Clinical trial results:
A Phase 1, First in Human, Single-Arm, Open-Label Study Of Once a Day, Orally Administered Talazoparib (bmn 673) in Patients With Advanced or Recurrent Solid Tumors

Summary

EudraCT number	2010-023062-40
Trial protocol	GB
Global end of trial date	

Results information

Result version number	v1 (current)
This version publication date	15 February 2018
First version publication date	15 February 2018

Trial information

Trial identification

Sponsor protocol code	PRP-001

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01286987
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Pfizer, Inc.
Sponsor organisation address	235 E 42nd Street, New York, United States, 10017
Public contact	Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., Pfizer ClinicalTrials.gov Call Center, 001 18007181021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer ClinicalTrials.gov Call Center, 001 18007181021, ClinicalTrials.gov_Inquiries@pfizer.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	Interim
Date of interim/final analysis	22 August 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	31 March 2015
Global end of trial reached?	No

Notes:

General information about the trial

Main objective of the trial:

To establish the MTD of daily, orally administered talazoparib.

Protection of trial subjects:

This study was conducted in accordance with the US Code of Federal Regulations (CFR) sections that address clinical research studies, and/or other national and local regulations, as applicable, ICH Harmonised Tripartite Guideline: Guideline for Good Clinical Practice E6 (ICH E6) and the ethical principles established by the Declaration of Helsinki.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	11 January 2011
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	United States: 110
Worldwide total number of subjects	110
EEA total number of subjects	0

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)	78
From 65 to 84 years	31
85 years and over	1

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Study was conducted in two parts: Part 1 was dose escalation phase (to determine the maximum tolerated dose [MTD]) and Part 2 was the dose expansion phase conducted at MTD determined in Part 1. Subjects were different in both of the Parts.

Period 1

Period 1 title	Baseline Period
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Part 1: Talazoparib 25 mcg

Arm description:

Subjects received talazoparib capsules at a dose of 25 microgram per day (mcg/day) once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

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

Dosage and administration details:

Subjects received talazoparib capsules at a dose of 25 mcg once daily.

Arm title	Part 1: Talazoparib 50 mcg

Arm description:

Subjects received talazoparib capsules at a dose of 50 mcg/day once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

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

Dosage and administration details:

Subjects received talazoparib capsules at a dose of 50 mcg once daily.

Arm title	Part 1: Talazoparib 100 mcg

Arm description:

Subjects received talazoparib capsules at a dose of 100 mcg/day once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Arm type	Experimental

Investigational medicinal product name	Talazoparib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Subjects received talazoparib capsules at a dose of 100 mcg once daily.

Arm title	Part 1: Talazoparib 200 mcg

Arm description:

Subjects received talazoparib capsules at a dose of 200 mcg/day once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

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

Dosage and administration details:

Subjects received talazoparib capsules at a dose of 200 mcg once daily.

Arm title	Part 1: Talazoparib 400 mcg

Arm description:

Subjects received talazoparib capsules at a dose of 400 mcg/day once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

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

Dosage and administration details:

Subjects received talazoparib capsules at a dose of 400 mcg once daily.

Arm title	Part 1: Talazoparib 600 mcg

Arm description:

Subjects received talazoparib capsules at a dose of 600 mcg/day once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

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

Dosage and administration details:

Subjects received talazoparib capsules at a dose of 600 mcg once daily.

Arm title	Part 1: Talazoparib 900 mcg

Arm description:

Subjects received talazoparib capsules at a dose of 900 mcg/day once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50

cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

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

Dosage and administration details:

Subjects received talazoparib capsules at a dose of 900 mcg once daily.

Arm title	Part 1: Talazoparib 1000 mcg

Arm description:

Subjects received talazoparib capsules at a dose of 1000 microgram per day (mcg/day) once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

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

Dosage and administration details:

Subjects received talazoparib capsules at a dose of 1000 mcg once daily.

Arm title	Part 1: Talazoparib 1100 mcg

Arm description:

Subjects received talazoparib capsules at a dose of 1100 microgram per day (mcg/day) once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

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

Dosage and administration details:

Subjects received talazoparib capsules at a dose of 1100 mcg once daily.

Arm title	Part 2: Talazoparib (Breast Cancer)

Arm description:

Subjects with breast cancer, received talazoparib capsules at the MTD as determined in Part 1 (1000 mcg/day), orally once daily in each 28-day treatment cycle (up to a maximum of 40 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

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

Dosage and administration details:

Subjects received talazoparib capsules at a dose of 1000 mcg once daily.

Arm title	Part 2: Talazoparib (Ovarian/ Peritoneal Cancer)

Arm description:

Subjects with ovarian/ peritoneal cancer, received talazoparib capsules at the MTD as determined in Part 1 (1000 mcg/day), orally once daily in each 28-day treatment cycle (up to a maximum of 40 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

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

Dosage and administration details:

Subjects received talazoparib capsules at a dose of 1000 mcg once daily.

Arm title	Part 2: Talazoparib (Pancreatic Cancer)

Arm description:

Subjects with pancreatic cancer, received talazoparib capsules at the MTD as determined in Part 1 (1000 mcg/day), orally once daily in each 28-day treatment cycle (up to a maximum of 40 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

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

Dosage and administration details:

Subjects received talazoparib capsules at a dose of 1000 mcg once daily.

Arm title	Part 2: Talazoparib (Ewing Cancer)

Arm description:

Subjects with ewing cancer, received talazoparib capsules at the MTD as determined in Part 1 (1000 mcg/day), orally once daily in each 28-day treatment cycle (up to a maximum of 40 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

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

Dosage and administration details:

Subjects received talazoparib capsules at a dose of 1000 mcg once daily.

Arm title	Part 2: Talazoparib (SCLC Cancer)

Arm description:

Subjects with SCLC cancer, received talazoparib capsules at the MTD as determined in Part 1 (1000 mcg/day), orally once daily in each 28-day treatment cycle (up to a maximum of 40 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

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

Dosage and administration details:

Subjects received talazoparib capsules at a dose of 1000 mcg once daily.

Arm title	Part 2: Talazoparib (Prostate Cancer)

Arm description:

Subjects with prostate cancer, received talazoparib capsules at the MTD as determined in Part 1 (1000 mcg/day), orally once daily in each 28-day treatment cycle (up to a maximum of 40 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

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

Dosage and administration details:

Subjects received talazoparib capsules at a dose of 1000 mcg once daily.

Number of subjects in period 1	Part 1: Talazoparib 25 mcg	Part 1: Talazoparib 50 mcg	Part 1: Talazoparib 100 mcg
Started	3	3	3
Completed	3	3	3

Number of subjects in period 1	Part 1: Talazoparib 200 mcg	Part 1: Talazoparib 400 mcg	Part 1: Talazoparib 600 mcg
Started	3	3	6
Completed	3	3	6

Number of subjects in period 1	Part 1: Talazoparib 900 mcg	Part 1: Talazoparib 1000 mcg	Part 1: Talazoparib 1100 mcg
Started	6	6	6
Completed	6	6	6

Number of subjects in period 1	Part 2: Talazoparib (Breast Cancer)	Part 2: Talazoparib (Ovarian/ Peritoneal Cancer)	Part 2: Talazoparib (Pancreatic Cancer)
Started	12	11	10
Completed	12	11	10

Number of subjects in period 1	Part 2: Talazoparib (Ewing Cancer)	Part 2: Talazoparib (SCLC Cancer)	Part 2: Talazoparib (Prostate Cancer)
Started	12	23	3
Completed	12	23	3

Period 2

Period 2 title	Part 1: Dose Escalation
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Part 1: Talazoparib 25 mcg

Arm description:

Subjects received talazoparib capsules at a dose of 25 mcg/day once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

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

Dosage and administration details:

Subjects received talazoparib capsules at a dose of 25 mcg once daily.

Arm title	Part 1: Talazoparib 50 mcg

Arm description:

Subjects received talazoparib capsules at a dose of 50 mcg/day once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

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

Dosage and administration details:

Subjects received talazoparib capsules at a dose of 50 mcg once daily.

Arm title	Part 1: Talazoparib 100 mcg

Arm description:

Subjects received talazoparib capsules at a dose of 100 mcg/day once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

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

Dosage and administration details:

Subjects received talazoparib capsules at a dose of 100 mcg once daily.

Arm title	Part 1: Talazoparib 200 mcg

Arm description:

Subjects received talazoparib capsules at a dose of 200 mcg/day once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

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

Dosage and administration details:

Subjects received talazoparib capsules at a dose of 200 mcg once daily.

Arm title	Part 1: Talazoparib 400 mcg

Arm description:

Subjects received talazoparib capsules at a dose of 400 mcg/day once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

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

Dosage and administration details:

Subjects received talazoparib capsules at a dose of 400 mcg once daily.

Arm title	Part 1: Talazoparib 600 mcg

Arm description:

Subjects received talazoparib capsules at a dose of 600 mcg/day once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

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

Dosage and administration details:

Subjects received talazoparib capsules at a dose of 600 mcg once daily.

Arm title	Part 1: Talazoparib 900 mcg

Arm description:

Subjects received talazoparib capsules at a dose of 900 mcg/day once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Arm type	Experimental

Investigational medicinal product name	Talazoparib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Subjects received talazoparib capsules at a dose of 900 mcg once daily.

Arm title	Part 1: Talazoparib 1000 mcg

Arm description:

Subjects received talazoparib capsules at a dose of 1000 mcg/day once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

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

Dosage and administration details:

Subjects received talazoparib capsules at a dose of 1000 mcg once daily.

Arm title	Part 1: Talazoparib 1100 mcg

Arm description:

Subjects received talazoparib capsules at a dose of 1100 mcg/day once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

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

Dosage and administration details:

Subjects received talazoparib capsules at a dose of 1100 mcg once daily.

Number of subjects in period 2[1]	Part 1: Talazoparib 25 mcg	Part 1: Talazoparib 50 mcg	Part 1: Talazoparib 100 mcg
Started	3	3	3
Colorectal Cancer	1	0	1
Prostate Cancer	0	0	0
Ewing Cancer	0	0	0
Pancreatic Cancer	1	2	0
Ovarian/ Peritoneal Cancer	1	1	2
Breast Cancer	0	0	0
Completed	0	0	0
Not completed	3	3	3

Physician decision	-	-	-
Progressive Disease	2	2	3
Clinical Progression	1	1	-

Number of subjects in period 2[1]	Part 1: Talazoparib 200 mcg	Part 1: Talazoparib 400 mcg	Part 1: Talazoparib 600 mcg
Started	3	3	6
Colorectal Cancer	0	0	0
Prostate Cancer	0	0	1
Ewing Cancer	0	0	0
Pancreatic Cancer	0	0	0
Ovarian/ Peritoneal Cancer	3	3	4
Breast Cancer	0	0	1
Completed	0	0	0
Not completed	3	3	6
Physician decision	-	1	-
Progressive Disease	2	1	5
Clinical Progression	1	1	1

Number of subjects in period 2[1]	Part 1: Talazoparib 900 mcg	Part 1: Talazoparib 1000 mcg	Part 1: Talazoparib 1100 mcg
Started	6	6	6
Colorectal Cancer	0 [2]	0 [3]	0
Prostate Cancer	0 [4]	0 [5]	0
Ewing Cancer	0 [6]	1	1
Pancreatic Cancer	0 [7]	0 [8]	0
Ovarian/ Peritoneal Cancer	4	3	2
Breast Cancer	2	2	3
Completed	1	1	0
Not completed	5	5	6
Physician decision	-	-	-
Progressive Disease	5	3	5
Clinical Progression	-	2	1

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: Period 1 and period 2 had different enrolled population.

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: The Milestone represents the number of subjects enrolled according to the type of cancer.

[3] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: The Milestone represents the number of subjects enrolled according to the type of cancer.

[4] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: The Milestone represents the number of subjects enrolled according to the type of cancer.

[5] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: The Milestone represents the number of subjects enrolled according to the type of cancer.

[6] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: The Milestone represents the number of subjects enrolled according to the type of cancer.

[7] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: The Milestone represents the number of subjects enrolled according to the type of cancer.

[8] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: The Milestone represents the number of subjects enrolled according to the type of cancer.

Period 3

Period 3 title	Part 2: Dose Expansion
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	No
Arm title	Part 2: Talazoparib (Breast Cancer)

Arm description:

Subjects with breast cancer, received talazoparib capsules at the MTD as determined in Part 1 (1000 mcg/day), orally once daily in each 28-day treatment cycle (up to a maximum of 40 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

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

Dosage and administration details:

Subjects received talazoparib capsules at a dose of 1000 mcg once daily.

Arm title	Part 2: Talazoparib (Ovarian/ Peritoneal Cancer)

Arm description:

Subjects with ovarian/ peritoneal cancer, received talazoparib capsules at the MTD as determined in Part 1 (1000 mcg/day), orally once daily in each 28-day treatment cycle (up to a maximum of 40 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

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

Dosage and administration details:

Subjects received talazoparib capsules at a dose of 1000 mcg once daily.

Arm title	Part 2: Talazoparib (Pancreatic Cancer)

Arm description:

Subjects with pancreatic cancer, received talazoparib capsules at the MTD as determined in Part 1 (1000 mcg/day), orally once daily in each 28-day treatment cycle (up to a maximum of 40 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

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

Dosage and administration details:

Subjects received talazoparib capsules at a dose of 1000 mcg once daily.

Arm title	Part 2: Talazoparib (Ewing Cancer)

Arm description:

Subjects with ewing cancer, received talazoparib capsules at the MTD as determined in Part 1 (1000 mcg/day), orally once daily in each 28-day treatment cycle (up to a maximum of 40 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

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

Dosage and administration details:

Subjects received talazoparib capsules at a dose of 1000 mcg once daily.

Arm title	Part 2: Talazoparib (SCLC Cancer)

Arm description:

Subjects with SCLC cancer, received talazoparib capsules at the MTD as determined in Part 1 (1000 mcg/day), orally once daily in each 28-day treatment cycle (up to a maximum of 40 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

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

Dosage and administration details:

Subjects received talazoparib capsules at a dose of 1000 mcg once daily.

Arm title	Part 2: Talazoparib (Prostate Cancer)

Arm description:

Subjects with prostate cancer, received talazoparib capsules at the MTD as determined in Part 1 (1000 mcg/day), orally once daily in each 28-day treatment cycle (up to a maximum of 40 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Arm type	Experimental

Investigational medicinal product name	Talazoparib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Subjects received talazoparib capsules at a dose of 1000 mcg once daily.

Number of subjects in period 3	Part 2: Talazoparib (Breast Cancer)	Part 2: Talazoparib (Ovarian/ Peritoneal Cancer)	Part 2: Talazoparib (Pancreatic Cancer)
Started	12	11	10
Completed	1	2	1
Not completed	11	9	9
Adverse event, serious fatal	-	-	-
Physician decision	-	1	-
Consent withdrawn by subject	-	1	-
Progressive Disease	11	6	7
Not specified	-	-	-
Clinical Progression	-	1	2

Number of subjects in period 3	Part 2: Talazoparib (Ewing Cancer)	Part 2: Talazoparib (SCLC Cancer)	Part 2: Talazoparib (Prostate Cancer)
Started	12	23	3
Completed	0	0	1
Not completed	12	23	2
Adverse event, serious fatal	1	1	-
Physician decision	-	-	-
Consent withdrawn by subject	-	-	-
Progressive Disease	11	19	2
Not specified	-	1	-
Clinical Progression	-	2	-

Baseline characteristics

Reporting groups

Reporting group title	Part 1: Talazoparib 25 mcg

Reporting group description:

Subjects received talazoparib capsules at a dose of 25 mcg/day once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 1: Talazoparib 50 mcg

Reporting group description:

Subjects received talazoparib capsules at a dose of 50 mcg/day once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 1: Talazoparib 100 mcg

Reporting group description:

Subjects received talazoparib capsules at a dose of 100 mcg/day once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 1: Talazoparib 200 mcg

Reporting group description:

Subjects received talazoparib capsules at a dose of 200 mcg/day once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 1: Talazoparib 400 mcg

Reporting group description:

Subjects received talazoparib capsules at a dose of 400 mcg/day once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 1: Talazoparib 600 mcg

Reporting group description:

Subjects received talazoparib capsules at a dose of 600 mcg/day once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 1: Talazoparib 900 mcg

Reporting group description:

Subjects received talazoparib capsules at a dose of 900 mcg/day once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 1: Talazoparib 1000 mcg

Reporting group description:

Subjects received talazoparib capsules at a dose of 1000 mcg/day once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 1: Talazoparib 1100 mcg

Reporting group description:

Subjects received talazoparib capsules at a dose of 1100 mcg/day once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 2: Talazoparib (Breast Cancer)

Reporting group description:

Subjects with breast cancer, received talazoparib capsules at the MTD as determined in Part 1 (1000 mcg/day), orally once daily in each 28-day treatment cycle (up to a maximum of 40 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 2: Talazoparib (Ovarian/ Peritoneal Cancer)

Reporting group description:

Subjects with ovarian/ peritoneal cancer, received talazoparib capsules at the MTD as determined in Part 1 (1000 mcg/day), orally once daily in each 28-day treatment cycle (up to a maximum of 40 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 2: Talazoparib (Pancreatic Cancer)

Reporting group description:

Subjects with pancreatic cancer, received talazoparib capsules at the MTD as determined in Part 1 (1000 mcg/day), orally once daily in each 28-day treatment cycle (up to a maximum of 40 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 2: Talazoparib (Ewing Cancer)

Reporting group description:

Subjects with ewing cancer, received talazoparib capsules at the MTD as determined in Part 1 (1000 mcg/day), orally once daily in each 28-day treatment cycle (up to a maximum of 40 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 2: Talazoparib (SCLC Cancer)

Reporting group description:

Subjects with SCLC cancer, received talazoparib capsules at the MTD as determined in Part 1 (1000 mcg/day), orally once daily in each 28-day treatment cycle (up to a maximum of 40 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 2: Talazoparib (Prostate Cancer)

Reporting group description:

Subjects with prostate cancer, received talazoparib capsules at the MTD as determined in Part 1 (1000 mcg/day), orally once daily in each 28-day treatment cycle (up to a maximum of 40 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group values	Part 1: Talazoparib 25 mcg	Part 1: Talazoparib 50 mcg	Part 1: Talazoparib 100 mcg
Number of subjects	3	3	3
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	2	1
From 65-84 years	3	1	2
85 years and over	0	0	0
Age Continuous Units: Years			
arithmetic mean	77.7	66.7	64.0
standard deviation	± 3.51	± 9.07	± 9.64

Sex: Female, Male Units: Subjects			
Male|	1	2	0
Female|	2	1	3
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaska Native|	0	0	0
Asian|	0	0	0
Black or African American|	0	0	0
Native Hawaiian or Pacific Islander|	0	0	0
White|	3	3	3
Other|	0	0	0

Reporting group values	Part 1: Talazoparib 200 mcg	Part 1: Talazoparib 400 mcg	Part 1: Talazoparib 600 mcg
Number of subjects	3	3	6
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	3	3	3
From 65-84 years	0	0	3
85 years and over	0	0	0
Age Continuous Units: Years			
arithmetic mean	48.7	60.7	61.3
standard deviation	± 11.50	± 5.77	± 19.00
Sex: Female, Male Units: Subjects			
Male|	0	0	1
Female|	3	3	5
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaska Native|	0	0	0
Asian|	0	0	0
Black or African American|	0	0	0
Native Hawaiian or Pacific Islander|	0	0	0
White|	3	3	6
Other|	0	0	0

Reporting group values	Part 1: Talazoparib 900 mcg	Part 1: Talazoparib 1000 mcg	Part 1: Talazoparib 1100 mcg
Number of subjects	6	6	6
Age categorical Units: Subjects			
In utero	0	0	0

Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	6	5	5
From 65-84 years	0	1	1
85 years and over	0	0	0
Age Continuous			
Units: Years			
arithmetic mean	48.2	45.0	38.8
standard deviation	± 8.66	± 18.25	± 13.73
Sex: Female, Male			
Units: Subjects			
Male|	0	1	1
Female|	6	5	5
Race/Ethnicity, Customized			
Units: Subjects			
American Indian or Alaska Native|	0	0	0
Asian|	0	0	1
Black or African American|	0	0	1
Native Hawaiian or Pacific Islander|	0	0	0
White|	5	5	4
Other|	1	1	0

Reporting group values	Part 2: Talazoparib (Breast Cancer)	Part 2: Talazoparib (Ovarian/ Peritoneal Cancer)	Part 2: Talazoparib (Pancreatic Cancer)
Number of subjects	12	11	10
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	11	9	5
From 65-84 years	1	2	5
85 years and over	0	0	0
Age Continuous			
Units: Years			
arithmetic mean	46.5	54.2	65.2
standard deviation	± 11.47	± 10.93	± 7.71
Sex: Female, Male			
Units: Subjects			
Male|	1	0	6
Female|	11	11	4

Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaska Native|	0	0	0
Asian|	2	0	0
Black or African American|	1	0	0
Native Hawaiian or Pacific Islander|	0	0	0
White|	9	11	10
Other|	0	0	0

Reporting group values	Part 2: Talazoparib (Ewing Cancer)	Part 2: Talazoparib (SCLC Cancer)	Part 2: Talazoparib (Prostate Cancer)
Number of subjects	12	23	3
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	11	11	3
From 65-84 years	1	11	0
85 years and over	0	1	0
Age Continuous Units: Years			
arithmetic mean	28.7	64.0	57.3
standard deviation	± 15.18	± 10.45	± 8.14
Sex: Female, Male Units: Subjects			
Male|	6	12	3
Female|	6	11	0
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaska Native|	0	0	0
Asian|	0	0	0
Black or African American|	1	0	0
Native Hawaiian or Pacific Islander|	0	0	0
White|	10	23	3
Other|	1	0	0

Reporting group values	Total		
Number of subjects	110		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	0		

Adolescents (12-17 years)	0		
Adults (18-64 years)	78		
From 65-84 years	31		
85 years and over	1		
Age Continuous Units: Years			
arithmetic mean			
standard deviation	-		
Sex: Female, Male Units: Subjects			
Male|	34		
Female|	76		
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaska Native|	0		
Asian|	3		
Black or African American|	3		
Native Hawaiian or Pacific Islander|	0		
White|	101		
Other|	3		

End points reporting groups

Reporting group title	Part 1: Talazoparib 25 mcg

Reporting group description:

Subjects received talazoparib capsules at a dose of 25 microgram per day (mcg/day) once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 1: Talazoparib 50 mcg

Reporting group description:

Subjects received talazoparib capsules at a dose of 50 mcg/day once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 1: Talazoparib 100 mcg

Reporting group description:

Subjects received talazoparib capsules at a dose of 100 mcg/day once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 1: Talazoparib 200 mcg

Reporting group description:

Subjects received talazoparib capsules at a dose of 200 mcg/day once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 1: Talazoparib 400 mcg

Reporting group description:

Subjects received talazoparib capsules at a dose of 400 mcg/day once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 1: Talazoparib 600 mcg

Reporting group description:

Subjects received talazoparib capsules at a dose of 600 mcg/day once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 1: Talazoparib 900 mcg

Reporting group description:

Subjects received talazoparib capsules at a dose of 900 mcg/day once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 1: Talazoparib 1000 mcg

Reporting group description:

Subjects received talazoparib capsules at a dose of 1000 microgram per day (mcg/day) once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 1: Talazoparib 1100 mcg

Reporting group description:

Subjects received talazoparib capsules at a dose of 1100 microgram per day (mcg/day) once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 2: Talazoparib (Breast Cancer)

Reporting group description:

Subjects with breast cancer, received talazoparib capsules at the MTD as determined in Part 1 (1000 mcg/day), orally once daily in each 28-day treatment cycle (up to a maximum of 40 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 2: Talazoparib (Ovarian/ Peritoneal Cancer)

Reporting group description:

Subjects with ovarian/ peritoneal cancer, received talazoparib capsules at the MTD as determined in Part 1 (1000 mcg/day), orally once daily in each 28-day treatment cycle (up to a maximum of 40 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 2: Talazoparib (Pancreatic Cancer)

Reporting group description:

Subjects with pancreatic cancer, received talazoparib capsules at the MTD as determined in Part 1 (1000 mcg/day), orally once daily in each 28-day treatment cycle (up to a maximum of 40 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 2: Talazoparib (Ewing Cancer)

Reporting group description:

Subjects with ewing cancer, received talazoparib capsules at the MTD as determined in Part 1 (1000 mcg/day), orally once daily in each 28-day treatment cycle (up to a maximum of 40 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 2: Talazoparib (SCLC Cancer)

Reporting group description:

Subjects with SCLC cancer, received talazoparib capsules at the MTD as determined in Part 1 (1000 mcg/day), orally once daily in each 28-day treatment cycle (up to a maximum of 40 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 2: Talazoparib (Prostate Cancer)

Reporting group description:

Subjects with prostate cancer, received talazoparib capsules at the MTD as determined in Part 1 (1000 mcg/day), orally once daily in each 28-day treatment cycle (up to a maximum of 40 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 1: Talazoparib 25 mcg

Reporting group description:

Subjects received talazoparib capsules at a dose of 25 mcg/day once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 1: Talazoparib 50 mcg

Reporting group description:

Subjects received talazoparib capsules at a dose of 50 mcg/day once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 1: Talazoparib 100 mcg

Reporting group description:

Subjects received talazoparib capsules at a dose of 100 mcg/day once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 1: Talazoparib 200 mcg

Reporting group description:

Subjects received talazoparib capsules at a dose of 200 mcg/day once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 1: Talazoparib 400 mcg

Reporting group description:

Subjects received talazoparib capsules at a dose of 400 mcg/day once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 1: Talazoparib 600 mcg

Reporting group description:

Subjects received talazoparib capsules at a dose of 600 mcg/day once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 1: Talazoparib 900 mcg

Reporting group description:

Subjects received talazoparib capsules at a dose of 900 mcg/day once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 1: Talazoparib 1000 mcg

Reporting group description:

Subjects received talazoparib capsules at a dose of 1000 mcg/day once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 1: Talazoparib 1100 mcg

Reporting group description:

Subjects received talazoparib capsules at a dose of 1100 mcg/day once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 2: Talazoparib (Breast Cancer)

Reporting group description:

Subjects with breast cancer, received talazoparib capsules at the MTD as determined in Part 1 (1000 mcg/day), orally once daily in each 28-day treatment cycle (up to a maximum of 40 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 2: Talazoparib (Ovarian/ Peritoneal Cancer)

Reporting group description:

Subjects with ovarian/ peritoneal cancer, received talazoparib capsules at the MTD as determined in Part 1 (1000 mcg/day), orally once daily in each 28-day treatment cycle (up to a maximum of 40 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 2: Talazoparib (Pancreatic Cancer)

Reporting group description:

Subjects with pancreatic cancer, received talazoparib capsules at the MTD as determined in Part 1 (1000 mcg/day), orally once daily in each 28-day treatment cycle (up to a maximum of 40 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 2: Talazoparib (Ewing Cancer)

Reporting group description:

Subjects with ewing cancer, received talazoparib capsules at the MTD as determined in Part 1 (1000 mcg/day), orally once daily in each 28-day treatment cycle (up to a maximum of 40 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 2: Talazoparib (SCLC Cancer)

Reporting group description:

Subjects with SCLC cancer, received talazoparib capsules at the MTD as determined in Part 1 (1000 mcg/day), orally once daily in each 28-day treatment cycle (up to a maximum of 40 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 2: Talazoparib (Prostate Cancer)

Reporting group description:

Subjects with prostate cancer, received talazoparib capsules at the MTD as determined in Part 1 (1000 mcg/day), orally once daily in each 28-day treatment cycle (up to a maximum of 40 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Subject analysis set title	Part 1 and Part 2: Talazoparib (Breast Cancer)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects with breast cancer who received talazoparib capsules in Part 1 and 2 at a dose of either 600 mcg/day, 900 mcg/day, 1000 mcg/day, 1100 mcg/day.

Subject analysis set title	Part 1 and Part 2: Talazoparib (Ovarian/ Peritoneal Cancer)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects with ovarian/ peritoneal cancer who received talazoparib capsules in Part 1 and 2 at a dose of either 25 mcg/day, 50 mcg/day, 100 mcg/day, 200 mcg/day, 400 mcg/day, 600 mcg/day, 900 mcg/day, 1000 mcg/day, 1100 mcg/day.

Subject analysis set title	Part 1 and Part 2: Talazoparib (Pancreatic Cancer)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects with pancreatic cancer who received talazoparib capsules in Part 1 and 2 at a dose of either 25 mcg/day, 50 mcg/day, 1000 mcg/day.

Subject analysis set title	Part 1 and Part 2: Talazoparib (Ewing Cancer)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects with ewing cancer who received talazoparib capsules in Part 1 and 2 at a dose of either 1000 mcg/day, 1100 mcg/day.

Subject analysis set title	Part 2: Talazoparib (SCLC Cancer)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects with small cell lung cancer (SCLC) cancer who received talazoparib capsules in Part 2 at a dose of 1000 mcg/day.

Subject analysis set title	Part 1 and Part 2: Talazoparib (Prostate Cancer)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects with prostate cancer who received talazoparib capsules in Part 1 and 2 at a dose of 600 mcg/day.

Subject analysis set title	Part 1: Talazoparib (Colorectal Cancer)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects with colorectal cancer who received talazoparib capsules in Part 1 at a dose of either 25 mcg/day or 100 mcg/day.

Subject analysis set title	Part 2: Talazoparib (SCLC Cancer)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects with SCLC cancer who received talazoparib capsules in Part 2 at a dose of 1000 mcg/day.

Subject analysis set title	Part 1 and Part 2: Talazoparib (Ovarian/ Peritoneal Cancer)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects with ovarian/ peritoneal cancer who received talazoparib capsules in Part 1 and 2 at a dose of either 25 mcg/day, 50 mcg/day, 100 mcg/day, 200 mcg/day, 400 mcg/day, 600 mcg/day, 900 mcg/day, 1000 mcg/day, 1100 mcg/day.

Subject analysis set title	Part 1 and Part 2: Talazoparib (Prostate Cancer)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects with prostate cancer who received talazoparib capsules in Part 1 and 2 at a dose of 600 mcg/day.

Subject analysis set title	Part 1 and Part 2: Talazoparib (Breast Cancer)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects with breast cancer who received talazoparib capsules in Part 1 and 2 at a dose of either 600 mcg/day,900 mcg/day,1000 mcg/day,1100 mcg/day.

Subject analysis set title	Part 1 and Part 2: Talazoparib (Ovarian/ Peritoneal Cancer)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects with ovarian/ peritoneal cancer who received talazoparib capsules in Part 1 and 2 at a dose of either 25 mcg/day, 50 mcg/day, 100 mcg/day, 200 mcg/day, 400 mcg/day, 600 mcg/day, 900 mcg/day, 1000 mcg/day, 1100 mcg/day.

Subject analysis set title	Part 1 and Part 2: Talazoparib (Ewing Cancer)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects with Ewing cancer who received talazoparib capsules in Part 1 and 2 at a dose of 1000 mcg/day.

Subject analysis set title	Part 1: Talazoparib: All Subjects
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All subjects who received talazoparib capsules at a dose of either 25 mcg/day, 50 mcg/day, 100 mcg/day, 200 mcg/day, 400 mcg/day, 600 mcg/day, 900 mcg/day, 1000 mcg/day and 1100 mcg/day once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met in Part 1.

Subject analysis set title	Part 2: Talazoparib 1000 mcg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All subjects with either breast, ovarian/peritoneal, pancreatic, ewing, SCLC, or prostate cancer who received talazoparib capsules at a dose of 1000 mcg/day in Part 2.

Subject analysis set title	Part 1: Talazoparib 1100 mcg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects received talazoparib capsules at a dose of 1100 microgram per day (mcg/day) once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Primary: Number of Subjects With Objective Response

End point title	Number of Subjects With Objective Response[1]

End point description:

Objective response: number of subjects with complete response (CR) or partial response (PR) after treatment with talazoparib and maintained for at least 4 weeks (28 days) as assessed by response evaluation criteria in solid tumors (RECIST) version 1.1. CR: disappearance of all non-nodal target lesions (where all target lesions were recorded with a length of 0 millimeter [mm] on the case report form [CRF]) and the reduction of the shortest diameter of all nodal lesions to less than [<] 10 mm. PR: 30% or more decrease in the sum of the longest diameters (SLD) + sum of shortest diameters (SSD) of target lesions, with reference to the baseline SLD+SSD. Response analysis population: all enrolled subjects who received at least 1 dose of talazoparib and had measurable disease at baseline. Data for this endpoint was planned to be analyzed combined for Part 1 and Part 2 on the basis of cancer type (pre-specified in protocol).

End point type	Primary

End point timeframe:

From Baseline until disease progression or death due to any cause (maximum duration: 1071 days for Part 1; 834 days for Part 2)

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: Only descriptive data was planned to be analysed for this endpoint.

End point values	Part 1 and Part 2: Talazoparib (Breast Cancer)	Part 1 and Part 2: Talazoparib (Ovarian/ Peritoneal Cancer)	Part 1 and Part 2: Talazoparib (Pancreatic Cancer)	Part 1 and Part 2: Talazoparib (Ewing Cancer)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	31	13	14
Units: subjects	8	12	2	0

End point values	Part 2: Talazoparib (SCLC Cancer)	Part 1 and Part 2: Talazoparib (Prostate Cancer)	Part 1: Talazoparib (Colorectal Cancer)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	23	1	2	
Units: subjects	2	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Best Overall Response

End point title	Number of Subjects With Best Overall Response[2]

End point description:

Best overall response: best response (in the order of confirmed CR, confirmed PR, stable disease[SD] and progressive disease[PD]) among all overall response as RECIST 1.1, recorded from date of first dose of talazoparib until subject withdrew from study/data cut-off date. CR: disappearance of all non-nodal target lesions and the reduction of the shortest diameter of all nodal lesions to < 10 mm. PR: at least a 30% decrease in sum of the diameters of target lesions, reference to baseline sum diameters. SD: neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for PD, taking as reference the smallest sum diameters on study. PD:at least a 20% increase in sum of diameters of target lesions, reference to the smallest sum on study. Response analysis population. Data for this endpoint was planned to be analyzed combined for Part 1 and Part 2 on the basis of cancer type and not planned to be analyzed for "Part 1: Colorectal Cancer" arm (pre-specified in protocol).

End point type	Primary

End point timeframe:

From Baseline until disease progression or death due to any cause (maximum duration: 1071 days for Part 1; 834 days for Part 2)

Notes:

[2] - 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: Only descriptive data was planned to be analysed for this endpoint.

End point values	Part 1 and Part 2: Talazoparib (Breast Cancer)	Part 1 and Part 2: Talazoparib (Ovarian/ Peritoneal Cancer)	Part 1 and Part 2: Talazoparib (Pancreatic Cancer)	Part 1 and Part 2: Talazoparib (Ewing Cancer)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	31	13	14
Units: subjects				
Complete Response (CR)|	1	1	0	0
Partial Response (PR)|	7	11	2	0

Stable Disease (SD)|	7	10	2	4
Progressive Disease (PD)|	5	6	6	9

End point values	Part 2: Talazoparib (SCLC Cancer)	Part 1 and Part 2: Talazoparib (Prostate Cancer)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	23	1		
Units: subjects				
Complete Response (CR)|	0	0		
Partial Response (PR)|	2	0		
Stable Disease (SD)|	4	1		
Progressive Disease (PD)|	14	0		

Statistical analyses

No statistical analyses for this end point

Primary: Progression-Free Survival (PFS)

End point title	Progression-Free Survival (PFS)[3]

End point description:

PFS was defined as the time (in weeks) from the date of first dose of study drug to the earlier date of the documented PD or death due to any cause. PD as per RECIST 1.1 defined as at least a 20% increase in the sum of diameters of target lesions, reference to the smallest sum on study (this includes the baseline sum if that was the smallest on study). Full analysis set (FAS) included all enrolled subjects who received at least 1 dose of talazoparib. Data for this endpoint was planned to be analyzed combined for Part 1 and Part 2 on the basis of cancer type and was not planned to be analyzed for "Part 1: Colorectal Cancer" arm, as pre-specified in protocol.

End point type	Primary

End point timeframe:

Baseline, until PD or death due to any cause (maximum duration:1071 days for Part 1; 834 days for Part 2)

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: Only descriptive data was planned to be analysed for this endpoint.

End point values	Part 1 and Part 2: Talazoparib (Breast Cancer)	Part 1 and Part 2: Talazoparib (Pancreatic Cancer)	Part 1 and Part 2: Talazoparib (Ewing Cancer)	Part 2: Talazoparib (SCLC Cancer)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	13	14	23
Units: weeks				
median (confidence interval 95%)	29.3 (12.1 to 43.4)	5.3 (2.4 to 21.3)	6.2 (3.1 to 14.0)	11.1 (4.3 to 13.0)

End point values	Part 1 and Part 2: Talazoparib (Ovarian/ Peritoneal Cancer)	Part 1 and Part 2: Talazoparib (Prostate Cancer)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	34	4		
Units: weeks				
median (confidence interval 95%)	32.1 (18.9 to 38.6)	12.1 (12.0 to 99999)		

Statistical analyses

No statistical analyses for this end point

Primary: Duration of Response

End point title	Duration of Response[4]

End point description:

Duration of response was defined as the time (in weeks) from the date of the first documented objective response confirmed at least 28 days later to the date of the first documented PD or date of death, whichever occurred first. PD as per RECIST v1.1 defined as at least a 20% increase in the sum of diameters of target lesions, reference to the smallest sum on study (this includes the baseline sum if that was the smallest on study). Analysis was performed on the subset of response analysis population which included all subjects who had response. Data for this endpoint was planned to be analyzed combined for Part 1 and Part 2 on the basis of cancer type and was not planned to be analyzed for "Part 1: Colorectal Cancer" arm, as pre-specified in protocol.

End point type	Primary

End point timeframe:

Baseline until PD or death due to any cause (maximum duration: 1071 days for Part 1; 834 days for Part 2)

Notes:

[4] - 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: Only descriptive data was planned to be analysed for this endpoint.

End point values	Part 1 and Part 2: Talazoparib (Breast Cancer)	Part 1 and Part 2: Talazoparib (Ovarian/ Peritoneal Cancer)	Part 1 and Part 2: Talazoparib (Pancreatic Cancer)	Part 1 and Part 2: Talazoparib (Ewing Cancer)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	8	12	2	0[5]
Units: weeks				
median (confidence interval 95%)	32.2 (20.1 to 64.1)	26.9 (15.7 to 35.1)	99999 (21.6 to 99999)	(to)

Notes:

[5] - None of the subjects had confirmed CR or PR, hence duration of response was not analyzed.

End point values	Part 2: Talazoparib (SCLC Cancer)	Part 1 and Part 2: Talazoparib (Prostate Cancer)	Part 1: Talazoparib (Colorectal Cancer)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	2	0[6]	0[7]	
Units: weeks				

median (confidence interval 95%)	13.6 (12.0 to 15.3)	(to)	(to)	

Notes:

[6] - None of the subjects had confirmed CR or PR, hence duration of response was not analyzed.

[7] - None of the subjects had confirmed CR or PR, hence duration of response was not analyzed.

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Stable Disease

End point title	Number of Subjects With Stable Disease[8]

End point description:

SD defined as neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for PD, taking as reference the smallest sum diameters while on study. PD defined as at least a 20% increase in sum of diameters of target lesions, reference to the smallest sum on study (this includes the baseline sum if that was the smallest on study). Response analysis population included all enrolled subjects who received at least 1 dose of talazoparib, and had measurable disease at baseline. Data for this endpoint was planned to be analyzed combined for Part 1 and Part 2 on the basis of cancer type and was not planned to be analyzed for "Part 1: Colorectal Cancer" arm, as pre-specified in protocol.

End point type	Primary

End point timeframe:

Baseline, until PD or death due to any cause (maximum duration: 1071 days for Part 1; 834 days for Part 2)

Notes:

[8] - 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: Only descriptive data was planned to be analysed for this endpoint.

End point values	Part 1 and Part 2: Talazoparib (Breast Cancer)	Part 1 and Part 2: Talazoparib (Ovarian/ Peritoneal Cancer)	Part 1 and Part 2: Talazoparib (Pancreatic Cancer)	Part 1 and Part 2: Talazoparib (Ewing Cancer)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	31	13	14
Units: subjects	7	10	2	4

End point values	Part 2: Talazoparib (SCLC Cancer)	Part 1 and Part 2: Talazoparib (Prostate Cancer)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	23	1		
Units: subjects	4	1		

Statistical analyses

No statistical analyses for this end point

Primary: Part 1: Maximum Tolerated Dose (MTD)

End point title	Part 1: Maximum Tolerated Dose (MTD) [9]

End point description:

MTD: the highest dose at which no more than 1 of 6 subjects experienced a Dose Limiting Toxicity (DLT). DLT: any of the following occurring during Cycle 1 of Part 1 of study, Hematologic toxicity: Any grade 4 or higher hematologic adverse event, Grade 3 thrombocytopenia associated with grade 2 or higher haemorrhage, Grade 3 thrombocytopenia or neutropenia that led to interruption of dosing for 5 or more days. Nonhematologic toxicity: grade 3 or higher laboratory AE which was asymptomatic and rapidly reversible AEs (returned to baseline or grade 1 within 7 days), Grade 3 nausea, vomiting, or diarrhea that could be medically managed to grade 2 or lower with anti-emetics and/or anti-diarrheals within 24 hours, Grade 3 fatigue improved to grade 2 or lower in 5 days or less, Alopecia. Grades based on National Cancer Institute Common Terminology Criteria for Adverse Events version 4.03. Safety analysis set included all enrolled subjects who received at least 1 dose of talazoparib.

End point type	Primary

End point timeframe:

Cycle 1 (Day 1 up to Day 42)

Notes:

[9] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be analysed for this endpoint.

End point values	Part 1: Talazoparib: All Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	39			
Units: mcg/day	1000			

Statistical analyses

No statistical analyses for this end point

Primary: Part 1: Recommended Part 2 Dose of Talazoparib

End point title	Part 1: Recommended Part 2 Dose of Talazoparib[10]

End point description:

The Recommended dose of talazoparib for use in Part 2 was determined in Part 1 (dose escalation) on the basis of the totality of safety, pharmacokinetics (PK), pharmacodynamic and preliminary efficacy data observed in Cycles 1 and 2 and beyond. Safety analysis set included all enrolled subjects who received at least 1 dose of talazoparib.

End point type	Primary

End point timeframe:

Baseline up to Cycle 50 (each Cycle 28 days)

Notes:

[10] - 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: Only descriptive data was planned to be analysed for this endpoint.

End point values	Part 1: Talazoparib: All Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	39			
Units: mcg/day	1000			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Part 1 and 2: Number of Subjects With Treatment-Emergent Adverse events and Serious Adverse Events

End point title	Part 1 and 2: Number of Subjects With Treatment-Emergent Adverse events and Serious Adverse Events

End point description:

An AE was any untoward medical occurrence in a subject who received study drug without regard to possibility of causal relationship. An SAE was an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly. Treatment-emergent were events between first dose of study drug and up to end of study (up to 1071 days for Part 1 and up to 834 days for Part 2) that were absent before treatment or that worsened relative to pre-treatment state. Safety analyses set included all enrolled subjects who received at least 1 dose of talazoparib.

End point type	Other pre-specified

End point timeframe:

Part 1: Baseline up to 1071 days; Part 2: Baseline up to 834 days

End point values	Part 1: Talazoparib 25 mcg	Part 2: Talazoparib (Breast Cancer)	Part 1: Talazoparib 50 mcg	Part 2: Talazoparib (Ovarian/ Peritoneal Cancer)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	12	3	11
Units: subjects				
AEs	2	12	3	11
SAEs	1	2	2	5

End point values	Part 1: Talazoparib 100 mcg	Part 2: Talazoparib (Pancreatic Cancer)	Part 1: Talazoparib 200 mcg	Part 2: Talazoparib (Ewing Cancer)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	10	3	12
Units: subjects				
AEs	2	10	3	12
SAEs	2	6	3	4

End point values	Part 1: Talazoparib 400 mcg	Part 2: Talazoparib (SCLC Cancer)	Part 1: Talazoparib 600 mcg	Part 2: Talazoparib (Prostate Cancer)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	23	6	3
Units: subjects				
AEs	3	21	6	2
SAEs	0	8	2	0

End point values	Part 1: Talazoparib 900 mcg	Part 1: Talazoparib 1000 mcg	Part 1: Talazoparib 1100 mcg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	6	6	
Units: subjects				
AEs	6	6	6	
SAEs	3	1	3	

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Part 1: Maximum Observed Plasma Concentration (Cmax) of Talazoparib

End point title	Part 1: Maximum Observed Plasma Concentration (Cmax) of Talazoparib

End point description:

The pharmacokinetic (PK) evaluable population included all subjects who received at least 1 dose of talazoparib with adequate PK results to perform PK calculations and was used for analysis of PK endpoints.

End point type	Other pre-specified

End point timeframe:

Cycle 1: 0.25, 0.5, 0.75, 1, 2, 3, 4, 5, 6, 8, 10, 24, 48, 72 and 96 hours postdose on Day 1 and Day 35

End point values	Part 1: Talazoparib 25 mcg	Part 1: Talazoparib 50 mcg	Part 1: Talazoparib 100 mcg	Part 1: Talazoparib 200 mcg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	3
Units: picograms per milliliter (pg/mL)				
arithmetic mean (standard deviation)				
Cycle 1 Day 1|	60.0 (± 15.9)	79.7 (± 7.50)	214 (± 50.9)	788 (± 369)

Cycle 1 Day 35|	300 (± 78.8)	615 (± 74.2)	1880 (± 332)	5620 (± 3530)

End point values	Part 1: Talazoparib 400 mcg	Part 1: Talazoparib 600 mcg	Part 1: Talazoparib 900 mcg	Part 1: Talazoparib 1000 mcg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	6	6
Units: picograms per milliliter (pg/mL)				
arithmetic mean (standard deviation)				
Cycle 1 Day 1|	1830 (± 699)	4100 (± 1400)	6100 (± 3060)	10600 (± 4220)
Cycle 1 Day 35|	6560 (± 1500)	11300 (± 3230)	15400 (± 1540)	21000 (± 7990)

End point values	Part 1: Talazoparib 1100 mcg			
Subject group type	Reporting group			
Number of subjects analysed	6			
Units: picograms per milliliter (pg/mL)				
arithmetic mean (standard deviation)				
Cycle 1 Day 1|	13200 (± 3220)			
Cycle 1 Day 35|	23400 (± 4810)			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Part 2: Maximum Observed Plasma Concentration (Cmax) of Talazoparib

End point title	Part 2: Maximum Observed Plasma Concentration (Cmax) of Talazoparib

End point description:

The PK evaluable population included all subjects who received at least 1 dose of talazoparib with adequate PK results to perform PK calculations and was used for analysis of PK endpoints. PK data was planned to be reported for the overall subjects in Part 2, as pre-specified in protocol.

End point type	Other pre-specified

End point timeframe:

Cycle 1 and 2: Predose, 0.5, 1, 2, 3 and 4 hours postdose on Day 1

End point values	Part 2: Talazoparib 1000 mcg			
Subject group type	Subject analysis set			
Number of subjects analysed	70			
Units: pg/mL				
arithmetic mean (standard deviation)				
Cycle 1 Day 1|	8480 (± 3890)			
Cycle 2 Day 1|	17700 (± 5790)			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Part 1: Time to Reach Maximum Observed Plasma Concentration (Tmax) of Talazoparib

End point title	Part 1: Time to Reach Maximum Observed Plasma Concentration (Tmax) of Talazoparib

End point description:

The PK evaluable population included all subjects who received at least 1 dose of talazoparib with adequate PK results to perform PK calculations and was used for analysis of PK endpoints.

End point type	Other pre-specified

End point timeframe:

Cycle 1: 0.25, 0.5, 0.75, 1, 2, 3, 4, 5, 6, 8, 10, 24, 48, 72 and 96 hours postdose on Day 1 and Day 35

End point values	Part 1: Talazoparib 25 mcg	Part 1: Talazoparib 50 mcg	Part 1: Talazoparib 100 mcg	Part 1: Talazoparib 200 mcg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	3
Units: hours				
median (full range (min-max))				
Cycle 1 Day 1|	7.92 (1.95 to 9.95)	1.00 (0.800 to 1.02)	1.02 (1.00 to 3.98)	1.03 (1.00 to 2.32)
Cycle 1 Day 35|	1.02 (0.580 to 3.98)	5.43 (0.770 to 10.1)	0.785 (0.750 to 0.820)	1.97 (1.00 to 3.02)

End point values	Part 1: Talazoparib 400 mcg	Part 1: Talazoparib 600 mcg	Part 1: Talazoparib 900 mcg	Part 1: Talazoparib 1000 mcg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	6	6
Units: hours				
median (full range (min-max))				
Cycle 1 Day 1|	2.03 (0.750 to 2.95)	0.835 (0.750 to 1.95)	2.00 (1.02 to 9.98)	1.03 (0.730 to 2.07)

Cycle 1 Day 35|	0.980 (0.750 to 2.00)	1.04 (0.730 to 5.98)	1.02 (0.970 to 2.07)	1.02 (0.750 to 2.00)

End point values	Part 1: Talazoparib 1100 mcg			
Subject group type	Reporting group			
Number of subjects analysed	6			
Units: hours				
median (full range (min-max))				
Cycle 1 Day 1|	1.00 (0.730 to 2.05)			
Cycle 1 Day 35|	1.48 (0.980 to 2.00)			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Part 2: Time to Reach Maximum Observed Plasma Concentration (Tmax) of Talazoparib

End point title	Part 2: Time to Reach Maximum Observed Plasma Concentration (Tmax) of Talazoparib

End point description:

The PK evaluable population included all subjects who received at least 1 dose of talazoparib with adequate PK results to perform PK calculations and was used for analysis of PK endpoints. PK data was planned to be reported for the overall subjects in Part 2, as pre-specified in protocol.

End point type	Other pre-specified

End point timeframe:

Cycle 1 and 2: Predose, 0.5, 1, 2, 3 and 4 hours postdose on Day 1

End point values	Part 2: Talazoparib 1000 mcg			
Subject group type	Subject analysis set			
Number of subjects analysed	70			
Units: hours				
median (full range (min-max))				
Cycle 1 Day 1|	1.00 (0.500 to 4.07)			
Cycle 2 Day 1|	1.07 (0.500 to 6.05)			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Part 1: Area Under the Plasma Concentration-Time Curve (AUC) From Time 0 to the Time of the Last Measurable Concentration (AUC0-last) of Talazoparib

End point title	Part 1: Area Under the Plasma Concentration-Time Curve (AUC) From Time 0 to the Time of the Last Measurable Concentration (AUC0-last) of Talazoparib

End point description:

Area under the plasma concentration time-curve from zero to the time of last measured concentration (AUC0-last). The PK evaluable population included all subjects who received at least 1 dose of talazoparib with adequate PK results to perform PK calculations and was used for analysis of PK endpoints. Data for this endpoint was analyzed on Cycle 1 Day 1.

End point type	Other pre-specified

End point timeframe:

Cycle 1: 0.25, 0.5, 0.75, 1, 2, 3, 4, 5, 6, 8, 10, 24, 48, 72 and 96 hours postdose on Day 1

End point values	Part 1: Talazoparib 25 mcg	Part 1: Talazoparib 50 mcg	Part 1: Talazoparib 100 mcg	Part 1: Talazoparib 200 mcg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	3
Units: pg*hr/mL				
arithmetic mean (standard deviation)	3600 (± 1360)	5340 (± 1960)	16600 (± 5320)	39300 (± 11700)

End point values	Part 1: Talazoparib 400 mcg	Part 1: Talazoparib 600 mcg	Part 1: Talazoparib 900 mcg	Part 1: Talazoparib 1000 mcg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	6	6
Units: pg*hr/mL				
arithmetic mean (standard deviation)	43700 (± 15000)	97900 (± 30000)	160000 (± 66100)	182000 (± 62400)

End point values	Part 1: Talazoparib 1100 mcg			
Subject group type	Reporting group			
Number of subjects analysed	6			
Units: pg*hr/mL				
arithmetic mean (standard deviation)	201000 (± 93400)			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Part 2: Area Under the Plasma Concentration-Time Curve (AUC) From Time 0 to the Time of the Last Measurable Concentration (AUC0-last) of Talazoparib

End point title	Part 2: Area Under the Plasma Concentration-Time Curve (AUC) From Time 0 to the Time of the Last Measurable Concentration (AUC0-last) of Talazoparib

End point description:

Area under the plasma concentration time-curve from zero to the time of last measured concentration (AUC0-last). The PK evaluable population included all subjects who received at least 1 dose of talazoparib with adequate PK results to perform PK calculations and was used for analysis of PK endpoints. PK data was planned to be reported for the overall subjects in Part 2, as pre-specified in protocol.

End point type	Other pre-specified

End point timeframe:

Cycle 1 and 2: Predose, 0.5, 1, 2, 3 and 4 hours postdose on Day 1

End point values	Part 2: Talazoparib 1000 mcg			
Subject group type	Subject analysis set			
Number of subjects analysed	70			
Units: pg*hr/mL				
arithmetic mean (standard deviation)				
Cycle 1 Day 1|	19100 (± 8850)			
Cycle 2 Day 1|	50200 (± 16300)			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Part 1: Minimum Observed Plasma Concentration (Cmin) of Talazoparib

End point title	Part 1: Minimum Observed Plasma Concentration (Cmin) of Talazoparib

End point description:

The PK evaluable population included all subjects who received at least 1 dose of talazoparib with adequate PK results to perform PK calculations and was used for analysis of PK endpoints. Data for this endpoint was not planned to be analyzed for Part 2, as pre-specified in protocol.

End point type	Other pre-specified

End point timeframe:

Cycle 1: 0.25, 0.5, 0.75, 1, 2, 3, 4, 5, 6, 8, 10, 24, 48, 72 and 96 hours postdose on Day 35

End point values	Part 1: Talazoparib 25 mcg	Part 1: Talazoparib 50 mcg	Part 1: Talazoparib 100 mcg	Part 1: Talazoparib 200 mcg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	3
Units: pg/mL				
arithmetic mean (standard deviation)	169 (± 58.0)	299 (± 133)	1020 (± 107)	2880 (± 1710)

End point values	Part 1: Talazoparib 400 mcg	Part 1: Talazoparib 600 mcg	Part 1: Talazoparib 900 mcg	Part 1: Talazoparib 1000 mcg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	6	6
Units: pg/mL				
arithmetic mean (standard deviation)	2230 (± 957)	3470 (± 1050)	3180 (± 802)	3720 (± 1590)

End point values	Part 1: Talazoparib 1100 mcg			
Subject group type	Reporting group			
Number of subjects analysed	4			
Units: pg/mL				
arithmetic mean (standard deviation)	2910 (± 803)			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Part 1: Area Under the Curve From Time Zero to Extrapolated Infinite Time [AUC (0-inf)] of Talazoparib

End point title	Part 1: Area Under the Curve From Time Zero to Extrapolated Infinite Time [AUC (0-inf)] of Talazoparib

End point description:

AUC (0-inf) = Area under the plasma concentration versus time curve (AUC) from time zero (pre-dose) to extrapolated infinite time. The PK evaluable population included all subjects who received at least 1 dose of talazoparib with adequate PK results to perform PK calculations and was used for analysis of PK endpoints. Data for this endpoint was not planned to be analyzed for Part 2, as pre-specified in protocol.

End point type	Other pre-specified

End point timeframe:

Cycle 1: 0.25, 0.5, 0.75, 1, 2, 3, 4, 5, 6, 8, 10, 24, 48, 72 and 96 hours postdose on Day 1

End point values	Part 1: Talazoparib 25 mcg	Part 1: Talazoparib 50 mcg	Part 1: Talazoparib 100 mcg	Part 1: Talazoparib 200 mcg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	3
Units: pg*hr/mL				
arithmetic mean (standard deviation)	5330 (± 1840)	8320 (± 1960)	37600 (± 6620)	92700 (± 48500)

End point values	Part 1: Talazoparib 400 mcg	Part 1: Talazoparib 600 mcg	Part 1: Talazoparib 900 mcg	Part 1: Talazoparib 1000 mcg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	6	6
Units: pg*hr/mL				
arithmetic mean (standard deviation)	60100 (± 15900)	120000 (± 26000)	188000 (± 85700)	200000 (± 64000)

End point values	Part 1: Talazoparib 1100 mcg			
Subject group type	Reporting group			
Number of subjects analysed	6			
Units: pg*hr/mL				
arithmetic mean (standard deviation)	235000 (± 111000)			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Part 1: Terminal Half-Life (t1/2) of Talazoparib

End point title	Part 1: Terminal Half-Life (t1/2) of Talazoparib

End point description:

T1/2 is the time measured for the plasma concentration of talazoparib to decrease by one half. The PK evaluable population included all subjects who received at least 1 dose of talazoparib with adequate PK results to perform PK calculations and was used for analysis of PK endpoints. Data for this endpoint was not planned to be analyzed for Part 2, as pre-specified in protocol.

End point type	Other pre-specified

End point timeframe:

Cycle 1: 0.25, 0.5, 0.75, 1, 2, 3, 4, 5, 6, 8, 10, 24, 48, 72 and 96 hours postdose on Day 1 and Day 35

End point values	Part 1: Talazoparib 25 mcg	Part 1: Talazoparib 50 mcg	Part 1: Talazoparib 100 mcg	Part 1: Talazoparib 200 mcg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	3
Units: Hours				
arithmetic mean (standard deviation)				
Cycle 1 Day 1|	100 (± 11.9)	129 (± 42.6)	229 (± 158)	212 (± 126)
Cycle 1 Day 35|	107 (± 84.2)	132 (± 12.3)	98.2 (± 4.83)	50.9 (± 19.1)

End point values	Part 1: Talazoparib 400 mcg	Part 1: Talazoparib 600 mcg	Part 1: Talazoparib 900 mcg	Part 1: Talazoparib 1000 mcg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	6	6
Units: Hours				
arithmetic mean (standard deviation)				
Cycle 1 Day 1|	102 (± 27.2)	58.6 (± 17.3)	60.4 (± 10.9)	52.9 (± 13.4)
Cycle 1 Day 35|	90.7 (± 32.7)	63.7 (± 12.7)	71.0 (± 14.5)	50.0 (± 16.6)

End point values	Part 1: Talazoparib 1100 mcg			
Subject group type	Reporting group			
Number of subjects analysed	6			
Units: Hours				
arithmetic mean (standard deviation)				
Cycle 1 Day 1|	71.0 (± 20.6)			
Cycle 1 Day 35|	52.8 (± 23.2)			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Part 1: Apparent Oral Clearance (CL/F) of Talazoparib

End point title	Part 1: Apparent Oral Clearance (CL/F) of Talazoparib

End point description:

Clearance of a drug was a measure of the rate at which a drug was metabolized or eliminated by normal biological processes. Clearance obtained after oral dose (apparent oral clearance) was influenced by the fraction of the dose absorbed. The PK evaluable population included all subjects who received at least 1 dose of talazoparib with adequate PK results to perform PK calculations and was used for analysis of PK endpoints. Data for this endpoint was not planned to be analyzed for Part 2, as pre-specified in protocol.

End point type	Other pre-specified

End point timeframe:

Cycle 1: 0.25, 0.5, 0.75, 1, 2, 3, 4, 5, 6, 8, 10, 24, 48, 72 and 96 hours postdose on Day 1

End point values	Part 1: Talazoparib 25 mcg	Part 1: Talazoparib 50 mcg	Part 1: Talazoparib 100 mcg	Part 1: Talazoparib 200 mcg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	3
Units: liter/hour				
arithmetic mean (standard deviation)	5.17 (± 2.10)	6.27 (± 1.66)	2.72 (± 0.532)	2.61 (± 1.35)

End point values	Part 1: Talazoparib 400 mcg	Part 1: Talazoparib 600 mcg	Part 1: Talazoparib 900 mcg	Part 1: Talazoparib 1000 mcg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	6	6
Units: liter/hour				
arithmetic mean (standard deviation)	6.95 (± 1.71)	5.19 (± 0.990)	5.49 (± 2.08)	5.39 (± 1.59)

End point values	Part 1: Talazoparib 1100 mcg			
Subject group type	Reporting group			
Number of subjects analysed	6			
Units: liter/hour				
arithmetic mean (standard deviation)	5.32 (± 1.64)			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Part 1: Apparent Volume of Distribution (Vz/F) of Talazoparib

End point title	Part 1: Apparent Volume of Distribution (Vz/F) of Talazoparib

End point description:

Volume of distribution was defined as the theoretical volume in which the total amount of drug would need to be uniformly distributed to produce the desired plasma concentration of a drug. Vz/F was influenced by the fraction absorbed. The PK evaluable population included all subjects who received at least 1 dose of talazoparib with adequate PK results to perform PK calculations and was used for analysis of PK endpoints. Data for this endpoint was not planned to be analyzed for Part 2, as pre-specified in protocol.

End point type	Other pre-specified

End point timeframe:

Cycle 1: 0.25, 0.5, 0.75, 1, 2, 3, 4, 5, 6, 8, 10, 24, 48, 72 and 96 hours postdose on Day 1 and Day 35

End point values	Part 1: Talazoparib 25 mcg	Part 1: Talazoparib 50 mcg	Part 1: Talazoparib 100 mcg	Part 1: Talazoparib 200 mcg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	3
Units: liter				
arithmetic mean (standard deviation)				
Cycle 1 Day 1|	756 (± 351)	1240 (± 742)	839 (± 487)	678 (± 217)
Cycle 1 Day 35|	1070 (± 971)	1020 (± 345)	475 (± 47.8)	264 (± 249)

End point values	Part 1: Talazoparib 400 mcg	Part 1: Talazoparib 600 mcg	Part 1: Talazoparib 900 mcg	Part 1: Talazoparib 1000 mcg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	6	6
Units: liter				
arithmetic mean (standard deviation)				
Cycle 1 Day 1|	1050 (± 431)	441 (± 143)	468 (± 169)	415 (± 170)
Cycle 1 Day 35|	818 (± 326)	477 (± 136)	604 (± 169)	373 (± 144)

End point values	Part 1: Talazoparib 1100 mcg			
Subject group type	Reporting group			
Number of subjects analysed	6			
Units: liter				
arithmetic mean (standard deviation)				
Cycle 1 Day 1|	549 (± 232)			
Cycle 1 Day 35|	472 (± 254)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline up to end of study (maximum duration: 1071 days for Part 1; 834 days for Part 2)

Adverse event reporting additional description:

The same event may appear as both an AE and a SAE. However, what is presented are distinct events. An event may be categorized as serious in one subject and as non serious in another subject, or one subject may have experienced both a serious and non serious event during the study.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	20.0

Reporting groups

Reporting group title	Part 1: Talazoparib 25 mcg

Reporting group description:

Subjects received talazoparib capsules at a dose of 25 microgram per day (mcg/day) once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 1: Talazoparib 50 mcg

Reporting group description:

Subjects received talazoparib capsules at a dose of 50 microgram per day (mcg/day) once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 1: Talazoparib 100 mcg

Reporting group description:

Subjects received talazoparib capsules at a dose of 100 microgram per day (mcg/day) once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 1: Talazoparib 200 mcg

Reporting group description:

Subjects received talazoparib capsules at a dose of 200 microgram per day (mcg/day) once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 1: Talazoparib 400 mcg

Reporting group description:

Subjects received talazoparib capsules at a dose of 400 microgram per day (mcg/day) once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 1: Talazoparib 900 mcg

Reporting group description:

Subjects received talazoparib capsules at a dose of 900 microgram per day (mcg/day) once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 1: Talazoparib 600 mcg

Reporting group description:

Subjects received talazoparib capsules at a dose of 600 microgram per day (mcg/day) once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 1: Talazoparib 1000 mcg

Reporting group description:

Subjects received talazoparib capsules at a dose of 1000 microgram per day (mcg/day) once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 1: Talazoparib 1100 mcg

Reporting group description:

Subjects received talazoparib capsules at a dose of 1100 microgram per day (mcg/day) once daily from Day 8 to 35 of Cycle 1 and thereafter once daily in each 28-day treatment cycle starting from Cycle 2 (up to a maximum of 50 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 2: Talazoparib (Breast Cancer)

Reporting group description:

Subjects with breast cancer, received talazoparib capsules at the MTD as determined in Part 1 (1000 mcg/day), orally once daily in each 28-day treatment cycle (up to a maximum of 40 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 2: Talazoparib (Ovarian/ Peritoneal Cancer)

Reporting group description:

Subjects with ovarian/ peritoneal cancer, received talazoparib capsules at the MTD as determined in Part 1 (1000 mcg/day), orally once daily in each 28-day treatment cycle (up to a maximum of 40 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 2: Talazoparib (Pancreatic Cancer)

Reporting group description:

Subjects with pancreatic cancer, received talazoparib capsules at the MTD as determined in Part 1 (1000 mcg/day), orally once daily in each 28-day treatment cycle (up to a maximum of 40 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 2: Talazoparib (Ewing Cancer)

Reporting group description:

Subjects with ewing cancer, received talazoparib capsules at the MTD as determined in Part 1 (1000 mcg/day), orally once daily in each 28-day treatment cycle (up to a maximum of 40 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 2: Talazoparib (SCLC Cancer)

Reporting group description:

Subjects with SCLC cancer, received talazoparib capsules at the MTD as determined in Part 1 (1000 mcg/day), orally once daily in each 28-day treatment cycle (up to a maximum of 40 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Reporting group title	Part 2: Talazoparib (Prostate Cancer)

Reporting group description:

Subjects with prostate cancer, received talazoparib capsules at the MTD as determined in Part 1 (1000 mcg/day), orally once daily in each 28-day treatment cycle (up to a maximum of 40 cycles) until documented disease progression or unacceptable toxicity, or until study discontinuation criteria were met.

Serious adverse events	Part 1: Talazoparib 25 mcg	Part 1: Talazoparib 50 mcg	Part 1: Talazoparib 100 mcg
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 3 (33.33%)	2 / 3 (66.67%)	2 / 3 (66.67%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Invasive ductal breast carcinoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to central nervous system			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic carcinoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour associated fever			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to lung			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian neoplasm			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cancer pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypotension			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disease progression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemothorax			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Investigations			
Transaminases increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood sodium decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Anastomotic stenosis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	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
Transfusion reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pubis fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Supraventricular tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Neuralgia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Ascites			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspepsia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Food poisoning			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Bile duct obstruction			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	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
Hyperbilirubinaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Bone pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bacteraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Community acquired infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infection			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part 1: Talazoparib 200 mcg	Part 1: Talazoparib 400 mcg	Part 1: Talazoparib 900 mcg
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	0 / 3 (0.00%)	3 / 6 (50.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Invasive ductal breast carcinoma			
subjects affected / exposed	0 / 3 (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
Metastases to central nervous system			

subjects affected / exposed	0 / 3 (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
Pancreatic carcinoma			
subjects affected / exposed	0 / 3 (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
Tumour associated fever			
subjects affected / exposed	0 / 3 (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
Metastases to lung			
subjects affected / exposed	0 / 3 (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
Ovarian neoplasm			
subjects affected / exposed	0 / 3 (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
Cancer pain			
subjects affected / exposed	0 / 3 (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			
Hypotension			
subjects affected / exposed	0 / 3 (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			
Pyrexia			
subjects affected / exposed	0 / 3 (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

Disease progression			
subjects affected / exposed	0 / 3 (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, thoracic and mediastinal disorders			
Pleural effusion			
subjects affected / exposed	0 / 3 (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 embolism			
subjects affected / exposed	0 / 3 (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
Dyspnoea			
subjects affected / exposed	0 / 3 (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
Haemothorax			
subjects affected / exposed	0 / 3 (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 / 3 (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			
Transaminases increased			
subjects affected / exposed	0 / 3 (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 sodium decreased			
subjects affected / exposed	0 / 3 (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			
Anastomotic stenosis			
subjects affected / exposed	0 / 3 (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
Transfusion reaction			
subjects affected / exposed	0 / 3 (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
Pubis fracture			
subjects affected / exposed	0 / 3 (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			
Supraventricular tachycardia			
subjects affected / exposed	0 / 3 (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 tachycardia			
subjects affected / exposed	0 / 3 (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			
Neuralgia			
subjects affected / exposed	0 / 3 (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
Cerebrovascular accident			
subjects affected / exposed	0 / 3 (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 / 3 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
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 / 3 (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			
Ascites			
subjects affected / exposed	1 / 3 (33.33%)	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
Abdominal pain			
subjects affected / exposed	0 / 3 (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
Dyspepsia			
subjects affected / exposed	0 / 3 (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
Intestinal obstruction			
subjects affected / exposed	1 / 3 (33.33%)	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
Nausea			
subjects affected / exposed	1 / 3 (33.33%)	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
Rectal haemorrhage			
subjects affected / exposed	0 / 3 (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 / 3 (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
Small intestinal obstruction			
subjects affected / exposed	0 / 3 (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
Food poisoning			
subjects affected / exposed	0 / 3 (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			
Bile duct obstruction			
subjects affected / exposed	0 / 3 (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
Hyperbilirubinaemia			
subjects affected / exposed	0 / 3 (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			
Acute kidney injury			
subjects affected / exposed	0 / 3 (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
Haematuria			
subjects affected / exposed	0 / 3 (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
Endocrine disorders			
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 3 (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			
Bone pain			
subjects affected / exposed	0 / 3 (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			
Bacteraemia			
subjects affected / exposed	0 / 3 (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
Community acquired infection			
subjects affected / exposed	1 / 3 (33.33%)	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
Sepsis			
subjects affected / exposed	0 / 3 (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 / 3 (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 infection			
subjects affected / exposed	0 / 3 (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
Otitis media			
subjects affected / exposed	0 / 3 (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 / 3 (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			
Hyponatraemia			
subjects affected / exposed	0 / 3 (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
Hypokalaemia			
subjects affected / exposed	0 / 3 (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	Part 1: Talazoparib 600 mcg	Part 1: Talazoparib 1000 mcg	Part 1: Talazoparib 1100 mcg
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 6 (33.33%)	2 / 6 (33.33%)	3 / 6 (50.00%)
number of deaths (all causes)	0	0	2
number of deaths resulting from adverse events	0	0	2
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Invasive ductal breast carcinoma			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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 / 1
Metastases to central nervous system			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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 / 1
Pancreatic carcinoma			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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
Tumour associated fever			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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
Metastases to lung			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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
Ovarian neoplasm			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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
Cancer pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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			
Hypotension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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			
Pyrexia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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
Disease progression			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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, thoracic and mediastinal disorders			
Pleural effusion			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (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
Pulmonary embolism			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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
Haemothorax			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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 / 6 (0.00%)	0 / 6 (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			
Transaminases increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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 sodium decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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			
Anastomotic stenosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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
Transfusion reaction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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

Pubis fracture			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Supraventricular tachycardia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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 tachycardia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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			
Neuralgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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
Cerebrovascular accident			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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 / 6 (0.00%)	0 / 6 (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 / 6 (0.00%)	0 / 6 (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			
Ascites			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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
Abdominal pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (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
Dyspepsia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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
Intestinal obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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 / 6 (0.00%)	0 / 6 (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
Rectal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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 / 6 (0.00%)	0 / 6 (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
Small intestinal obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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
Food poisoning			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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			
Bile duct obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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
Hyperbilirubinaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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			
Acute kidney injury			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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
Haematuria			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (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
Endocrine disorders			
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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			
Bone pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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
Infections and infestations			
Bacteraemia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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
Community acquired infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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 / 6 (0.00%)	0 / 6 (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
Device related infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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 infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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
Otitis media			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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 / 6 (0.00%)	0 / 6 (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			
Hyponatraemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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
Hypokalaemia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (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	Part 2: Talazoparib (Breast Cancer)	Part 2: Talazoparib (Ovarian/ Peritoneal Cancer)	Part 2: Talazoparib (Pancreatic Cancer)
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 12 (16.67%)	5 / 11 (45.45%)	6 / 10 (60.00%)
number of deaths (all causes)	0	0	2
number of deaths resulting from adverse events	0	0	2
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Invasive ductal breast carcinoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to central nervous system			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 10 (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
Pancreatic carcinoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Tumour associated fever			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to lung			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian neoplasm			

subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cancer pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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			
Pyrexia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disease progression			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Respiratory, thoracic and mediastinal disorders			
Pleural effusion			
subjects affected / exposed	1 / 12 (8.33%)	1 / 11 (9.09%)	0 / 10 (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
Pulmonary embolism			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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			

subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemothorax			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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			
Transaminases increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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 sodium decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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			
Anastomotic stenosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transfusion reaction			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 10 (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
Pubis fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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			
Supraventricular tachycardia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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 tachycardia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 10 (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
Nervous system disorders			
Neuralgia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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			
Ascites			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			

subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 10 (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
Dyspepsia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 12 (0.00%)	2 / 11 (18.18%)	0 / 10 (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
Food poisoning			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Bile duct obstruction			

subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Bone pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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			
Bacteraemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Community acquired infection			

subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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 / 12 (0.00%)	2 / 11 (18.18%)	0 / 10 (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
Lung infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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 / 12 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hyponatraemia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 10 (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
Hypokalaemia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 10 (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

Serious adverse events	Part 2: Talazoparib	Part 2: Talazoparib	Part 2: Talazoparib

	(Ewing Cancer)	(SCLC Cancer)	(Prostate Cancer)
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 12 (33.33%)	8 / 23 (34.78%)	0 / 3 (0.00%)
number of deaths (all causes)	2	2	0
number of deaths resulting from adverse events	2	2	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Invasive ductal breast carcinoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (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
Metastases to central nervous system			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	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
Pancreatic carcinoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour associated fever			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (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
Metastases to lung			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	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
Ovarian neoplasm			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (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
Cancer pain			
subjects affected / exposed	1 / 12 (8.33%)	0 / 23 (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

Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	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			
Pyrexia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (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
Disease progression			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (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			
Pleural effusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (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
Dyspnoea			
subjects affected / exposed	2 / 12 (16.67%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Haemothorax			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (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 / 12 (8.33%)	0 / 23 (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
Investigations			
Transaminases increased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	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
Blood sodium decreased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	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
Injury, poisoning and procedural complications			
Anastomotic stenosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (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
Transfusion reaction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (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
Pubis fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (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			
Supraventricular tachycardia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	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
Ventricular tachycardia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (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			
Neuralgia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (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
Cerebrovascular accident			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	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
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (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
Thrombocytopenia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Ascites			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (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
Abdominal pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (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
Dyspepsia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (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
Intestinal obstruction			

subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (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 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (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 / 12 (0.00%)	1 / 23 (4.35%)	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
Small intestinal obstruction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (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
Food poisoning			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (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			
Bile duct obstruction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (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
Hyperbilirubinaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (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			

Acute kidney injury			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	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
Haematuria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (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
Endocrine disorders			
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (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 and connective tissue disorders			
Bone pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (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			
Bacteraemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (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
Community acquired infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (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	0 / 12 (0.00%)	0 / 23 (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 / 12 (0.00%)	0 / 23 (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 infection			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	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
Otitis media			
subjects affected / exposed	1 / 12 (8.33%)	0 / 23 (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
Pneumonia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	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
Metabolism and nutrition disorders			
Hyponatraemia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	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
Hypokalaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (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

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

Non-serious adverse events	Part 1: Talazoparib 25 mcg	Part 1: Talazoparib 50 mcg	Part 1: Talazoparib 100 mcg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	3 / 3 (100.00%)	3 / 3 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Neoplasm skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymphostasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymphoedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Superior vena cava syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Tooth extraction			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Breast reconstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Frontal sinus operation			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Early satiety			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Fatigue			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 3 (66.67%)
occurrences (all)	0	0	3
Chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Axillary pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Local swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Medical device site reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Feeling hot			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sensation of foreign body			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Temperature intolerance			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Feeling abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Feeling cold			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Localised oedema			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nodule			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thirst			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Autoimmune disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Genital discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Penile pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Breast pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nipple pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Adnexa uteri pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Prostatic pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal dryness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Breast tenderness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Dyspnoea exertional			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Oropharyngeal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Productive cough			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sneezing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lung hyperinflation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Throat tightness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dyspnoea at rest			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rales			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Insomnia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Stress			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abnormal dreams			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Agitation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Depressed mood			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Irritability			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Panic attack			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Breath sounds abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Biopsy bone marrow			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood calcium decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood chloride decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram T wave inversion			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Troponin increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bilirubin conjugated increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood magnesium decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood potassium increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Anastomotic stenosis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Limb injury			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Foot fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Injury corneal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Joint injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Wound complication			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Incisional hernia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1

Bundle branch block left			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Pericardial effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ventricular tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Angina pectoris			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Supraventricular tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Hyperaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hypoaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Tension headache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Neuropathy peripheral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Somnolence			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Amnesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Aphasia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cognitive disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Balance disorder			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cerebrovascular accident			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dizziness postural			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nerve compression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia vitamin B12 deficiency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Thrombocytosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ear pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ear swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ear discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Eye pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	4
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Abdominal pain lower			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Ascites			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Constipation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Diarrhoea			
subjects affected / exposed	2 / 3 (66.67%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	3	1	0
Dry mouth			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Flatulence			
subjects affected / exposed	0 / 3 (0.00%)	2 / 3 (66.67%)	1 / 3 (33.33%)
occurrences (all)	0	2	1

Nausea			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences (all)	1	1	1
Toothache			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Abdominal pain upper			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Frequent bowel movements			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Intestinal obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oesophagitis ulcerative			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abnormal faeces			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dental caries			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Femoral hernia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Glossodynia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Inguinal hernia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal tenderness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eructation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Food poisoning			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia oral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral mucosal erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Odynophagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oesophagitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Bile duct obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Erythema			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nail bed disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Penile ulceration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash papular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ingrowing nail			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Swelling face			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Acne			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nail disorder			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nail ridging			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain of skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypotrichosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary tract obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urogenital haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Micturition frequency decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Micturition urgency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chromaturia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Flank pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Mobility decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Muscle spasms			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Groin pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Joint stiffness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal discomfort			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Arthralgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Limb discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Spinal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bursitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Diastasis recti abdominis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Joint swelling			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Trigger finger			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Limb mass			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Osteoporosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Skin candida			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Breast abscess			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Campylobacter gastroenteritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Laryngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bacteraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Diverticulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Escherichia infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Hypercholesterolaemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hypokalaemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 deficiency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypermagnesaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			

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

Non-serious adverse events	Part 1: Talazoparib 200 mcg	Part 1: Talazoparib 400 mcg	Part 1: Talazoparib 900 mcg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	3 / 3 (100.00%)	6 / 6 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Neoplasm skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Lymphostasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Lymphoedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypotension			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Superior vena cava syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Tooth extraction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Breast reconstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Frontal sinus operation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Early satiety			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Fatigue			
subjects affected / exposed	2 / 3 (66.67%)	3 / 3 (100.00%)	3 / 6 (50.00%)
occurrences (all)	3	3	8
Chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Axillary pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Chills			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Local swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Medical device site reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Oedema peripheral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	3 / 6 (50.00%)
occurrences (all)	0	0	3
Discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Feeling hot			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sensation of foreign body			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Temperature intolerance			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Feeling abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Feeling cold			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nodule			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Thirst			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Autoimmune disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			

Genital discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Penile pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Breast pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nipple pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Adnexa uteri pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Prostatic pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal dryness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Breast tenderness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	2
Dyspnoea			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Dyspnoea exertional			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Oropharyngeal pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Productive cough			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Sneezing			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Wheezing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Pulmonary embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Lung hyperinflation			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Throat tightness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dyspnoea at rest			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rales			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Insomnia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1

Stress			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Abnormal dreams			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Agitation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Depressed mood			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Irritability			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Panic attack			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Blood bilirubin increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Breath sounds abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Biopsy bone marrow			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood calcium decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Blood chloride decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram T wave inversion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Troponin increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bilirubin conjugated increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood magnesium decreased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood potassium increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Anastomotic stenosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Skin abrasion			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Contusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2
Foot fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Injury corneal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Procedural pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Joint injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Wound complication			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eye injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Incisional hernia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bundle branch block left			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pericardial effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ventricular tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Angina pectoris			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Supraventricular tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Nervous system disorders			
Headache			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	2 / 6 (33.33%)
occurrences (all)	1	0	2
Hyperaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tension headache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Somnolence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	2
Dysgeusia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	3
Neuralgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Amnesia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Aphasia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cognitive disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Balance disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cerebrovascular accident			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dizziness postural			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nerve compression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			

Anaemia vitamin B12 deficiency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	2 / 6 (33.33%)
occurrences (all)	0	1	2
Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Leukopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Thrombocytosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Ear pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ear swelling			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ear discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Eye pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eye swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	2
Abdominal pain			

subjects affected / exposed	2 / 3 (66.67%)	1 / 3 (33.33%)	0 / 6 (0.00%)
occurrences (all)	3	1	0
Abdominal pain lower			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Constipation			
subjects affected / exposed	2 / 3 (66.67%)	2 / 3 (66.67%)	3 / 6 (50.00%)
occurrences (all)	3	3	5
Diarrhoea			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	2 / 6 (33.33%)
occurrences (all)	2	0	11
Dry mouth			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Nausea			
subjects affected / exposed	3 / 3 (100.00%)	2 / 3 (66.67%)	5 / 6 (83.33%)
occurrences (all)	8	4	11
Toothache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	2 / 3 (66.67%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	2	0	9
Abdominal pain upper			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	2 / 6 (33.33%)
occurrences (all)	0	2	2
Dyspepsia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	2	0	1
Frequent bowel movements			

subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Gastritis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Intestinal obstruction			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Oesophagitis ulcerative			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Abnormal faeces			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dental caries			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Femoral hernia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Glossodynia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Haematochezia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Haemorrhoids			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Inguinal hernia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Oral pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Abdominal discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Abdominal tenderness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eructation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Food poisoning			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia oral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oral mucosal erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Odynophagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oesophagitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bile duct obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	3 / 6 (50.00%)
occurrences (all)	1	1	5
Erythema			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Nail bed disorder			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Penile ulceration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash papular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dry skin			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Ingrowing nail			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	3
Rash			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Swelling face			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Acne			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nail disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nail ridging			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pain of skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypotrichosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			

Haematuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary tract obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urogenital haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Micturition frequency decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Micturition urgency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Chromaturia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			

Back pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Mobility decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2
Groin pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Joint stiffness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Pain in extremity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Arthralgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2

Limb discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Myalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Spinal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Bursitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Diastasis recti abdominis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Trigger finger			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Limb mass			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Osteoporosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Skin candida			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	1 / 6 (16.67%)
occurrences (all)	0	1	2
Influenza			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Sepsis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Urinary tract infection			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	2
Breast abscess			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Fungal skin infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Gastroenteritis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Oral candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Tooth infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Campylobacter gastroenteritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bacteraemia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Diverticulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Escherichia infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	2 / 3 (66.67%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	3	0	1
Hypercholesterolaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1

Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Vitamin B12 deficiency			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Hypophosphataemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypermagnesaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoproteinaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part 1: Talazoparib 600 mcg	Part 1: Talazoparib 1000 mcg	Part 1: Talazoparib 1100 mcg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 6 (100.00%)	6 / 6 (100.00%)	6 / 6 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Neoplasm skin			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Lymphostasis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Thrombosis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Hot flush			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Lymphoedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Hypotension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Superior vena cava syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Tooth extraction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Breast reconstruction			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Frontal sinus operation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Early satiety			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	3 / 6 (50.00%)	5 / 6 (83.33%)	1 / 6 (16.67%)
occurrences (all)	6	8	1
Chest pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Influenza like illness			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Mucosal inflammation			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	1	4	1
Pain			
subjects affected / exposed	2 / 6 (33.33%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	2	1	1
Peripheral swelling			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Asthenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Axillary pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Catheter site pain			

subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Chest discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Local swelling			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2
Medical device site reaction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 6 (0.00%)	3 / 6 (50.00%)	1 / 6 (16.67%)
occurrences (all)	0	3	4
Discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Feeling hot			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sensation of foreign body			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Temperature intolerance			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Feeling abnormal			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Feeling cold			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nodule			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Thirst			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Autoimmune disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Genital discomfort			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Penile pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Vaginal haemorrhage			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Breast pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Nipple pain			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Adnexa uteri pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Prostatic pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal dryness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal pruritus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Breast tenderness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	3 / 6 (50.00%)	1 / 6 (16.67%)	3 / 6 (50.00%)
occurrences (all)	4	1	3
Dyspnoea			
subjects affected / exposed	2 / 6 (33.33%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	5	0	1
Dyspnoea exertional			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			

subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	1	1	2
Productive cough			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Rhinorrhoea			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Sneezing			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	4 / 6 (66.67%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	4	1	0
Dysphonia			
subjects affected / exposed	0 / 6 (0.00%)	2 / 6 (33.33%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Epistaxis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Pulmonary embolism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lung hyperinflation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Throat tightness			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dyspnoea at rest			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rales			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Insomnia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Depression			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Stress			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Abnormal dreams			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Agitation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Depressed mood			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Irritability			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Panic attack			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Blood bilirubin increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Breath sounds abnormal			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Biopsy bone marrow			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Blood calcium decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood chloride decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram T wave inversion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Troponin increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bilirubin conjugated increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood magnesium decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood potassium increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Anastomotic stenosis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 6 (0.00%)	2 / 6 (33.33%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Fall			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Foot fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Injury corneal			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Procedural pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Joint injury			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Wound complication			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eye injury			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Incisional hernia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			

Atrial fibrillation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bundle branch block left			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2
Pericardial effusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ventricular tachycardia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Angina pectoris			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Supraventricular tachycardia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 6 (33.33%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	3	1	6
Hyperaesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tension headache			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			

subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	2	0	1
Somnolence			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Dizziness			
subjects affected / exposed	0 / 6 (0.00%)	2 / 6 (33.33%)	0 / 6 (0.00%)
occurrences (all)	0	3	0
Dysgeusia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Neuralgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Paraesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	4
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Amnesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Aphasia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cognitive disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Syncope			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Balance disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cerebrovascular accident			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dizziness postural			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nerve compression			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia vitamin B12 deficiency			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Neutropenia			
subjects affected / exposed	1 / 6 (16.67%)	2 / 6 (33.33%)	1 / 6 (16.67%)
occurrences (all)	1	5	3
Thrombocytopenia			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	2 / 6 (33.33%)
occurrences (all)	2	3	7
Anaemia			
subjects affected / exposed	0 / 6 (0.00%)	4 / 6 (66.67%)	2 / 6 (33.33%)
occurrences (all)	0	14	4
Leukopenia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	0	2	8

Lymph node pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Thrombocytosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ear pruritus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Ear swelling			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Ear discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Eye pruritus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Lacrimation increased			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Eye pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eye swelling			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 6 (0.00%)	2 / 6 (33.33%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	2 / 6 (33.33%)	1 / 6 (16.67%)	2 / 6 (33.33%)
occurrences (all)	2	2	2
Abdominal pain lower			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Ascites			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	1	1	1
Diarrhoea			
subjects affected / exposed	1 / 6 (16.67%)	2 / 6 (33.33%)	1 / 6 (16.67%)
occurrences (all)	3	6	1
Dry mouth			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Flatulence			
subjects affected / exposed	0 / 6 (0.00%)	2 / 6 (33.33%)	0 / 6 (0.00%)
occurrences (all)	0	3	0
Nausea			
subjects affected / exposed	4 / 6 (66.67%)	2 / 6 (33.33%)	1 / 6 (16.67%)
occurrences (all)	5	5	1
Toothache			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	2 / 6 (33.33%)	2 / 6 (33.33%)	2 / 6 (33.33%)
occurrences (all)	2	5	2
Abdominal pain upper			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	2 / 6 (33.33%)	0 / 6 (0.00%)	2 / 6 (33.33%)
occurrences (all)	2	0	2
Frequent bowel movements			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Intestinal obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oesophagitis ulcerative			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Abnormal faeces			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0

Dental caries			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Dysphagia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Femoral hernia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Glossodynia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Haemorrhoids			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Inguinal hernia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Abdominal discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Abdominal tenderness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Eructation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Food poisoning			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia oral			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oral mucosal erythema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Odynophagia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oesophagitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bile duct obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			

Alopecia			
subjects affected / exposed	2 / 6 (33.33%)	4 / 6 (66.67%)	0 / 6 (0.00%)
occurrences (all)	4	4	0
Erythema			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Nail bed disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Penile ulceration			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Rash papular			
subjects affected / exposed	2 / 6 (33.33%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Skin swelling			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Dry skin			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Ingrowing nail			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2
Pruritus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 6 (0.00%)	2 / 6 (33.33%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Swelling face			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Acne			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Dermatitis acneiform			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nail disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nail ridging			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pain of skin			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypotrichosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Pollakiuria			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Urinary retention			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Urinary tract obstruction			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Urogenital haemorrhage			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Dysuria			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Micturition frequency decreased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Micturition urgency			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Chromaturia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	2 / 6 (33.33%)
occurrences (all)	0	2	2
Flank pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Mobility decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Groin pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Joint stiffness			

subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Muscular weakness			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Musculoskeletal discomfort			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Neck pain			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	1	2	0
Pain in extremity			
subjects affected / exposed	1 / 6 (16.67%)	3 / 6 (50.00%)	1 / 6 (16.67%)
occurrences (all)	1	3	2
Arthralgia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Limb discomfort			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	0	2	4
Myalgia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	0	2	1
Pain in jaw			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Spinal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2
Bursitis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Diastasis recti abdominis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Trigger finger			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Limb mass			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Osteoporosis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin candida			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0

Influenza			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Sepsis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	2 / 6 (33.33%)	2 / 6 (33.33%)	0 / 6 (0.00%)
occurrences (all)	3	2	0
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	1	2	1
Breast abscess			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Rhinitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Skin infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0

Upper respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Campylobacter gastroenteritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bacteraemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Diverticulitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Escherichia infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Hordeolum			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	2 / 6 (33.33%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	2	1	1
Hypercholesterolaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dehydration			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 deficiency			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypermagnesaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoproteinaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part 2: Talazoparib (Breast Cancer)	Part 2: Talazoparib (Ovarian/ Peritoneal Cancer)	Part 2: Talazoparib (Pancreatic Cancer)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	12 / 12 (100.00%)	11 / 11 (100.00%)	10 / 10 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Neoplasm skin			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Lymphostasis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Thrombosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hot flush			

subjects affected / exposed	1 / 12 (8.33%)	1 / 11 (9.09%)	1 / 10 (10.00%)
occurrences (all)	1	1	1
Lymphoedema			
subjects affected / exposed	2 / 12 (16.67%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	2	0	0
Hypotension			
subjects affected / exposed	1 / 12 (8.33%)	1 / 11 (9.09%)	1 / 10 (10.00%)
occurrences (all)	1	1	1
Haematoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Superior vena cava syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Tooth extraction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Breast reconstruction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Frontal sinus operation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Early satiety			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	6 / 12 (50.00%)	9 / 11 (81.82%)	4 / 10 (40.00%)
occurrences (all)	16	22	7
Chest pain			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Influenza like illness			

subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Mucosal inflammation			
subjects affected / exposed	3 / 12 (25.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	3	1	0
Pain			
subjects affected / exposed	2 / 12 (16.67%)	1 / 11 (9.09%)	1 / 10 (10.00%)
occurrences (all)	2	1	1
Peripheral swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	2
Asthenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Axillary pain			
subjects affected / exposed	1 / 12 (8.33%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
Catheter site pain			
subjects affected / exposed	0 / 12 (0.00%)	2 / 11 (18.18%)	0 / 10 (0.00%)
occurrences (all)	0	4	0
Chest discomfort			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Chills			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Local swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Medical device site reaction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 12 (0.00%)	4 / 11 (36.36%)	0 / 10 (0.00%)
occurrences (all)	0	4	0
Pyrexia			

subjects affected / exposed	2 / 12 (16.67%)	2 / 11 (18.18%)	2 / 10 (20.00%)
occurrences (all)	2	2	5
Discomfort			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Feeling hot			
subjects affected / exposed	0 / 12 (0.00%)	3 / 11 (27.27%)	0 / 10 (0.00%)
occurrences (all)	0	3	0
Sensation of foreign body			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Temperature intolerance			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Feeling abnormal			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Feeling cold			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Nodule			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Oedema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Thirst			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0

Autoimmune disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Genital discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Penile pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	2 / 11 (18.18%)	0 / 10 (0.00%)
occurrences (all)	0	3	0
Breast pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Nipple pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Adnexa uteri pain			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Pelvic pain			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Prostatic pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal dryness			
subjects affected / exposed	1 / 12 (8.33%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
Vulvovaginal pruritus			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Breast tenderness			

subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	2 / 12 (16.67%)	4 / 11 (36.36%)	0 / 10 (0.00%)
occurrences (all)	6	5	0
Dyspnoea			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 12 (0.00%)	4 / 11 (36.36%)	0 / 10 (0.00%)
occurrences (all)	0	6	0
Oropharyngeal pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	1 / 12 (8.33%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
Rhinorrhoea			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Sneezing			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 12 (0.00%)	2 / 11 (18.18%)	0 / 10 (0.00%)
occurrences (all)	0	2	0
Dysphonia			
subjects affected / exposed	2 / 12 (16.67%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	2	1	0
Epistaxis			

subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Lung hyperinflation			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Nasal congestion			
subjects affected / exposed	2 / 12 (16.67%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	2	0	0
Pleural effusion			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Rhinitis allergic			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Throat tightness			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Dyspnoea at rest			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Rales			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	4 / 12 (33.33%)	1 / 11 (9.09%)	1 / 10 (10.00%)
occurrences (all)	7	1	1

Insomnia			
subjects affected / exposed	4 / 12 (33.33%)	3 / 11 (27.27%)	1 / 10 (10.00%)
occurrences (all)	4	4	1
Depression			
subjects affected / exposed	1 / 12 (8.33%)	1 / 11 (9.09%)	1 / 10 (10.00%)
occurrences (all)	3	1	1
Stress			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Abnormal dreams			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Agitation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Depressed mood			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Irritability			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Panic attack			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	2
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	1	0	2
Blood bilirubin increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Breath sounds abnormal			

subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Biopsy bone marrow			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 12 (8.33%)	1 / 11 (9.09%)	1 / 10 (10.00%)
occurrences (all)	1	1	1
Blood calcium decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Blood chloride decreased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Electrocardiogram T wave inversion			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Transaminases increased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	2	0
Troponin increased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Weight decreased			
subjects affected / exposed	2 / 12 (16.67%)	1 / 11 (9.09%)	1 / 10 (10.00%)
occurrences (all)	2	1	2
Bilirubin conjugated increased			

subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Blood creatinine increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Blood magnesium decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Blood potassium increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Anastomotic stenosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Foot fracture			

subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Injury corneal			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Joint injury			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Wound complication			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Eye injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Incisional hernia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Bundle branch block left			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	1 / 12 (8.33%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
Pericardial effusion			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	3	0	0
Ventricular tachycardia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0

Angina pectoris			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Supraventricular tachycardia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	4 / 12 (33.33%)	5 / 11 (45.45%)	0 / 10 (0.00%)
occurrences (all)	6	7	0
Hyperaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Hypoaesthesia			
subjects affected / exposed	2 / 12 (16.67%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Tension headache			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	1 / 12 (8.33%)	1 / 11 (9.09%)	1 / 10 (10.00%)
occurrences (all)	1	1	1
Somnolence			
subjects affected / exposed	1 / 12 (8.33%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
Dizziness			
subjects affected / exposed	2 / 12 (16.67%)	4 / 11 (36.36%)	0 / 10 (0.00%)
occurrences (all)	2	5	0
Dysgeusia			
subjects affected / exposed	3 / 12 (25.00%)	4 / 11 (36.36%)	0 / 10 (0.00%)
occurrences (all)	3	4	0
Neuralgia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Paraesthesia			

subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Amnesia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Aphasia			
subjects affected / exposed	0 / 12 (0.00%)	2 / 11 (18.18%)	0 / 10 (0.00%)
occurrences (all)	0	2	0
Cognitive disorder			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Memory impairment			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Presyncope			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Syncope			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Balance disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Cerebrovascular accident			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Dizziness postural			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Nerve compression			

subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia vitamin B12 deficiency			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	3 / 12 (25.00%)	3 / 11 (27.27%)	3 / 10 (30.00%)
occurrences (all)	7	4	9
Thrombocytopenia			
subjects affected / exposed	1 / 12 (8.33%)	3 / 11 (27.27%)	0 / 10 (0.00%)
occurrences (all)	1	8	0
Anaemia			
subjects affected / exposed	5 / 12 (41.67%)	6 / 11 (54.55%)	3 / 10 (30.00%)
occurrences (all)	14	27	5
Leukopenia			
subjects affected / exposed	2 / 12 (16.67%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	3	0	0
Lymph node pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Thrombocytosis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			

subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Ear pruritus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Ear swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Ear discomfort			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Tinnitus			
subjects affected / exposed	2 / 12 (16.67%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	2	0	0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Lacrimation increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Visual impairment			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Eye swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0

Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	3 / 12 (25.00%)	4 / 11 (36.36%)	3 / 10 (30.00%)
occurrences (all)	3	7	3
Abdominal pain lower			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Constipation			
subjects affected / exposed	4 / 12 (33.33%)	4 / 11 (36.36%)	2 / 10 (20.00%)
occurrences (all)	5	5	2
Diarrhoea			
subjects affected / exposed	4 / 12 (33.33%)	4 / 11 (36.36%)	1 / 10 (10.00%)
occurrences (all)	4	7	2
Dry mouth			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	1 / 10 (10.00%)
occurrences (all)	0	1	1
Flatulence			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	1 / 10 (10.00%)
occurrences (all)	0	1	1
Nausea			
subjects affected / exposed	5 / 12 (41.67%)	10 / 11 (90.91%)	4 / 10 (40.00%)
occurrences (all)	20	20	7
Toothache			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	3 / 12 (25.00%)	3 / 11 (27.27%)	0 / 10 (0.00%)
occurrences (all)	4	4	0
Abdominal pain upper			

subjects affected / exposed	1 / 12 (8.33%)	3 / 11 (27.27%)	2 / 10 (20.00%)
occurrences (all)	1	3	2
Dyspepsia			
subjects affected / exposed	3 / 12 (25.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	3	0	0
Frequent bowel movements			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Intestinal obstruction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Oesophagitis ulcerative			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	2 / 12 (16.67%)	2 / 11 (18.18%)	0 / 10 (0.00%)
occurrences (all)	4	2	0
Abnormal faeces			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Dental caries			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	2	0	0
Femoral hernia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Glossodynia			

subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Inguinal hernia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	1 / 12 (8.33%)	1 / 11 (9.09%)	1 / 10 (10.00%)
occurrences (all)	1	1	1
Abdominal discomfort			
subjects affected / exposed	0 / 12 (0.00%)	3 / 11 (27.27%)	1 / 10 (10.00%)
occurrences (all)	0	3	1
Abdominal tenderness			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Aphthous ulcer			
subjects affected / exposed	2 / 12 (16.67%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	2	0	0
Eructation			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Food poisoning			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia oral			
subjects affected / exposed	2 / 12 (16.67%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	2	0	0
Mouth ulceration			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Oral mucosal erythema			

subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Odynophagia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Oesophagitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Bile duct obstruction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Hyperbilirubinaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	2 / 10 (20.00%)
occurrences (all)	0	0	2
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	5 / 12 (41.67%)	6 / 11 (54.55%)	0 / 10 (0.00%)
occurrences (all)	6	6	0
Erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Nail bed disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Penile ulceration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Rash papular			

subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Skin swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	1 / 12 (8.33%)	3 / 11 (27.27%)	0 / 10 (0.00%)
occurrences (all)	1	3	0
Ingrowing nail			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Rash			
subjects affected / exposed	0 / 12 (0.00%)	2 / 11 (18.18%)	0 / 10 (0.00%)
occurrences (all)	0	2	0
Swelling face			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Acne			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Dermatitis acneiform			
subjects affected / exposed	1 / 12 (8.33%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
Nail disorder			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Nail ridging			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Pain of skin			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Hyperhidrosis			

subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Hypotrichosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Urinary tract obstruction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Urogenital haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Micturition frequency decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Micturition urgency			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Acute kidney injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Chromaturia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1

Hydronephrosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	4 / 12 (33.33%)	1 / 11 (9.09%)	2 / 10 (20.00%)
occurrences (all)	5	1	3
Flank pain			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	1 / 10 (10.00%)
occurrences (all)	0	1	1
Mobility decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	2 / 12 (16.67%)	2 / 11 (18.18%)	1 / 10 (10.00%)
occurrences (all)	2	4	1
Groin pain			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Joint stiffness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Musculoskeletal discomfort			
subjects affected / exposed	2 / 12 (16.67%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	3	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	2	0
Neck pain			
subjects affected / exposed	3 / 12 (25.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	4	1	0
Pain in extremity			

subjects affected / exposed	2 / 12 (16.67%)	2 / 11 (18.18%)	0 / 10 (0.00%)
occurrences (all)	2	2	0
Arthralgia			
subjects affected / exposed	1 / 12 (8.33%)	3 / 11 (27.27%)	0 / 10 (0.00%)
occurrences (all)	1	3	0
Limb discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	2 / 12 (16.67%)	1 / 11 (9.09%)	1 / 10 (10.00%)
occurrences (all)	3	1	1
Myalgia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Spinal pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Bursitis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Diastasis recti abdominis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Joint swelling			
subjects affected / exposed	2 / 12 (16.67%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	2	1	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Trigger finger			

subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Limb mass			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Osteoporosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	2	0	0
Skin candida			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	3 / 12 (25.00%)	3 / 11 (27.27%)	0 / 10 (0.00%)
occurrences (all)	3	5	0
Viral upper respiratory tract infection			
subjects affected / exposed	3 / 12 (25.00%)	3 / 11 (27.27%)	1 / 10 (10.00%)
occurrences (all)	3	7	2
Breast abscess			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0

Fungal skin infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Sinusitis			
subjects affected / exposed	1 / 12 (8.33%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
Skin infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 12 (8.33%)	1 / 11 (9.09%)	2 / 10 (20.00%)
occurrences (all)	1	1	2
Campylobacter gastroenteritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Respiratory tract infection			
subjects affected / exposed	0 / 12 (0.00%)	2 / 11 (18.18%)	0 / 10 (0.00%)
occurrences (all)	0	2	0
Vaginal infection			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0

Vulvovaginal candidiasis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Bacteraemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Candida infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Diverticulitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Escherichia infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	2 / 12 (16.67%)	2 / 11 (18.18%)	1 / 10 (10.00%)
occurrences (all)	2	2	1
Hypercholesterolaemia			

subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 12 (0.00%)	2 / 11 (18.18%)	1 / 10 (10.00%)
occurrences (all)	0	4	1
Dehydration			
subjects affected / exposed	1 / 12 (8.33%)	1 / 11 (9.09%)	2 / 10 (20.00%)
occurrences (all)	1	1	2
Hypocalcaemia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	2	0
Vitamin B12 deficiency			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Hypophosphataemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Hyperglycaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hypermagnesaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hypoproteinaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part 2: Talazoparib (Ewing Cancer)	Part 2: Talazoparib (SCLC Cancer)	Part 2: Talazoparib (Prostate Cancer)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	12 / 12 (100.00%)	20 / 23 (86.96%)	3 / 3 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Neoplasm skin			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymphostasis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thrombosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymphoedema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Superior vena cava syndrome			
subjects affected / exposed	1 / 12 (8.33%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Surgical and medical procedures			

Tooth extraction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Breast reconstruction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Frontal sinus operation			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Early satiety			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	3 / 12 (25.00%)	12 / 23 (52.17%)	0 / 3 (0.00%)
occurrences (all)	5	17	0
Chest pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	1 / 12 (8.33%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	1	2	0
Axillary pain			

subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Chills			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Local swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Medical device site reaction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	2 / 12 (16.67%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Pyrexia			
subjects affected / exposed	1 / 12 (8.33%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Feeling hot			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sensation of foreign body			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Temperature intolerance			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Feeling abnormal			

subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Feeling cold			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Localised oedema			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Nodule			
subjects affected / exposed	1 / 12 (8.33%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Oedema			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Thirst			
subjects affected / exposed	1 / 12 (8.33%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Autoimmune disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Genital discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Penile pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Breast pain			

subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nipple pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Adnexa uteri pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Prostatic pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Vulvovaginal dryness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal pruritus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Breast tenderness			
subjects affected / exposed	1 / 12 (8.33%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Vulvovaginal discomfort			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	3 / 12 (25.00%)	4 / 23 (17.39%)	0 / 3 (0.00%)
occurrences (all)	3	4	0
Dyspnoea			
subjects affected / exposed	1 / 12 (8.33%)	2 / 23 (8.70%)	0 / 3 (0.00%)
occurrences (all)	2	2	0
Dyspnoea exertional			

subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Oropharyngeal pain			
subjects affected / exposed	1 / 12 (8.33%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Productive cough			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sneezing			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Epistaxis			
subjects affected / exposed	0 / 12 (0.00%)	3 / 23 (13.04%)	0 / 3 (0.00%)
occurrences (all)	0	4	0
Pulmonary embolism			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lung hyperinflation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			

subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Throat tightness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dyspnoea at rest			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Haemoptysis			
subjects affected / exposed	0 / 12 (0.00%)	2 / 23 (8.70%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Rales			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Sinus congestion			
subjects affected / exposed	1 / 12 (8.33%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	3	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	2 / 12 (16.67%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	2	1	0
Insomnia			
subjects affected / exposed	1 / 12 (8.33%)	5 / 23 (21.74%)	1 / 3 (33.33%)
occurrences (all)	1	6	1
Depression			
subjects affected / exposed	1 / 12 (8.33%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	1	2	0
Stress			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abnormal dreams			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Agitation			
subjects affected / exposed	1 / 12 (8.33%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0

Depressed mood			
subjects affected / exposed	1 / 12 (8.33%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Irritability			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Panic attack			
subjects affected / exposed	1 / 12 (8.33%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 12 (8.33%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 12 (8.33%)	2 / 23 (8.70%)	0 / 3 (0.00%)
occurrences (all)	1	2	0
Blood bilirubin increased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Breath sounds abnormal			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Biopsy bone marrow			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Blood calcium decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood chloride decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			

subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram T wave inversion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Troponin increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bilirubin conjugated increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 12 (0.00%)	2 / 23 (8.70%)	0 / 3 (0.00%)
occurrences (all)	0	5	0
Blood magnesium decreased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Blood potassium increased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
C-reactive protein increased			
subjects affected / exposed	1 / 12 (8.33%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Lipase increased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0

Injury, poisoning and procedural complications			
Anastomotic stenosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Foot fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Injury corneal			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Joint injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Wound complication			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye injury			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Incisional hernia			

subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Bundle branch block left			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pericardial effusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ventricular tachycardia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Angina pectoris			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Supraventricular tachycardia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 12 (16.67%)	4 / 23 (17.39%)	0 / 3 (0.00%)
occurrences (all)	2	4	0
Hyperaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tension headache			

subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	2 / 12 (16.67%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Somnolence			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Dizziness			
subjects affected / exposed	0 / 12 (0.00%)	4 / 23 (17.39%)	0 / 3 (0.00%)
occurrences (all)	0	4	0
Dysgeusia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Neuralgia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 12 (0.00%)	2 / 23 (8.70%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Amnesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Aphasia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cognitive disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Presyncope			

subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Syncope			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Balance disorder			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Cerebrovascular accident			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Disturbance in attention			
subjects affected / exposed	1 / 12 (8.33%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Dizziness postural			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nerve compression			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Restless legs syndrome			
subjects affected / exposed	1 / 12 (8.33%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Anaemia vitamin B12 deficiency			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 12 (0.00%)	3 / 23 (13.04%)	0 / 3 (0.00%)
occurrences (all)	0	5	0
Thrombocytopenia			
subjects affected / exposed	3 / 12 (25.00%)	8 / 23 (34.78%)	0 / 3 (0.00%)
occurrences (all)	5	19	0
Anaemia			
subjects affected / exposed	5 / 12 (41.67%)	8 / 23 (34.78%)	1 / 3 (33.33%)
occurrences (all)	13	22	3

Leukopenia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	5	0
Lymph node pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thrombocytosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Lymphopenia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ear pruritus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ear swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ear discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			

subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye swelling			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Vision blurred			
subjects affected / exposed	1 / 12 (8.33%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	1 / 12 (8.33%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Abdominal pain			
subjects affected / exposed	1 / 12 (8.33%)	2 / 23 (8.70%)	0 / 3 (0.00%)
occurrences (all)	2	2	0
Abdominal pain lower			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	2 / 12 (16.67%)	5 / 23 (21.74%)	2 / 3 (66.67%)
occurrences (all)	2	7	2
Diarrhoea			
subjects affected / exposed	2 / 12 (16.67%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0

Dry mouth			
subjects affected / exposed	1 / 12 (8.33%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Flatulence			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Nausea			
subjects affected / exposed	3 / 12 (25.00%)	9 / 23 (39.13%)	0 / 3 (0.00%)
occurrences (all)	4	12	0
Toothache			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Vomiting			
subjects affected / exposed	2 / 12 (16.67%)	5 / 23 (21.74%)	0 / 3 (0.00%)
occurrences (all)	4	6	0
Abdominal pain upper			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Dyspepsia			
subjects affected / exposed	0 / 12 (0.00%)	2 / 23 (8.70%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Frequent bowel movements			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Intestinal obstruction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oesophagitis ulcerative			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Abnormal faeces			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dental caries			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Femoral hernia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Glossodynia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Inguinal hernia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal tenderness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Aphthous ulcer			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eructation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Food poisoning			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Hypoaesthesia oral			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral mucosal erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Odynophagia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Paraesthesia oral			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Oesophagitis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bile duct obstruction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			

subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 12 (0.00%)	2 / 23 (8.70%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nail bed disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Penile ulceration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash papular			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Ingrowing nail			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 12 (0.00%)	2 / 23 (8.70%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Swelling face			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Acne			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nail disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nail ridging			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain of skin			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hypotrichosis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary tract obstruction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urogenital haemorrhage			

subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Micturition frequency decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Micturition urgency			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Chromaturia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	3 / 12 (25.00%)	2 / 23 (8.70%)	1 / 3 (33.33%)
occurrences (all)	3	2	1
Flank pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mobility decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	3 / 12 (25.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	3	0	0
Groin pain			

subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Joint stiffness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Pain in extremity			
subjects affected / exposed	1 / 12 (8.33%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Arthralgia			
subjects affected / exposed	4 / 12 (33.33%)	1 / 23 (4.35%)	1 / 3 (33.33%)
occurrences (all)	4	1	1
Limb discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	3 / 12 (25.00%)	2 / 23 (8.70%)	0 / 3 (0.00%)
occurrences (all)	3	2	0
Myalgia			
subjects affected / exposed	1 / 12 (8.33%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Pain in jaw			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Spinal pain			

subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bursitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Diastasis recti abdominis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Osteoarthritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Trigger finger			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Limb mass			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Osteoporosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin candida			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Cellulitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Breast abscess			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 12 (0.00%)	2 / 23 (8.70%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Rhinitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Skin infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Tooth infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 12 (8.33%)	2 / 23 (8.70%)	0 / 3 (0.00%)
occurrences (all)	1	2	0
Campylobacter gastroenteritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	2
Laryngitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bacteraemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Diverticulitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Escherichia infection			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Folliculitis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0

Gastroenteritis viral			
subjects affected / exposed	1 / 12 (8.33%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hordeolum			
subjects affected / exposed	1 / 12 (8.33%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Otitis media			
subjects affected / exposed	1 / 12 (8.33%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Pneumonia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 12 (8.33%)	4 / 23 (17.39%)	0 / 3 (0.00%)
occurrences (all)	1	4	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	1 / 12 (8.33%)	2 / 23 (8.70%)	0 / 3 (0.00%)
occurrences (all)	2	6	0
Dehydration			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hypocalcaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 deficiency			
subjects affected / exposed	0 / 12 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hyponatraemia			

subjects affected / exposed	1 / 12 (8.33%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Hyperglycaemia			
subjects affected / exposed	0 / 12 (0.00%)	2 / 23 (8.70%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Hypermagnesaemia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hypoglycaemia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hypoproteinaemia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
09 December 2010	Reporting period for nonserious adverse events to initial dose was updated through 30 days after final dose.
05 October 2011	1-Extended PK/pharmacodynamic sampling window to 2 hours 2-Increased part 2 enrollment from 20 to 40 subjects and up to 10 subjects with confirmed PTEN loss
27 July 2012	1-Increased study enrollment from 70 to 85 subjects 2-Modified cancer types for part 2 to include ~10 subjects each with breast BRCA (deleterious or pathogenic), ovarian BRCA (including fallopian or primary peritoneal cancer, deleterious or pathogenic), SCLC, and Ewing, and ~5 subjects with prostate/pancreatic BRCA (deleterious or pathogenic) and to exclude BRCA-like tumors, PTEN-loss tumors, and other cancer types showing no response in part 1 3-Extended dose escalation during part 1 following a grade 3 adverse event to 25% to 33% 4-Combined end-of-treatment and study-follow-up visits.
06 September 2013	Increased enrollment of subjects with SCLC from ~10 to ~20
08 January 2014	1-Increased part 2 enrollment from 55 to 70 subjects

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported