for the 2 schedules of BI 811283 in combination with cytarabine. •The investigators´ awareness was raised regarding the potential occurrence of tumour lysis syndrome in connection with cytoreductive treatment, and hence to support early diagnosis and management of tumour lysis syndrome within this trial.
08 July 2011	•Due to a strategic decision by BI not to further develop the substance BI 811283 in any indication, and since the dose in Group B has been escalated to twice the MTD in schedule A without any DLTs, further dose escalation in Group B was considered unreasonable. In addition, the following changes were made in the TSAP from that specified in the protocol. These changes were made before database lock: •The TSAP further clarified the definition of best response, with this being defined by best overall response and objective response.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
08 July 2011	The enrolment of new subjects to participate in this study was stopped, thus no new subjects were entered in the trial as the sponsor decided to discontinue the clinical development of BI 811283.	-

Notes:

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Treatment Arm C defined in the protocol was not implemented, because with protocol amendment(19May10) the study design was changed from a phase I/II to a phase I only, so there was never a treatment arm in which Cytarabine was given alone

Notes: