Clinical trial results:
An open phase I/IIa trial to investigate the maximum tolerated dose, safety, pharmacokinetics and efficacy of intravenous BI 6727 as monotherapy or in combination with subcutaneous cytarabine in patients with acute myeloid leukaemia

Summary

EudraCT number	2008-003617-27
Trial protocol	DE BE AT
Global end of trial date	23 April 2021

Results information

Result version number	v1 (current)
This version publication date	22 April 2022
First version publication date	22 April 2022

Trial information

Trial identification

Sponsor protocol code	1230.4

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00804856
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Boehringer Ingelheim
Sponsor organisation address	Binger Strasse 173, Ingelheim am Rhein, Germany,
Public contact	Boehringer Ingelheim, Call Center, Boehringer Ingelheim, 001 18002430127, clintriage.rdg@boehringer-ingelheim.com
Scientific contact	Boehringer Ingelheim, Call Center, Boehringer Ingelheim, 001 18002430127, 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 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	05 May 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	09 March 2012
Global end of trial reached?	Yes
Global end of trial date	23 April 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To investigate the maximum tolerated dose (MTD), safety, pharmacokinetics and efficacy of volasertib monotherapy and volasertib in combination with low dose cytarabine (LDAC) in patients with acute myeloid leukaemia (AML)

Protection of trial subjects:

Only subjects that met all the 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. If a subject continued to take trial medication, close monitoring was adhered to and all adverse events recorded. Rules were implemented in all trials whereby doses would be reduced if required. Thereafter, if further events were reported, the subject would be withdrawn from the trial. Symptomatic treatment of tumour associated symptoms were allowed throughout.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	05 December 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	Austria: 2
Country: Number of subjects enrolled	Belgium: 20
Country: Number of subjects enrolled	Canada: 7
Country: Number of subjects enrolled	Germany: 126
Country: Number of subjects enrolled	France: 23
Country: Number of subjects enrolled	Italy: 8
Country: Number of subjects enrolled	Norway: 7
Worldwide total number of subjects	193
EEA total number of subjects	186

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)	18
From 65 to 84 years	169
85 years and over	6

Subject disposition

Recruitment

Recruitment details:

Open-label, randomized, dose escalation study. In this trial 180 patients were entered and randomised. However 3 patients were entered but not treated in Phase I and 2 patients were not treated in Phase II. Thus total 175 patients were treated in this trial.

Pre-assignment

Screening details:

Patients were assigned to two treatment schedules (A and B) in the phase I part of the trial (dose escalation phase to determine maximum tolerated dose (MTD)). In the phase IIa part of the trial (after MTD was determined), patients were randomised to two treatment schedules (A and C).

Period 1

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

Blinding implementation details:

This trial was conducted according to an open-label design.

Arms

Are arms mutually exclusive?	Yes
Arm title	Phase I Schedule A. Volasertib 150 mg+LDAC

Arm description:

Volasertib 150 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle) and Low-dose cytarabine (LDAC) 2x20mg per day administered by subcutaneous injection on days 1-10 of each 28 day treatment cycle.

Arm type	Experimental
Investigational medicinal product name	Low-dose cytarabine (LDAC)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Low-dose cytarabine (LDAC) 2x20 milligram (mg) per day administered by subcutaneous injection on days 1-10 of each 28 day treatment cycle.

Investigational medicinal product name	Volasertib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Volasertib 150 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle)

Arm title	Phase I Schedule A. Volasertib 200 mg+LDAC

Arm description:

Volasertib 200 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle) and Low-dose cytarabine (LDAC) 2x20mg per day administered by subcutaneous injection on days 1-10 of each 28 day treatment cycle.

Arm type	Experimental

Investigational medicinal product name	Low-dose cytarabine (LDAC)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Low-dose cytarabine (LDAC) 2x20 milligram (mg) per day administered by subcutaneous injection on days 1-10 of each 28 day treatment cycle.

Investigational medicinal product name	Volasertib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Volasertib 200 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle)

Arm title	Phase I Schedule A. Volasertib 250 mg+LDAC

Arm description:

Volasertib 250 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle) and Low-dose cytarabine (LDAC) 2x20mg per day administered by subcutaneous injection on days 1-10 of each 28 day treatment cycle.

Arm type	Experimental
Investigational medicinal product name	Volasertib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Volasertib 200 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle)

Investigational medicinal product name	Low-dose cytarabine (LDAC)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Low-dose cytarabine (LDAC) 2x20 milligram (mg) per day administered by subcutaneous injection on days 1-10 of each 28 day treatment cycle.

Arm title	Phase I Schedule A. Volasertib 300 mg+LDAC

Arm description:

Volasertib 300 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle) and Low-dose cytarabine (LDAC) 2x20mg per day administered by subcutaneous injection on days 1-10 of each 28 day treatment cycle.

Arm type	Experimental
Investigational medicinal product name	Volasertib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Volasertib 300 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle)

Investigational medicinal product name	Low-dose cytarabine (LDAC)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Low-dose cytarabine (LDAC) 2x20 milligram (mg) per day administered by subcutaneous injection on days 1-10 of each 28 day treatment cycle.

Arm title	Phase I Schedule A. Volasertib 350 mg+LDAC

Arm description:

Volasertib 350 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle) and Low-dose cytarabine (LDAC) 2x20mg per day administered by subcutaneous injection on days 1-10 of each 28 day treatment cycle.

Arm type	Experimental
Investigational medicinal product name	Volasertib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Volasertib 350 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle)

Investigational medicinal product name	Low-dose cytarabine (LDAC)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Low-dose cytarabine (LDAC) 2x20 milligram (mg) per day administered by subcutaneous injection on days 1-10 of each 28 day treatment cycle.

Arm title	Phase I Schedule A. Volasertib 400 mg+LDAC

Arm description:

Volasertib 400 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle) and Low-dose cytarabine (LDAC) 2x20mg per day administered by subcutaneous injection on days 1-10 of each 28 day treatment cycle.

Arm type	Experimental
Investigational medicinal product name	Volasertib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Volasertib 400 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle)

Investigational medicinal product name	Low-dose cytarabine (LDAC)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Low-dose cytarabine (LDAC) 2x20 milligram (mg) per day administered by subcutaneous injection on days 1-10 of each 28 day treatment cycle.

Arm title	Phase I Schedule B. Volasertib 150 mg

Arm description:	
Volasertib 150 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle).	
Arm type	Experimental
Investigational medicinal product name	Volasertib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Volasertib 150 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle)	
Arm title	Phase I Schedule B. Volasertib 200 mg
Arm description:	
Volasertib 200 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle).	
Arm type	Experimental
Investigational medicinal product name	Volasertib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Volasertib 200 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle)	
Arm title	Phase I Schedule B. Volasertib 350 mg
Arm description:	
Volasertib 350 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle).	
Arm type	Experimental
Investigational medicinal product name	Volasertib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Volasertib 350 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle)	
Arm title	Phase I Schedule B. Volasertib 400 mg
Arm description:	
Volasertib 400 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle).	
Arm type	Experimental
Investigational medicinal product name	Volasertib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Volasertib 400 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle)	
Arm title	Phase I Schedule B. Volasertib 450 mg

Arm description:	
Volasertib 450 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle).	
Arm type	Experimental
Investigational medicinal product name	Volasertib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Volasertib 450 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle)	
Arm title	Phase I Schedule B. Volasertib 500 mg
Arm description:	
Volasertib 500 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle).	
Arm type	Experimental
Investigational medicinal product name	Volasertib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Volasertib 500 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle)	
Arm title	Phase I Schedule B. Volasertib 550 mg
Arm description:	
Volasertib 550 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle).	
Arm type	Experimental
Investigational medicinal product name	Volasertib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Volasertib 550 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle)	
Arm title	Phase II Schedule C. LDAC
Arm description:	
Low-dose cytarabine (LDAC) monotherapy 2x20 milligram (mg) per day administered by subcutaneous injection on days 1-10 of each 28 days treatment cycle.	
Arm type	Active comparator
Investigational medicinal product name	Low-dose cytarabine (LDAC)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
Low-dose cytarabine (LDAC) 2x20 milligram (mg) per day administered by subcutaneous injection on days 1-10 of each 28 day treatment cycle.	
Arm title	Phase II Schedule A. Volasertib 350 mg+LDAC

Arm description:	
Volasertib 350 milligram (mg) on Days 1 and 15 (28-day cycle) administered by Intravenous Infusion (IV) over 60 minutes and Low-dose cytarabine (LDAC) 2x20mg per day administered by subcutaneous injection on days 1-10 of each 28 days treatment cycle.	
Arm type	Experimental
Investigational medicinal product name	Low-dose cytarabine (LDAC)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
Low-dose cytarabine (LDAC) 2x20 milligram (mg) per day administered by subcutaneous injection on days 1-10 of each 28 day treatment cycle.	
Investigational medicinal product name	Volasertib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Volasertib 350 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle)	

Number of subjects in period 1[1]	Phase I Schedule A. Volasertib 150 mg+LDAC	Phase I Schedule A. Volasertib 200 mg+LDAC	Phase I Schedule A. Volasertib 250 mg+LDAC
Started	4	3	5
Completed	0	0	0
Not completed	4	3	5
Other Adverse Event	1	1	1
Dose Limiting Toxicity (DLT)	-	-	-
Progressive Disease	3	2	4
Other reason than listed above	-	-	-
Refused to continue medication	-	-	-
Non compliance with protocol	-	-	-

Number of subjects in period 1[1]	Phase I Schedule A. Volasertib 300 mg+LDAC	Phase I Schedule A. Volasertib 350 mg+LDAC	Phase I Schedule A. Volasertib 400 mg+LDAC
Started	9	8	3
Completed	0	0	0
Not completed	9	8	3
Other Adverse Event	2	2	1
Dose Limiting Toxicity (DLT)	-	1	-
Progressive Disease	6	4	1
Other reason than listed above	-	-	1
Refused to continue medication	1	1	-
Non compliance with protocol	-	-	-

Number of subjects in period 1[1]	Phase I Schedule B. Volasertib 150 mg	Phase I Schedule B. Volasertib 200 mg	Phase I Schedule B. Volasertib 350 mg
Started	11	2	5
Completed	0	0	0
Not completed	11	2	5
Other Adverse Event	3	-	-
Dose Limiting Toxicity (DLT)	-	-	-
Progressive Disease	8	2	4
Other reason than listed above	-	-	1
Refused to continue medication	-	-	-
Non compliance with protocol	-	-	-

Number of subjects in period 1[1]	Phase I Schedule B. Volasertib 400 mg	Phase I Schedule B. Volasertib 450 mg	Phase I Schedule B. Volasertib 500 mg
Started	6	23	5
Completed	0	0	0
Not completed	6	23	5
Other Adverse Event	1	5	2
Dose Limiting Toxicity (DLT)	-	-	-
Progressive Disease	5	12	2
Other reason than listed above	-	3	1
Refused to continue medication	-	3	-
Non compliance with protocol	-	-	-

Number of subjects in period 1[1]	Phase I Schedule B. Volasertib 550 mg	Phase II Schedule C. LDAC	Phase II Schedule A. Volasertib 350 mg+LDAC
Started	4	45	42
Completed	0	0	0
Not completed	4	45	42
Other Adverse Event	-	6	13
Dose Limiting Toxicity (DLT)	-	-	1
Progressive Disease	2	26	20
Other reason than listed above	1	10	3
Refused to continue medication	1	1	5
Non compliance with protocol	-	2	-

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: Out of the 193 enrolled subjects, 175 were treated and displayed here.

Baseline characteristics

Reporting groups	
Reporting group title	Phase I Schedule A. Volasertib 150 mg+LDAC
Reporting group description:	
Volasertib 150 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle) and Low-dose cytarabine (LDAC) 2x20mg per day administered by subcutaneous injection on days 1-10 of each 28 day treatment cycle.	
Reporting group title	Phase I Schedule A. Volasertib 200 mg+LDAC
Reporting group description:	
Volasertib 200 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle) and Low-dose cytarabine (LDAC) 2x20mg per day administered by subcutaneous injection on days 1-10 of each 28 day treatment cycle.	
Reporting group title	Phase I Schedule A. Volasertib 250 mg+LDAC
Reporting group description:	
Volasertib 250 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle) and Low-dose cytarabine (LDAC) 2x20mg per day administered by subcutaneous injection on days 1-10 of each 28 day treatment cycle.	
Reporting group title	Phase I Schedule A. Volasertib 300 mg+LDAC
Reporting group description:	
Volasertib 300 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle) and Low-dose cytarabine (LDAC) 2x20mg per day administered by subcutaneous injection on days 1-10 of each 28 day treatment cycle.	
Reporting group title	Phase I Schedule A. Volasertib 350 mg+LDAC
Reporting group description:	
Volasertib 350 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle) and Low-dose cytarabine (LDAC) 2x20mg per day administered by subcutaneous injection on days 1-10 of each 28 day treatment cycle.	
Reporting group title	Phase I Schedule A. Volasertib 400 mg+LDAC
Reporting group description:	
Volasertib 400 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle) and Low-dose cytarabine (LDAC) 2x20mg per day administered by subcutaneous injection on days 1-10 of each 28 day treatment cycle.	
Reporting group title	Phase I Schedule B. Volasertib 150 mg
Reporting group description:	
Volasertib 150 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle).	
Reporting group title	Phase I Schedule B. Volasertib 200 mg
Reporting group description:	
Volasertib 200 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle).	
Reporting group title	Phase I Schedule B. Volasertib 350 mg
Reporting group description:	
Volasertib 350 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle).	
Reporting group title	Phase I Schedule B. Volasertib 400 mg
Reporting group description:	
Volasertib 400 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle).	
Reporting group title	Phase I Schedule B. Volasertib 450 mg
Reporting group description:	
Volasertib 450 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle).	
Reporting group title	Phase I Schedule B. Volasertib 500 mg
Reporting group description:	
Volasertib 500 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1	

and 15 (28-day cycle).

Reporting group title	Phase I Schedule B. Volasertib 550 mg
Reporting group description:	
Volasertib 550 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle).	
Reporting group title	Phase II Schedule C. LDAC
Reporting group description:	
Low-dose cytarabine (LDAC) monotherapy 2x20 milligram (mg) per day administered by subcutaneous injection on days 1-10 of each 28 days treatment cycle.	
Reporting group title	Phase II Schedule A. Volasertib 350 mg+LDAC
Reporting group description:	
Volasertib 350 milligram (mg) on Days 1 and 15 (28-day cycle) administered by Intravenous Infusion (IV) over 60 minutes and Low-dose cytarabine (LDAC) 2x20mg per day administered by subcutaneous injection on days 1-10 of each 28 days treatment cycle.	

Reporting group values	Phase I Schedule A. Volasertib 150 mg+LDAC	Phase I Schedule A. Volasertib 200 mg+LDAC	Phase I Schedule A. Volasertib 250 mg+LDAC
Number of subjects	4	3	5
Age categorical			
Treated Set: All patients in Phase I who received at least a single dose of either Volasertib or LDAC, including patients who were replaced for any reason. For the Phase II part, the treated set (Phase II) was defined as all patients in Phase II who received at least a single dose of either Volasertib or LDAC.			
Units: participants			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	1	1	1
From 65-84 years	3	2	4
85 years and over	0	0	0
Age Continuous			
Treated Set: All patients in Phase I who received at least a single dose of either Volasertib or LDAC, including patients who were replaced for any reason. For the Phase II part, the treated set (Phase II) was defined as all patients in Phase II who received at least a single dose of either Volasertib or LDAC.			
Units: years			
arithmetic mean	69.5	67.0	71.2
standard deviation	± 12.1	± 3.0	± 6.8
Gender, Male/Female			
Treated Set: All patients in Phase I who received at least a single dose of either Volasertib or LDAC, including patients who were replaced for any reason. For the Phase II part, the treated set (Phase II) was defined as all patients in Phase II who received at least a single dose of either Volasertib or LDAC.			
Units: Participants			
Female	2	0	2
Male	2	3	3
Race (NIH/OMB)			
Treated Set: All patients in Phase I who received at least a single dose of either Volasertib or LDAC, including patients who were replaced for any reason. For the Phase II part, the treated set (Phase II) was defined as all patients in Phase II who received at least a single dose of either Volasertib or LDAC.			
Units: Subjects			
American Indian or Alaska Native	0	0	0

Asian	0	0	1
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	4	3	4
More than one race	0	0	0
Unknown or Not Reported	0	0	0

Reporting group values	Phase I Schedule A. Volasertib 300 mg+LDAC	Phase I Schedule A. Volasertib 350 mg+LDAC	Phase I Schedule A. Volasertib 400 mg+LDAC
Number of subjects	9	8	3
Age categorical			
Treated Set: All patients in Phase I who received at least a single dose of either Volasertib or LDAC, including patients who were replaced for any reason. For the Phase II part, the treated set (Phase II) was defined as all patients in Phase II who received at least a single dose of either Volasertib or LDAC.			
Units: participants			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	2	1	0
From 65-84 years	7	7	3
85 years and over	0	0	0
Age Continuous			
Treated Set: All patients in Phase I who received at least a single dose of either Volasertib or LDAC, including patients who were replaced for any reason. For the Phase II part, the treated set (Phase II) was defined as all patients in Phase II who received at least a single dose of either Volasertib or LDAC.			
Units: years			
arithmetic mean	67.9	72.5	73.3
standard deviation	± 12.0	± 6.1	± 7.6
Gender, Male/Female			
Treated Set: All patients in Phase I who received at least a single dose of either Volasertib or LDAC, including patients who were replaced for any reason. For the Phase II part, the treated set (Phase II) was defined as all patients in Phase II who received at least a single dose of either Volasertib or LDAC.			
Units: Participants			
Female	3	3	1
Male	6	5	2
Race (NIH/OMB)			
Treated Set: All patients in Phase I who received at least a single dose of either Volasertib or LDAC, including patients who were replaced for any reason. For the Phase II part, the treated set (Phase II) was defined as all patients in Phase II who received at least a single dose of either Volasertib or LDAC.			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	1	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	8	8	3
More than one race	0	0	0
Unknown or Not Reported	0	0	0

Reporting group values	Phase I Schedule B. Volasertib 150 mg	Phase I Schedule B. Volasertib 200 mg	Phase I Schedule B. Volasertib 350 mg
Number of subjects	11	2	5
Age categorical			
Treated Set: All patients in Phase I who received at least a single dose of either Volasertib or LDAC, including patients who were replaced for any reason. For the Phase II part, the treated set (Phase II) was defined as all patients in Phase II who received at least a single dose of either Volasertib or LDAC.			
Units: participants			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	11	2	5
85 years and over	0	0	0
Age Continuous			
Treated Set: All patients in Phase I who received at least a single dose of either Volasertib or LDAC, including patients who were replaced for any reason. For the Phase II part, the treated set (Phase II) was defined as all patients in Phase II who received at least a single dose of either Volasertib or LDAC.			
Units: years			
arithmetic mean	73.5	73.0	70.6
standard deviation	± 3.9	± 4.2	± 2.9
Gender, Male/Female			
Treated Set: All patients in Phase I who received at least a single dose of either Volasertib or LDAC, including patients who were replaced for any reason. For the Phase II part, the treated set (Phase II) was defined as all patients in Phase II who received at least a single dose of either Volasertib or LDAC.			
Units: Participants			
Female	3	1	3
Male	8	1	2
Race (NIH/OMB)			
Treated Set: All patients in Phase I who received at least a single dose of either Volasertib or LDAC, including patients who were replaced for any reason. For the Phase II part, the treated set (Phase II) was defined as all patients in Phase II who received at least a single dose of either Volasertib or LDAC.			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	11	2	5
More than one race	0	0	0
Unknown or Not Reported	0	0	0

Reporting group values	Phase I Schedule B. Volasertib 400 mg	Phase I Schedule B. Volasertib 450 mg	Phase I Schedule B. Volasertib 500 mg
Number of subjects	6	23	5
Age categorical			
Treated Set: All patients in Phase I who received at least a single dose of either Volasertib or LDAC, including patients who were replaced for any reason. For the Phase II part, the treated set (Phase II) was defined as all patients in Phase II who received at least a single dose of either Volasertib or LDAC.			
Units: participants			
In utero	0	0	0

Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	1	7	1
From 65-84 years	5	16	4
85 years and over	0	0	0
Age Continuous			
Treated Set: All patients in Phase I who received at least a single dose of either Volasertib or LDAC, including patients who were replaced for any reason. For the Phase II part, the treated set (Phase II) was defined as all patients in Phase II who received at least a single dose of either Volasertib or LDAC.			
Units: years			
arithmetic mean	65.2	68.2	66.4
standard deviation	± 20.1	± 7.7	± 7.3
Gender, Male/Female			
Treated Set: All patients in Phase I who received at least a single dose of either Volasertib or LDAC, including patients who were replaced for any reason. For the Phase II part, the treated set (Phase II) was defined as all patients in Phase II who received at least a single dose of either Volasertib or LDAC.			
Units: Participants			
Female	2	16	1
Male	4	7	4
Race (NIH/OMB)			
Treated Set: All patients in Phase I who received at least a single dose of either Volasertib or LDAC, including patients who were replaced for any reason. For the Phase II part, the treated set (Phase II) was defined as all patients in Phase II who received at least a single dose of either Volasertib or LDAC.			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	6	21	5
More than one race	0	0	0
Unknown or Not Reported	0	2	0

Reporting group values	Phase I Schedule B. Volasertib 550 mg	Phase II Schedule C. LDAC	Phase II Schedule A. Volasertib 350 mg+LDAC
Number of subjects	4	45	42
Age categorical			
Treated Set: All patients in Phase I who received at least a single dose of either Volasertib or LDAC, including patients who were replaced for any reason. For the Phase II part, the treated set (Phase II) was defined as all patients in Phase II who received at least a single dose of either Volasertib or LDAC.			
Units: participants			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	2	0

From 65-84 years	4	41	40
85 years and over	0	2	2

Age Continuous			
Treated Set: All patients in Phase I who received at least a single dose of either Volasertib or LDAC, including patients who were replaced for any reason. For the Phase II part, the treated set (Phase II) was defined as all patients in Phase II who received at least a single dose of either Volasertib or LDAC.			
Units: years			
arithmetic mean	69.8	75.2	75.6
standard deviation	± 4.1	± 5.5	± 4.9
Gender, Male/Female			
Treated Set: All patients in Phase I who received at least a single dose of either Volasertib or LDAC, including patients who were replaced for any reason. For the Phase II part, the treated set (Phase II) was defined as all patients in Phase II who received at least a single dose of either Volasertib or LDAC.			
Units: Participants			
Female	3	20	19
Male	1	25	23
Race (NIH/OMB)			
Treated Set: All patients in Phase I who received at least a single dose of either Volasertib or LDAC, including patients who were replaced for any reason. For the Phase II part, the treated set (Phase II) was defined as all patients in Phase II who received at least a single dose of either Volasertib or LDAC.			
Units: Subjects			
American Indian or Alaska Native	0	1	0
Asian	0	1	1
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	4	35	34
More than one race	0	0	0
Unknown or Not Reported	0	8	7

Reporting group values	Total		
Number of subjects	175		
Age categorical			
Treated Set: All patients in Phase I who received at least a single dose of either Volasertib or LDAC, including patients who were replaced for any reason. For the Phase II part, the treated set (Phase II) was defined as all patients in Phase II who received at least a single dose of either Volasertib or LDAC.			
Units: participants			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	0		
Adolescents (12-17 years)	0		
Adults (18-64 years)	17		
From 65-84 years	154		
85 years and over	4		
Age Continuous			
Treated Set: All patients in Phase I who received at least a single dose of either Volasertib or LDAC, including patients who were replaced for any reason. For the Phase II part, the treated set (Phase II) was defined as all patients in Phase II who received at least a single dose of either Volasertib or LDAC.			
Units: years			
arithmetic mean			

standard deviation	-		

Gender, Male/Female			
Treated Set: All patients in Phase I who received at least a single dose of either Volasertib or LDAC, including patients who were replaced for any reason. For the Phase II part, the treated set (Phase II) was defined as all patients in Phase II who received at least a single dose of either Volasertib or LDAC.			
Units: Participants			
Female	79		
Male	96		
Race (NIH/OMB)			
Treated Set: All patients in Phase I who received at least a single dose of either Volasertib or LDAC, including patients who were replaced for any reason. For the Phase II part, the treated set (Phase II) was defined as all patients in Phase II who received at least a single dose of either Volasertib or LDAC.			
Units: Subjects			
American Indian or Alaska Native	1		
Asian	4		
Native Hawaiian or Other Pacific Islander	0		
Black or African American	0		
White	153		
More than one race	0		
Unknown or Not Reported	17		

End points

End points reporting groups

Reporting group title	Phase I Schedule A. Volasertib 150 mg+LDAC
Reporting group description:	
Volasertib 150 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle) and Low-dose cytarabine (LDAC) 2x20mg per day administered by subcutaneous injection on days 1-10 of each 28 day treatment cycle.	
Reporting group title	Phase I Schedule A. Volasertib 200 mg+LDAC
Reporting group description:	
Volasertib 200 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle) and Low-dose cytarabine (LDAC) 2x20mg per day administered by subcutaneous injection on days 1-10 of each 28 day treatment cycle.	
Reporting group title	Phase I Schedule A. Volasertib 250 mg+LDAC
Reporting group description:	
Volasertib 250 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle) and Low-dose cytarabine (LDAC) 2x20mg per day administered by subcutaneous injection on days 1-10 of each 28 day treatment cycle.	
Reporting group title	Phase I Schedule A. Volasertib 300 mg+LDAC
Reporting group description:	
Volasertib 300 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle) and Low-dose cytarabine (LDAC) 2x20mg per day administered by subcutaneous injection on days 1-10 of each 28 day treatment cycle.	
Reporting group title	Phase I Schedule A. Volasertib 350 mg+LDAC
Reporting group description:	
Volasertib 350 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle) and Low-dose cytarabine (LDAC) 2x20mg per day administered by subcutaneous injection on days 1-10 of each 28 day treatment cycle.	
Reporting group title	Phase I Schedule A. Volasertib 400 mg+LDAC
Reporting group description:	
Volasertib 400 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle) and Low-dose cytarabine (LDAC) 2x20mg per day administered by subcutaneous injection on days 1-10 of each 28 day treatment cycle.	
Reporting group title	Phase I Schedule B. Volasertib 150 mg
Reporting group description:	
Volasertib 150 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle).	
Reporting group title	Phase I Schedule B. Volasertib 200 mg
Reporting group description:	
Volasertib 200 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle).	
Reporting group title	Phase I Schedule B. Volasertib 350 mg
Reporting group description:	
Volasertib 350 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle).	
Reporting group title	Phase I Schedule B. Volasertib 400 mg
Reporting group description:	
Volasertib 400 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle).	
Reporting group title	Phase I Schedule B. Volasertib 450 mg
Reporting group description:	
Volasertib 450 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle).	
Reporting group title	Phase I Schedule B. Volasertib 500 mg
Reporting group description:	
Volasertib 500 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1	

and 15 (28-day cycle).

Reporting group title	Phase I Schedule B. Volasertib 550 mg

Reporting group description:

Volasertib 550 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle).

Reporting group title	Phase II Schedule C. LDAC

Reporting group description:

Low-dose cytarabine (LDAC) monotherapy 2x20 milligram (mg) per day administered by subcutaneous injection on days 1-10 of each 28 days treatment cycle.

Reporting group title	Phase II Schedule A. Volasertib 350 mg+LDAC

Reporting group description:

Volasertib 350 milligram (mg) on Days 1 and 15 (28-day cycle) administered by Intravenous Infusion (IV) over 60 minutes and Low-dose cytarabine (LDAC) 2x20mg per day administered by subcutaneous injection on days 1-10 of each 28 days treatment cycle.

Subject analysis set title	Phase I Schedule A. Volasertib+LDAC
Subject analysis set type	Per protocol

Subject analysis set description:

PVolasertib escalating dose on Days 1 and 15 (28-day cycle). Dose escalation in 50 milligram (mg) steps up to 400 mg, with a starting dose of 150 mg and LDAC 2x20 milligram (mg) per day administered by subcutaneous injection on days 1-10 of each 28 day treatment cycle until the patient met criteria for stopping study medication during the MTD evaluation period.

Subject analysis set title	Phase I Schedule B. Volasertib
Subject analysis set type	Per protocol

Subject analysis set description:

Volasertib escalating dose on Days 1 and 15 (28-day cycle). Dose escalation in 50 milligram (mg) steps from an initial starting dose of 150 mg; dose escalation stopped at 200 mg and then restarted from the MTD dose in Schedule A (350 mg); dose was escalated up to 550 mg. Volasertib administered by Intravenous Infusion (IV) over 60 minutes.

Subject analysis set title	Phase II Combined. Schedule A and C
Subject analysis set type	Per protocol

Subject analysis set description:

Volasertib escalating dose on Days 1 and 15 (28-day cycle). Dose escalation in 50 milligram (mg) steps up to 400 mg, with a starting dose of 150 mg. Volasertib 350 mg on Days 1+15 (28-day cycle) administered by Intravenous Infusion (IV) over 60 minutes and Low-dose cytarabine (LDAC) 2x20mg per day administered by subcutaneous injection on days 1-10 of each 28 day treatment cycle.

Subject analysis set title	Dose norm Volasertib+LDAC (Phase I A). 150-400 mg Volasertib
Subject analysis set type	Per protocol

Subject analysis set description:

Volasertib 150 to 400 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle) and Low-dose cytarabine (LDAC) 2x20mg per day administered by subcutaneous injection on days 1-10 of each 28 day treatment cycle. Dose groups of Phase I were combined by dose normalizing as pre specified in the study protocol.

Subject analysis set title	Phase I+II Volasertib 350 mg+LDAC
Subject analysis set type	Per protocol

Subject analysis set description:

Phase I+II: Volasertib 350 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle) and Low-dose cytarabine (LDAC) 2x20mg per day administered by subcutaneous injection on days 1-10 of each 28 day treatment cycle.

Primary: Phase I: Maximum Tolerated Dose (MTD) of Volasertib in Combination with LDAC (schedule A) and Volasertib monotherapy (schedule B)

End point title	Phase I: Maximum Tolerated Dose (MTD) of Volasertib in Combination with LDAC (schedule A) and Volasertib monotherapy (schedule B)[1]

End point description:

To determine the Maximum tolerated dose (MTD), dose escalation was conducted following 3+3 design with de-escalation. The MTD was defined as the highest dose at which 6 patients had been treated and less than 2 patients experienced a Dose limiting toxicity (DLT), first cycle only. DLT is defined as drug

related Common terminology criteria for adverse events (CTCAE) grade ≥ 3 nonhaematological toxicity (excluding: untreated nausea, untreated vomiting, CTCAE grade 3 untreated diarrhoea, CTCAE grade 3 "febrile neutropenia" and CTCAE grade 3 "infection with grade 3 or 4 neutrophils"). In patients with CRi or PR, persistent CTCAE grade 4 neutropenia or thrombocytopenia until three weeks after the end of the treatment cycle were regarded a DLT. Treated Set-phase I part: all patients who received at least a single dose of either Volasertib or LDAC, including patients who were replaced for any reason.

End point type	Primary

End point timeframe:

First Treatment cycle, up to 28 days.

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: As pre-specified in the protocol this end point only analyses the Phase I arms.

End point values	Phase I Schedule A. Volasertib+LDAC	Phase I Schedule B. Volasertib		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	32	56		
Units: milligram (mg)	350	450		

Statistical analyses

No statistical analyses for this end point

Primary: Phase II: Number of patients with Objective Response (Complete remission (CR) + Complete remission with incomplete blood count recovery (CRi))

End point title	Phase II: Number of patients with Objective Response (Complete remission (CR) + Complete remission with incomplete blood count recovery (CRi))[2]

End point description:

Phase II: Number of patients with Objective Response (Complete remission (CR) + Complete remission with incomplete blood count recovery (CRi)).
Treated set-phase II part: Treated Set was defined as all patients who received at least a single dose of either Volasertib or LDAC.

End point type	Primary

End point timeframe:

The best overall response recorded during the time period from the start of the treatment until end of the treatment period, progression or death (whichever was earlier), up to 869 days.

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As pre-specified in the protocol this end point only analyses the Phase II arms.

End point values	Phase II Schedule C. LDAC	Phase II Schedule A. Volasertib 350 mg+LDAC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	45	42		
Units: Participants	6	13		

Statistical analyses

Statistical analysis title	Statistical Analysis
Statistical analysis description:	
Analysis for Objective Response. Ratio calculated as Phase II Schedule A Volasertib 350mg+LDAC divided by Phase II Schedule C LDAC.	
Comparison groups	Phase II Schedule C. LDAC v Phase II Schedule A. Volasertib 350 mg+LDAC
Number of subjects included in analysis	87
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0523
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	2.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.99
upper limit	8.58

Primary: Phase I: Number of Participants with Dose Limiting Toxicities (DLTs) in the First Cycle for the Determination of the Maximum Tolerated Dose (MTD)

End point title	Phase I: Number of Participants with Dose Limiting Toxicities (DLTs) in the First Cycle for the Determination of the Maximum Tolerated Dose (MTD)[3][4]
End point description:	
A DLT was defined as a drug related CTCAE (Common Toxicity Criteria for Adverse Events) Grade ≥3 non-haematological toxicity (excluding untreated nausea, untreated vomiting, Grade 3 untreated diarrhea, Grade 3 febrile neutropenia, and Grade 3 infection with Grade 3 or 4 neutrophils). In patients with CRi (Complete Remission with Incomplete Blood Count Recovery) or PR (Partial Remission), persistent Grade 4 neutropenia or thrombocytopenia for 3 weeks after the end of the treatment cycle was regarded as a DLT unless the respective Grade 4 cytopenia was preexistent. In patients who required platelet substitution to maintain a Grade <4 before treatment, a Grade 4 thrombocytopenia after treatment did not constitute a DLT. Treated Set-Phase I part: Treated Set was defined as all patients who received at least a single dose of either Volasertib (BI 6727) or LDAC (Low-Dose Cytarabine), including patients who were replaced for any reason.	
End point type	Primary
End point timeframe:	
First Treatment cycle, up to 28 days.	
Notes:	
[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point. Justification: As pre-specified in the protocol this end point only analyses the Phase I arms.	
[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: As pre-specified in the protocol this end point only analyses the Phase I arms.	

End point values	Phase I Schedule A. Volasertib 150 mg+LDAC	Phase I Schedule A. Volasertib 200 mg+LDAC	Phase I Schedule A. Volasertib 250 mg+LDAC	Phase I Schedule A. Volasertib 300 mg+LDAC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	5	9
Units: Participants	0	0	0	1

End point values	Phase I Schedule A. Volasertib 350 mg+LDAC	Phase I Schedule A. Volasertib 400 mg+LDAC	Phase I Schedule B. Volasertib 150 mg	Phase I Schedule B. Volasertib 200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	3	11	2
Units: Participants	1	2	1	0

End point values	Phase I Schedule B. Volasertib 350 mg	Phase I Schedule B. Volasertib 400 mg	Phase I Schedule B. Volasertib 450 mg	Phase I Schedule B. Volasertib 500 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	6	23	5
Units: Participants	0	1	1	2

End point values	Phase I Schedule B. Volasertib 550 mg	Phase I Schedule A. Volasertib+LDAC	Phase I Schedule B. Volasertib	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	4	32	56	
Units: Participants	2	4	7	

Statistical analyses

No statistical analyses for this end point

Secondary: Best Overall Response

End point title	Best Overall Response

End point description:

Best overall response: The best overall response recorded during the time period from the start of the treatment until end of the treatment period, progression or death (whichever was earlier). Possible responses for best overall response were: Complete remission (CR), Complete remission with incomplete blood count recovery (CRi), Partial remission (PR), no change, aplasia, Indeterminate, Progressive disease (PD), Not evaluable or missing. Patients dying before any assessment were classified as PD for best overall response. The number of participants for each response is reported.
Treated Set-phase I part: Treated Set was defined as all patients who received at least a single dose of either Volasertib or LDAC, including patients who were replaced for any reason. Phase II part, the

Treated Set was defined as all patients who received at least a single dose of either Volasertib or LDAC.

End point type	Secondary

End point timeframe:

The best overall response recorded during the time period from the start of the treatment until end of the treatment period, progression or death (whichever was earlier), up to 869 days.

End point values	Phase I Schedule A. Volasertib 150 mg+LDAC	Phase I Schedule A. Volasertib 200 mg+LDAC	Phase I Schedule A. Volasertib 250 mg+LDAC	Phase I Schedule A. Volasertib 300 mg+LDAC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	5	9
Units: Participants				
Complete remission	0	0	2	0
CRi	0	2	0	1
Partial remission	0	0	0	0
No change	2	1	2	1
Aplasia	0	0	0	0
Indeterminate	0	0	0	2
Progressive disease	2	0	1	3
Not evaluable	0	0	0	1
Missing	0	0	0	1

End point values	Phase I Schedule A. Volasertib 350 mg+LDAC	Phase I Schedule A. Volasertib 400 mg+LDAC	Phase I Schedule B. Volasertib 150 mg	Phase I Schedule B. Volasertib 200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	3	11	2
Units: Participants				
Complete remission	0	0	0	0
CRi	1	0	0	0
Partial remission	0	0	0	0
No change	1	1	4	0
Aplasia	0	0	0	0
Indeterminate	3	1	1	0
Progressive disease	3	1	6	2
Not evaluable	0	0	0	0
Missing	0	0	0	0

End point values	Phase I Schedule B. Volasertib 350 mg	Phase I Schedule B. Volasertib 400 mg	Phase I Schedule B. Volasertib 450 mg	Phase I Schedule B. Volasertib 500 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	6	23	5
Units: Participants				

Complete remission	0	0	0	0
CRi	1	2	2	0
Partial remission	1	0	2	0
No change	2	2	7	3
Aplasia	0	1	3	1
Indeterminate	0	0	0	0
Progressive disease	1	1	7	1
Not evaluable	0	0	2	0
Missing	0	0	0	0

End point values	Phase I Schedule B. Volasertib 550 mg	Phase II Schedule C. LDAC	Phase II Schedule A. Volasertib 350 mg+LDAC	Phase I Schedule A. Volasertib+LDAC
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	4	45	42	32
Units: Participants				
Complete remission	0	3	6	2
CRi	0	3	7	4
Partial remission	1	2	2	0
No change	0	18	15	8
Aplasia	1	0	0	0
Indeterminate	0	3	5	6
Progressive disease	1	14	7	10
Not evaluable	1	2	0	1
Missing	0	0	0	1

End point values	Phase I Schedule B. Volasertib	Phase II Combined. Schedule A and C		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	56	87		
Units: Participants				
Complete remission	0	9		
CRi	5	10		
Partial remission	4	4		
No change	18	33		
Aplasia	6	0		
Indeterminate	1	8		
Progressive disease	19	21		
Not evaluable	3	2		
Missing	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase I: Number of Patients with Objective Response: Complete remission or Complete remission with incomplete blood count recovery (CR+CRi)

End point title	Phase I: Number of Patients with Objective Response: Complete remission or Complete remission with incomplete blood count recovery (CR+CRi)[5]

End point description:

Phase I: Objective Response (yes/no): yes=Best Overall Response of Complete remission (CR) or Complete remission with incomplete blood count recovery (CRi), no=all others.
Treated Set-phase I part: Treated Set was defined as all patients who received at least a single dose of either Volasertib or LDAC, including patients who were replaced for any reason.

End point type	Secondary

End point timeframe:

The best overall response recorded during the time period from the start of the treatment until end of the treatment period, progression or death (whichever was earlier), up to 594 days.

Notes:

[5] - 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: As pre-specified in the protocol this end point only analyses the Phase I arms.

End point values	Phase I Schedule A. Volasertib 150 mg+LDAC	Phase I Schedule A. Volasertib 200 mg+LDAC	Phase I Schedule A. Volasertib 250 mg+LDAC	Phase I Schedule A. Volasertib 300 mg+LDAC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	5	9
Units: Participants	0	2	2	1

End point values	Phase I Schedule A. Volasertib 350 mg+LDAC	Phase I Schedule A. Volasertib 400 mg+LDAC	Phase I Schedule B. Volasertib 150 mg	Phase I Schedule B. Volasertib 200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	3	11	2
Units: Participants	1	0	0	0

End point values	Phase I Schedule B. Volasertib 350 mg	Phase I Schedule B. Volasertib 400 mg	Phase I Schedule B. Volasertib 450 mg	Phase I Schedule B. Volasertib 500 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	6	23	5
Units: Participants	1	2	2	0

End point values	Phase I Schedule B. Volasertib 550 mg	Phase I Schedule A. Volasertib+LDAC	Phase I Schedule B. Volasertib	

Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	4	32	56	
Units: Participants	0	6	5	

Statistical analyses

No statistical analyses for this end point

Secondary: Phase II: Event Free Survival

End point title	Phase II: Event Free Survival[6]

End point description:

Event-free survival (EFS) [days] was the shortest duration of the following: (a) Date of assessment indicating PD on the response page of the eCRF (Electronic Case Report Form) – date of randomisation + 1 day (b) Date of assessment indicating clinical progressive disease (PD) on the disease or responses pages of the of eCRF– date of randomisation + 1 day (c) Date of assessment indicating PD on the patient status page of the eCRF – date of randomisation +1 day (for patients who had not been censored before this time point) (d) Death date – date of randomisation +1 day. Patients not being assessed PD, clinical PD, or death during the trial were censored. EFS was analysed with the Kaplan-Meier method for each of the treatment arms.

Treated Set-Phase II part: Treated Set was defined as all patients who received at least a single dose of either Volasertib or LDAC.

End point type	Secondary

End point timeframe:

The patients that entered the trial, and measured from the date of randomization to the date of disease progression (treatment failure), relapse or death from any cause, whichever occurred first, up to 1000 days..

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: As pre-specified in the protocol this end point only analyses the Phase II arms.

End point values	Phase II Schedule C. LDAC	Phase II Schedule A. Volasertib 350 mg+LDAC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	45	42		
Units: Days				
median (inter-quartile range (Q1-Q3))	69.0 (27 to 215)	169.0 (39 to 470)		

Statistical analyses

Statistical analysis title	Statistical analysis 2

Statistical analysis description:

An exploratory (non-stratified) logrank test was used to compare the different treatment arms.

Comparison groups	Phase II Schedule C. LDAC v Phase II Schedule A. Volasertib 350 mg+LDAC

Number of subjects included in analysis	87
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0208
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.57
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.35
upper limit	0.92

Secondary: Phase II: Overall Survival	
End point title	Phase II: Overall Survival[7]

End point description:

Overall survival [days] = (date of death - date of randomisation + 1 day), for patients with known date of death. Overall survival (censored) [days] = (date of last trial visit or follow-up - date of randomisation + 1 day), for patients who were still alive at time of database lock.
Overall survival (OS) was analysed with the Kaplan-Meier method for each of the treatment arms.
Treated Set-Phase II part: Treated Set was defined as all patients who received at least a single dose of either Volasertib or LDAC.

End point type	Secondary

End point timeframe:

The patients that entered the trial, and measured from the date of randomisation until death from any cause, up to 1100 days..

Notes:

[7] - 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: As pre-specified in the protocol this end point only analyses the Phase II arms.

End point values	Phase II Schedule C. LDAC	Phase II Schedule A. Volasertib 350 mg+LDAC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	45	42		
Units: Days				
median (inter-quartile range (Q1-Q3))	158.0 (78 to 347)	245.0 (73 to 689)		

Statistical analyses

Statistical analysis title	Statistical analysis 3

Statistical analysis description:

An exploratory (non-stratified) logrank test was used to compare the different treatment arms.

Comparison groups	Phase II Schedule C. LDAC v Phase II Schedule A. Volasertib 350 mg+LDAC

Number of subjects included in analysis	87
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0465
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.63
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.4
upper limit	1

Secondary: Phase II: Relapse - Free Survival

End point title	Phase II: Relapse - Free Survival[8]

End point description:

Relapse-free survival [days] = (date of first recurrence of disease or death after entering the trial – date of first occurrence of CR or CRi after entering the trial+ 1 day) for patients with a recurrence (this value should be positive).
Relapse-free survival (censored) [days] = (date of last trial visit or follow-up - date of first occurrence of CR or CRi after entering the trial + 1 day) for patients who did not experience recurrence of disease or death at the time of analysis.
Patients in Treated Set-Phase II with objective response. Treated Set-Phase II part: Treated Set was defined as all patients who received at least a single dose of either Volasertib or LDAC.

End point type	Secondary

End point timeframe:

The patients who achieved CR or CRi, and was measured from the date of attaining CR or CRi until the date of disease recurrence or death from any cause, whichever occurred first, up to 900 days.

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As pre-specified in the protocol this end point only analyses the Phase II arms.

End point values	Phase II Schedule C. LDAC	Phase II Schedule A. Volasertib 350 mg+LDAC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	13[9]		
Units: Days				
median (inter-quartile range (Q1-Q3))	304.0 (113 to 367)	563.0 (427 to 99999)		

Notes:

[9] - 99999 = NA, 25% quartile not reached, not enough events occurred.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase II: Remission Duration

End point title	Phase II: Remission Duration[10]

End point description:

Remission duration analysis was defined only for patients who achieved Complete remission (CR) or Complete remission with incomplete blood count recovery (CRi), and was measured from the date of attaining CR or CRi 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 cause.
Patients in Treated Set-Phase II with objective response. Treated Set-Phase II part: Treated Set was defined as all patients who received at least a single dose of either Volasertib or LDAC.

End point type	Secondary

End point timeframe:

The patients who achieved CR or CRi, and was measured from the date of attaining CR or CRi until the date of disease recurrence (relapse), up to 900 days.

Notes:

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As pre-specified in the protocol this end point only analyses the Phase II arms.

End point values	Phase II Schedule C. LDAC	Phase II Schedule A. Volasertib 350 mg+LDAC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	13[11]		
Units: Days				
median (inter-quartile range (Q1-Q3))	367.0 (113 to 367)	687.0 (427 to 99999)		

Notes:

[11] - 99999 = NA, 25% quartile not reached, not enough events occurred.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase II: Time to Remission

End point title	Phase II: Time to Remission[12]

End point description:

Time to remission [days] = (date of first occurrence of CR or CRi after entering the trial–date of randomisation + 1 day) for patients with an objective response.
Patients in Treated Set-Phase II with objective response. Treated Set-Phase II part: Treated Set was defined as all patients who received at least a single dose of either Volasertib or LDAC.

End point type	Secondary

End point timeframe:

The patients who achieved CR or CRi, and was measured from the date of attaining CR or CRi until the date of disease recurrence (relapse), up to 158 days.

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As pre-specified in the protocol this end point only analyses the Phase II arms.

End point values	Phase II Schedule C. LDAC	Phase II Schedule A. Volasertib 350 mg+LDAC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	13		
Units: Days				

median (full range (min-max))	63.5 (30 to 125)	71.0 (29 to 158)		

Statistical analyses

No statistical analyses for this end point

Secondary: Best Eastern Co-operative Oncology Group (ECOG) Performance Score from Baseline until End of Treatment

End point title	Best Eastern Co-operative Oncology Group (ECOG) Performance Score from Baseline until End of Treatment

End point description:

ECOG performance score change from baseline to last visit of last cycle = ECOG performance score at last visit of the last cycle – ECOG performance score at baseline. ECOG performance score changes from baseline were also categorised on a 3-point categorical scale: deteriorated (-1), unchanged (0), and improved (1). The number of participants for category of ECOG score change is reported.
Treated Set-Phase I part: Treated Set was defined as all patients who received at least a single dose of either Volasertib or LDAC, including patients who were replaced for any reason. Phase II part, the Treated Set was defined as all patients who received at least a single dose of either Volasertib or LDAC.
Only participants with non-missing values are reported.

End point type	Secondary

End point timeframe:

Baseline and End of Treatment (up to 869 days).

End point values	Phase I Schedule A. Volasertib 150 mg+LDAC	Phase I Schedule A. Volasertib 200 mg+LDAC	Phase I Schedule A. Volasertib 250 mg+LDAC	Phase I Schedule A. Volasertib 300 mg+LDAC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	5	5
Units: Participants				
Unchanged	3	1	5	2
Improved	0	2	0	1
Deteriorated	1	0	0	2

End point values	Phase I Schedule A. Volasertib 350 mg+LDAC	Phase I Schedule A. Volasertib 400 mg+LDAC	Phase I Schedule B. Volasertib 150 mg	Phase I Schedule B. Volasertib 200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	2	10	2
Units: Participants				
Unchanged	5	1	9	1
Improved	0	0	0	0
Deteriorated	3	1	1	1

End point values	Phase I Schedule B. Volasertib 350 mg	Phase I Schedule B. Volasertib 400 mg	Phase I Schedule B. Volasertib 450 mg	Phase I Schedule B. Volasertib 500 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	6	22	5
Units: Participants				
Unchanged	0	4	14	2
Improved	1	1	3	1
Deteriorated	4	1	5	2

End point values	Phase I Schedule B. Volasertib 550 mg	Phase II Schedule C. LDAC	Phase II Schedule A. Volasertib 350 mg+LDAC	Phase I Schedule A. Volasertib+LDAC
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	3	42	39	27
Units: Participants				
Unchanged	3	22	15	17
Improved	0	8	13	3
Deteriorated	0	12	11	7

End point values	Phase I Schedule B. Volasertib	Phase II Combined. Schedule A and C		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	53	81		
Units: Participants				
Unchanged	33	37		
Improved	6	21		
Deteriorated	14	23		

Statistical analyses

No statistical analyses for this end point

Secondary: Total Clearance (CL) of Volasertib in Plasma after i.v (Intravenous) Administration of Volasertib

End point title	Total Clearance (CL) of Volasertib in Plasma after i.v (Intravenous) Administration of Volasertib[13]

End point description:

Total Clearance (CL) of Volasertib in Plasma after Intravenous (i.v.) Administration of Volasertib. Pharmacokinetic (PK) set which included all patients in the treated set who had at least 1 evaluable

blood sample during cycle 1. Phase I Schedule B Volasertib 200mg+LDAC was not analysed as there was insufficient data, Only participants with non-missing values are reported.

End point type	Secondary

End point timeframe:

Cycle 1: -0:05 hour (h), 0:30h, 1:00h, 1:30h, 2h, 3h, 4h, 24h, 96h, 216h, 335:55h, 336:30h, 337h, 337:30h, 338h, 339h, 340h, 648h after first drug administration.

Notes:

[13] - 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: As pre-specified in the protocol this end point only analyses the Phase I and Phase IIA arms.

End point values	Phase I Schedule A. Volasertib 150 mg+LDAC	Phase I Schedule A. Volasertib 200 mg+LDAC	Phase I Schedule A. Volasertib 250 mg+LDAC	Phase I Schedule A. Volasertib 300 mg+LDAC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	5	8
Units: millilitre/minute (mL/min)				
geometric mean (geometric coefficient of variation)	1280 (± 52.8)	972 (± 26.6)	864 (± 27.6)	1150 (± 34.4)

End point values	Phase I Schedule A. Volasertib 350 mg+LDAC	Phase I Schedule A. Volasertib 400 mg+LDAC	Phase I Schedule B. Volasertib 150 mg	Phase I Schedule B. Volasertib 200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	3	10	1[14]
Units: millilitre/minute (mL/min)				
geometric mean (geometric coefficient of variation)	1000 (± 36.2)	852 (± 49.6)	1330 (± 29.3)	9999 (± 9999)

Notes:

[14] - 9999 = not calculable with one subject

End point values	Phase I Schedule B. Volasertib 350 mg	Phase I Schedule B. Volasertib 400 mg	Phase I Schedule B. Volasertib 450 mg	Phase I Schedule B. Volasertib 500 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	6	22	5
Units: millilitre/minute (mL/min)				
geometric mean (geometric coefficient of variation)	810 (± 35.1)	1120 (± 62.1)	920 (± 36.2)	1140 (± 38.5)

End point values	Phase I Schedule B. Volasertib 550 mg	Phase II Schedule A. Volasertib 350 mg+LDAC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	31		
Units: millilitre/minute (mL/min)				

geometric mean (geometric coefficient of variation)	939 (± 93.2)	897 (± 42.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Apparent Volume of Distribution of volasertib at steady state (VSS)

End point title	Apparent Volume of Distribution of volasertib at steady state (VSS)[15]

End point description:

Apparent Volume of Distribution of volasertib at steady state (VSS) following Intravenous (i.v.) administration.
Pharmacokinetic (PK) set which included all patients in the treated set who had at least 1 evaluable blood sample during cycle 1. Phase I Schedule B Volasertib 200mg+LDAC was not analysed as there was insufficient data.

End point type	Secondary

End point timeframe:

Cycle 1: -0:05 hour (h), 0:30h, 1:00h, 1:30h, 2h, 3h, 4h, 24h, 96h, 216h, 335:55h, 336:30h, 337h, 337:30h, 338h, 339h, 340h, 648h after first drug administration.

Notes:

[15] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As pre-specified in the protocol this end point only analyses the Phase I and Phase IIA arms.

End point values	Phase I Schedule A. Volasertib 150 mg+LDAC	Phase I Schedule A. Volasertib 200 mg+LDAC	Phase I Schedule A. Volasertib 250 mg+LDAC	Phase I Schedule A. Volasertib 300 mg+LDAC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	5	8
Units: Liter (L)				
geometric mean (geometric coefficient of variation)	10600 (± 111.0)	8640 (± 14.1)	7000 (± 26.6)	6320 (± 35.9)

End point values	Phase I Schedule A. Volasertib 350 mg+LDAC	Phase I Schedule A. Volasertib 400 mg+LDAC	Phase I Schedule B. Volasertib 150 mg	Phase I Schedule B. Volasertib 200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	3	10	1[16]
Units: Liter (L)				
geometric mean (geometric coefficient of variation)	5270 (± 58.2)	4830 (± 56.7)	10300 (± 36.3)	9999 (± 9999)

Notes:

[16] - 9999 = Not calculable with one subject

End point values	Phase I	Phase I	Phase I	Phase I

	Schedule B. Volasertib 350 mg	Schedule B. Volasertib 400 mg	Schedule B. Volasertib 450 mg	Schedule B. Volasertib 500 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	6	22	5
Units: Liter (L)				
geometric mean (geometric coefficient of variation)	5800 (± 35.1)	7150 (± 70.6)	5740 (± 38.7)	6360 (± 50.1)

End point values	Phase I Schedule B. Volasertib 550 mg	Phase II Schedule A. Volasertib 350 mg+LDAC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	31		
Units: Liter (L)				
geometric mean (geometric coefficient of variation)	5680 (± 81.9)	6130 (± 42.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Dose normalized maximum measured concentration of cytarabine in plasma (Cmax, norm)

End point title	Dose normalized maximum measured concentration of cytarabine in plasma (Cmax, norm)[17]

End point description:

Cmax, norm: Maximum measured concentration of Cytarabine in plasma. The dose normalisation was done by dividing by the dose applied. Unit: nanogram/milliliter/milligram: ((ng/mL)/mg). Dose groups of Phase I were combined by dose normalizing as pre specified in the study protocol.
Pharmacokinetic (PK) set which included all patients in the treated set who had at least 1 evaluable blood sample during cycle 1, Only participants with non-missing values are reported.

End point type	Secondary

End point timeframe:

Cycle 1: -0:05 hour (h), 0:30h, 1:00h, 1:30h, 2h, 3h, 4h, 24h, 96h, 216h, 335:55h, 336:30h, 337h, 337:30h, 338h, 339h, 340h, 648h after first drug administration.

Notes:

[17] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As pre-specified in the protocol this end point Phase IA arms were combined and compared to the Phase II C and Phase II A (350 mg) arms.

End point values	Phase II Schedule C. LDAC	Phase II Schedule A. Volasertib 350 mg+LDAC	Dose norm Volasertib+LDAC (Phase I A). 150-400 mg Volasertib	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	40	41	32	
Units: (ng/mL)/mg				
geometric mean (geometric coefficient	2.36 (± 77.6)	2.83 (± 52.8)	2.92 (± 61.3)	

of variation)

Statistical analyses

No statistical analyses for this end point

Secondary: Dose Normalized Area Under the Concentration-Time Curve of Cytarabine in Plasma Over the Time Interval from 0 Extrapolated up to 4 hours

End point title	Dose Normalized Area Under the Concentration-Time Curve of Cytarabine in Plasma Over the Time Interval from 0 Extrapolated up to 4 hours[18]

End point description:

AUC0-4,norm: Area under the concentration-time curve of Cytarabine in plasma over the time interval from zero extrapolated to 4 hours. The dose normalisation was done by dividing by dose applied. Unit: nanogram*hour/milliliter/milligram: ((ng*h/mL)/mg). Dose groups of Phase I were combined by dose normalizing as pre specified in the study protocol.
Pharmacokinetic (PK) set which included all patients in the treated set who had at least 1 evaluable blood sample during cycle 1, Only participants with non-missing values are reported.

End point type	Secondary

End point timeframe:

Cycle 1: -0:05 hour (h), 0:30h, 1:00h, 1:30h, 2h, 3h, 4h after first drug administration.

Notes:

[18] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As pre-specified in the protocol this end point Phase IA arms were combined and compared to the Phase II C and Phase II A (350 mg) arms.

End point values	Phase II Schedule C. LDAC	Phase II Schedule A. Volasertib 350 mg+LDAC	Dose norm Volasertib+LDAC (Phase I A). 150-400 mg Volasertib	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	40	41	32	
Units: (ng*h/mL)/mg				
geometric mean (geometric coefficient of variation)	3.94 (± 43.8)	4.00 (± 35.6)	3.84 (± 30.6)	

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute QTcF (QT Interval Corrected for Heart Rate Using Fridericia's Formula) Intervals

End point title	Absolute QTcF (QT Interval Corrected for Heart Rate Using Fridericia's Formula) Intervals[19]

End point description:

ECG (electrocardiogram) Measurements: Absolute QTcF (QT Interval (interval from the beginning of the QRS complex to the end of the T wave) Corrected for Heart Rate Using Fridericia's Formula) Intervals.

Treated Set-Phase I part: Treated Set was defined as all patients who received at least a single dose of either Volasertib or LDAC, including patients who were replaced for any reason. Only participants with non-missing values are reported. The 350 mg + LDAC arm of phase I and II were combined into one arm to provide maximum information on QT changes and presented together with the Phase I schedule B 450 mg arm, as pre specified in the study protocol.

End point type	Secondary

End point timeframe:

Baseline (Days -14 to -1) and day 1 (1 hour and 24 hours) after start of infusion.

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: As pre-specified in the protocol only arms with sufficient subject numbers were included in this endpoint.

End point values	Phase I Schedule B. Volasertib 450 mg	Phase I+II Volasertib 350 mg+LDAC		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	23	50		
Units: milliseconds (ms)				
arithmetic mean (standard deviation)				
Individual baseline	412.4 (± 18.7)	411.6 (± 20.7)		
1 hour after start of infusion	441.1 (± 20.0)	430.0 (± 20.4)		
24 hour after start of infusion	411.9 (± 18.4)	414.0 (± 21.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: QTcF (QT Interval Corrected for Heart Rate Using Fridericia's Formula) Change from Baseline at Cycle 1

End point title	QTcF (QT Interval Corrected for Heart Rate Using Fridericia's Formula) Change from Baseline at Cycle 1[20]

End point description:

ECG Measurements: QTcF (QT Interval (interval from the beginning of the QRS complex to the end of the T wave) changes from baseline at each time point: The QTcF post baseline measurement obtained at time t minus baseline QTcF measurement.
Treated Set-Phase I part: Treated Set was defined as all patients who received at least a single dose of either Volasertib or LDAC, including patients who were replaced for any reason. Only participants with non-missing values are reported. The 350 mg + LDAC arm of phase I and II were combined into one arm to provide maximum information on QT changes and presented together with the Phase I schedule B 450 mg arm, as pre specified in the study protocol.

End point type	Secondary

End point timeframe:

Baseline (Days -14 to -1) and day 1 (1 hour and 24 hours) after start of infusion.

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: As pre-specified in the protocol only arms with sufficient subject numbers were included in this endpoint.

End point values	Phase I Schedule B. Volasertib 450 mg	Phase I+II Volasertib 350 mg+LDAC		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	23	50		
Units: millisecond (ms)				
arithmetic mean (standard deviation)				
Change from baseline after 1 hour	29.6 (± 8.1)	18.5 (± 10.4)		
Change from baseline after 24 hour	-0.5 (± 9.8)	1.9 (± 10.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase I Schedule A: Incidence and Intensity of Adverse Events (AEs) Graded According to Common Terminology Criteria for Adverse Events (CTCAE), based on the number of patients with AEs with CTCAE Grade ≥3 during Cycle 1

End point title	Phase I Schedule A: Incidence and Intensity of Adverse Events (AEs) Graded According to Common Terminology Criteria for Adverse Events (CTCAE), based on the number of patients with AEs with CTCAE Grade ≥3 during Cycle 1[21]

End point description:

Number of patients with AEs following in the categories 3 (severe AE), 4 (life-threatening or disabling AE), 5 (death related AE) of CTCAE is reported.
Treated set-Phase I part: Treated set was defined as all patients in Phase I who received at least a single dose of either Volasertib or LDAC, including patients who were replaced for any reason.

End point type	Secondary

End point timeframe:

First treatment cycle, up to 28 days.

Notes:

[21] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint only considers the Phase IA arms, other arms are reported in a separate endpoint.

End point values	Phase I Schedule A. Volasertib 150 mg+LDAC	Phase I Schedule A. Volasertib 200 mg+LDAC	Phase I Schedule A. Volasertib 250 mg+LDAC	Phase I Schedule A. Volasertib 300 mg+LDAC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	5	9
Units: Participants				
Grade 3	0	0	1	1
Grade 4	2	3	3	5
Grade 5	0	0	0	3

End point values	Phase I Schedule A. Volasertib 350 mg+LDAC	Phase I Schedule A. Volasertib 400 mg+LDAC	Phase I Schedule A. Volasertib+LDAC	

Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	8	3	32	
Units: Participants				
Grade 3	2	1	5	
Grade 4	3	1	17	
Grade 5	2	1	6	

Statistical analyses

No statistical analyses for this end point

Secondary: Phase I Schedule B: Incidence and Intensity of Adverse Events (AEs) Graded According to Common Terminology Criteria for Adverse Events (CTCAE), based on the number of patients with AEs with CTCAE Grade ≥3 during Cycle 1

End point title	Phase I Schedule B: Incidence and Intensity of Adverse Events (AEs) Graded According to Common Terminology Criteria for Adverse Events (CTCAE), based on the number of patients with AEs with CTCAE Grade ≥3 during Cycle 1[22]

End point description:

Number of patients with AEs following in the categories 3 (severe AE), 4 (life-threatening or disabling AE), 5 (death related AE) of CTCAE is reported.
Treated set-Phase I part: Treated set was defined as all patients in Phase I who received at least a single dose of either Volasertib or LDAC, including patients who were replaced for any reason.

End point type	Secondary

End point timeframe:

First treatment cycle, up to 28 days.

Notes:

[22] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint only considers the Phase IB arms, other arms are reported in a separate endpoint.

End point values	Phase I Schedule B. Volasertib 150 mg	Phase I Schedule B. Volasertib 200 mg	Phase I Schedule B. Volasertib 350 mg	Phase I Schedule B. Volasertib 400 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	2	5	6
Units: Participants				
Grade 3	5	0	1	0
Grade 4	4	1	3	4
Grade 5	1	1	0	0

End point values	Phase I Schedule B. Volasertib 450 mg	Phase I Schedule B. Volasertib 500 mg	Phase I Schedule B. Volasertib 550 mg	Phase I Schedule B. Volasertib
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	23	5	4	56
Units: Participants				

Grade 3	5	0	0	11
Grade 4	14	1	3	30
Grade 5	2	1	1	6

Statistical analyses

No statistical analyses for this end point

Secondary: Phase I Schedule A: Incidence and Intensity of Adverse Events (AEs) Graded According to Common Terminology Criteria for Adverse Events (CTCAE), based on the number of patients with AEs with CTCAE Grade ≥3 during all cycles

End point title	Phase I Schedule A: Incidence and Intensity of Adverse Events (AEs) Graded According to Common Terminology Criteria for Adverse Events (CTCAE), based on the number of patients with AEs with CTCAE Grade ≥3 during all cycles[23]

End point description:

Number of patients with AEs following in the categories 3 (severe AE), 4 (life-threatening or disabling AE), 5 (death related AE) of CTCAE is reported.
Treated set-Phase I part: Treated set was defined as all patients in Phase I who received at least a single dose of either Volasertib or LDAC, including patients who were replaced for any reason.

End point type	Secondary

End point timeframe:

From first drug administration until 21 days after the last trial drug administration in the last treatment cycle, up to 615 days.

Notes:

[23] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint only considers the Phase IA arms, other arms are reported in a separate endpoint.

End point values	Phase I Schedule A. Volasertib 150 mg+LDAC	Phase I Schedule A. Volasertib 200 mg+LDAC	Phase I Schedule A. Volasertib 250 mg+LDAC	Phase I Schedule A. Volasertib 300 mg+LDAC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	5	9
Units: Participants				
Grade 3	1	0	0	1
Grade 4	1	3	5	5
Grade 5	1	0	0	3

End point values	Phase I Schedule A. Volasertib 350 mg+LDAC	Phase I Schedule A. Volasertib 400 mg+LDAC	Phase I Schedule A. Volasertib+LDAC	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	8	3	32	
Units: Participants				
Grade 3	2	1	5	
Grade 4	3	1	18	
Grade 5	2	1	7	

Statistical analyses

No statistical analyses for this end point

Secondary: Phase I Schedule B: Incidence and Intensity of Adverse Events (AEs) Graded According to Common Terminology Criteria for Adverse Events (CTCAE), based on the number of patients with AEs with CTCAE Grade ≥3 during all cycles

End point title	Phase I Schedule B: Incidence and Intensity of Adverse Events (AEs) Graded According to Common Terminology Criteria for Adverse Events (CTCAE), based on the number of patients with AEs with CTCAE Grade ≥3 during all cycles[24]

End point description:

Number of patients with AEs following in the categories 3 (severe AE), 4 (life-threatening or disabling AE), 5 (death related AE) of CTCAE is reported.
Treated set-Phase I part: the treated set was defined as all patients in Phase I who received at least a single dose of either Volasertib or LDAC, including patients who were replaced for any reason.

End point type	Secondary

End point timeframe:

From first drug administration until 21 days after the last trial drug administration in the last treatment cycle, up to 597 days.

Notes:

[24] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint only considers the Phase IB arms, other arms are reported in a separate endpoint.

End point values	Phase I Schedule B. Volasertib 150 mg	Phase I Schedule B. Volasertib 200 mg	Phase I Schedule B. Volasertib 350 mg	Phase I Schedule B. Volasertib 400 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	2	5	6
Units: Participants				
Grade 3	5	0	1	0
Grade 4	4	1	3	5
Grade 5	2	1	0	0

End point values	Phase I Schedule B. Volasertib 450 mg	Phase I Schedule B. Volasertib 500 mg	Phase I Schedule B. Volasertib 550 mg	Phase I Schedule B. Volasertib
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	23	5	4	56
Units: Participants				
Grade 3	3	0	0	9
Grade 4	15	1	3	32
Grade 5	3	2	1	9

Statistical analyses

No statistical analyses for this end point

Secondary: Phase II: Incidence and Intensity of Adverse Events (AEs) Graded According to Common Terminology Criteria for Adverse Events (CTCAE), based on the number of patients with AEs with CTCAE Grade ≥3 during all cycles

End point title	Phase II: Incidence and Intensity of Adverse Events (AEs) Graded According to Common Terminology Criteria for Adverse Events (CTCAE), based on the number of patients with AEs with CTCAE Grade ≥3 during all cycles[25]

End point description:

Number of patients with AEs following in the in the categories 3 (severe AE), 4 (life-threatening or disabling AE), 5 (death related AE) of CTCAE is reported.
Treated set-Phase II part: the treated set (Phase II) was defined as all patients in Phase II who received at least a single dose of either Volasertib or LDAC.

End point type	Secondary

End point timeframe:

From first drug administration until 21 days after the last trial drug administration in the last treatment cycle, up to 890 days.

Notes:

[25] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint only considers the Phase II arms, other arms are reported in a separate endpoint.

End point values	Phase II Schedule C. LDAC	Phase II Schedule A. Volasertib 350 mg+LDAC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	45	42		
Units: Participants				
Grade 3	13	12		
Grade 4	13	20		
Grade 5	6	8		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From first drug administration until 21 days after the last trial drug administration in the last treatment cycle, up to 3325 days.

Adverse event reporting additional description:

Treated Set-phase I part: patients who received at least a single dose of either Volasertib or LDAC, including patients who were replaced for any reason. Phase I: all patients who received at least a single dose of either Volasertib or LDAC.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	19.0

Reporting groups

Reporting group title	Phase I Schedule A. Volasertib 150 mg+LDAC

Reporting group description:

Volasertib 150 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle) and Low-dose cytarabine (LDAC) 2x20mg per day administered by subcutaneous injection on days 1-10 of each 28 day treatment cycle.

Reporting group title	Phase II Schedule C. LDAC

Reporting group description:

Low-dose cytarabine (LDAC) monotherapy 2x20 milligram (mg) per day administered by subcutaneous injection on days 1-10 of each 28 days treatment cycle.

Reporting group title	Phase I Schedule A. Volasertib 200 mg+LDAC

Reporting group description:

Volasertib 200 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle) and Low-dose cytarabine (LDAC) 2x20mg per day administered by subcutaneous injection on days 1-10 of each 28 day treatment cycle.

Reporting group title	Phase I Schedule A. Volasertib 250 mg+LDAC

Reporting group description:

Volasertib 250 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle) and Low-dose cytarabine (LDAC) 2x20mg per day administered by subcutaneous injection on days 1-10 of each 28 day treatment cycle.

Reporting group title	Phase I Schedule A. Volasertib 300 mg+LDAC

Reporting group description:

Volasertib 300 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle) and Low-dose cytarabine (LDAC) 2x20mg per day administered by subcutaneous injection on days 1-10 of each 28 day treatment cycle.

Reporting group title	Phase II Schedule A. Volasertib 350 mg+LDAC

Reporting group description:

Volasertib 350 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle) and Low-dose cytarabine (LDAC) 2x20mg per day administered by subcutaneous injection on days 1-10 of each 28 day treatment cycle.

Reporting group title	Phase I Schedule A. Volasertib 350 mg+LDAC

Reporting group description:

Volasertib 350 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle) and Low-dose cytarabine (LDAC) 2x20mg per day administered by subcutaneous injection on days 1-10 of each 28 day treatment cycle.

Reporting group title	Phase I Schedule A. Volasertib 400 mg+LDAC

Reporting group description:

Volasertib 400 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle) and Low-dose cytarabine (LDAC) 2x20mg per day administered by subcutaneous injection on days 1-10 of each 28 day treatment cycle.

Reporting group title	Phase I Schedule B. Volasertib 400 mg

Reporting group description:	
Volasertib 400 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle).	
Reporting group title	Phase I Schedule B. Volasertib 350 mg
Reporting group description:	
Volasertib 350 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle).	
Reporting group title	Phase I Schedule B. Volasertib 150 mg
Reporting group description:	
Volasertib 150 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle).	
Reporting group title	Phase I Schedule B. Volasertib 200 mg
Reporting group description:	
Volasertib 200 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle).	
Reporting group title	Phase I Schedule B. Volasertib 500 mg
Reporting group description:	
Volasertib 500 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle).	
Reporting group title	Phase I Schedule B. Volasertib 450 mg
Reporting group description:	
Volasertib 450 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle).	
Reporting group title	Phase I Schedule B. Volasertib 550 mg
Reporting group description:	
Volasertib 550 milligram (mg) administered by Intravenous Infusion (IV) over 60 minutes on Days 1 and 15 (28-day cycle).	

Serious adverse events	Phase I Schedule A. Volasertib 150 mg+LDAC	Phase II Schedule C. LDAC	Phase I Schedule A. Volasertib 200 mg+LDAC
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 4 (50.00%)	29 / 45 (64.44%)	3 / 3 (100.00%)
number of deaths (all causes)	4	45	3
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute myeloid leukaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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
Malignant neoplasm progression			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (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
Neoplasm malignant			

subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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
Central nervous system leukaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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			
Circulatory collapse			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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
Deep vein thrombosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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
Haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (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
Hypotension			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Catheterisation venous			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (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 / 4 (0.00%)	1 / 45 (2.22%)	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

Chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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 physical health deterioration			
subjects affected / exposed	0 / 4 (0.00%)	5 / 45 (11.11%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	2 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypothermia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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
Mucosal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	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
Mucosal inflammation			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	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
Pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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
Pyrexia			
subjects affected / exposed	0 / 4 (0.00%)	8 / 45 (17.78%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 8	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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
Oedema peripheral			

subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (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
Dyspnoea exertional			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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	1 / 4 (25.00%)	0 / 45 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperventilation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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
Hypoxia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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
Interstitial lung disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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 / 45 (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 oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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 distress			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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	1 / 4 (25.00%)	0 / 45 (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
Psychiatric disorders			
Acute psychosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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
Confusional state			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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			
Brain natriuretic peptide increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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 / 45 (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
Oxygen saturation decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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			
Meniscus injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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	0 / 4 (0.00%)	0 / 45 (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 disorders			
Acute coronary syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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
Acute myocardial infarction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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
Angina pectoris			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (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
Angina unstable			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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

Arrhythmia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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
Cardiac failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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 congestive			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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
Long QT syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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
Myocardial infarction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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
Myocardial ischaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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
Ventricular fibrillation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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 / 45 (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 / 45 (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
Headache			
subjects affected / exposed	0 / 4 (0.00%)	2 / 45 (4.44%)	0 / 3 (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
Hypoaesthesia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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
Neuralgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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
Somnolence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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
Syncope			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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
Seizure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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			
Anaemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	3 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone marrow failure			

subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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 bone marrow aplasia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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	2 / 4 (50.00%)	6 / 45 (13.33%)	2 / 3 (66.67%)
occurrences causally related to treatment / all	0 / 3	5 / 9	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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
Lymphadenopathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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
Neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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
Pancytopenia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	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
Thrombocytopenia			
subjects affected / exposed	0 / 4 (0.00%)	2 / 45 (4.44%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	3 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Ear and labyrinth disorders			
Vertigo			

subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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
Constipation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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
Diarrhoea			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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 disorder			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (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	0 / 4 (0.00%)	0 / 45 (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
Haemorrhoids			

subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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
Ileus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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
Mouth ulceration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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
Tongue haematoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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 / 45 (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
Vomiting			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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
Gastritis erosive			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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 / 45 (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			
Hepatic failure			

subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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
Dermatitis allergic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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			
Dysuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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
Nephropathy			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	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
Renal failure			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (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
Urinary retention			
subjects affected / exposed	0 / 4 (0.00%)	2 / 45 (4.44%)	0 / 3 (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
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (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

Bone pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (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
Crystal arthropathy			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (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
Muscular weakness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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
Musculoskeletal chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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
Osteoarthritis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (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
Pain in extremity			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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
Polyarthritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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 / 45 (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
Abscess neck			

subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	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
Arthritis bacterial			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (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
Aspergillus infection			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (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
Bacterial pyelonephritis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (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
Bronchitis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (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
Cellulitis			
subjects affected / exposed	0 / 4 (0.00%)	2 / 45 (4.44%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	4 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral fungal infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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 / 45 (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
Cystitis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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 / 45 (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 / 45 (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
Erysipelas			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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 / 45 (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
Gastroenteritis norovirus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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
Herpes zoster			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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 / 45 (2.22%)	0 / 3 (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 infection			

subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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
Neutropenic sepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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	0 / 4 (0.00%)	2 / 45 (4.44%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Pneumonia fungal			
subjects affected / exposed	1 / 4 (25.00%)	0 / 45 (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
Pseudomembranous colitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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
Pseudomonal sepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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 mycosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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
Sepsis			

subjects affected / exposed	1 / 4 (25.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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 / 45 (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
Stenotrophomonas infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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
Tonsillitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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
Urinary tract infection			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	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
Urosepsis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (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
Klebsiella sepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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			
Dehydration			

subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (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
Hypoalbuminaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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

Serious adverse events	Phase I Schedule A. Volasertib 250 mg+LDAC	Phase I Schedule A. Volasertib 300 mg+LDAC	Phase II Schedule A. Volasertib 350 mg+LDAC
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 5 (60.00%)	7 / 9 (77.78%)	34 / 42 (80.95%)
number of deaths (all causes)	4	9	38
number of deaths resulting from adverse events	0	1	6
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute myeloid leukaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm progression			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	2 / 42 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 2
Neoplasm malignant			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Central nervous system leukaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Circulatory collapse			

subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (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
Haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Catheterisation venous			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
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 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	1 / 5 (20.00%)	2 / 9 (22.22%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0

Hypothermia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucosal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucosal inflammation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
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 / 5 (20.00%)	0 / 9 (0.00%)	5 / 42 (11.90%)
occurrences causally related to treatment / all	0 / 1	0 / 0	3 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal			

disorders			
Dyspnoea			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea exertional			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
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 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperventilation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Interstitial lung disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infiltration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			

subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Respiratory failure			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	2 / 42 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Psychiatric disorders			
Acute psychosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Confusional state			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Brain natriuretic peptide increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
C-reactive protein increased			
subjects affected / exposed	3 / 5 (60.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oxygen saturation decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
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			
Meniscus injury			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
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 / 5 (0.00%)	0 / 9 (0.00%)	2 / 42 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myocardial infarction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina pectoris			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina unstable			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
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 / 5 (20.00%)	1 / 9 (11.11%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 1	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	1 / 1

Cardiac failure congestive			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Long QT syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial ischaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular fibrillation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
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 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
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 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoaesthesia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuralgia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	5 / 42 (11.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	4 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone marrow failure			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
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 bone marrow aplasia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			

subjects affected / exposed	2 / 5 (40.00%)	2 / 9 (22.22%)	23 / 42 (54.76%)
occurrences causally related to treatment / all	0 / 3	0 / 2	22 / 27
deaths causally related to treatment / all	0 / 0	0 / 0	2 / 2
Leukocytosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenopathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	5 / 42 (11.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	5 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal haemorrhage			

subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (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
Constipation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	2 / 42 (4.76%)
occurrences causally related to treatment / all	0 / 1	0 / 0	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
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 disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
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 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoids			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mouth ulceration			

subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tongue haematoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis erosive			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hepatic failure			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis allergic			

subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (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
Nephropathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (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
Urinary retention			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Crystal arthropathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Muscular weakness			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polyarthritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abscess			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess neck			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
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 bacterial			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspergillus infection			

subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
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 pyelonephritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
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 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral fungal infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
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 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocarditis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
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 / 5 (0.00%)	0 / 9 (0.00%)	2 / 42 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis norovirus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
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 infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	2 / 42 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic sepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			

subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	8 / 42 (19.05%)
occurrences causally related to treatment / all	0 / 0	1 / 1	3 / 11
deaths causally related to treatment / all	0 / 0	1 / 1	1 / 3
Pneumonia fungal			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	2 / 42 (4.76%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomembranous colitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonal sepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary mycosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
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 syncytial virus infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
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 / 5 (0.00%)	0 / 9 (0.00%)	3 / 42 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal infection			

subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stenotrophomonas infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella sepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
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			
Dehydration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoalbuminaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Phase I Schedule A.	Phase I Schedule A.	Phase I Schedule B.

	Volasertib 350 mg+LDAC	Volasertib 400 mg+LDAC	Volasertib 400 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 8 (75.00%)	3 / 3 (100.00%)	3 / 6 (50.00%)
number of deaths (all causes)	8	3	6
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute myeloid leukaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm progression			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm malignant			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Central nervous system leukaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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			
Circulatory collapse			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Catheterisation venous			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 8 (12.50%)	1 / 3 (33.33%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Hypothermia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucosal haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Mucosal inflammation			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (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
Oedema peripheral			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	0 / 6 (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
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea exertional			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (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 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperventilation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial lung disease			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 distress			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			

Acute psychosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Confusional state			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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			
Brain natriuretic peptide increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oxygen saturation decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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			
Meniscus injury			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (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 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myocardial infarction			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (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
Angina pectoris			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina unstable			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Long QT syndrome			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial ischaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular fibrillation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoaesthesia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuralgia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone marrow failure			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 bone marrow aplasia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	3 / 8 (37.50%)	2 / 3 (66.67%)	2 / 6 (33.33%)
occurrences causally related to treatment / all	0 / 4	1 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenopathy			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 disorder			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoids			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mouth ulceration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tongue haematoma			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis erosive			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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			
Hepatic failure			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	0 / 6 (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
Dermatitis allergic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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			
Dysuria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Nephropathy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Crystal arthropathy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Osteoarthritis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polyarthritis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess neck			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 bacterial			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspergillus infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 pyelonephritis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 fungal infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis norovirus			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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	1 / 8 (12.50%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia fungal			
subjects affected / exposed	2 / 8 (25.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomembranous colitis			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonal sepsis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary mycosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 syncytial virus infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stenotrophomonas infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			

subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (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
Urinary tract infection			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (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
Urosepsis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella sepsis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
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			
Dehydration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoalbuminaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Phase I Schedule B. Volasertib 350 mg	Phase I Schedule B. Volasertib 150 mg	Phase I Schedule B. Volasertib 200 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 5 (60.00%)	7 / 11 (63.64%)	1 / 2 (50.00%)
number of deaths (all causes)	3	11	2
number of deaths resulting from adverse events	0	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute myeloid leukaemia			

subjects affected / exposed	1 / 5 (20.00%)	0 / 11 (0.00%)	0 / 2 (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
Malignant neoplasm progression			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	1 / 2 (50.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Neoplasm malignant			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Central nervous system leukaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
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			
Circulatory collapse			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (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
Deep vein thrombosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			

Catheterisation venous			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
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 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
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 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (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
Hypothermia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucosal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucosal inflammation			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (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
Pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pyrexia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (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
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea exertional			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
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 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperventilation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hypoxia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial lung disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
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 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
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 distress			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
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 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Acute psychosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Confusional state			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			

subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
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			
Brain natriuretic peptide increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
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 / 5 (20.00%)	1 / 11 (9.09%)	0 / 2 (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
Oxygen saturation decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
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			
Meniscus injury			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
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 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myocardial infarction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Angina pectoris			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina unstable			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
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 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Long QT syndrome			
subjects affected / exposed	1 / 5 (20.00%)	0 / 11 (0.00%)	0 / 2 (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
Myocardial infarction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial ischaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular fibrillation			

subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
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 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
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 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoaesthesia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuralgia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			

subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone marrow failure			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
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 bone marrow aplasia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
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 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenopathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 11 (0.00%)	0 / 2 (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
Pancytopenia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	1 / 2 (50.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
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 disorder			

subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
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 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoids			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mouth ulceration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tongue haematoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
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 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis erosive			

subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
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 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
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			
Hepatic failure			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis allergic			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
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			
Dysuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephropathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (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

Urinary retention			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Crystal arthropathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Polyarthritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
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 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess neck			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
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 bacterial			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspergillus infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
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 pyelonephritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
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 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
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 fungal infection			

subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
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 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
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 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
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 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
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 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis norovirus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			

subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
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 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
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 infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
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 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
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 / 5 (0.00%)	3 / 11 (27.27%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia fungal			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Pseudomembranous colitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonal sepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary mycosis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
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 syncytial virus infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
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 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
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 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stenotrophomonas infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella sepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
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			
Dehydration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoalbuminaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Phase I Schedule B. Volasertib 500 mg	Phase I Schedule B. Volasertib 450 mg	Phase I Schedule B. Volasertib 550 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 5 (60.00%)	16 / 23 (69.57%)	3 / 4 (75.00%)
number of deaths (all causes)	5	21	4
number of deaths resulting from adverse events	1	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute myeloid leukaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Malignant neoplasm progression			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Neoplasm malignant			

subjects affected / exposed	1 / 5 (20.00%)	0 / 23 (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 / 1	0 / 0	0 / 0
Central nervous system leukaemia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	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 / 1	0 / 0
Vascular disorders			
Circulatory collapse			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Deep vein thrombosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Hypotension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Surgical and medical procedures			
Catheterisation venous			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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 disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	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

Chest pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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	0 / 5 (0.00%)	1 / 23 (4.35%)	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
Hypothermia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Mucosal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Mucosal inflammation			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	2 / 4 (50.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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	0 / 5 (0.00%)	1 / 23 (4.35%)	0 / 4 (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
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Oedema peripheral			

subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	1 / 5 (20.00%)	0 / 23 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea exertional			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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	1 / 5 (20.00%)	0 / 23 (0.00%)	0 / 4 (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
Hyperventilation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Hypoxia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Interstitial lung disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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

Lung infiltration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Pulmonary oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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 distress			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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 / 5 (0.00%)	0 / 23 (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			
Acute psychosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Confusional state			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Depression			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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			
Brain natriuretic peptide increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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	0 / 5 (0.00%)	0 / 23 (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
Oxygen saturation decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Meniscus injury			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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 / 5 (0.00%)	0 / 23 (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 coronary syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Acute myocardial infarction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Angina pectoris			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Angina unstable			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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

Arrhythmia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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 failure			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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 failure congestive			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Long QT syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Myocardial infarction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Myocardial ischaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Ventricular fibrillation			
subjects affected / exposed	1 / 5 (20.00%)	0 / 23 (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 / 1	0 / 0	0 / 0
Nervous system disorders			
Cerebral haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	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
Dizziness			

subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Headache			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Hypoaesthesia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Neuralgia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Somnolence			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	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
Syncope			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Seizure			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	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
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Bone marrow failure			

subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	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
Febrile bone marrow aplasia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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	2 / 5 (40.00%)	9 / 23 (39.13%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	1 / 2	0 / 15	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Lymphadenopathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Neutropenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Pancytopenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Thrombocytopenia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 23 (0.00%)	0 / 4 (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
Ear and labyrinth disorders			
Vertigo			

subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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			
Abdominal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Anal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Constipation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Diarrhoea			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	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 disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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 haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	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
Haemorrhoids			

subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Ileus			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	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
Mouth ulceration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Tongue haematoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Gastritis erosive			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Nausea			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Hepatobiliary disorders			
Hepatic failure			

subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Dermatitis allergic			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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 and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Nephropathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Urinary retention			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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

Bone pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Crystal arthropathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Muscular weakness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Musculoskeletal chest pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Osteoarthritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Pain in extremity			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Polyarthritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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 / 5 (0.00%)	0 / 23 (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
Abscess neck			

subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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 bacterial			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Aspergillus infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Bacterial pyelonephritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Bronchitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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 / 5 (0.00%)	0 / 23 (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 fungal infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Cystitis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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 / 5 (0.00%)	0 / 23 (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 / 5 (0.00%)	0 / 23 (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
Erysipelas			
subjects affected / exposed	1 / 5 (20.00%)	0 / 23 (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
Escherichia sepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Gastroenteritis norovirus			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	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
Herpes zoster			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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 / 5 (0.00%)	1 / 23 (4.35%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infection			

subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Neutropenic sepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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	2 / 5 (40.00%)	4 / 23 (17.39%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	1 / 2	0 / 4	1 / 1
deaths causally related to treatment / all	1 / 1	0 / 2	1 / 1
Pneumonia fungal			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Pseudomembranous colitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Pseudomonal sepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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 mycosis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	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 / 1	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	1 / 5 (20.00%)	0 / 23 (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
Sepsis			

subjects affected / exposed	1 / 5 (20.00%)	0 / 23 (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 / 1	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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 / 5 (0.00%)	0 / 23 (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
Stenotrophomonas infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Tonsillitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Urinary tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Urosepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Klebsiella sepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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
Metabolism and nutrition disorders			
Dehydration			

subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	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
Hypoalbuminaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (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

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

Non-serious adverse events	Phase I Schedule A. Volasertib 150 mg+LDAC	Phase II Schedule C. LDAC	Phase I Schedule A. Volasertib 200 mg+LDAC
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 4 (100.00%)	43 / 45 (95.56%)	3 / 3 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Chloroma			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Leukaemia cutis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Meningioma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neoplasm progression			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Small intestine carcinoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Angiopathy			
subjects affected / exposed	1 / 4 (25.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Circulatory collapse			

subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	1 / 4 (25.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	1 / 4 (25.00%)	4 / 45 (8.89%)	0 / 3 (0.00%)
occurrences (all)	1	4	0
Hypertensive crisis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hypotension			
subjects affected / exposed	0 / 4 (0.00%)	2 / 45 (4.44%)	1 / 3 (33.33%)
occurrences (all)	0	2	1
Infarction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peripheral coldness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peripheral embolism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis			
subjects affected / exposed	0 / 4 (0.00%)	4 / 45 (8.89%)	0 / 3 (0.00%)
occurrences (all)	0	4	0
Varicose vein			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymphoedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Phlebitis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nail operation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 4 (0.00%)	11 / 45 (24.44%)	0 / 3 (0.00%)
occurrences (all)	0	16	0
Calcinosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Catheter site erythema			
subjects affected / exposed	1 / 4 (25.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Catheter site oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 4 (0.00%)	3 / 45 (6.67%)	1 / 3 (33.33%)
occurrences (all)	0	4	3
Chills			
subjects affected / exposed	1 / 4 (25.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Fatigue			

subjects affected / exposed	1 / 4 (25.00%)	11 / 45 (24.44%)	1 / 3 (33.33%)
occurrences (all)	1	14	1
Feeling cold			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Feeling hot			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Feeling of body temperature change			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
General physical health deterioration			
subjects affected / exposed	1 / 4 (25.00%)	0 / 45 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1
Granuloma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Induration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Inflammation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Infusion site pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Injection site haematoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			

subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Local swelling			
subjects affected / exposed	1 / 4 (25.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Localised oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 4 (0.00%)	2 / 45 (4.44%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Oedema			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	1 / 3 (33.33%)
occurrences (all)	0	2	1
Oedema mucosal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 4 (0.00%)	9 / 45 (20.00%)	2 / 3 (66.67%)
occurrences (all)	0	11	3
Pain			
subjects affected / exposed	1 / 4 (25.00%)	3 / 45 (6.67%)	0 / 3 (0.00%)
occurrences (all)	1	3	0
Puncture site pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 4 (0.00%)	8 / 45 (17.78%)	1 / 3 (33.33%)
occurrences (all)	0	11	1
Thirst decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			

subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hyperthermia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mucosal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Social circumstances			
Fasting			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Breast enlargement			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Genital swelling			
subjects affected / exposed	1 / 4 (25.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Haematospermia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nipple disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Penile oedema			

subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Scrotal oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal erythema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Genital burning sensation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (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 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bronchial secretion retention			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Cough			
subjects affected / exposed	0 / 4 (0.00%)	6 / 45 (13.33%)	1 / 3 (33.33%)
occurrences (all)	0	8	1
Dyspnoea			
subjects affected / exposed	0 / 4 (0.00%)	8 / 45 (17.78%)	1 / 3 (33.33%)
occurrences (all)	0	10	1
Dyspnoea exertional			
subjects affected / exposed	1 / 4 (25.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Haemoptysis			

subjects affected / exposed	1 / 4 (25.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Epistaxis			
subjects affected / exposed	0 / 4 (0.00%)	9 / 45 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	11	0
Hiccups			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Laryngeal disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lung infiltration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lung disorder			
subjects affected / exposed	1 / 4 (25.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Nasal inflammation			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Oropharyngeal pain			
subjects affected / exposed	0 / 4 (0.00%)	2 / 45 (4.44%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Pharyngeal inflammation			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Pleural effusion			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Productive cough			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pulmonary hypertension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory failure			

subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Sputum discoloured			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sputum retention			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vocal cord disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rales			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhonchi			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Anxiety			
subjects affected / exposed	0 / 4 (0.00%)	2 / 45 (4.44%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Communication disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 4 (0.00%)	2 / 45 (4.44%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Depressed mood			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Depression			
subjects affected / exposed	1 / 4 (25.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Disorientation			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hallucination			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hallucination, visual			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Initial insomnia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 4 (0.00%)	4 / 45 (8.89%)	0 / 3 (0.00%)
occurrences (all)	0	4	0
Panic attack			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Restlessness			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Sleep disorder			
subjects affected / exposed	1 / 4 (25.00%)	1 / 45 (2.22%)	1 / 3 (33.33%)
occurrences (all)	1	3	1
Suicidal ideation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Activated partial thromboplastin time shortened			

subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	3 / 3 (100.00%)
occurrences (all)	0	2	4
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	2 / 3 (66.67%)
occurrences (all)	0	3	2
Blast cell count increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood albumin decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood albumin increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Blood bilirubin increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	2 / 3 (66.67%)
occurrences (all)	0	0	2
Blood chloride increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Blood creatinine			

subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood creatinine decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	1 / 4 (25.00%)	3 / 45 (6.67%)	0 / 3 (0.00%)
occurrences (all)	1	3	0
Blood fibrinogen increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood glucose increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood iron decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood iron increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Blood phosphorus decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood potassium decreased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Blood pressure increased			

subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood triglycerides increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood urea decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood urea increased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	0	3	0
Blood uric acid increased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Blood urine present			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Body temperature increased			
subjects affected / exposed	1 / 4 (25.00%)	2 / 45 (4.44%)	0 / 3 (0.00%)
occurrences (all)	1	2	0
Breath sounds abnormal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	2 / 4 (50.00%)	5 / 45 (11.11%)	1 / 3 (33.33%)
occurrences (all)	2	6	1
Candida test positive			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ejection fraction decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	2
Electrocardiogram change			

subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Enterococcus test positive			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Escherichia test positive			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	2 / 3 (66.67%)
occurrences (all)	0	0	2
Heart rate increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Hepatic enzyme increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Liver function test abnormal			
subjects affected / exposed	1 / 4 (25.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Oxygen saturation decreased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Prostatic specific antigen increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Protein total decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Prothrombin time prolonged			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Serum ferritin increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Thrombin time shortened			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Troponin T increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Troponin increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	1 / 4 (25.00%)	1 / 45 (2.22%)	1 / 3 (33.33%)
occurrences (all)	1	1	1
Weight increased			
subjects affected / exposed	1 / 4 (25.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
White blood cells urine			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Allergic transfusion reaction			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Drug administration error			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Excoriation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Fall			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Laceration			

subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lip injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Transfusion reaction			
subjects affected / exposed	0 / 4 (0.00%)	2 / 45 (4.44%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Wound			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Stoma site haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Aortic valve incompetence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Arteriosclerosis coronary artery			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Atrioventricular block			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Bundle branch block right			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cardiac arrest			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cardiac disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cardiac failure			
subjects affected / exposed	0 / 4 (0.00%)	2 / 45 (4.44%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Cardiac valve disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cardiomegaly			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cardiomyopathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cardiovascular disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Congestive cardiomyopathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Extrasystoles			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Heart valve incompetence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypertensive heart disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Left ventricular hypertrophy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mitral valve incompetence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 4 (0.00%)	4 / 45 (8.89%)	0 / 3 (0.00%)
occurrences (all)	0	4	0
Pericardial effusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tachyarrhythmia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Tricuspid valve incompetence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ventricular extrasystoles			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Arrhythmia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Burning sensation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dizziness			

subjects affected / exposed	1 / 4 (25.00%)	2 / 45 (4.44%)	1 / 3 (33.33%)
occurrences (all)	1	2	1
Headache			
subjects affected / exposed	1 / 4 (25.00%)	7 / 45 (15.56%)	0 / 3 (0.00%)
occurrences (all)	2	9	0
Hemiparesis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Orthostatic intolerance			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 4 (0.00%)	3 / 45 (6.67%)	0 / 3 (0.00%)
occurrences (all)	0	3	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 4 (0.00%)	2 / 45 (4.44%)	1 / 3 (33.33%)
occurrences (all)	0	2	1
Polyneuropathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Sinus headache			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Tremor			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Ageusia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypotonia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 4 (25.00%)	12 / 45 (26.67%)	2 / 3 (66.67%)
occurrences (all)	1	31	3
Febrile neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	4 / 45 (8.89%)	0 / 3 (0.00%)
occurrences (all)	0	6	0
Leukocytosis			
subjects affected / exposed	0 / 4 (0.00%)	3 / 45 (6.67%)	0 / 3 (0.00%)
occurrences (all)	0	6	0
Leukopenia			
subjects affected / exposed	1 / 4 (25.00%)	3 / 45 (6.67%)	1 / 3 (33.33%)
occurrences (all)	1	7	2
Lymphadenopathy			
subjects affected / exposed	1 / 4 (25.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	5 / 45 (11.11%)	2 / 3 (66.67%)
occurrences (all)	0	10	2
Splenomegaly			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 4 (0.00%)	8 / 45 (17.78%)	2 / 3 (66.67%)
occurrences (all)	0	26	2
Cytopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear haemorrhage			

subjects affected / exposed	1 / 4 (25.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Vertigo			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Dry eye			
subjects affected / exposed	1 / 4 (25.00%)	0 / 45 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1
Erythema of eyelid			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eyelid oedema			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Glaucoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Macular degeneration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Visual acuity reduced			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Visual impairment			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	0	1	0

Hyphaema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Photopsia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 4 (0.00%)	4 / 45 (8.89%)	0 / 3 (0.00%)
occurrences (all)	0	6	0
Abdominal pain upper			
subjects affected / exposed	1 / 4 (25.00%)	4 / 45 (8.89%)	1 / 3 (33.33%)
occurrences (all)	1	4	1
Abnormal faeces			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Anal haemorrhage			
subjects affected / exposed	1 / 4 (25.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Ascites			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 4 (0.00%)	12 / 45 (26.67%)	3 / 3 (100.00%)
occurrences (all)	0	14	4
Diarrhoea			
subjects affected / exposed	2 / 4 (50.00%)	11 / 45 (24.44%)	2 / 3 (66.67%)
occurrences (all)	2	14	4
Dry mouth			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	2 / 3 (66.67%)
occurrences (all)	0	0	2
Dyspepsia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Dysphagia			

subjects affected / exposed	0 / 4 (0.00%)	2 / 45 (4.44%)	2 / 3 (66.67%)
occurrences (all)	0	2	2
Enterocolitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Faecaloma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal inflammation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gingival bleeding			
subjects affected / exposed	0 / 4 (0.00%)	2 / 45 (4.44%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Gingival discolouration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Gingival swelling			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Glossodynia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Haemorrhoids			

subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hiatus hernia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mouth haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	3 / 45 (6.67%)	0 / 3 (0.00%)
occurrences (all)	0	3	0
Mouth ulceration			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Nausea			
subjects affected / exposed	2 / 4 (50.00%)	16 / 45 (35.56%)	0 / 3 (0.00%)
occurrences (all)	2	22	0
Oesophagitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral mucosal erythema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Periodontal disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Rectal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Small intestine ulcer			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Stomatitis			

subjects affected / exposed	1 / 4 (25.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Tongue coated			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tongue ulceration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	1 / 4 (25.00%)	2 / 45 (4.44%)	0 / 3 (0.00%)
occurrences (all)	1	2	0
Vomiting			
subjects affected / exposed	2 / 4 (50.00%)	6 / 45 (13.33%)	1 / 3 (33.33%)
occurrences (all)	2	7	1
Anal incontinence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Tongue discolouration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastric ulcer			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Palatal disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tongue haemorrhage			

subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hepatic congestion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hepatic cyst			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hepatic lesion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hepatomegaly			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	2
Hepatic steatosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blister			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood blister			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dermatitis atopic			

subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Dermatitis exfoliative			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 4 (0.00%)	3 / 45 (6.67%)	0 / 3 (0.00%)
occurrences (all)	0	3	0
Erythema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Haemorrhage subcutaneous			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 4 (0.00%)	2 / 45 (4.44%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Night sweats			
subjects affected / exposed	0 / 4 (0.00%)	3 / 45 (6.67%)	1 / 3 (33.33%)
occurrences (all)	0	3	1
Pain of skin			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Parapsoriasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 4 (0.00%)	5 / 45 (11.11%)	0 / 3 (0.00%)
occurrences (all)	0	8	0
Pruritus			
subjects affected / exposed	0 / 4 (0.00%)	7 / 45 (15.56%)	0 / 3 (0.00%)
occurrences (all)	0	8	0
Psoriasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Purpura			

subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed	0 / 4 (0.00%)	4 / 45 (8.89%)	0 / 3 (0.00%)
occurrences (all)	0	4	0
Skin erosion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin hyperpigmentation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Swelling face			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Eczema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ingrowing nail			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Intertrigo			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Anuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Bladder pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Dysuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Glycosuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Haematuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	2 / 3 (66.67%)
occurrences (all)	0	0	3
Leukocyturia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Micturition disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nephropathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Renal atrophy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Renal cyst			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Renal impairment			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Renal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urethral haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urethral pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	1 / 4 (25.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Urinary retention			
subjects affected / exposed	1 / 4 (25.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	1	2	0
Chronic kidney disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Incontinence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Micturition urgency			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 4 (0.00%)	4 / 45 (8.89%)	1 / 3 (33.33%)
occurrences (all)	0	5	1
Arthritis			

subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Back pain			
subjects affected / exposed	2 / 4 (50.00%)	10 / 45 (22.22%)	1 / 3 (33.33%)
occurrences (all)	2	10	1
Bone lesion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	0 / 4 (0.00%)	2 / 45 (4.44%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Flank pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Groin pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 4 (0.00%)	2 / 45 (4.44%)	1 / 3 (33.33%)
occurrences (all)	0	2	1
Muscle spasms			
subjects affected / exposed	0 / 4 (0.00%)	3 / 45 (6.67%)	1 / 3 (33.33%)
occurrences (all)	0	3	1
Muscular weakness			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Musculoskeletal pain			
subjects affected / exposed	0 / 4 (0.00%)	2 / 45 (4.44%)	2 / 3 (66.67%)
occurrences (all)	0	2	2
Myalgia			
subjects affected / exposed	1 / 4 (25.00%)	2 / 45 (4.44%)	0 / 3 (0.00%)
occurrences (all)	1	2	0
Myopathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Osteoarthritis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Osteolysis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Osteopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Osteoporosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 4 (0.00%)	6 / 45 (13.33%)	0 / 3 (0.00%)
occurrences (all)	0	7	0
Spinal osteoarthritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bacterial infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Beta haemolytic streptococcal infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cystitis			

subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Device related infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Diverticulitis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Enterococcal infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Erysipelas			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Escherichia bacteraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Escherichia infection			
subjects affected / exposed	1 / 4 (25.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Fungal infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fusobacterium infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Herpes simplex			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Herpes virus infection			

subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Herpes zoster			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Micrococcus infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nail bed infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 4 (0.00%)	2 / 45 (4.44%)	1 / 3 (33.33%)
occurrences (all)	0	2	1
Oral candidiasis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Oral herpes			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Pharyngitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Pneumonia fungal			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Pseudomonas infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin infection			

subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Staphylococcal infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Urinary tract infection			
subjects affected / exposed	1 / 4 (25.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Urosepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Osteomyelitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Post procedural infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Soft tissue infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Acidosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Alkalosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	2 / 4 (50.00%)	6 / 45 (13.33%)	2 / 3 (66.67%)
occurrences (all)	2	6	2
Dehydration			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Diabetes mellitus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1

Hypercalcaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Hyperglycaemia			
subjects affected / exposed	1 / 4 (25.00%)	2 / 45 (4.44%)	2 / 3 (66.67%)
occurrences (all)	1	2	3
Hyperkalaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	3
Hypernatraemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Hyperuricaemia			
subjects affected / exposed	0 / 4 (0.00%)	4 / 45 (8.89%)	0 / 3 (0.00%)
occurrences (all)	0	6	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Hypocalcaemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Hypoglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 4 (0.00%)	3 / 45 (6.67%)	1 / 3 (33.33%)
occurrences (all)	0	5	1
Hyponatraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Hypoproteinaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Iron overload			
subjects affected / exposed	0 / 4 (0.00%)	1 / 45 (2.22%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Uraemic acidosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fluid overload			
subjects affected / exposed	0 / 4 (0.00%)	0 / 45 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Phase I Schedule A. Volasertib 250 mg+LDAC	Phase I Schedule A. Volasertib 300 mg+LDAC	Phase II Schedule A. Volasertib 350 mg+LDAC
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 5 (100.00%)	9 / 9 (100.00%)	41 / 42 (97.62%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Chloroma			
subjects affected / exposed	0 / 5 (0.00%)	2 / 9 (22.22%)	0 / 42 (0.00%)
occurrences (all)	0	2	0
Leukaemia cutis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	2 / 42 (4.76%)
occurrences (all)	0	0	2
Meningioma			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Neoplasm progression			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Small intestine carcinoma			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
Angiopathy			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0

Circulatory collapse			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	1 / 42 (2.38%)
occurrences (all)	0	1	1
Haematoma			
subjects affected / exposed	2 / 5 (40.00%)	1 / 9 (11.11%)	2 / 42 (4.76%)
occurrences (all)	2	1	2
Haemorrhage			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences (all)	1	0	1
Hypertension			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	2 / 42 (4.76%)
occurrences (all)	1	0	2
Hypertensive crisis			
subjects affected / exposed	1 / 5 (20.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	1	1	0
Hypotension			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	7 / 42 (16.67%)
occurrences (all)	0	1	7
Infarction			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Peripheral coldness			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Peripheral embolism			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Thrombophlebitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Varicose vein			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Lymphoedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0

Phlebitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences (all)	0	0	1
Surgical and medical procedures			
Central venous catheterisation			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Nail operation			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	1 / 42 (2.38%)
occurrences (all)	0	1	1
General disorders and administration site conditions			
Adverse drug reaction			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Asthenia			
subjects affected / exposed	1 / 5 (20.00%)	1 / 9 (11.11%)	10 / 42 (23.81%)
occurrences (all)	1	1	15
Calcinosis			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Catheter site erythema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Catheter site oedema			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Chest discomfort			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Chest pain			
subjects affected / exposed	0 / 5 (0.00%)	2 / 9 (22.22%)	4 / 42 (9.52%)
occurrences (all)	0	2	4
Chills			
subjects affected / exposed	2 / 5 (40.00%)	1 / 9 (11.11%)	2 / 42 (4.76%)
occurrences (all)	2	1	2
Fatigue			

subjects affected / exposed	5 / 5 (100.00%)	5 / 9 (55.56%)	11 / 42 (26.19%)
occurrences (all)	10	6	11
Feeling cold			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Feeling hot			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Feeling of body temperature change			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
General physical health deterioration			
subjects affected / exposed	2 / 5 (40.00%)	1 / 9 (11.11%)	5 / 42 (11.90%)
occurrences (all)	3	1	6
Granuloma			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Induration			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Inflammation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences (all)	0	0	1
Influenza like illness			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences (all)	1	0	1
Infusion site pain			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Injection site haematoma			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	3 / 42 (7.14%)
occurrences (all)	0	1	3
Injection site reaction			

subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Local swelling			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Malaise			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	2 / 42 (4.76%)
occurrences (all)	0	0	2
Mucosal inflammation			
subjects affected / exposed	1 / 5 (20.00%)	2 / 9 (22.22%)	10 / 42 (23.81%)
occurrences (all)	1	2	12
Oedema			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	2 / 42 (4.76%)
occurrences (all)	0	1	2
Oedema mucosal			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	1 / 5 (20.00%)	5 / 9 (55.56%)	12 / 42 (28.57%)
occurrences (all)	1	8	16
Pain			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	5 / 42 (11.90%)
occurrences (all)	0	2	5
Puncture site pain			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Pyrexia			
subjects affected / exposed	1 / 5 (20.00%)	4 / 9 (44.44%)	13 / 42 (30.95%)
occurrences (all)	1	10	18
Thirst decreased			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Peripheral swelling			

subjects affected / exposed	1 / 5 (20.00%)	2 / 9 (22.22%)	2 / 42 (4.76%)
occurrences (all)	1	4	2
Catheter site pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Hyperthermia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences (all)	0	0	1
Discomfort			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Mucosal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences (all)	0	0	4
Social circumstances			
Fasting			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Reproductive system and breast disorders			
Breast enlargement			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Genital swelling			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Haematospermia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Nipple disorder			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Pelvic pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Penile oedema			

subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Scrotal oedema			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal erythema			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Genital burning sensation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Atelectasis			
subjects affected / exposed	2 / 5 (40.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	2	1	0
Bronchial secretion retention			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Dysphonia			
subjects affected / exposed	1 / 5 (20.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	1	1	0
Cough			
subjects affected / exposed	2 / 5 (40.00%)	4 / 9 (44.44%)	10 / 42 (23.81%)
occurrences (all)	2	4	18
Dyspnoea			
subjects affected / exposed	0 / 5 (0.00%)	4 / 9 (44.44%)	10 / 42 (23.81%)
occurrences (all)	0	5	12
Dyspnoea exertional			
subjects affected / exposed	3 / 5 (60.00%)	2 / 9 (22.22%)	0 / 42 (0.00%)
occurrences (all)	4	2	0
Haemoptysis			

subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	5 / 42 (11.90%)
occurrences (all)	0	2	6
Epistaxis			
subjects affected / exposed	1 / 5 (20.00%)	3 / 9 (33.33%)	16 / 42 (38.10%)
occurrences (all)	1	7	24
Hiccups			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Laryngeal disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Lung infiltration			
subjects affected / exposed	0 / 5 (0.00%)	2 / 9 (22.22%)	0 / 42 (0.00%)
occurrences (all)	0	2	0
Lung disorder			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Nasal inflammation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	5 / 42 (11.90%)
occurrences (all)	0	1	5
Pharyngeal inflammation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	2 / 5 (40.00%)	4 / 9 (44.44%)	3 / 42 (7.14%)
occurrences (all)	2	4	3
Productive cough			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences (all)	0	0	1
Pulmonary hypertension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Respiratory failure			

subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Sputum discoloured			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Sputum retention			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Vocal cord disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Rales			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Rhonchi			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Anxiety			
subjects affected / exposed	1 / 5 (20.00%)	1 / 9 (11.11%)	5 / 42 (11.90%)
occurrences (all)	1	1	5
Communication disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	1 / 5 (20.00%)	1 / 9 (11.11%)	2 / 42 (4.76%)
occurrences (all)	1	1	2
Depressed mood			
subjects affected / exposed	1 / 5 (20.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	1	1	0

Depression			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences (all)	0	0	1
Disorientation			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Hallucination			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	2 / 42 (4.76%)
occurrences (all)	0	0	2
Hallucination, visual			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Initial insomnia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	3 / 42 (7.14%)
occurrences (all)	0	0	3
Panic attack			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences (all)	1	0	3
Restlessness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences (all)	0	0	2
Sleep disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	3 / 42 (7.14%)
occurrences (all)	0	0	3
Suicidal ideation			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Activated partial thromboplastin time shortened			

subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	2	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Blast cell count increased			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Blood albumin decreased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Blood albumin increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences (all)	1	0	3
Blood bilirubin increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Blood chloride increased			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Blood creatine phosphokinase decreased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Blood creatinine			

subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Blood creatinine decreased			
subjects affected / exposed	0 / 5 (0.00%)	2 / 9 (22.22%)	0 / 42 (0.00%)
occurrences (all)	0	4	0
Blood creatinine increased			
subjects affected / exposed	1 / 5 (20.00%)	3 / 9 (33.33%)	2 / 42 (4.76%)
occurrences (all)	3	4	2
Blood fibrinogen increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Blood glucose increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Blood iron decreased			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Blood iron increased			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Blood lactate dehydrogenase decreased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Blood potassium decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	2 / 42 (4.76%)
occurrences (all)	0	0	2
Blood pressure increased			

subjects affected / exposed	2 / 5 (40.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	2	0	0
Blood triglycerides increased			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Blood urea decreased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Blood urea increased			
subjects affected / exposed	1 / 5 (20.00%)	2 / 9 (22.22%)	0 / 42 (0.00%)
occurrences (all)	2	2	0
Blood uric acid increased			
subjects affected / exposed	1 / 5 (20.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	1	1	0
Blood urine present			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	1 / 42 (2.38%)
occurrences (all)	0	1	1
Body temperature increased			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Breath sounds abnormal			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
C-reactive protein increased			
subjects affected / exposed	2 / 5 (40.00%)	4 / 9 (44.44%)	2 / 42 (4.76%)
occurrences (all)	3	4	2
Candida test positive			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Ejection fraction decreased			
subjects affected / exposed	1 / 5 (20.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	1	1	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences (all)	0	0	1
Electrocardiogram change			

subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Enterococcus test positive			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Escherichia test positive			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 5 (20.00%)	1 / 9 (11.11%)	1 / 42 (2.38%)
occurrences (all)	1	1	1
Heart rate increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Liver function test abnormal			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Oxygen saturation decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Prostatic specific antigen increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Protein total decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Prothrombin time prolonged			
subjects affected / exposed	1 / 5 (20.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	1	1	0
Serum ferritin increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0

Thrombin time shortened			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Troponin T increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Troponin increased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Weight decreased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	2 / 42 (4.76%)
occurrences (all)	0	1	3
Weight increased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	1 / 42 (2.38%)
occurrences (all)	0	2	1
White blood cells urine			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Allergic transfusion reaction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Drug administration error			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Excoriation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	1 / 5 (20.00%)	4 / 9 (44.44%)	4 / 42 (9.52%)
occurrences (all)	2	4	4
Laceration			

subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Lip injury			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	1 / 42 (2.38%)
occurrences (all)	0	1	1
Transfusion reaction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	1 / 42 (2.38%)
occurrences (all)	0	1	1
Skin abrasion			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Stoma site haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	2 / 42 (4.76%)
occurrences (all)	1	0	2
Aortic valve incompetence			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Arteriosclerosis coronary artery			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Atrioventricular block			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences (all)	0	0	1
Bradycardia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0

Bundle branch block right			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Cardiac arrest			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Cardiac disorder			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Cardiac failure			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	2 / 42 (4.76%)
occurrences (all)	0	0	3
Cardiac valve disease			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Cardiomegaly			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Cardiomyopathy			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Cardiovascular disorder			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Congestive cardiomyopathy			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Extrasystoles			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Heart valve incompetence			
subjects affected / exposed	2 / 5 (40.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	2	0	0
Hypertensive heart disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0

Left ventricular hypertrophy			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Mitral valve incompetence			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Palpitations			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences (all)	0	0	2
Pericardial effusion			
subjects affected / exposed	1 / 5 (20.00%)	2 / 9 (22.22%)	0 / 42 (0.00%)
occurrences (all)	1	2	0
Tachyarrhythmia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	1 / 42 (2.38%)
occurrences (all)	0	1	1
Tachycardia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	1 / 42 (2.38%)
occurrences (all)	0	2	1
Tricuspid valve incompetence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences (all)	0	0	1
Ventricular extrasystoles			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Arrhythmia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences (all)	0	0	1
Atrial fibrillation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences (all)	0	0	2
Nervous system disorders			
Burning sensation			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Dizziness			

subjects affected / exposed	4 / 5 (80.00%)	2 / 9 (22.22%)	3 / 42 (7.14%)
occurrences (all)	4	2	6
Headache			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	4 / 42 (9.52%)
occurrences (all)	0	0	6
Hemiparesis			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Orthostatic intolerance			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Paraesthesia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences (all)	0	0	1
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Polyneuropathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Sinus headache			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	1 / 42 (2.38%)
occurrences (all)	0	1	1
Syncope			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Tremor			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences (all)	0	0	1
Ageusia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Hypotonia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	4 / 5 (80.00%)	6 / 9 (66.67%)	14 / 42 (33.33%)
occurrences (all)	5	20	27
Febrile neutropenia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	8 / 42 (19.05%)
occurrences (all)	0	2	9
Leukocytosis			
subjects affected / exposed	1 / 5 (20.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	1	1	0
Leukopenia			
subjects affected / exposed	2 / 5 (40.00%)	5 / 9 (55.56%)	1 / 42 (2.38%)
occurrences (all)	3	9	1
Lymphadenopathy			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences (all)	1	0	1
Neutropenia			
subjects affected / exposed	1 / 5 (20.00%)	1 / 9 (11.11%)	11 / 42 (26.19%)
occurrences (all)	1	1	36
Splenomegaly			
subjects affected / exposed	0 / 5 (0.00%)	2 / 9 (22.22%)	0 / 42 (0.00%)
occurrences (all)	0	2	0
Thrombocytopenia			
subjects affected / exposed	4 / 5 (80.00%)	5 / 9 (55.56%)	9 / 42 (21.43%)
occurrences (all)	5	16	45
Cytopenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear haemorrhage			

subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	2 / 5 (40.00%)	2 / 9 (22.22%)	3 / 42 (7.14%)
occurrences (all)	2	2	3
Eye disorders			
Cataract			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Erythema of eyelid			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Eye haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	2 / 42 (4.76%)
occurrences (all)	0	0	3
Eyelid oedema			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Glaucoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Macular degeneration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Visual acuity reduced			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0

Hyphaema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Photopsia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	2 / 5 (40.00%)	2 / 9 (22.22%)	4 / 42 (9.52%)
occurrences (all)	2	3	4
Abdominal pain upper			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	3 / 42 (7.14%)
occurrences (all)	0	1	4
Abnormal faeces			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Anal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences (all)	0	0	1
Ascites			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Constipation			
subjects affected / exposed	2 / 5 (40.00%)	2 / 9 (22.22%)	18 / 42 (42.86%)
occurrences (all)	3	2	26
Diarrhoea			
subjects affected / exposed	2 / 5 (40.00%)	4 / 9 (44.44%)	13 / 42 (30.95%)
occurrences (all)	7	7	21
Dry mouth			
subjects affected / exposed	0 / 5 (0.00%)	2 / 9 (22.22%)	2 / 42 (4.76%)
occurrences (all)	0	2	2
Dyspepsia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	3 / 42 (7.14%)
occurrences (all)	0	0	3
Dysphagia			

subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	3 / 42 (7.14%)
occurrences (all)	0	1	3
Enterocolitis			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Faecaloma			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Flatulence			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Gastritis			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal inflammation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Gingival bleeding			
subjects affected / exposed	1 / 5 (20.00%)	1 / 9 (11.11%)	1 / 42 (2.38%)
occurrences (all)	1	2	1
Gingival discolouration			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Gingival pain			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences (all)	1	0	1
Gingival swelling			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Glossodynia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	0	2	0
Haematochezia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			

subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Hiatus hernia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences (all)	1	0	1
Mouth haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	2 / 42 (4.76%)
occurrences (all)	0	0	2
Mouth ulceration			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	2 / 42 (4.76%)
occurrences (all)	0	1	2
Nausea			
subjects affected / exposed	2 / 5 (40.00%)	4 / 9 (44.44%)	19 / 42 (45.24%)
occurrences (all)	5	6	28
Oesophagitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Oral mucosal erythema			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Oral pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	3 / 42 (7.14%)
occurrences (all)	0	0	3
Periodontal disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences (all)	0	0	1
Rectal haemorrhage			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Small intestine ulcer			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Stomatitis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	2 / 42 (4.76%)
occurrences (all)	0	0	3
Tongue coated			
subjects affected / exposed	1 / 5 (20.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	1	1	0
Tongue ulceration			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	0	2	0
Toothache			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 5 (20.00%)	4 / 9 (44.44%)	16 / 42 (38.10%)
occurrences (all)	2	5	30
Anal incontinence			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	3 / 42 (7.14%)
occurrences (all)	0	0	4
Tongue discolouration			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Abdominal discomfort			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Gastric ulcer			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences (all)	0	0	1
Palatal disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences (all)	0	0	1
Tongue haemorrhage			

subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Hepatic congestion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Hepatic cyst			
subjects affected / exposed	1 / 5 (20.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	1	1	0
Hepatic lesion			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Hepatomegaly			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Hepatic steatosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	3 / 42 (7.14%)
occurrences (all)	1	0	5
Blister			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Blood blister			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences (all)	0	0	1
Dermatitis atopic			

subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Dermatitis exfoliative			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Dry skin			
subjects affected / exposed	0 / 5 (0.00%)	3 / 9 (33.33%)	2 / 42 (4.76%)
occurrences (all)	0	3	2
Erythema			
subjects affected / exposed	2 / 5 (40.00%)	1 / 9 (11.11%)	1 / 42 (2.38%)
occurrences (all)	2	1	1
Haemorrhage subcutaneous			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	3 / 42 (7.14%)
occurrences (all)	0	1	3
Night sweats			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	4 / 42 (9.52%)
occurrences (all)	1	0	5
Pain of skin			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences (all)	1	0	1
Parapsoriasis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Petechiae			
subjects affected / exposed	2 / 5 (40.00%)	2 / 9 (22.22%)	10 / 42 (23.81%)
occurrences (all)	4	2	12
Pruritus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	4 / 42 (9.52%)
occurrences (all)	0	0	5
Psoriasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Purpura			

subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	3 / 42 (7.14%)
occurrences (all)	0	0	3
Rash			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	3 / 42 (7.14%)
occurrences (all)	1	0	3
Skin erosion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Skin haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Skin hyperpigmentation			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	1 / 42 (2.38%)
occurrences (all)	0	1	1
Skin lesion			
subjects affected / exposed	1 / 5 (20.00%)	1 / 9 (11.11%)	2 / 42 (4.76%)
occurrences (all)	1	1	2
Swelling face			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences (all)	1	0	1
Eczema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Ingrowing nail			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Intertrigo			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Anuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0

Bladder pain			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	0	2	0
Dysuria			
subjects affected / exposed	1 / 5 (20.00%)	1 / 9 (11.11%)	3 / 42 (7.14%)
occurrences (all)	1	2	3
Glycosuria			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Haematuria			
subjects affected / exposed	2 / 5 (40.00%)	2 / 9 (22.22%)	1 / 42 (2.38%)
occurrences (all)	2	2	1
Leukocyturia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Micturition disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Nephropathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Pollakiuria			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Proteinuria			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Renal atrophy			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Renal cyst			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	1 / 42 (2.38%)
occurrences (all)	0	1	1

Renal impairment			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	1 / 42 (2.38%)
occurrences (all)	0	1	1
Renal pain			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Urethral haemorrhage			
subjects affected / exposed	1 / 5 (20.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	1	1	0
Urethral pain			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Urinary incontinence			
subjects affected / exposed	2 / 5 (40.00%)	1 / 9 (11.11%)	1 / 42 (2.38%)
occurrences (all)	2	1	1
Urinary retention			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Chronic kidney disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Incontinence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Micturition urgency			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal disorder			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 5 (0.00%)	3 / 9 (33.33%)	7 / 42 (16.67%)
occurrences (all)	0	3	9
Arthritis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	2 / 42 (4.76%)
occurrences (all)	0	0	4
Back pain			
subjects affected / exposed	1 / 5 (20.00%)	2 / 9 (22.22%)	6 / 42 (14.29%)
occurrences (all)	1	2	6
Bone lesion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	2 / 42 (4.76%)
occurrences (all)	0	0	2
Flank pain			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Groin pain			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	1 / 42 (2.38%)
occurrences (all)	0	1	1
Joint swelling			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	2 / 42 (4.76%)
occurrences (all)	2	0	3
Muscular weakness			
subjects affected / exposed	1 / 5 (20.00%)	1 / 9 (11.11%)	1 / 42 (2.38%)
occurrences (all)	1	2	1
Musculoskeletal pain			
subjects affected / exposed	2 / 5 (40.00%)	1 / 9 (11.11%)	2 / 42 (4.76%)
occurrences (all)	2	1	2
Myalgia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	3 / 42 (7.14%)
occurrences (all)	0	0	3
Myopathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Osteolysis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Osteopenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Osteoporosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	2 / 5 (40.00%)	3 / 9 (33.33%)	3 / 42 (7.14%)
occurrences (all)	3	4	7
Spinal osteoarthritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences (all)	0	0	1
Infections and infestations			
Bacterial infection			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Beta haemolytic streptococcal infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	2 / 42 (4.76%)
occurrences (all)	1	0	3
Candida infection			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences (all)	1	0	1
Clostridium difficile infection			
subjects affected / exposed	2 / 5 (40.00%)	0 / 9 (0.00%)	2 / 42 (4.76%)
occurrences (all)	2	0	2
Cystitis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Device related infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Diverticulitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Enterococcal infection			
subjects affected / exposed	1 / 5 (20.00%)	1 / 9 (11.11%)	1 / 42 (2.38%)
occurrences (all)	1	1	1
Erysipelas			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Escherichia bacteraemia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	2	0	0
Escherichia infection			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Fungal infection			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	2 / 42 (4.76%)
occurrences (all)	0	1	2
Fungal skin infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Fusobacterium infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences (all)	1	0	1
Herpes simplex			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	2 / 42 (4.76%)
occurrences (all)	2	0	2
Herpes virus infection			

subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences (all)	0	0	2
Herpes zoster			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	1 / 42 (2.38%)
occurrences (all)	0	1	1
Micrococcus infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Nail bed infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	2 / 5 (40.00%)	4 / 9 (44.44%)	0 / 42 (0.00%)
occurrences (all)	2	4	0
Oral candidiasis			
subjects affected / exposed	1 / 5 (20.00%)	1 / 9 (11.11%)	2 / 42 (4.76%)
occurrences (all)	1	1	2
Oral herpes			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	2 / 42 (4.76%)
occurrences (all)	0	0	2
Pharyngitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	5 / 42 (11.90%)
occurrences (all)	1	0	5
Pneumonia fungal			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Pseudomonas infection			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Sepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 42 (2.38%)
occurrences (all)	0	0	1
Skin infection			

subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Staphylococcal infection			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Urinary tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	3 / 42 (7.14%)
occurrences (all)	0	0	3
Urosepsis			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Osteomyelitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Post procedural infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Soft tissue infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Acidosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Alkalosis			
subjects affected / exposed	2 / 5 (40.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	3	2	0
Decreased appetite			
subjects affected / exposed	4 / 5 (80.00%)	5 / 9 (55.56%)	6 / 42 (14.29%)
occurrences (all)	5	6	10
Dehydration			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	1 / 42 (2.38%)
occurrences (all)	0	1	1
Diabetes mellitus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0

Hypercalcaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	2 / 42 (4.76%)
occurrences (all)	0	0	2
Hypercholesterolaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	4 / 5 (80.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	8	1	0
Hyperkalaemia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	3 / 42 (7.14%)
occurrences (all)	1	0	6
Hypernatraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	2 / 5 (40.00%)	2 / 9 (22.22%)	1 / 42 (2.38%)
occurrences (all)	2	4	6
Hypoalbuminaemia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Hypocalcaemia			
subjects affected / exposed	3 / 5 (60.00%)	2 / 9 (22.22%)	2 / 42 (4.76%)
occurrences (all)	3	5	2
Hypoglycaemia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	2 / 42 (4.76%)
occurrences (all)	1	0	2
Hypokalaemia			
subjects affected / exposed	4 / 5 (80.00%)	4 / 9 (44.44%)	8 / 42 (19.05%)
occurrences (all)	5	6	11
Hyponatraemia			
subjects affected / exposed	3 / 5 (60.00%)	4 / 9 (44.44%)	0 / 42 (0.00%)
occurrences (all)	4	4	0
Hypoproteinaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0

Iron overload			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Uraemic acidosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Fluid overload			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Phase I Schedule A. Volasertib 350 mg+LDAC	Phase I Schedule A. Volasertib 400 mg+LDAC	Phase I Schedule B. Volasertib 400 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 8 (100.00%)	3 / 3 (100.00%)	6 / 6 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Chloroma			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Leukaemia cutis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Meningioma			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neoplasm progression			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Small intestine carcinoma			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Angiopathy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Circulatory collapse			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Haematoma			
subjects affected / exposed	3 / 8 (37.50%)	0 / 3 (0.00%)	3 / 6 (50.00%)
occurrences (all)	3	0	4
Haemorrhage			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hypertension			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Hypertensive crisis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	1 / 8 (12.50%)	1 / 3 (33.33%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Infarction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Peripheral coldness			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Peripheral embolism			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Varicose vein			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lymphoedema			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0

Phlebitis			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Surgical and medical procedures			
Central venous catheterisation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nail operation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Adverse drug reaction			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Asthenia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Calcinosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Catheter site erythema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Catheter site oedema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Chest pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	3 / 8 (37.50%)	2 / 3 (66.67%)	0 / 6 (0.00%)
occurrences (all)	3	2	0
Fatigue			

subjects affected / exposed	4 / 8 (50.00%)	1 / 3 (33.33%)	0 / 6 (0.00%)
occurrences (all)	5	1	0
Feeling cold			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Feeling hot			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Feeling of body temperature change			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
General physical health deterioration			
subjects affected / exposed	3 / 8 (37.50%)	1 / 3 (33.33%)	2 / 6 (33.33%)
occurrences (all)	6	1	2
Granuloma			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Induration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Inflammation			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Influenza like illness			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Infusion site pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Injection site haematoma			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Injection site reaction			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Local swelling			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Mucosal inflammation			
subjects affected / exposed	3 / 8 (37.50%)	0 / 3 (0.00%)	2 / 6 (33.33%)
occurrences (all)	3	0	2
Oedema			
subjects affected / exposed	1 / 8 (12.50%)	1 / 3 (33.33%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Oedema mucosal			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Oedema peripheral			
subjects affected / exposed	2 / 8 (25.00%)	1 / 3 (33.33%)	1 / 6 (16.67%)
occurrences (all)	5	1	1
Pain			
subjects affected / exposed	3 / 8 (37.50%)	1 / 3 (33.33%)	1 / 6 (16.67%)
occurrences (all)	3	1	1
Puncture site pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Thirst decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			

subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Catheter site pain			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hyperthermia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Discomfort			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Mucosal haemorrhage			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Social circumstances			
Fasting			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Breast enlargement			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Genital swelling			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haematospermia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nipple disorder			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Penile oedema			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Scrotal oedema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal erythema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Genital burning sensation			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Atelectasis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bronchial secretion retention			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	2 / 8 (25.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	2	0	1
Dyspnoea			
subjects affected / exposed	2 / 8 (25.00%)	0 / 3 (0.00%)	2 / 6 (33.33%)
occurrences (all)	2	0	2
Dyspnoea exertional			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Haemoptysis			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	2 / 8 (25.00%)	0 / 3 (0.00%)	2 / 6 (33.33%)
occurrences (all)	2	0	5
Hiccups			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Laryngeal disorder			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Lung infiltration			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Lung disorder			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nasal inflammation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 8 (12.50%)	1 / 3 (33.33%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Pharyngeal inflammation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Productive cough			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Pulmonary hypertension			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory failure			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sputum discoloured			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sputum retention			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vocal cord disorder			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Rales			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Rhonchi			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Throat irritation			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Agitation			
subjects affected / exposed	2 / 8 (25.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Anxiety			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Communication disorder			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Depressed mood			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1

Depression			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Disorientation			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hallucination			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hallucination, visual			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Initial insomnia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Insomnia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Panic attack			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Restlessness			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Sleep disorder			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Suicidal ideation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Activated partial thromboplastin time shortened			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Blast cell count increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood albumin decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood albumin increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2
Blood chloride increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood creatinine			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood creatinine decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	2 / 6 (33.33%)
occurrences (all)	1	0	2
Blood fibrinogen increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood glucose increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood iron decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood iron increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood potassium decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	3
Blood pressure increased			

subjects affected / exposed	2 / 8 (25.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Blood triglycerides increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood urea decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood urea increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	5
Blood uric acid increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	3
Blood urine present			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Body temperature increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Breath sounds abnormal			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	4 / 8 (50.00%)	1 / 3 (33.33%)	3 / 6 (50.00%)
occurrences (all)	4	1	3
Candida test positive			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ejection fraction decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram change			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Enterococcus test positive			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Escherichia test positive			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Heart rate increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Liver function test abnormal			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oxygen saturation decreased			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Prostatic specific antigen increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Protein total decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Prothrombin time prolonged			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Serum ferritin increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Thrombin time shortened			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Troponin T increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Troponin increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
White blood cells urine			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Allergic transfusion reaction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Drug administration error			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Excoriation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	1 / 8 (12.50%)	1 / 3 (33.33%)	1 / 6 (16.67%)
occurrences (all)	1	1	1
Laceration			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lip injury			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Transfusion reaction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Stoma site haemorrhage			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Aortic valve incompetence			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Arteriosclerosis coronary artery			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Atrioventricular block			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0

Bundle branch block right			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Cardiac arrest			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cardiac disorder			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cardiac failure			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Cardiac valve disease			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cardiomegaly			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cardiomyopathy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cardiovascular disorder			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Congestive cardiomyopathy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Extrasystoles			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Heart valve incompetence			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypertensive heart disease			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1

Left ventricular hypertrophy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Mitral valve incompetence			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Palpitations			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pericardial effusion			
subjects affected / exposed	2 / 8 (25.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	2	0	1
Tachyarrhythmia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tricuspid valve incompetence			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ventricular extrasystoles			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Arrhythmia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Atrial fibrillation			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Burning sensation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dizziness			

subjects affected / exposed	2 / 8 (25.00%)	1 / 3 (33.33%)	0 / 6 (0.00%)
occurrences (all)	3	1	0
Headache			
subjects affected / exposed	1 / 8 (12.50%)	1 / 3 (33.33%)	1 / 6 (16.67%)
occurrences (all)	1	1	2
Hemiparesis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Orthostatic intolerance			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Polyneuropathy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sinus headache			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	2 / 8 (25.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	2	0	1
Ageusia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Dysgeusia			

subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hypotonia			
subjects affected / exposed	2 / 8 (25.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 8 (37.50%)	1 / 3 (33.33%)	4 / 6 (66.67%)
occurrences (all)	6	1	6
Febrile neutropenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	1 / 8 (12.50%)	1 / 3 (33.33%)	2 / 6 (33.33%)
occurrences (all)	2	1	2
Lymphadenopathy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	3 / 6 (50.00%)
occurrences (all)	0	0	5
Splenomegaly			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	3 / 8 (37.50%)	1 / 3 (33.33%)	2 / 6 (33.33%)
occurrences (all)	9	1	5
Cytopenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	2
Ear and labyrinth disorders			
Ear haemorrhage			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Erythema of eyelid			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Eye haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Eyelid oedema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Glaucoma			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Macular degeneration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Visual acuity reduced			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1

Hyphaema			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Photopsia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Abdominal pain upper			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Abnormal faeces			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Anal haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	3 / 8 (37.50%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	3	0	1
Diarrhoea			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	3 / 6 (50.00%)
occurrences (all)	1	0	5
Dry mouth			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dysphagia			

subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Enterocolitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Faecaloma			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	4 / 8 (50.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	4	0	1
Gastritis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal inflammation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gingival bleeding			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	3
Gingival discolouration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gingival swelling			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Glossodynia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			

subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Hiatus hernia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Mouth haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	4 / 8 (50.00%)	2 / 3 (66.67%)	1 / 6 (16.67%)
occurrences (all)	6	2	2
Oesophagitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oral mucosal erythema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Periodontal disease			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Small intestine ulcer			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Stomatitis			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tongue coated			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tongue ulceration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Anal incontinence			
subjects affected / exposed	2 / 8 (25.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tongue discolouration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Abdominal discomfort			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Gastric ulcer			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorder			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Palatal disorder			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Tongue haemorrhage			

subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hepatic congestion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hepatic cyst			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hepatic lesion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hepatomegaly			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hepatic steatosis			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	2 / 8 (25.00%)	1 / 3 (33.33%)	3 / 6 (50.00%)
occurrences (all)	2	1	3
Blister			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood blister			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Dermatitis atopic			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dermatitis exfoliative			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haemorrhage subcutaneous			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Hyperhidrosis			
subjects affected / exposed	1 / 8 (12.50%)	1 / 3 (33.33%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Night sweats			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	3 / 6 (50.00%)
occurrences (all)	0	1	4
Pain of skin			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Parapsoriasis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	2 / 8 (25.00%)	2 / 3 (66.67%)	4 / 6 (66.67%)
occurrences (all)	2	2	4
Pruritus			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	2
Psoriasis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Purpura			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	3 / 6 (50.00%)
occurrences (all)	1	0	3
Skin erosion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin hyperpigmentation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	1 / 8 (12.50%)	1 / 3 (33.33%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Swelling face			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Urticaria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Ingrowing nail			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Intertrigo			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Renal and urinary disorders			
Anuria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Bladder pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Glycosuria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Leukocyturia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Micturition disorder			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nephropathy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Pollakiuria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Proteinuria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Renal atrophy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Renal cyst			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Renal impairment			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Renal pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urethral haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urethral pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Chronic kidney disease			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Incontinence			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Micturition urgency			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Endocrine disorders			
Adrenal disorder			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
Arthritis			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Bone lesion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Bone pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	3
Flank pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Muscle spasms			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	2
Muscular weakness			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal pain			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Myalgia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Myopathy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Osteolysis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Osteopenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Osteoporosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Spinal osteoarthritis			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Bacterial infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Beta haemolytic streptococcal infection			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Bronchitis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Candida infection			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Clostridium difficile infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cystitis			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Device related infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Diverticulitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Enterococcal infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Erysipelas			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Escherichia bacteraemia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Escherichia infection			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Fungal infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Fusobacterium infection			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Gingivitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Herpes virus infection			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Micrococcus infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Nail bed infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	2 / 8 (25.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Oral candidiasis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Pharyngitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Pneumonia fungal			
subjects affected / exposed	1 / 8 (12.50%)	1 / 3 (33.33%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Pseudomonas infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Skin infection			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Staphylococcal infection			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Urinary tract infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urosepsis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Osteomyelitis			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Post procedural infection			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Soft tissue infection			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Acidosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Alkalosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	2 / 8 (25.00%)	1 / 3 (33.33%)	2 / 6 (33.33%)
occurrences (all)	5	1	2
Dehydration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Diabetes mellitus			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Hypercalcaemia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hypernatraemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Hypoglycaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	6 / 8 (75.00%)	3 / 3 (100.00%)	0 / 6 (0.00%)
occurrences (all)	6	3	0
Hyponatraemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoproteinaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Iron overload			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Uraemic acidosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fluid overload			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	Phase I Schedule B. Volasertib 350 mg	Phase I Schedule B. Volasertib 150 mg	Phase I Schedule B. Volasertib 200 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 5 (100.00%)	11 / 11 (100.00%)	2 / 2 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Chloroma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Leukaemia cutis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Meningioma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Neoplasm progression			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Small intestine carcinoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Angiopathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Circulatory collapse			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 5 (0.00%)	2 / 11 (18.18%)	1 / 2 (50.00%)
occurrences (all)	0	2	1
Haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Hypertensive crisis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infarction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Peripheral coldness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Peripheral embolism			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Varicose vein			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Lymphoedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Phlebitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Central venous catheterisation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nail operation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Adverse drug reaction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Calcinosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Catheter site erythema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Catheter site oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	1 / 5 (20.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Chills			
subjects affected / exposed	1 / 5 (20.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Fatigue			

subjects affected / exposed	1 / 5 (20.00%)	3 / 11 (27.27%)	2 / 2 (100.00%)
occurrences (all)	1	3	2
Feeling cold			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Feeling hot			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Feeling of body temperature change			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
General physical health deterioration			
subjects affected / exposed	1 / 5 (20.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Granuloma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Induration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Inflammation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infusion site pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Injection site haematoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			

subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Local swelling			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Localised oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	1 / 5 (20.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Oedema			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Oedema mucosal			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	1 / 5 (20.00%)	2 / 11 (18.18%)	1 / 2 (50.00%)
occurrences (all)	1	2	1
Pain			
subjects affected / exposed	1 / 5 (20.00%)	3 / 11 (27.27%)	0 / 2 (0.00%)
occurrences (all)	1	3	0
Puncture site pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	3	0
Thirst decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			

subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperthermia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Discomfort			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Mucosal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Social circumstances			
Fasting			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Breast enlargement			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Genital swelling			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Haematospermia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Nipple disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Penile oedema			

subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Scrotal oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal erythema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Genital burning sensation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Atelectasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Bronchial secretion retention			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	1 / 5 (20.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Cough			
subjects affected / exposed	0 / 5 (0.00%)	2 / 11 (18.18%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Dyspnoea			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Dyspnoea exertional			
subjects affected / exposed	1 / 5 (20.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Haemoptysis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	2 / 5 (40.00%)	2 / 11 (18.18%)	1 / 2 (50.00%)
occurrences (all)	2	2	2
Hiccups			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Laryngeal disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lung infiltration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lung disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nasal inflammation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pharyngeal inflammation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 5 (0.00%)	2 / 11 (18.18%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Productive cough			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pulmonary hypertension			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Respiratory failure			

subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sputum discoloured			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sputum retention			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Vocal cord disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rales			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rhonchi			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Communication disorder			
subjects affected / exposed	1 / 5 (20.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Confusional state			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Depressed mood			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Depression			
subjects affected / exposed	1 / 5 (20.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Disorientation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hallucination, visual			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Initial insomnia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Panic attack			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Restlessness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 5 (0.00%)	2 / 11 (18.18%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Suicidal ideation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Activated partial thromboplastin time shortened			

subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 5 (0.00%)	2 / 11 (18.18%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	1 / 2 (50.00%)
occurrences (all)	0	1	1
Blast cell count increased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Blood albumin decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood albumin increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 5 (0.00%)	3 / 11 (27.27%)	0 / 2 (0.00%)
occurrences (all)	0	6	0
Blood bilirubin increased			
subjects affected / exposed	0 / 5 (0.00%)	2 / 11 (18.18%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Blood chloride increased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Blood creatine phosphokinase decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood creatinine			

subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood creatinine decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	2 / 5 (40.00%)	2 / 11 (18.18%)	1 / 2 (50.00%)
occurrences (all)	2	3	1
Blood fibrinogen increased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Blood glucose increased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Blood iron decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood iron increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase decreased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 5 (0.00%)	4 / 11 (36.36%)	0 / 2 (0.00%)
occurrences (all)	0	4	0
Blood phosphorus decreased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Blood potassium decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood pressure increased			

subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Blood triglycerides increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood urea decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood urea increased			
subjects affected / exposed	1 / 5 (20.00%)	3 / 11 (27.27%)	1 / 2 (50.00%)
occurrences (all)	1	3	1
Blood uric acid increased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	1 / 2 (50.00%)
occurrences (all)	0	1	1
Blood urine present			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Body temperature increased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Breath sounds abnormal			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	1 / 5 (20.00%)	4 / 11 (36.36%)	2 / 2 (100.00%)
occurrences (all)	1	4	2
Candida test positive			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ejection fraction decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram change			

subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Enterococcus test positive			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Escherichia test positive			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 5 (20.00%)	4 / 11 (36.36%)	0 / 2 (0.00%)
occurrences (all)	1	4	0
Heart rate increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Liver function test abnormal			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oxygen saturation decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Prostatic specific antigen increased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Protein total decreased			
subjects affected / exposed	0 / 5 (0.00%)	3 / 11 (27.27%)	0 / 2 (0.00%)
occurrences (all)	0	3	0
Prothrombin time prolonged			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Serum ferritin increased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	1	0

Thrombin time shortened			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Troponin T increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Troponin increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Weight increased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	1 / 2 (50.00%)
occurrences (all)	0	1	1
White blood cells urine			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Allergic transfusion reaction			
subjects affected / exposed	2 / 5 (40.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Drug administration error			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Excoriation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Fall			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Laceration			

subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lip injury			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Procedural pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Transfusion reaction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Stoma site haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Aortic valve incompetence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Arteriosclerosis coronary artery			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Atrioventricular block			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Bradycardia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Bundle branch block right			
subjects affected / exposed	1 / 5 (20.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Cardiac arrest			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cardiac disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cardiac failure			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Cardiac valve disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cardiomegaly			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Cardiomyopathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cardiovascular disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Congestive cardiomyopathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Extrasystoles			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Heart valve incompetence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypertensive heart disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Left ventricular hypertrophy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Mitral valve incompetence			
subjects affected / exposed	0 / 5 (0.00%)	2 / 11 (18.18%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Palpitations			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pericardial effusion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tachyarrhythmia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tricuspid valve incompetence			
subjects affected / exposed	0 / 5 (0.00%)	2 / 11 (18.18%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Ventricular extrasystoles			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Arrhythmia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Burning sensation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dizziness			

subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Headache			
subjects affected / exposed	2 / 5 (40.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	3	1	0
Hemiparesis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Orthostatic intolerance			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Polyneuropathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sinus headache			
subjects affected / exposed	1 / 5 (20.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Somnolence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ageusia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypotonia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	5 / 5 (100.00%)	4 / 11 (36.36%)	2 / 2 (100.00%)
occurrences (all)	6	4	2
Febrile neutropenia			
subjects affected / exposed	1 / 5 (20.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Leukocytosis			
subjects affected / exposed	0 / 5 (0.00%)	4 / 11 (36.36%)	0 / 2 (0.00%)
occurrences (all)	0	5	0
Leukopenia			
subjects affected / exposed	1 / 5 (20.00%)	2 / 11 (18.18%)	1 / 2 (50.00%)
occurrences (all)	2	3	1
Lymphadenopathy			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	1 / 2 (50.00%)
occurrences (all)	0	1	1
Neutropenia			
subjects affected / exposed	1 / 5 (20.00%)	2 / 11 (18.18%)	1 / 2 (50.00%)
occurrences (all)	1	3	1
Splenomegaly			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	1 / 2 (50.00%)
occurrences (all)	0	1	1
Thrombocytopenia			
subjects affected / exposed	3 / 5 (60.00%)	5 / 11 (45.45%)	1 / 2 (50.00%)
occurrences (all)	3	5	1
Cytopenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear haemorrhage			

subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Erythema of eyelid			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eye haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eyelid oedema			
subjects affected / exposed	1 / 5 (20.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Glaucoma			
subjects affected / exposed	1 / 5 (20.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Lacrimation increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Macular degeneration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Visual acuity reduced			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	1 / 5 (20.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0

Hyphaema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Photopsia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 5 (20.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Abnormal faeces			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Anal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 5 (0.00%)	3 / 11 (27.27%)	1 / 2 (50.00%)
occurrences (all)	0	4	1
Diarrhoea			
subjects affected / exposed	2 / 5 (40.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	3	1	0
Dry mouth			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dysphagia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Enterocolitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Faecaloma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal inflammation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gingival bleeding			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gingival discolouration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gingival swelling			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Glossodynia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			

subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hiatus hernia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Mouth haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 5 (0.00%)	2 / 11 (18.18%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Oesophagitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oral mucosal erythema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	1 / 5 (20.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Periodontal disease			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Proctalgia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Rectal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Small intestine ulcer			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Stomatitis			

subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Tongue coated			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tongue ulceration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	1 / 2 (50.00%)
occurrences (all)	0	1	1
Anal incontinence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tongue discolouration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Abdominal discomfort			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastric ulcer			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Palatal disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tongue haemorrhage			

subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hepatic congestion			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Hepatic cyst			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hepatic lesion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hepatomegaly			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Hyperbilirubinaemia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Hepatic steatosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Blister			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood blister			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	2 / 2 (100.00%)
occurrences (all)	0	1	2
Dermatitis atopic			

subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dermatitis exfoliative			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Haemorrhage subcutaneous			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Hyperhidrosis			
subjects affected / exposed	0 / 5 (0.00%)	2 / 11 (18.18%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Night sweats			
subjects affected / exposed	1 / 5 (20.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Pain of skin			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Parapsoriasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	1 / 5 (20.00%)	4 / 11 (36.36%)	0 / 2 (0.00%)
occurrences (all)	1	4	0
Pruritus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Psoriasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Purpura			

subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	1 / 5 (20.00%)	2 / 11 (18.18%)	1 / 2 (50.00%)
occurrences (all)	1	2	1
Skin erosion			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Skin haemorrhage			
subjects affected / exposed	1 / 5 (20.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Skin hyperpigmentation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Swelling face			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Eczema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ingrowing nail			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Intertrigo			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Anuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1

Bladder pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Glycosuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Leukocyturia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Micturition disorder			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Nephropathy			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Nocturia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Renal atrophy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Renal cyst			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Renal impairment			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Renal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urethral haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Urethral pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Chronic kidney disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Incontinence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Micturition urgency			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Arthritis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Bone lesion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Flank pain			
subjects affected / exposed	1 / 5 (20.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Groin pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Myopathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Osteolysis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Osteopenia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Osteoporosis			
subjects affected / exposed	1 / 5 (20.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Pain in extremity			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Spinal osteoarthritis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Bacterial infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Beta haemolytic streptococcal infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cystitis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Device related infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Diverticulitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Enterococcal infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Erysipelas			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Escherichia bacteraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Escherichia infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Fusobacterium infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Herpes simplex			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Herpes virus infection			

subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Micrococcus infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nail bed infection			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Nasopharyngitis			
subjects affected / exposed	1 / 5 (20.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Oral candidiasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Pharyngitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pneumonia fungal			
subjects affected / exposed	1 / 5 (20.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Pseudomonas infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin infection			

subjects affected / exposed	1 / 5 (20.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Staphylococcal infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urosepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Osteomyelitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Post procedural infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Soft tissue infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Acidosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Alkalosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	1 / 5 (20.00%)	3 / 11 (27.27%)	0 / 2 (0.00%)
occurrences (all)	1	3	0
Dehydration			
subjects affected / exposed	1 / 5 (20.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Diabetes mellitus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Hypercalcaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	2 / 2 (100.00%)
occurrences (all)	0	2	2
Hyperkalaemia			
subjects affected / exposed	1 / 5 (20.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Hypernatraemia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Hyperuricaemia			
subjects affected / exposed	0 / 5 (0.00%)	2 / 11 (18.18%)	0 / 2 (0.00%)
occurrences (all)	0	3	0
Hypoalbuminaemia			
subjects affected / exposed	1 / 5 (20.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Hypocalcaemia			
subjects affected / exposed	2 / 5 (40.00%)	2 / 11 (18.18%)	2 / 2 (100.00%)
occurrences (all)	2	2	2
Hypoglycaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 5 (0.00%)	2 / 11 (18.18%)	0 / 2 (0.00%)
occurrences (all)	0	3	0
Hyponatraemia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	1 / 2 (50.00%)
occurrences (all)	0	1	1
Hypoproteinaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Iron overload			
subjects affected / exposed	1 / 5 (20.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Uraemic acidosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Vitamin D deficiency			
subjects affected / exposed	0 / 5 (0.00%)	1 / 11 (9.09%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Fluid overload			
subjects affected / exposed	0 / 5 (0.00%)	0 / 11 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Phase I Schedule B. Volasertib 500 mg	Phase I Schedule B. Volasertib 450 mg	Phase I Schedule B. Volasertib 550 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 5 (100.00%)	23 / 23 (100.00%)	4 / 4 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Chloroma			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Leukaemia cutis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Meningioma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neoplasm progression			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Small intestine carcinoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Angiopathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Circulatory collapse			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	2 / 5 (40.00%)	3 / 23 (13.04%)	0 / 4 (0.00%)
occurrences (all)	2	3	0
Haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	1 / 5 (20.00%)	5 / 23 (21.74%)	2 / 4 (50.00%)
occurrences (all)	1	5	3
Hypertensive crisis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Infarction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Peripheral coldness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Peripheral embolism			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis			
subjects affected / exposed	0 / 5 (0.00%)	2 / 23 (8.70%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Varicose vein			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lymphoedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Phlebitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Central venous catheterisation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nail operation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Adverse drug reaction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Calcinosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Catheter site erythema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Catheter site oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	2 / 5 (40.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	2	1	0
Fatigue			

subjects affected / exposed	2 / 5 (40.00%)	4 / 23 (17.39%)	2 / 4 (50.00%)
occurrences (all)	2	5	2
Feeling cold			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Feeling hot			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Feeling of body temperature change			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Gait disturbance			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
General physical health deterioration			
subjects affected / exposed	1 / 5 (20.00%)	13 / 23 (56.52%)	0 / 4 (0.00%)
occurrences (all)	1	13	0
Granuloma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Induration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Inflammation			
subjects affected / exposed	0 / 5 (0.00%)	2 / 23 (8.70%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Influenza like illness			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Infusion site pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injection site haematoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			

subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Local swelling			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Localised oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Mucosal inflammation			
subjects affected / exposed	0 / 5 (0.00%)	2 / 23 (8.70%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Oedema			
subjects affected / exposed	0 / 5 (0.00%)	3 / 23 (13.04%)	1 / 4 (25.00%)
occurrences (all)	0	4	1
Oedema mucosal			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Oedema peripheral			
subjects affected / exposed	0 / 5 (0.00%)	9 / 23 (39.13%)	0 / 4 (0.00%)
occurrences (all)	0	9	0
Pain			
subjects affected / exposed	0 / 5 (0.00%)	3 / 23 (13.04%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
Puncture site pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 5 (0.00%)	2 / 23 (8.70%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Thirst decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			

subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperthermia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Discomfort			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mucosal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Social circumstances			
Fasting			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Breast enlargement			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Genital swelling			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haematospermia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nipple disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Penile oedema			

subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Scrotal oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Vulvovaginal erythema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Genital burning sensation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Atelectasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bronchial secretion retention			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Cough			
subjects affected / exposed	1 / 5 (20.00%)	6 / 23 (26.09%)	0 / 4 (0.00%)
occurrences (all)	1	10	0
Dyspnoea			
subjects affected / exposed	1 / 5 (20.00%)	4 / 23 (17.39%)	0 / 4 (0.00%)
occurrences (all)	1	4	0
Dyspnoea exertional			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Haemoptysis			

subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Epistaxis			
subjects affected / exposed	2 / 5 (40.00%)	5 / 23 (21.74%)	1 / 4 (25.00%)
occurrences (all)	2	6	1
Hiccups			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Laryngeal disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lung infiltration			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Lung disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nasal inflammation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 5 (20.00%)	3 / 23 (13.04%)	0 / 4 (0.00%)
occurrences (all)	1	3	0
Pharyngeal inflammation			
subjects affected / exposed	0 / 5 (0.00%)	2 / 23 (8.70%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Pleural effusion			
subjects affected / exposed	1 / 5 (20.00%)	2 / 23 (8.70%)	0 / 4 (0.00%)
occurrences (all)	1	2	0
Productive cough			
subjects affected / exposed	1 / 5 (20.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Pulmonary hypertension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory failure			

subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Sputum discoloured			
subjects affected / exposed	1 / 5 (20.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Sputum retention			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vocal cord disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rales			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rhonchi			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	1 / 5 (20.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Communication disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 5 (0.00%)	2 / 23 (8.70%)	1 / 4 (25.00%)
occurrences (all)	0	2	1
Depressed mood			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	1	0

Depression			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Disorientation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Hallucination, visual			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Initial insomnia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Panic attack			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Restlessness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Sleep disorder			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Suicidal ideation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 5 (0.00%)	3 / 23 (13.04%)	1 / 4 (25.00%)
occurrences (all)	0	5	1
Activated partial thromboplastin time shortened			

subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	1 / 5 (20.00%)	4 / 23 (17.39%)	0 / 4 (0.00%)
occurrences (all)	1	4	0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 5 (20.00%)	5 / 23 (21.74%)	0 / 4 (0.00%)
occurrences (all)	1	7	0
Blast cell count increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood albumin decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood albumin increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 5 (0.00%)	2 / 23 (8.70%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
Blood bilirubin increased			
subjects affected / exposed	0 / 5 (0.00%)	2 / 23 (8.70%)	0 / 4 (0.00%)
occurrences (all)	0	7	0
Blood chloride increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood creatinine			

subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood creatinine decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 5 (0.00%)	6 / 23 (26.09%)	2 / 4 (50.00%)
occurrences (all)	0	12	2
Blood fibrinogen increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood glucose increased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	4	0
Blood iron decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood iron increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 5 (0.00%)	3 / 23 (13.04%)	0 / 4 (0.00%)
occurrences (all)	0	5	0
Blood phosphorus decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood potassium decreased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Blood pressure increased			

subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood triglycerides increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood urea decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood urea increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood uric acid increased			
subjects affected / exposed	0 / 5 (0.00%)	2 / 23 (8.70%)	1 / 4 (25.00%)
occurrences (all)	0	4	2
Blood urine present			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Body temperature increased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Breath sounds abnormal			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	1 / 5 (20.00%)	7 / 23 (30.43%)	3 / 4 (75.00%)
occurrences (all)	1	8	3
Candida test positive			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ejection fraction decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	1 / 5 (20.00%)	5 / 23 (21.74%)	1 / 4 (25.00%)
occurrences (all)	1	14	1
Electrocardiogram change			

subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Enterococcus test positive			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Escherichia test positive			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 5 (0.00%)	3 / 23 (13.04%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
Heart rate increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	1 / 5 (20.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Liver function test abnormal			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oxygen saturation decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Prostatic specific antigen increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Protein total decreased			
subjects affected / exposed	0 / 5 (0.00%)	2 / 23 (8.70%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Prothrombin time prolonged			
subjects affected / exposed	0 / 5 (0.00%)	2 / 23 (8.70%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
Serum ferritin increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Thrombin time shortened			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Troponin T increased			
subjects affected / exposed	1 / 5 (20.00%)	3 / 23 (13.04%)	0 / 4 (0.00%)
occurrences (all)	1	5	0
Troponin increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Weight increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
White blood cells urine			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Allergic transfusion reaction			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Drug administration error			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Excoriation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	1 / 5 (20.00%)	4 / 23 (17.39%)	0 / 4 (0.00%)
occurrences (all)	1	4	0
Laceration			

subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lip injury			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Transfusion reaction			
subjects affected / exposed	1 / 5 (20.00%)	2 / 23 (8.70%)	0 / 4 (0.00%)
occurrences (all)	1	2	0
Wound			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Stoma site haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Aortic valve incompetence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Arteriosclerosis coronary artery			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Atrioventricular block			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed	1 / 5 (20.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	1	2	0

Bundle branch block right			
subjects affected / exposed	0 / 5 (0.00%)	2 / 23 (8.70%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Cardiac arrest			
subjects affected / exposed	1 / 5 (20.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Cardiac disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cardiac failure			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cardiac valve disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cardiomegaly			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cardiomyopathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cardiovascular disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Congestive cardiomyopathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Extrasystoles			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Heart valve incompetence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypertensive heart disease			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	1	0

Left ventricular hypertrophy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mitral valve incompetence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pericardial effusion			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Tachyarrhythmia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tricuspid valve incompetence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ventricular extrasystoles			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Arrhythmia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Burning sensation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dizziness			

subjects affected / exposed	0 / 5 (0.00%)	4 / 23 (17.39%)	1 / 4 (25.00%)
occurrences (all)	0	4	1
Headache			
subjects affected / exposed	2 / 5 (40.00%)	5 / 23 (21.74%)	1 / 4 (25.00%)
occurrences (all)	3	6	1
Hemiparesis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Orthostatic intolerance			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Polyneuropathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinus headache			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Tremor			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Ageusia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypotonia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 5 (20.00%)	11 / 23 (47.83%)	2 / 4 (50.00%)
occurrences (all)	3	16	2
Febrile neutropenia			
subjects affected / exposed	0 / 5 (0.00%)	4 / 23 (17.39%)	1 / 4 (25.00%)
occurrences (all)	0	4	1
Leukocytosis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Leukopenia			
subjects affected / exposed	1 / 5 (20.00%)	7 / 23 (30.43%)	1 / 4 (25.00%)
occurrences (all)	1	10	1
Lymphadenopathy			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Neutropenia			
subjects affected / exposed	1 / 5 (20.00%)	12 / 23 (52.17%)	1 / 4 (25.00%)
occurrences (all)	1	16	1
Splenomegaly			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Thrombocytopenia			
subjects affected / exposed	1 / 5 (20.00%)	12 / 23 (52.17%)	2 / 4 (50.00%)
occurrences (all)	1	22	2
Cytopenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear haemorrhage			

subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 5 (0.00%)	2 / 23 (8.70%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Dry eye			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Erythema of eyelid			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	2 / 23 (8.70%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Eyelid oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Glaucoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	1 / 5 (20.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Macular degeneration			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Visual acuity reduced			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Hyphaema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Photopsia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 5 (0.00%)	4 / 23 (17.39%)	0 / 4 (0.00%)
occurrences (all)	0	4	0
Abdominal pain upper			
subjects affected / exposed	0 / 5 (0.00%)	2 / 23 (8.70%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Abnormal faeces			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Anal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Ascites			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	1 / 5 (20.00%)	6 / 23 (26.09%)	2 / 4 (50.00%)
occurrences (all)	1	7	2
Diarrhoea			
subjects affected / exposed	2 / 5 (40.00%)	6 / 23 (26.09%)	0 / 4 (0.00%)
occurrences (all)	2	8	0
Dry mouth			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysphagia			

subjects affected / exposed	1 / 5 (20.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Enterocolitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Faecaloma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	1 / 5 (20.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Gastritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal inflammation			
subjects affected / exposed	1 / 5 (20.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Gingival bleeding			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Gingival discolouration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gingival swelling			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Glossodynia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Haemorrhoids			

subjects affected / exposed	2 / 5 (40.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Hiatus hernia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mouth haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	3 / 23 (13.04%)	1 / 4 (25.00%)
occurrences (all)	0	3	1
Mouth ulceration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	2 / 5 (40.00%)	7 / 23 (30.43%)	2 / 4 (50.00%)
occurrences (all)	3	14	2
Oesophagitis			
subjects affected / exposed	1 / 5 (20.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Oral mucosal erythema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Periodontal disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Rectal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Small intestine ulcer			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Stomatitis			

subjects affected / exposed	3 / 5 (60.00%)	5 / 23 (21.74%)	0 / 4 (0.00%)
occurrences (all)	3	5	0
Tongue coated			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tongue ulceration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 5 (20.00%)	6 / 23 (26.09%)	1 / 4 (25.00%)
occurrences (all)	1	8	1
Anal incontinence			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Aphthous ulcer			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Tongue discolouration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal discomfort			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastric ulcer			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Palatal disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tongue haemorrhage			

subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hepatic congestion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hepatic cyst			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hepatic lesion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hepatomegaly			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 5 (0.00%)	3 / 23 (13.04%)	1 / 4 (25.00%)
occurrences (all)	0	4	1
Hepatic steatosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 5 (0.00%)	3 / 23 (13.04%)	2 / 4 (50.00%)
occurrences (all)	0	3	2
Blister			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood blister			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dermatitis atopic			

subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dermatitis exfoliative			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	1 / 5 (20.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Haemorrhage subcutaneous			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 5 (0.00%)	3 / 23 (13.04%)	1 / 4 (25.00%)
occurrences (all)	0	3	1
Pain of skin			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Parapsoriasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	2 / 5 (40.00%)	3 / 23 (13.04%)	0 / 4 (0.00%)
occurrences (all)	2	3	0
Pruritus			
subjects affected / exposed	0 / 5 (0.00%)	2 / 23 (8.70%)	1 / 4 (25.00%)
occurrences (all)	0	2	1
Psoriasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Purpura			

subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 5 (0.00%)	4 / 23 (17.39%)	0 / 4 (0.00%)
occurrences (all)	0	5	0
Skin erosion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin hyperpigmentation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Swelling face			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ingrowing nail			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Intertrigo			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Anuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Bladder pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 5 (0.00%)	3 / 23 (13.04%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
Glycosuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Leukocyturia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Micturition disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nephropathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal atrophy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal cyst			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	1	0

Renal impairment			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urethral haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urethral pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 5 (0.00%)	2 / 23 (8.70%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Urinary retention			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chronic kidney disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Incontinence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Micturition urgency			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	3 / 5 (60.00%)	3 / 23 (13.04%)	0 / 4 (0.00%)
occurrences (all)	3	4	0
Arthritis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Back pain			
subjects affected / exposed	0 / 5 (0.00%)	3 / 23 (13.04%)	1 / 4 (25.00%)
occurrences (all)	0	3	3
Bone lesion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Joint swelling			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Muscular weakness			
subjects affected / exposed	0 / 5 (0.00%)	3 / 23 (13.04%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
Musculoskeletal pain			
subjects affected / exposed	1 / 5 (20.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Myalgia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Myopathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Osteolysis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Osteopenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Osteoporosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 5 (0.00%)	3 / 23 (13.04%)	1 / 4 (25.00%)
occurrences (all)	0	3	1
Spinal osteoarthritis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Bacterial infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Beta haemolytic streptococcal infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed	1 / 5 (20.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Clostridium difficile infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cystitis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Device related infection			
subjects affected / exposed	1 / 5 (20.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Diverticulitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Enterococcal infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Erysipelas			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Escherichia bacteraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Escherichia infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fusobacterium infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	1 / 5 (20.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Herpes virus infection			

subjects affected / exposed	1 / 5 (20.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Herpes zoster			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Micrococcus infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nail bed infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	1 / 5 (20.00%)	3 / 23 (13.04%)	0 / 4 (0.00%)
occurrences (all)	1	5	0
Pharyngitis			
subjects affected / exposed	0 / 5 (0.00%)	3 / 23 (13.04%)	0 / 4 (0.00%)
occurrences (all)	0	4	0
Pneumonia			
subjects affected / exposed	0 / 5 (0.00%)	3 / 23 (13.04%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
Pneumonia fungal			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pseudomonas infection			
subjects affected / exposed	0 / 5 (0.00%)	2 / 23 (8.70%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Sepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin infection			

subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Staphylococcal infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urosepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Osteomyelitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Post procedural infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Soft tissue infection			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
Acidosis			
subjects affected / exposed	1 / 5 (20.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Alkalosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	1 / 5 (20.00%)	10 / 23 (43.48%)	1 / 4 (25.00%)
occurrences (all)	1	14	1
Dehydration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Diabetes mellitus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Hypercalcaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hyperkalaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 23 (4.35%)	1 / 4 (25.00%)
occurrences (all)	0	1	2
Hyperuricaemia			
subjects affected / exposed	0 / 5 (0.00%)	3 / 23 (13.04%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 5 (0.00%)	4 / 23 (17.39%)	1 / 4 (25.00%)
occurrences (all)	0	6	1
Hypocalcaemia			
subjects affected / exposed	1 / 5 (20.00%)	6 / 23 (26.09%)	0 / 4 (0.00%)
occurrences (all)	1	9	0
Hypoglycaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 5 (0.00%)	10 / 23 (43.48%)	2 / 4 (50.00%)
occurrences (all)	0	17	4
Hyponatraemia			
subjects affected / exposed	0 / 5 (0.00%)	2 / 23 (8.70%)	1 / 4 (25.00%)
occurrences (all)	0	7	1
Hypoproteinaemia			
subjects affected / exposed	0 / 5 (0.00%)	2 / 23 (8.70%)	0 / 4 (0.00%)
occurrences (all)	0	2	0

Iron overload			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Uraemic acidosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fluid overload			
subjects affected / exposed	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
20 October 2008	To allow for close cardiac monitoring of patients during the trial, additional Electrocardiogram (ECG) and troponin analyses were added. A formal safety analysis after the Phase I part of the trial and if necessary an updated benefit risk assessment was implemented. The Phase I part safety analysis was to be made available to all involved competent authorities and ethics committees. The blood sample for pharmacogenetic analysis was increased to 10 milliLiter (mL) to allow for different additives and different volumes in commercial tubes. The addition of further Pharmacokinetics (PK) analyses on volasertib metabolites, if applicable, was added to obtain further information on the PK of volasertib
11 August 2009	The procedure was changed for allocation of patients in the Phase I part to treatment groups. This change in allocation for the Phase I part of the trial was implemented to avoid or shorten periods with stopped recruitment. Recruitment was to be stopped if the planned number of patients at a dose level was recruited in both schedules until all patients at that dose level finished the first treatment cycle. A non-randomised allocation of patients to treatment groups reduced the risk that the planned number of patients was recruited in both schedules at the same time. Changed dose escalation in Schedule B (volasertib monotherapy) to minimise the number of patients treated at suboptimal doses of volasertib. Change in details of packaging and labelling for Low-dose cytarabine (LDAC) used in the Phase II part of the trial. Details on serious adverse event (SAE) reporting changed to enhance comprehensibility of the procedure.
12 November 2009	The procedure for allocating patients in the Phase I part to treatment schedules was changed. This change was implemented based on the first preliminary results that suggested an inferior clinical effect of volasertib monotherapy at the dose levels investigated at this point compared to the combination of volasertib and Low-dose cytarabine (LDAC). Screening for additional mutations and deregulated expression of genes was added to the planned cytogenetic and molecular genetic testing to allow the most up to date diagnostics in the trial. The sample volume of blood needed was adapted. The wording for the replacement of patients was considered misleading for the Phase II part of the trial so this was clarified. The address of the coordinating investigator was changed. The rules for pharmacodynamic investigations were changed, with the Progressive disease (PD) analysis being changed to being optional in Phase II part of the trial
01 December 2010	Details on exclusion of patients with QT interval corrected (QTc) prolongation were added to provide more accurate recommendations for the management of QTc interval prolongation and ventricular tachyarrhythmia
26 May 2011	Details were added on timing and preparation of the clinical trial report (CTR) at the end of the trial. An early analysis of response to therapy was added to support internal strategic decisions/planning regarding future clinical trials.
20 March 2012	Details on timing and preparation of the CTR were clarified.
23 July 2013	Details on timing and preparation of the CTR were clarified.
14 October 2014	The vial size of volasertib was changed to administer a dose of 350 milligram (mg) by the use of only 1 vial.

12 January 2017	Procedures and data collection were reduced to a minimum because the sponsor decided to discontinue volasertib development; however, patients with a clinical benefit could continue treatment. The sample size changed from about 143 to 177 enrolled (175 evaluable) to provide current and up-to-date information.
07 February 2019	Details on electronic data capture were updated.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported