Clinical trial results:
An Open-Label, Randomized Phase 3 Trial of Nivolumab, or Nivolumab Plus Ipilimumab, or Nivolumab Plus Platinum Doublet Chemotherapy Versus Platinum Doublet Chemotherapy in Subjects With Chemotherapy-Naïve Stage IV or Recurrent Non-Small Cell Lung Cancer (NSCLC)

Summary

EudraCT number	2014-003630-23
Trial protocol	ES DE NL BE IE CZ AT PL HU FI GR RO IT
Global end of trial date	25 October 2024

Results information

Result version number	v1 (current)
This version publication date	06 November 2025
First version publication date	06 November 2025

Trial information

Trial identification

Sponsor protocol code	CA209-227

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02477826
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Bristol-Myers Squibb
Sponsor organisation address	Chaussée de la Hulpe 185, Brussels, Belgium,
Public contact	Global Submission Management, Clinical Trials, Bristol-Myers Squibb International Corporation, mg-gsm-ct@bms.com
Scientific contact	Global Submission Management, Clinical Trials, Bristol-Myers Squibb International Corporation, mg-gsm-ct@bms.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	28 October 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	25 October 2024
Global end of trial reached?	Yes
Global end of trial date	25 October 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of this study is to show that Nivolumab, or Nivolumab plus Ipilimumab, or Nivolumab plus Platinum-Doublet Chemotherapy improves progression free survival and/or overall survival compared with chemotherapy in patients with advanced lung cancer.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonization Good Clinical Practice Guidelines. All the local regulatory requirements pertinent to safety of trial participants were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	05 August 2015
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	Argentina: 102
Country: Number of subjects enrolled	Australia: 105
Country: Number of subjects enrolled	Austria: 9
Country: Number of subjects enrolled	Belgium: 28
Country: Number of subjects enrolled	Brazil: 67
Country: Number of subjects enrolled	Canada: 65
Country: Number of subjects enrolled	Switzerland: 28
Country: Number of subjects enrolled	Chile: 69
Country: Number of subjects enrolled	China: 350
Country: Number of subjects enrolled	Colombia: 26
Country: Number of subjects enrolled	Czechia: 21
Country: Number of subjects enrolled	Germany: 61
Country: Number of subjects enrolled	Spain: 157
Country: Number of subjects enrolled	Finland: 13
Country: Number of subjects enrolled	France: 192
Country: Number of subjects enrolled	United Kingdom: 69
Country: Number of subjects enrolled	Greece: 48
Country: Number of subjects enrolled	Hungary: 24
Country: Number of subjects enrolled	Ireland: 25

Country: Number of subjects enrolled	Israel: 21
Country: Number of subjects enrolled	Italy: 83
Country: Number of subjects enrolled	Japan: 269
Country: Number of subjects enrolled	Korea, Republic of: 130
Country: Number of subjects enrolled	Lebanon: 8
Country: Number of subjects enrolled	Mexico: 62
Country: Number of subjects enrolled	Netherlands: 32
Country: Number of subjects enrolled	Peru: 21
Country: Number of subjects enrolled	Poland: 161
Country: Number of subjects enrolled	Romania: 236
Country: Number of subjects enrolled	Russian Federation: 54
Country: Number of subjects enrolled	Taiwan: 32
Country: Number of subjects enrolled	United States: 171
Country: Number of subjects enrolled	South Africa: 8
Worldwide total number of subjects	2747
EEA total number of subjects	1090

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)	1488
From 65 to 84 years	1253
85 years and over	6

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Participants were enrolled in 33 countries.

Period 1

Period 1 title	Pre-Treatment
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Part 1-Arm B: Nivo + Ipi

Arm description:

Participants with PD-L1 positive status Non Small Cell Lung Cancer received nivolumab 3 mg/kg IV over 30 minutes Q2W + ipilimumab 1 mg/kg over 30minutes every 6 weeks (Q6W) given for up to 24 months in the absence of disease progression or unacceptable toxicity.

Arm type	Experimental
Investigational medicinal product name	No Treatment
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Route of administration not applicable

Dosage and administration details:

No Treatment

Arm title	Part 1-Arm A: Nivolumab

Arm description:

Participants with PD-L1 positive status Non Small Cell Lung Cancer received nivolumab 240 mg intravenously (IV) over 30 minutes every 2 weeks (Q2W) given for up to 24months in the absence of disease progression or unacceptable toxicity.

Arm type	Experimental
Investigational medicinal product name	No Treatment
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Route of administration not applicable

Dosage and administration details:

No Treatment

Arm title	Part 1-Arm C: Chemotherapy

Arm description:

Participants with PD-L1 positive status Non Small Cell Lung Cancer received histology-based platinum-doublet chemotherapy IV in3-week cycles for a maximum of 4 cycles or until disease progression or unacceptable toxicity (whichever comes first). For participants with NSQ histology, pemetrexed maintenance was allowed until disease progression or unacceptable toxicity after 4 cycles of chemotherapy.

Arm type	Active comparator

Investigational medicinal product name	No Treatment
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Route of administration not applicable

Dosage and administration details:

No Treatment

Arm title	Part 1-Arm D: Nivo + Ipi

Arm description:

Participants with PD-L1 negative status Non Small Cell Lung Cancer received nivolumab 3 mg/kg IV over 30 minutes Q2W + ipilimumab 1 mg/kg over 30minutes Q6W given for up to 24 months in the absence of disease progression or unacceptable toxicity.

Arm type	Experimental
Investigational medicinal product name	No Treatment
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Route of administration not applicable

Dosage and administration details:

No Treatment

Arm title	Part 1-Arm G: Nivo + Chemo

Arm description:

Participants with PD-L1 negative status Non Small Cell Lung Cancer received nivolumab 360 mg IV over 30 minutes combined with platinum-doublet chemotherapy administered IV every 3 weeks for a maximum of 4 cycles. Participants who have not experienced disease progression were to receive nivolumab 360 mg every 3weeks until the progression of disease, discontinuation due to toxicity, or up to 24 months (whichever comes first). For subjects with NSQ histology, pemetrexed maintenance was allowed until disease progression or unacceptable toxicity after 4 cycles of chemotherapy.

Arm type	Experimental
Investigational medicinal product name	No Treatment
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Route of administration not applicable

Dosage and administration details:

No Treatment

Arm title	Part 1-Arm F: Chemotherapy

Arm description:

Participants with PD-L1 negative status Non Small Cell Lung Cancer received histology-based platinum-doublet chemotherapy IV in 3-week cycles for a maximum of 4 cycles or until disease progression or unacceptable toxicity (whichever comes first). For participants with NSQ histology, pemetrexed maintenance was allowed until disease progression or unacceptable toxicity after 4 cycles of chemotherapy.

Arm type	Active comparator
Investigational medicinal product name	No Treatment
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Route of administration not applicable

Dosage and administration details:

No Treatment

Arm title	Part 2 - Arm H: Nivolumab + Chemotherapy

Arm description:

Chemotherapy-naive participants with stage IV or recurrent NSCLC irrespective of PD-L1 expressing levels received nivolumab 360 mg IV over 30 minutes combined with platinum-doublet chemotherapy administered IV every 3 weeks for a maximum of 4 cycles. Participants who have not experienced disease progression were to receive nivolumab 360 mg every 3weeks until the progression of disease, discontinuation due to toxicity, or up to 24 months (whichever comes first). For subjects with NSQ histology, pemetrexed maintenance was allowed until disease progression or unacceptable toxicity after 4 cycles of chemotherapy.

Arm type	Experimental
Investigational medicinal product name	No Treatment
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Route of administration not applicable

Dosage and administration details:

No Treatment

Arm title	Part 2 - Arm I: Chemotherapy

Arm description:

Chemotherapy-naive participants with stage IV or recurrent NSCLC irrespective of PD-L1 expressing levels received histology-based platinum-doublet chemotherapy IV in 3-week cycles for a maximum of 4 cycles or until disease progression or unacceptable toxicity (whichever comes first). For participants with NSQ histology, pemetrexed maintenance was allowed until disease progression or unacceptable toxicity after 4 cycles of chemotherapy.

Arm type	Active comparator
Investigational medicinal product name	No Treatment
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Route of administration not applicable

Dosage and administration details:

No Treatment

Arm title	Part 3 -Arm J: Nivolumab + Ipilimumab

Arm description:

Participants in China with PD-L1 Non Small Cell Lung Cancer received nivolumab 3 mg/kg IV over 30 minutes Q2W + ipilimumab 1 mg/kg over 30minutes every 6 weeks (Q6W) given for up to 24 months in the absence of disease progression or unacceptable toxicity.

Arm type	Active comparator
Investigational medicinal product name	No Treatment
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Route of administration not applicable

Dosage and administration details:

No Treatment

Arm title	Part 3 - Arm K: Chemotherapy

Arm description:

Participants in China with PD-L1 Non Small Cell Lung Cancer received histology-based platinum-doublet chemotherapy IV in3-week cycles for a maximum of 4 cycles or until disease progression or unacceptable toxicity (whichever comes first). For participants with NSQ histology, pemetrexed maintenance was allowed until disease progression or unacceptable toxicity after 4 cycles of chemotherapy.

Arm type	Active comparator

Investigational medicinal product name	No Treatment
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Route of administration not applicable

Dosage and administration details:

No Treatment

Number of subjects in period 1	Part 1-Arm B: Nivo + Ipi	Part 1-Arm A: Nivolumab	Part 1-Arm C: Chemotherapy
Started	396	396	397
Completed	391	391	387
Not completed	5	5	10
Adverse event, serious fatal	-	-	-
Subject withdrew consent	-	-	3
Subject request to discontinue study treatment	-	1	-
Adverse events unrelated to study drug	-	1	2
Other reasons	4	1	4
Subject no longer meets study criteria	1	2	1

Number of subjects in period 1	Part 1-Arm D: Nivo + Ipi	Part 1-Arm G: Nivo + Chemo	Part 1-Arm F: Chemotherapy
Started	187	177	186
Completed	185	172	183
Not completed	2	5	3
Adverse event, serious fatal	-	-	-
Subject withdrew consent	-	-	1
Subject request to discontinue study treatment	-	-	-
Adverse events unrelated to study drug	1	-	-
Other reasons	1	4	2
Subject no longer meets study criteria	-	1	-

Number of subjects in period 1	Part 2 - Arm H: Nivolumab + Chemotherapy	Part 2 - Arm I: Chemotherapy	Part 3 -Arm J: Nivolumab + Ipilimumab
Started	377	378	126
Completed	375	371	126
Not completed	2	7	0
Adverse event, serious fatal	1	-	-
Subject withdrew consent	-	1	-
Subject request to discontinue study treatment	-	-	-
Adverse events unrelated to study drug	1	5	-

Other reasons	-	-	-
Subject no longer meets study criteria	-	1	-

Number of subjects in period 1	Part 3 - Arm K: Chemotherapy
Started	127
Completed	123
Not completed	4
Adverse event, serious fatal	-
Subject withdrew consent	3
Subject request to discontinue study treatment	1
Adverse events unrelated to study drug	-
Other reasons	-
Subject no longer meets study criteria	-

Period 2	
Period 2 title	Treatment Period
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms	
Are arms mutually exclusive?	Yes
Arm title	Part 1-Arm B: Nivo + Ipi

Arm description:

Participants with PD-L1 Non Small Cell Lung Cancer received nivolumab 3 mg/kg IV over 30 minutes Q2W + ipilimumab 1 mg/kg over 30minutes every 6 weeks (Q6W) given for up to 24 months in the absence of disease progression or unacceptable toxicity.

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

Dosage and administration details:

Administered as infusion

Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered as infusion

Arm title	Part 1-Arm A: Nivolumab

Arm description:

Participants with PD-L1 Non Small Cell Lung Cancer received nivolumab 240 mg intravenously (IV) over 30 minutes every 2 weeks (Q2W) given for up to 24months in the absence of disease progression or unacceptable toxicity.

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

Dosage and administration details:

Administered as infusion

Arm title	Part 1-Arm C: Chemotherapy

Arm description:

Participants with PD-L1 Non Small Cell Lung Cancer received histology-based platinum-doublet chemotherapy IV in3-week cycles for a maximum of 4 cycles or until disease progression or unacceptable toxicity (whichever comes first). For participants with NSQ histology, pemetrexed maintenance was allowed until disease progression or unacceptable toxicity after 4 cycles of chemotherapy.

Arm type	Active comparator
Investigational medicinal product name	Carboplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered as SOC

Investigational medicinal product name	Pemetrexed
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered as infusion.

Investigational medicinal product name	Cisplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered as infusion

Arm title	Part 1-Arm D: Nivo + Ipi

Arm description:

Participants with PD-L1 negative status Non Small Cell Lung Cancer received nivolumab 3 mg/kg IV over 30 minutes Q2W + ipilimumab 1 mg/kg over 30minutes Q6W given for up to 24 months in the absence of disease progression or unacceptable toxicity.

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

Dosage and administration details: Administered as infusion	
Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details: Administered as infusion	
Arm title	Part 1-Arm G: Nivo + Chemo

Arm description:

Participants with PD-L1 negative status Non Small Cell Lung Cancer received nivolumab 360 mg IV over 30 minutes combined with platinum-doublet chemotherapy administered IV every 3 weeks for a maximum of 4 cycles. Participants who have not experienced disease progression were to receive nivolumab 360 mg every 3weeks until the progression of disease, discontinuation due to toxicity, or up to 24 months (whichever comes first). For subjects with NSQ histology, pemetrexed maintenance was allowed until disease progression or unacceptable toxicity after 4 cycles of chemotherapy.

Arm type	Experimental
Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details: Administered as infusion	
Investigational medicinal product name	Pemetrexed
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details: Administered as infusion.	
Investigational medicinal product name	Cisplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details: Administered as infusion	
Investigational medicinal product name	Carboplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details: Administered as SOC	
Arm title	Part 1-Arm F: Chemotherapy

Arm description:

Participants with PD-L1 negative status Non Small Cell Lung Cancer received histology-based platinum-doublet chemotherapy IV in 3-week cycles for a maximum of 4 cycles or until disease progression or unacceptable toxicity (whichever comes first). For participants with NSQ histology, pemetrexed maintenance was allowed until disease progression or unacceptable toxicity after 4 cycles of chemotherapy.

Arm type	Active comparator

Investigational medicinal product name	Carboplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered as SOC

Investigational medicinal product name	Pemetrexed
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered as infusion.

Investigational medicinal product name	Cisplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered as infusion

Arm title	Part 2 - Arm H: Nivolumab + Chemotherapy

Arm description:

Chemotherapy-naive participants with stage IV or recurrent NSCLC irrespective of PD-L1 expressing levels received nivolumab 360 mg IV over 30 minutes combined with platinum-doublet chemotherapy administered IV every 3 weeks for a maximum of 4 cycles. Participants who have not experienced disease progression were to receive nivolumab 360 mg every 3weeks until the progression of disease, discontinuation due to toxicity, or up to 24 months (whichever comes first). For subjects with NSQ histology, pemetrexed maintenance was allowed until disease progression or unacceptable toxicity after 4 cycles of chemotherapy.

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

Dosage and administration details:

Administered as infusion

Investigational medicinal product name	Pemetrexed
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered as infusion.

Investigational medicinal product name	Cisplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered as infusion

Arm title	Part 2 - Arm I: Chemotherapy

Arm description:

Chemotherapy-naive participants with stage IV or recurrent NSCLC irrespective of PD-L1 expressing levels received histology-based platinum-doublet chemotherapy IV in 3-week cycles for a maximum of 4 cycles or until disease progression or unacceptable toxicity (whichever comes first). For participants with NSQ histology, pemetrexed maintenance was allowed until disease progression or unacceptable toxicity after 4 cycles of chemotherapy.

Arm type	Active comparator
Investigational medicinal product name	Carboplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered as SOC

Investigational medicinal product name	Pemetrexed
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered as infusion.

Investigational medicinal product name	Cisplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered as infusion

Arm title	Part 3 -Arm J: Nivolumab + Ipilimumab

Arm description:

Participants in China with PD-L1 Non Small Cell Lung Cancer received nivolumab 3 mg/kg IV over 30 minutes Q2W + ipilimumab 1 mg/kg over 30minutes every 6 weeks (Q6W) given for up to 24 months in the absence of disease progression or unacceptable toxicity.

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

Dosage and administration details:

Administered as infusion

Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered as infusion

Arm title	Part 3 - Arm K: Chemotherapy

Arm description:

Participants in China with PD-L1 Non Small Cell Lung Cancer received histology-based platinum-doublet chemotherapy IV in3-week cycles for a maximum of 4 cycles or until disease progression or unacceptable toxicity (whichever comes first). For participants with NSQ histology, pemetrexed maintenance was allowed until disease progression or unacceptable toxicity after 4 cycles of

chemotherapy.

Arm type	Active comparator
Investigational medicinal product name	Carboplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details: Administered as SOC	
Investigational medicinal product name	Pemetrexed
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details: Administered as infusion.	
Investigational medicinal product name	Cisplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details: Administered as infusion	

Number of subjects in period 2	Part 1-Arm B: Nivo + Ipi	Part 1-Arm A: Nivolumab	Part 1-Arm C: Chemotherapy
Started	391	391	387
Completed	45	37	94
Not completed	346	354	293
Participant request to discontinue treatment	5	3	15
Adverse event, serious fatal	4	7	-
Disease progression	212	240	202
Maximum Clinical Benefit	3	3	1
Participant withdrew Consent	5	5	3
Other reasons	5	6	12
Study Drug Toxicity	79	51	31
Participant meet no longer study criteria	1	1	-
Not reported	8	6	4
Poor/Non Compliance	1	-	2
Pregnancy	-	-	-
Unknown	-	-	-
Adverse event unrelated to study drug	23	29	22
Lost to follow-up	-	-	1

Administrative reason by sponsor	-	3	-

Number of subjects in period 2	Part 1-Arm D: Nivo + Ipi	Part 1-Arm G: Nivo + Chemo	Part 1-Arm F: Chemotherapy
Started	185	172	183
Completed	14	20	32
Not completed	171	152	151
Participant request to discontinue treatment	5	3	6
Adverse event, serious fatal	-	1	2
Disease progression	93	113	96
Maximum Clinical Benefit	1	3	-
Participant withdrew Consent	3	1	3
Other reasons	7	5	1
Study Drug Toxicity	39	12	25
Participant meet no longer study criteria	-	1	1
Not reported	4	2	1
Poor/Non Compliance	-	-	1
Pregnancy	-	-	-
Unknown	-	-	-
Adverse event unrelated to study drug	18	11	15
Lost to follow-up	1	-	-
Administrative reason by sponsor	-	-	-

Number of subjects in period 2	Part 2 - Arm H: Nivolumab + Chemotherapy	Part 2 - Arm I: Chemotherapy	Part 3 -Arm J: Nivolumab + Ipilimumab
Started	375	371	126
Completed	40	83	0
Not completed	335	288	126
Participant request to discontinue treatment	13	15	4
Adverse event, serious fatal	6	5	9
Disease progression	208	195	59
Maximum Clinical Benefit	3	2	2
Participant withdrew Consent	3	3	2
Other reasons	8	8	21
Study Drug Toxicity	52	30	20
Participant meet no longer study criteria	-	1	-
Not reported	14	8	5
Poor/Non Compliance	1	-	-
Pregnancy	-	-	-
Unknown	-	-	-

Adverse event unrelated to study drug	25	19	4
Lost to follow-up	2	2	-
Administrative reason by sponsor	-	-	-

Number of subjects in period 2	Part 3 - Arm K: Chemotherapy
Started	123
Completed	37
Not completed	86
Participant request to discontinue treatment	18
Adverse event, serious fatal	-
Disease progression	46
Maximum Clinical Benefit	2
Participant withdrew Consent	3
Other reasons	1
Study Drug Toxicity	9
Participant meet no longer study criteria	-
Not reported	2
Poor/Non Compliance	1
Pregnancy	1
Unknown	1
Adverse event unrelated to study drug	2
Lost to follow-up	-
Administrative reason by sponsor	-

Reporting groups

Reporting group title	Part 1-Arm B: Nivo + Ipi

Reporting group description:

Participants with PD-L1 positive status Non Small Cell Lung Cancer received nivolumab 3 mg/kg IV over 30 minutes Q2W + ipilimumab 1 mg/kg over 30minutes every 6 weeks (Q6W) given for up to 24 months in the absence of disease progression or unacceptable toxicity.

Reporting group title	Part 1-Arm A: Nivolumab

Reporting group description:

Participants with PD-L1 positive status Non Small Cell Lung Cancer received nivolumab 240 mg intravenously (IV) over 30 minutes every 2 weeks (Q2W) given for up to 24months in the absence of disease progression or unacceptable toxicity.

Reporting group title	Part 1-Arm C: Chemotherapy

Reporting group description:

Participants with PD-L1 positive status Non Small Cell Lung Cancer received histology-based platinum-doublet chemotherapy IV in3-week cycles for a maximum of 4 cycles or until disease progression or unacceptable toxicity (whichever comes first). For participants with NSQ histology, pemetrexed maintenance was allowed until disease progression or unacceptable toxicity after 4 cycles of chemotherapy.

Reporting group title	Part 1-Arm D: Nivo + Ipi

Reporting group description:

Participants with PD-L1 negative status Non Small Cell Lung Cancer received nivolumab 3 mg/kg IV over 30 minutes Q2W + ipilimumab 1 mg/kg over 30minutes Q6W given for up to 24 months in the absence of disease progression or unacceptable toxicity.

Reporting group title	Part 1-Arm G: Nivo + Chemo

Reporting group description:

Participants with PD-L1 negative status Non Small Cell Lung Cancer received nivolumab 360 mg IV over 30 minutes combined with platinum-doublet chemotherapy administered IV every 3 weeks for a maximum of 4 cycles. Participants who have not experienced disease progression were to receive nivolumab 360 mg every 3weeks until the progression of disease, discontinuation due to toxicity, or up to 24 months (whichever comes first). For subjects with NSQ histology, pemetrexed maintenance was allowed until disease progression or unacceptable toxicity after 4 cycles of chemotherapy.

Reporting group title	Part 1-Arm F: Chemotherapy

Reporting group description:

Participants with PD-L1 negative status Non Small Cell Lung Cancer received histology-based platinum-doublet chemotherapy IV in 3-week cycles for a maximum of 4 cycles or until disease progression or unacceptable toxicity (whichever comes first). For participants with NSQ histology, pemetrexed maintenance was allowed until disease progression or unacceptable toxicity after 4 cycles of chemotherapy.

Reporting group title	Part 2 - Arm H: Nivolumab + Chemotherapy

Reporting group description:

Chemotherapy-naive participants with stage IV or recurrent NSCLC irrespective of PD-L1 expressing levels received nivolumab 360 mg IV over 30 minutes combined with platinum-doublet chemotherapy administered IV every 3 weeks for a maximum of 4 cycles. Participants who have not experienced disease progression were to receive nivolumab 360 mg every 3weeks until the progression of disease, discontinuation due to toxicity, or up to 24 months (whichever comes first). For subjects with NSQ histology, pemetrexed maintenance was allowed until disease progression or unacceptable toxicity after 4 cycles of chemotherapy.

Reporting group title	Part 2 - Arm I: Chemotherapy

Reporting group description:

Chemotherapy-naive participants with stage IV or recurrent NSCLC irrespective of PD-L1 expressing levels received histology-based platinum-doublet chemotherapy IV in 3-week cycles for a maximum of 4 cycles or until disease progression or unacceptable toxicity (whichever comes first). For participants with NSQ histology, pemetrexed maintenance was allowed until disease progression or unacceptable toxicity after 4 cycles of chemotherapy.

Reporting group title	Part 3 -Arm J: Nivolumab + Ipilimumab

Reporting group description:

Participants in China with PD-L1 Non Small Cell Lung Cancer received nivolumab 3 mg/kg IV over 30

minutes Q2W + ipilimumab 1 mg/kg over 30minutes every 6 weeks (Q6W) given for up to 24 months in the absence of disease progression or unacceptable toxicity.

Reporting group title	Part 3 - Arm K: Chemotherapy

Reporting group description:

Participants in China with PD-L1 Non Small Cell Lung Cancer received histology-based platinum-doublet chemotherapy IV in3-week cycles for a maximum of 4 cycles or until disease progression or unacceptable toxicity (whichever comes first). For participants with NSQ histology, pemetrexed maintenance was allowed until disease progression or unacceptable toxicity after 4 cycles of chemotherapy.

Reporting group values	Part 1-Arm B: Nivo + Ipi	Part 1-Arm A: Nivolumab	Part 1-Arm C: Chemotherapy
Number of subjects	396	396	397
Age Categorical Units: participants			
< 65	199	210	207
=>65	197	186	190
Age continuous Units: years			
arithmetic mean	62.9	63.5	63.4
standard deviation	± 9.70	± 9.71	± 9.22
Sex: Female, Male Units: participants			
Female	141	124	137
Male	255	272	260
Race/Ethnicity, Customized Units: Subjects			
White	299	317	305
Black	4	6	5
Asian	84	67	82
Other	5	6	3
American Indian or Alaska Native	4	0	2
Native Hawaiian or other pacific islander	0	0	0
Not Reported	0	0	0

Reporting group values	Part 1-Arm D: Nivo + Ipi	Part 1-Arm G: Nivo + Chemo	Part 1-Arm F: Chemotherapy
Number of subjects	187	177	186
Age Categorical Units: participants			
< 65	107	91	98
=>65	80	86	88
Age continuous Units: years			
arithmetic mean	63.1	63.1	63.3
standard deviation	± 9.51	± 9.58	± 8.73
Sex: Female, Male Units: participants			
Female	49	47	61
Male	138	130	125

Race/Ethnicity, Customized Units: Subjects			
White	143	136	133
Black	0	2	2
Asian	41	38	45
Other	1	1	5
American Indian or Alaska Native	2	0	1
Native Hawaiian or other pacific islander	0	0	0
Not Reported	0	0	0

Reporting group values	Part 2 - Arm H: Nivolumab + Chemotherapy	Part 2 - Arm I: Chemotherapy	Part 3 -Arm J: Nivolumab + Ipilimumab
Number of subjects	377	378	126
Age Categorical Units: participants			
< 65	214	196	82
=>65	163	182	44
Age continuous Units: years			
arithmetic mean	62.4	62.5	61.3
standard deviation	± 9.84	± 9.53	± 7.6
Sex: Female, Male Units: participants			
Female	113	115	18
Male	264	263	108
Race/Ethnicity, Customized Units: Subjects			
White	272	266	0
Black	1	3	0
Asian	93	94	126
Other	8	12	0
American Indian or Alaska Native	3	1	0
Native Hawaiian or other pacific islander	0	1	0
Not Reported	0	1	0

Reporting group values	Part 3 - Arm K: Chemotherapy	Total	
Number of subjects	127	2747	
Age Categorical Units: participants			
< 65	84	1488	
=>65	43	1259	
Age continuous Units: years			
arithmetic mean	61.2		
standard deviation	± 8.7	-	
Sex: Female, Male Units: participants			
Female	20	825	
Male	107	1922	

Race/Ethnicity, Customized Units: Subjects			
White	0	1871	
Black	0	23	
Asian	127	797	
Other	0	41	
American Indian or Alaska Native	0	13	
Native Hawaiian or other pacific islander	0	1	
Not Reported	0	1	

End points

End points reporting groups

Reporting group title	Part 1-Arm B: Nivo + Ipi
Reporting group description:	
Participants with PD-L1 positive status Non Small Cell Lung Cancer received nivolumab 3 mg/kg IV over 30 minutes Q2W + ipilimumab 1 mg/kg over 30minutes every 6 weeks (Q6W) given for up to 24 months in the absence of disease progression or unacceptable toxicity.	
Reporting group title	Part 1-Arm A: Nivolumab
Reporting group description:	
Participants with PD-L1 positive status Non Small Cell Lung Cancer received nivolumab 240 mg intravenously (IV) over 30 minutes every 2 weeks (Q2W) given for up to 24months in the absence of disease progression or unacceptable toxicity.	
Reporting group title	Part 1-Arm C: Chemotherapy
Reporting group description:	
Participants with PD-L1 positive status Non Small Cell Lung Cancer received histology-based platinum-doublet chemotherapy IV in3-week cycles for a maximum of 4 cycles or until disease progression or unacceptable toxicity (whichever comes first). For participants with NSQ histology, pemetrexed maintenance was allowed until disease progression or unacceptable toxicity after 4 cycles of chemotherapy.	
Reporting group title	Part 1-Arm D: Nivo + Ipi
Reporting group description:	
Participants with PD-L1 negative status Non Small Cell Lung Cancer received nivolumab 3 mg/kg IV over 30 minutes Q2W + ipilimumab 1 mg/kg over 30minutes Q6W given for up to 24 months in the absence of disease progression or unacceptable toxicity.	
Reporting group title	Part 1-Arm G: Nivo + Chemo
Reporting group description:	
Participants with PD-L1 negative status Non Small Cell Lung Cancer received nivolumab 360 mg IV over 30 minutes combined with platinum-doublet chemotherapy administered IV every 3 weeks for a maximum of 4 cycles. Participants who have not experienced disease progression were to receive nivolumab 360 mg every 3weeks until the progression of disease, discontinuation due to toxicity, or up to 24 months (whichever comes first). For subjects with NSQ histology, pemetrexed maintenance was allowed until disease progression or unacceptable toxicity after 4 cycles of chemotherapy.	
Reporting group title	Part 1-Arm F: Chemotherapy
Reporting group description:	
Participants with PD-L1 negative status Non Small Cell Lung Cancer received histology-based platinum-doublet chemotherapy IV in 3-week cycles for a maximum of 4 cycles or until disease progression or unacceptable toxicity (whichever comes first). For participants with NSQ histology, pemetrexed maintenance was allowed until disease progression or unacceptable toxicity after 4 cycles of chemotherapy.	
Reporting group title	Part 2 - Arm H: Nivolumab + Chemotherapy
Reporting group description:	
Chemotherapy-naive participants with stage IV or recurrent NSCLC irrespective of PD-L1 expressing levels received nivolumab 360 mg IV over 30 minutes combined with platinum-doublet chemotherapy administered IV every 3 weeks for a maximum of 4 cycles. Participants who have not experienced disease progression were to receive nivolumab 360 mg every 3weeks until the progression of disease, discontinuation due to toxicity, or up to 24 months (whichever comes first). For subjects with NSQ histology, pemetrexed maintenance was allowed until disease progression or unacceptable toxicity after 4 cycles of chemotherapy.	
Reporting group title	Part 2 - Arm I: Chemotherapy
Reporting group description:	
Chemotherapy-naive participants with stage IV or recurrent NSCLC irrespective of PD-L1 expressing levels received histology-based platinum-doublet chemotherapy IV in 3-week cycles for a maximum of 4 cycles or until disease progression or unacceptable toxicity (whichever comes first). For participants with NSQ histology, pemetrexed maintenance was allowed until disease progression or unacceptable toxicity after 4 cycles of chemotherapy.	
Reporting group title	Part 3 -Arm J: Nivolumab + Ipilimumab
Reporting group description:	
Participants in China with PD-L1 Non Small Cell Lung Cancer received nivolumab 3 mg/kg IV over 30	

minutes Q2W + ipilimumab 1 mg/kg over 30minutes every 6 weeks (Q6W) given for up to 24 months in the absence of disease progression or unacceptable toxicity.

Reporting group title	Part 3 - Arm K: Chemotherapy

Reporting group description:

Participants in China with PD-L1 Non Small Cell Lung Cancer received histology-based platinum-doublet chemotherapy IV in3-week cycles for a maximum of 4 cycles or until disease progression or unacceptable toxicity (whichever comes first). For participants with NSQ histology, pemetrexed maintenance was allowed until disease progression or unacceptable toxicity after 4 cycles of chemotherapy.

Reporting group title	Part 1-Arm B: Nivo + Ipi

Reporting group description:

Participants with PD-L1 Non Small Cell Lung Cancer received nivolumab 3 mg/kg IV over 30 minutes Q2W + ipilimumab 1 mg/kg over 30minutes every 6 weeks (Q6W) given for up to 24 months in the absence of disease progression or unacceptable toxicity.

Reporting group title	Part 1-Arm A: Nivolumab

Reporting group description:

Participants with PD-L1 Non Small Cell Lung Cancer received nivolumab 240 mg intravenously (IV) over 30 minutes every 2 weeks (Q2W) given for up to 24months in the absence of disease progression or unacceptable toxicity.

Reporting group title	Part 1-Arm C: Chemotherapy

Reporting group description:

Participants with PD-L1 Non Small Cell Lung Cancer received histology-based platinum-doublet chemotherapy IV in3-week cycles for a maximum of 4 cycles or until disease progression or unacceptable toxicity (whichever comes first). For participants with NSQ histology, pemetrexed maintenance was allowed until disease progression or unacceptable toxicity after 4 cycles of chemotherapy.

Reporting group title	Part 1-Arm D: Nivo + Ipi

Reporting group description:

Participants with PD-L1 negative status Non Small Cell Lung Cancer received nivolumab 3 mg/kg IV over 30 minutes Q2W + ipilimumab 1 mg/kg over 30minutes Q6W given for up to 24 months in the absence of disease progression or unacceptable toxicity.

Reporting group title	Part 1-Arm G: Nivo + Chemo

Reporting group description:

Participants with PD-L1 negative status Non Small Cell Lung Cancer received nivolumab 360 mg IV over 30 minutes combined with platinum-doublet chemotherapy administered IV every 3 weeks for a maximum of 4 cycles. Participants who have not experienced disease progression were to receive nivolumab 360 mg every 3weeks until the progression of disease, discontinuation due to toxicity, or up to 24 months (whichever comes first). For subjects with NSQ histology, pemetrexed maintenance was allowed until disease progression or unacceptable toxicity after 4 cycles of chemotherapy.

Reporting group title	Part 1-Arm F: Chemotherapy

Reporting group description:

Participants with PD-L1 negative status Non Small Cell Lung Cancer received histology-based platinum-doublet chemotherapy IV in 3-week cycles for a maximum of 4 cycles or until disease progression or unacceptable toxicity (whichever comes first). For participants with NSQ histology, pemetrexed maintenance was allowed until disease progression or unacceptable toxicity after 4 cycles of chemotherapy.

Reporting group title	Part 2 - Arm H: Nivolumab + Chemotherapy

Reporting group description:

Chemotherapy-naive participants with stage IV or recurrent NSCLC irrespective of PD-L1 expressing levels received nivolumab 360 mg IV over 30 minutes combined with platinum-doublet chemotherapy administered IV every 3 weeks for a maximum of 4 cycles. Participants who have not experienced disease progression were to receive nivolumab 360 mg every 3weeks until the progression of disease, discontinuation due to toxicity, or up to 24 months (whichever comes first). For subjects with NSQ histology, pemetrexed maintenance was allowed until disease progression or unacceptable toxicity after 4 cycles of chemotherapy.

Reporting group title	Part 2 - Arm I: Chemotherapy

Reporting group description:

Chemotherapy-naive participants with stage IV or recurrent NSCLC irrespective of PD-L1 expressing levels received histology-based platinum-doublet chemotherapy IV in 3-week cycles for a maximum of 4 cycles or until disease progression or unacceptable toxicity (whichever comes first). For participants with NSQ histology, pemetrexed maintenance was allowed until disease progression or unacceptable toxicity

after 4 cycles of chemotherapy.

Reporting group title	Part 3 -Arm J: Nivolumab + Ipilimumab

Reporting group description:

Participants in China with PD-L1 Non Small Cell Lung Cancer received nivolumab 3 mg/kg IV over 30 minutes Q2W + ipilimumab 1 mg/kg over 30minutes every 6 weeks (Q6W) given for up to 24 months in the absence of disease progression or unacceptable toxicity.

Reporting group title	Part 3 - Arm K: Chemotherapy

Reporting group description:

Participants in China with PD-L1 Non Small Cell Lung Cancer received histology-based platinum-doublet chemotherapy IV in3-week cycles for a maximum of 4 cycles or until disease progression or unacceptable toxicity (whichever comes first). For participants with NSQ histology, pemetrexed maintenance was allowed until disease progression or unacceptable toxicity after 4 cycles of chemotherapy.

Primary: Progression-Free Survival per BICR

End point title	Progression-Free Survival per BICR

End point description:

Progression-Free Survival then (PFS) is defined as the time between the date of randomization and the date of first documented disease progression, based on BICR assessments (per RECIST v1.1), or death due to any cause, whichever occurs first based on Kaplan-Meier estimates. Progressive Disease (PD): At least a 20% increase in the sum of diameters of target lesions, taking as reference the smallest sum during the study (this includes the baseline sum if that is the smallest on study). In addition to the relative increase of 20%, the sum must also demonstrate an absolute increase of at least 5 mm.

End point type	Primary

End point timeframe:

From randomization untill disease progression or death, whichever occurs first (up to approximately 481 weeks)

End point values	Part 1-Arm B: Nivo + Ipi	Part 1-Arm A: Nivolumab	Part 1-Arm C: Chemotherapy	Part 1-Arm D: Nivo + Ipi
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	396	396	397	187
Units: months				
median (confidence interval 95%)	5.06 (4.07 to 6.31)	4.17 (3.22 to 5.32)	5.55 (4.63 to 5.82)	4.90 (3.15 to 6.28)

End point values	Part 1-Arm G: Nivo + Chemo	Part 1-Arm F: Chemotherapy	Part 2 - Arm H: Nivolumab + Chemotherapy	Part 2 - Arm I: Chemotherapy
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	177	186	377	378
Units: months				
median (confidence interval 95%)	5.55 (4.63 to 6.90)	4.70 (4.21 to 5.59)	8.34 (7.10 to 9.59)	5.52 (4.47 to 5.85)

End point values	Part 3 -Arm J: Nivolumab +	Part 3 - Arm K: Chemotherapy		

	Ipilimumab			
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	126	127		
Units: months				
median (confidence interval 95%)	5.78 (4.14 to 8.34)	5.49 (4.37 to 6.77)		

Statistical analyses

Statistical analysis title	Statistical Analysis 2
Comparison groups	Part 1-Arm A: Nivolumab v Part 1-Arm C: Chemotherapy
Number of subjects included in analysis	793
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Hazard ratio (HR)
Point estimate	0.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.12

Statistical analysis title	Statistical Analysis 1
Comparison groups	Part 1-Arm B: Nivo + Ipi v Part 1-Arm C: Chemotherapy
Number of subjects included in analysis	793
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Hazard ratio (HR)
Point estimate	0.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.67
upper limit	0.93

Statistical analysis title	Statistical Analysis 5
Comparison groups	Part 1-Arm F: Chemotherapy v Part 1-Arm G: Nivo + Chemo
Number of subjects included in analysis	363
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Hazard ratio (HR)
Point estimate	0.74

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.59
upper limit	0.93

Statistical analysis title	Statistical Analysis 7
Comparison groups	Part 2 - Arm H: Nivolumab + Chemotherapy v Part 2 - Arm I: Chemotherapy
Number of subjects included in analysis	755
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Hazard ratio (HR)
Point estimate	0.61
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.52
upper limit	0.72

Statistical analysis title	Statistical Analysis 7
Comparison groups	Part 3 -Arm J: Nivolumab + Ipilimumab v Part 3 - Arm K: Chemotherapy
Number of subjects included in analysis	253
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Hazard ratio (HR)
Point estimate	0.66
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.49
upper limit	0.89

Statistical analysis title	Statistical Analysis 3
Comparison groups	Part 1-Arm B: Nivo + Ipi v Part 1-Arm A: Nivolumab
Number of subjects included in analysis	792
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Hazard ratio (HR)
Point estimate	0.85

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.72
upper limit	0.99

Statistical analysis title	Statistical Analysis 4
Comparison groups	Part 1-Arm D: Nivo + Ipi v Part 1-Arm F: Chemotherapy
Number of subjects included in analysis	373
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Cox proportional hazard
Point estimate	0.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.6
upper limit	0.97

Primary: Overall Survival

End point title	Overall Survival

End point description:

OS for all randomized participants is the time between randomization date and the date of death from any cause.

End point type	Primary

End point timeframe:

From randomization untill death or last follow up whichever occurs first (up to approximately 481 weeks)

End point values	Part 1-Arm B: Nivo + Ipi	Part 1-Arm A: Nivolumab	Part 1-Arm C: Chemotherapy	Part 1-Arm D: Nivo + Ipi
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	396	396	397	187
Units: months				
median (confidence interval 95%)	17.12 (14.95 to 20.17)	15.70 (13.27 to 18.14)	14.88 (12.71 to 16.72)	17.45 (13.21 to 22.05)

End point values	Part 1-Arm G: Nivo + Chemo	Part 1-Arm F: Chemotherapy	Part 2 - Arm H: Nivolumab + Chemotherapy	Part 2 - Arm I: Chemotherapy
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	177	186	377	378
Units: months				

median (confidence interval 95%)	15.21 (12.29 to 19.78)	12.19 (9.17 to 14.32)	18.27 (15.84 to 21.65)	14.72 (12.42 to 16.79)

End point values	Part 3 -Arm J: Nivolumab + Ipilimumab	Part 3 - Arm K: Chemotherapy		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	126	127		
Units: months				
median (confidence interval 95%)	20.99 (16.95 to 25.17)	15.11 (13.17 to 18.89)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Part 1-Arm B: Nivo + Ipi v Part 1-Arm C: Chemotherapy
Number of subjects included in analysis	793
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Hazard ratio (HR)
Point estimate	0.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.67
upper limit	0.91

Statistical analysis title	Statistical Analysis 2
Comparison groups	Part 1-Arm A: Nivolumab v Part 1-Arm C: Chemotherapy
Number of subjects included in analysis	793
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Hazard ratio (HR)
Point estimate	0.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.78
upper limit	1.05

Statistical analysis title	Statistical Analysis 3
Comparison groups	Part 1-Arm B: Nivo + Ipi v Part 1-Arm A: Nivolumab

Number of subjects included in analysis	792
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Hazard ratio (HR)
Point estimate	0.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.74
upper limit	1.01

Statistical analysis title	Statistical Analysis 7
Comparison groups	Part 3 -Arm J: Nivolumab + Ipilimumab v Part 3 - Arm K: Chemotherapy
Number of subjects included in analysis	253
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Hazard ratio (HR)
Point estimate	0.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.64
upper limit	1.14

Statistical analysis title	Statistical Analysis 5
Comparison groups	Part 1-Arm G: Nivo + Chemo v Part 1-Arm F: Chemotherapy
Number of subjects included in analysis	363
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Hazard ratio (HR)
Point estimate	0.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.63
upper limit	0.96

Statistical analysis title	Statistical Analysis 6
Comparison groups	Part 2 - Arm H: Nivolumab + Chemotherapy v Part 2 - Arm I: Chemotherapy

Number of subjects included in analysis	755
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Hazard ratio (HR)
Point estimate	0.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.64
upper limit	0.87

Statistical analysis title	Statistical Analysis 4
Comparison groups	Part 1-Arm D: Nivo + Ipi v Part 1-Arm F: Chemotherapy
Number of subjects included in analysis	373
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Hazard ratio (HR)
Point estimate	0.64
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.51
upper limit	0.79

Secondary: Objective Response Rate (ORR) per BICR

End point title	Objective Response Rate (ORR) per BICR

End point description:

Objective response rate (ORR) is defined as the number of participants who achieve a best overall response (BOR) of confirmed complete response (CR) or confirmed partial response (PR), based on blinded independent central review (BICR) assessments using Response Evaluation Criteria in Solid Tumors (RECIST 1.1), divided by the number of all randomized participants.

Complete Response (CR): Disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to \< 10 mm.

Partial Response (PR): At least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters.

End point type	Secondary

End point timeframe:

From randomization untill disease progression or death, whichever occurs first (up to approximately 481 weeks)

End point values	Part 1-Arm B: Nivo + Ipi	Part 1-Arm A: Nivolumab	Part 1-Arm C: Chemotherapy	Part 1-Arm D: Nivo + Ipi
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	396	396	397	187
Units: percentage of participants				
number (confidence interval 95%)	36.4 (31.6 to 41.3)	27.5 (23.2 to 32.2)	29.7 (25.3 to 34.5)	26.2 (20.1 to 33.1)

End point values	Part 1-Arm G: Nivo + Chemo	Part 1-Arm F: Chemotherapy	Part 2 - Arm H: Nivolumab + Chemotherapy	Part 2 - Arm I: Chemotherapy
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	177	186	377	378
Units: percentage of participants				
number (confidence interval 95%)	37.9 (30.7 to 45.4)	23.1 (17.3 to 29.8)	52.3 (47.1 to 57.4)	29.9 (25.3 to 34.8)

End point values	Part 3 -Arm J: Nivolumab + Ipilimumab	Part 3 - Arm K: Chemotherapy		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	126	127		
Units: percentage of participants				
number (confidence interval 95%)	38.1 (29.6 to 47.2)	30.7 (22.8 to 39.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Symptom Deterioration at Week 12 assessed via Lung Cancer Symptom Scale

End point title	Percentage of Participants with Symptom Deterioration at Week 12 assessed via Lung Cancer Symptom Scale

End point description:

The Lung Cancer Symptom Scale (LCSS) is a disease measure of quality of life which evaluates six major lung cancer symptoms and their effect on overall distress and symptom severity, impact on day-to-day activities, and overall quality of life. This patient reported outcome (PRO) questionnaire assesses the following 6 symptoms items (appetite loss, fatigue, cough, dyspnea, hemoptysis, pain) and 3 summary global items (symptom distress, activity level, overall quality of life) for patients using visual analogue scales (VAS) (100 mm horizontal line) ranging from 0 (best rating) to 100 (worst rating). The LCSS average total score is sum of items 1 to 9 divided by the total number of items ((sum of items 1 to 9)/9) ranging from 0 to 100 where high score represent worst outcome. Disease-Related Symptom Deterioration by Week 12 defined as a 10 points or more increase from baseline in LCSS average score at any time (on or off-treatment) up to 95 days from randomization date.

End point type	Secondary

End point timeframe:

Week 12

End point values	Part 1-Arm B: Nivo + Ipi	Part 1-Arm A: Nivolumab	Part 1-Arm C: Chemotherapy	Part 1-Arm D: Nivo + Ipi
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	396	396	397	187
Units: percentage of participants				
number (confidence interval 95%)	31.3 (26.8 to 36.1)	35.4 (30.6 to 40.3)	25.7 (21.5 to 30.3)	33.2 (26.5 to 40.4)

End point values	Part 1-Arm G: Nivo + Chemo	Part 1-Arm F: Chemotherapy	Part 2 - Arm H: Nivolumab + Chemotherapy	Part 2 - Arm I: Chemotherapy
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	177	186	377	378
Units: percentage of participants				
number (confidence interval 95%)	28.8 (22.3 to 36.1)	37.6 (30.7 to 45.0)	30.0 (25.4 to 34.9)	24.3 (20.1 to 29.0)

End point values	Part 3 -Arm J: Nivolumab + Ipilimumab	Part 3 - Arm K: Chemotherapy		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	126	127		
Units: percentage of participants				
number (confidence interval 95%)	23.0 (16.0 to 31.4)	26.0 (18.6 to 34.5)		

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

Serious and non-serious adverse events were collected from first dose (Day 1) and 30 days after last dose of study therapy (up to approximately 105 months) and all cause mortality was collected from Day 1 and up to 481 weeks.

Adverse event reporting additional description:

All treated participants

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	27.0

Reporting groups

Reporting group title	Part 1-Arm A: Nivolumab

Reporting group description:

Participants with PD-L1 positive status Non Small Cell Lung Cancer received nivolumab 240 mg intravenously (IV) over 30 minutes every 2 weeks (Q2W) given for up to 24months in the absence of disease progression or unacceptable toxicity.

Reporting group title	Part 1-Arm B: Nivo + Ipi

Reporting group description:

Participants with PD-L1 positive status Non Small Cell Lung Cancer received nivolumab 3 mg/kg IV over 30 minutes Q2W + ipilimumab 1 mg/kg over 30minutes every 6 weeks (Q6W) given for up to 24 months in the absence of disease progression or unacceptable toxicity.

Reporting group title	Part 1-Arm D: Nivo + Ipi

Reporting group description:

Participants with PD-L1 negative status Non Small Cell Lung Cancer received nivolumab 3 mg/kg IV over 30 minutes Q2W + ipilimumab 1 mg/kg over 30minutes Q6W given for up to 24 months in the absence of disease progression or unacceptable toxicity.

Reporting group title	Part 1-Arm C: Chemotherapy

Reporting group description:

Participants with PD-L1 positive status Non Small Cell Lung Cancer received histology-based platinum-doublet chemotherapy IV in3-week cycles for a maximum of 4 cycles or until disease progression or unacceptable toxicity (whichever comes first). For participants with NSQ histology, pemetrexed maintenance was allowed until disease progression or unacceptable toxicity after 4 cycles of chemotherapy.

Reporting group title	Part 1-Arm G: Nivo + Chemo

Reporting group description:

Participants with PD-L1 negative status Non Small Cell Lung Cancer received nivolumab 360 mg IV over 30 minutes combined with platinum-doublet chemotherapy administered IV every 3 weeks for a maximum of 4 cycles. Participants who have not experienced disease progression were to receive nivolumab 360 mg every 3weeks until the progression of disease, discontinuation due to toxicity, or up to 24 months (whichever comes first). For subjects with NSQ histology, pemetrexed maintenance was allowed until disease progression or unacceptable toxicity after 4 cycles of chemotherapy.

Reporting group title	Part 1-Arm F: Chemotherapy

Reporting group description:

Participants with PD-L1 negative status Non Small Cell Lung Cancer received histology-based platinum-doublet chemotherapy IV in 3-week cycles for a maximum of 4 cycles or until disease progression or unacceptable toxicity (whichever comes first). For participants with NSQ histology, pemetrexed maintenance was allowed until disease progression or unacceptable toxicity after 4 cycles of chemotherapy.

Reporting group title	Part 2 - Arm H: Nivolumab + Chemotherapy

Reporting group description:

Chemotherapy-naive participants with stage IV or recurrent NSCLC irrespective of PD-L1 expressing levels received nivolumab 360 mg IV over 30 minutes combined with platinum-doublet chemotherapy administered IV every 3 weeks for a maximum of 4 cycles. Participants who have not experienced disease progression were to receive nivolumab 360 mg every 3weeks until the progression of disease,

discontinuation due to toxicity, or up to 24 months (whichever comes first). For subjects with NSQ histology, pemetrexed maintenance was allowed until disease progression or unacceptable toxicity after 4 cycles of chemotherapy.

Reporting group title	Part 2 - Arm I: Chemotherapy

Reporting group description:

Chemotherapy-naive participants with stage IV or recurrent NSCLC irrespective of PD-L1 expressing levels received histology-based platinum-doublet chemotherapy IV in 3-week cycles for a maximum of 4 cycles or until disease progression or unacceptable toxicity (whichever comes first). For participants with NSQ histology, pemetrexed maintenance was allowed until disease progression or unacceptable toxicity after 4 cycles of chemotherapy.

Reporting group title	Part 3 -Arm J: Nivolumab + Ipilimumab

Reporting group description:

Participants in China with PD-L1 Non Small Cell Lung Cancer received nivolumab 3 mg/kg IV over 30 minutes Q2W + ipilimumab 1 mg/kg over 30minutes every 6 weeks (Q6W) given for up to 24 months in the absence of disease progression or unacceptable toxicity.

Reporting group title	Part 3 - Arm K: Chemotherapy

Reporting group description:

Participants in China with PD-L1 Non Small Cell Lung Cancer received histology-based platinum-doublet chemotherapy IV in3-week cycles for a maximum of 4 cycles or until disease progression or unacceptable toxicity (whichever comes first). For participants with NSQ histology, pemetrexed maintenance was allowed until disease progression or unacceptable toxicity after 4 cycles of chemotherapy.

Serious adverse events	Part 1-Arm A: Nivolumab	Part 1-Arm B: Nivo + Ipi	Part 1-Arm D: Nivo + Ipi
Total subjects affected by serious adverse events			
subjects affected / exposed	239 / 391 (61.13%)	275 / 391 (70.33%)	128 / 185 (69.19%)
number of deaths (all causes)	333	316	159
number of deaths resulting from adverse events	114	115	44
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma gastric			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenocarcinoma of colon			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute leukaemia			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal cell carcinoma			

subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Benign breast neoplasm			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder transitional cell carcinoma			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
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	3 / 391 (0.77%)	5 / 391 (1.28%)	3 / 185 (1.62%)
occurrences causally related to treatment / all	0 / 4	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cholangiocarcinoma			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon cancer			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Chronic myeloid leukaemia			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Extranodal marginal zone B-cell lymphoma (MALT type)			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemangioma			

subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric neoplasm			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Female reproductive neoplasm			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematological malignancy			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic cancer			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary cancer			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected neoplasm			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
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 adenocarcinoma			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Intestinal metastasis			

subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung neoplasm malignant			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
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 cancer metastatic			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Lung adenocarcinoma			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphangiosis carcinomatosa			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	2 / 185 (1.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to meninges			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
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 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
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 bone			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Metastases to adrenals			

subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm progression			
subjects affected / exposed	102 / 391 (26.09%)	98 / 391 (25.06%)	39 / 185 (21.08%)
occurrences causally related to treatment / all	0 / 114	0 / 105	0 / 43
deaths causally related to treatment / all	0 / 81	0 / 80	0 / 29
Metastases to pleura			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraneoplastic syndrome			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oncologic complication			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm progression			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Neoplasm malignant			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastasis			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			

subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Tumour associated fever			
subjects affected / exposed	1 / 391 (0.26%)	1 / 391 (0.26%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour compression			
subjects affected / exposed	2 / 391 (0.51%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Tumour invasion			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
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 pseudoprogression			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			
subjects affected / exposed	2 / 391 (0.51%)	2 / 391 (0.51%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour necrosis			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
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			
Arterial thrombosis			

subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic thrombosis			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteritis			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Extremity necrosis			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	3 / 391 (0.77%)	2 / 391 (0.51%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Deep vein thrombosis			
subjects affected / exposed	2 / 391 (0.51%)	2 / 391 (0.51%)	2 / 185 (1.08%)
occurrences causally related to treatment / all	0 / 2	0 / 2	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Circulatory collapse			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematoma			
subjects affected / exposed	2 / 391 (0.51%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemic shock			

subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Hypertensive crisis			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Hypertension			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Infarction			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Peripheral embolism			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery stenosis			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Peripheral arterial occlusive disease			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic hypotension			

subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral ischaemia			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Subclavian vein thrombosis			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superficial vein thrombosis			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior vena cava occlusion			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior vena cava syndrome			
subjects affected / exposed	2 / 391 (0.51%)	2 / 391 (0.51%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombosis			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Vasculitis			

subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vena cava thrombosis			
subjects affected / exposed	0 / 391 (0.00%)	2 / 391 (0.51%)	0 / 185 (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
Venous thrombosis			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous thrombosis limb			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Pregnancy, puerperium and perinatal conditions			
Pregnancy			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	4 / 391 (1.02%)	3 / 391 (0.77%)	5 / 185 (2.70%)
occurrences causally related to treatment / all	0 / 4	1 / 3	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Adverse drug reaction			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	2 / 391 (0.51%)	1 / 391 (0.26%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 1

Complication associated with device			
subjects affected / exposed	1 / 391 (0.26%)	1 / 391 (0.26%)	0 / 185 (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
Chills			
subjects affected / exposed	1 / 391 (0.26%)	1 / 391 (0.26%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Drug withdrawal syndrome			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest discomfort			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	3 / 391 (0.77%)	3 / 391 (0.77%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	1 / 3	1 / 3	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Face oedema			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
General physical health deterioration			
subjects affected / exposed	4 / 391 (1.02%)	0 / 391 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthermia			

subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Generalised oedema			
subjects affected / exposed	2 / 391 (0.51%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Mucosal inflammation			
subjects affected / exposed	3 / 391 (0.77%)	0 / 391 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza like illness			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inflammation			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypothermia			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	5 / 391 (1.28%)	5 / 391 (1.28%)	3 / 185 (1.62%)
occurrences causally related to treatment / all	1 / 5	2 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Performance status decreased			

subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Sudden death			
subjects affected / exposed	5 / 391 (1.28%)	3 / 391 (0.77%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 5	0 / 3	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Swelling			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaphylactic shock			

subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Drug hypersensitivity			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Contrast media reaction			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contrast media allergy			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related hypersensitivity reaction			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intermenstrual bleeding			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Pelvic pain			

subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal prolapse			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Apnoea			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspiration			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Asthma			
subjects affected / exposed	0 / 391 (0.00%)	2 / 391 (0.51%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atelectasis			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial haemorrhage			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial obstruction			

subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	3 / 391 (0.77%)	2 / 391 (0.51%)	2 / 185 (1.08%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	9 / 391 (2.30%)	8 / 391 (2.05%)	2 / 185 (1.08%)
occurrences causally related to treatment / all	0 / 9	0 / 9	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Emphysema			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	2 / 391 (0.51%)	2 / 391 (0.51%)	3 / 185 (1.62%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Hypercapnia			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Hypoxia			
subjects affected / exposed	2 / 391 (0.51%)	2 / 391 (0.51%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial lung disease			

subjects affected / exposed	2 / 391 (0.51%)	4 / 391 (1.02%)	2 / 185 (1.08%)
occurrences causally related to treatment / all	2 / 2	4 / 4	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated lung disease			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Lung disorder			
subjects affected / exposed	1 / 391 (0.26%)	1 / 391 (0.26%)	0 / 185 (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
Lung infiltration			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
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 opacity			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant pleural effusion			
subjects affected / exposed	4 / 391 (1.02%)	9 / 391 (2.30%)	3 / 185 (1.62%)
occurrences causally related to treatment / all	0 / 4	0 / 10	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mediastinal disorder			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstructive airways disorder			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Oesophagobronchial fistula			

subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Organising pneumonia			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleurisy			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	4 / 391 (1.02%)	5 / 391 (1.28%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 5	2 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	11 / 391 (2.81%)	20 / 391 (5.12%)	7 / 185 (3.78%)
occurrences causally related to treatment / all	11 / 11	23 / 25	8 / 8
deaths causally related to treatment / all	2 / 2	2 / 2	1 / 1
Productive cough			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	1 / 391 (0.26%)	3 / 391 (0.77%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pulmonary embolism			
subjects affected / exposed	7 / 391 (1.79%)	13 / 391 (3.32%)	4 / 185 (2.16%)
occurrences causally related to treatment / all	0 / 7	0 / 13	0 / 4
deaths causally related to treatment / all	0 / 3	0 / 3	0 / 0
Pulmonary haemorrhage			

subjects affected / exposed	2 / 391 (0.51%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary hilum mass			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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 venous thrombosis			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory alkalosis			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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	4 / 391 (1.02%)	2 / 391 (0.51%)	5 / 185 (2.70%)
occurrences causally related to treatment / all	0 / 5	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 3	0 / 1	0 / 2
Wheezing			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Bipolar disorder			

subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Confusional state			
subjects affected / exposed	0 / 391 (0.00%)	3 / 391 (0.77%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Completed suicide			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disorientation			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	2 / 391 (0.51%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide attempt			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device dislocation			

subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Device physical property issue			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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			
Acute hepatic failure			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Autoimmune hepatitis			
subjects affected / exposed	0 / 391 (0.00%)	3 / 391 (0.77%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile duct stone			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis acute			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Biliary obstruction			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Cholecystitis			

subjects affected / exposed	2 / 391 (0.51%)	1 / 391 (0.26%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	1 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	1 / 391 (0.26%)	1 / 391 (0.26%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholestasis			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Drug-induced liver injury			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	4 / 391 (1.02%)	3 / 391 (0.77%)	6 / 185 (3.24%)
occurrences causally related to treatment / all	3 / 4	2 / 3	6 / 6
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Hepatic function abnormal			
subjects affected / exposed	0 / 391 (0.00%)	2 / 391 (0.51%)	2 / 185 (1.08%)
occurrences causally related to treatment / all	0 / 0	1 / 2	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatorenal failure			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatotoxicity			

subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Hydrocholecystis			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertransaminasaemia			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated hepatic disorder			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated hepatitis			
subjects affected / exposed	0 / 391 (0.00%)	3 / 391 (0.77%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	3 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice cholestatic			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Liver disorder			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver injury			

subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
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			
Amylase increased			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alanine aminotransferase increased			
subjects affected / exposed	3 / 391 (0.77%)	2 / 391 (0.51%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	3 / 3	2 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	2 / 185 (1.08%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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 glucose increased			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
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 creatinine increased			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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 creatine phosphokinase increased			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood calcium decreased			

subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical condition abnormal			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Eosinophil count increased			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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 potassium decreased			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 391 (0.00%)	2 / 391 (0.51%)	0 / 185 (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
Lymphocyte count decreased			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test increased			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Liver function test abnormal			

subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Lipase increased			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	2 / 185 (1.08%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutrophil count decreased			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic enzyme increased			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	1 / 1	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
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 enzymes increased			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Transaminases increased			
subjects affected / exposed	0 / 391 (0.00%)	2 / 391 (0.51%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight decreased			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Troponin increased			

subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
White blood cell count decreased			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
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			
Acetabulum fracture			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Accidental overdose			
subjects affected / exposed	0 / 391 (0.00%)	2 / 391 (0.51%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle fracture			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Contusion			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Forearm fracture			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral neck fracture			

subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Femoral nerve injury			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Femur fracture			
subjects affected / exposed	3 / 391 (0.77%)	1 / 391 (0.26%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Hip fracture			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Head injury			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Injury			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fracture displacement			

subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple fractures			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar vertebral fracture			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb injury			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament sprain			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle strain			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Overdose			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural complication			

subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haemorrhage			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Procedural pain			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radiation pneumonitis			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radiation oesophagitis			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Rib fracture			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal fracture			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			

subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound dehiscence			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Tracheo-oesophageal fistula			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	1 / 391 (0.26%)	2 / 391 (0.51%)	2 / 185 (1.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Acute left ventricular failure			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute coronary syndrome			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina pectoris			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Angina unstable			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Arrhythmia			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriosclerosis coronary artery			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	4 / 391 (1.02%)	4 / 391 (1.02%)	4 / 185 (2.16%)
occurrences causally related to treatment / all	0 / 4	1 / 4	1 / 4
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Atrial flutter			
subjects affected / exposed	1 / 391 (0.26%)	1 / 391 (0.26%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	4 / 391 (1.02%)	2 / 391 (0.51%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 2	0 / 0
Bradycardia			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block complete			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	2 / 391 (0.51%)	3 / 391 (0.77%)	3 / 185 (1.62%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cardio-respiratory arrest			

subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
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 tamponade			
subjects affected / exposed	3 / 391 (0.77%)	1 / 391 (0.26%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 3	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	1 / 1
Cardiac fibrillation			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 391 (0.00%)	2 / 391 (0.51%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 2	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure acute			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Cardiogenic shock			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiopulmonary failure			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Hypertensive cardiomyopathy			

subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated myocarditis			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 391 (0.00%)	2 / 391 (0.51%)	3 / 185 (1.62%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 2
Myocarditis			
subjects affected / exposed	0 / 391 (0.00%)	2 / 391 (0.51%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Myocardial ischaemia			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Palpitations			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion malignant			
subjects affected / exposed	4 / 391 (1.02%)	0 / 391 (0.00%)	2 / 185 (1.08%)
occurrences causally related to treatment / all	0 / 7	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	5 / 391 (1.28%)	2 / 391 (0.51%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	2 / 5	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			

subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Pleuropericarditis			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress cardiomyopathy			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Right ventricular failure			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular extrasystoles			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachyarrhythmia			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Torsade de pointes			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Tachycardia			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			

subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
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			
Brain oedema			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Atonic seizures			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Cerebellar infarction			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haemorrhage			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral ischaemia			
subjects affected / exposed	1 / 391 (0.26%)	1 / 391 (0.26%)	0 / 185 (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
Cerebral microangiopathy			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
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	5 / 391 (1.28%)	4 / 391 (1.02%)	3 / 185 (1.62%)
occurrences causally related to treatment / all	0 / 5	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 0
Dizziness			
subjects affected / exposed	2 / 391 (0.51%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular disorder			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Dysarthria			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis autoimmune			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Embolic cerebral infarction			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Encephalopathy			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Epilepsy			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised tonic-clonic seizure			

subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Facial paralysis			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic stroke			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Haemorrhagic transformation stroke			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Headache			
subjects affected / exposed	1 / 391 (0.26%)	3 / 391 (0.77%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoaesthesia			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic cerebral infarction			

subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	2 / 185 (1.08%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Lethargy			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar radiculopathy			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myasthenia gravis			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myasthenic syndrome			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nerve compression			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuralgia			
subjects affected / exposed	1 / 391 (0.26%)	1 / 391 (0.26%)	0 / 185 (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
Neuropathy peripheral			

subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paralysis recurrent laryngeal nerve			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraplegia			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polyneuropathy			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Partial seizures			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Sensory loss			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 391 (0.00%)	2 / 391 (0.51%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	2 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Quadriparesis			

subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Vasogenic cerebral oedema			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vocal cord paralysis			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Vertebrobasilar artery dissection			

subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	4 / 391 (1.02%)	4 / 391 (1.02%)	4 / 185 (2.16%)
occurrences causally related to treatment / all	1 / 4	2 / 4	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune haemolytic anaemia			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Febrile neutropenia			
subjects affected / exposed	3 / 391 (0.77%)	0 / 391 (0.00%)	2 / 185 (1.08%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eosinophilia			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Febrile bone marrow aplasia			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone marrow failure			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukopenia			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenopathy			

subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron deficiency anaemia			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heparin-induced thrombocytopenia			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Haematotoxicity			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelosuppression			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	3 / 391 (0.77%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	1 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Splenic haematoma			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic haemorrhage			

subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
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 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic thrombosis			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Thrombocytosis			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Sudden hearing loss			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertigo			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diplopia			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			

Abdominal hernia			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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 distension			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	2 / 391 (0.51%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Ascites			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	4 / 391 (1.02%)	9 / 391 (2.30%)	3 / 185 (1.62%)
occurrences causally related to treatment / all	5 / 5	9 / 10	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune colitis			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ischaemic			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ulcerative			

subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Colitis microscopic			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	2 / 391 (0.51%)	3 / 391 (0.77%)	2 / 185 (1.08%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	3 / 391 (0.77%)	6 / 391 (1.53%)	9 / 185 (4.86%)
occurrences causally related to treatment / all	2 / 3	6 / 6	8 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer haemorrhage			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	1 / 391 (0.26%)	3 / 391 (0.77%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 1	1 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 391 (0.00%)	3 / 391 (0.77%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	4 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erosive oesophagitis			

subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric haemorrhage			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 391 (0.00%)	3 / 391 (0.77%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	4 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorder			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gingival hypertrophy			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Haemorrhoidal haemorrhage			

subjects affected / exposed	1 / 391 (0.26%)	1 / 391 (0.26%)	0 / 185 (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
Haemorrhoids			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated enterocolitis			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	2 / 391 (0.51%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated gastritis			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal ischaemia			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated pancreatitis			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	3 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant ascites			

subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal ulcer			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
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 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal stenosis			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Oesophageal ulcer			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal fistula			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Odynophagia			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Oesophagitis			

subjects affected / exposed	1 / 391 (0.26%)	1 / 391 (0.26%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	2 / 391 (0.51%)	1 / 391 (0.26%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal ulcer			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
subjects affected / exposed	2 / 391 (0.51%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
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	7 / 391 (1.79%)	1 / 391 (0.26%)	2 / 185 (1.08%)
occurrences causally related to treatment / all	1 / 7	1 / 1	1 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Subileus			

subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Skin and subcutaneous tissue disorders			
Diabetic foot			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Autoimmune dermatitis			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Drug eruption			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Erythema multiforme			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Exfoliative rash			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Erythema			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Eczema			

subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Neutrophilic dermatosis			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	2 / 391 (0.51%)	2 / 391 (0.51%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	2 / 2	1 / 2	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Pruritus			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash maculo-papular			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	2 / 185 (1.08%)
occurrences causally related to treatment / all	0 / 0	1 / 1	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash vesicular			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash pruritic			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin ulcer			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stevens-Johnson syndrome			

subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxic skin eruption			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	4 / 391 (1.02%)	2 / 391 (0.51%)	3 / 185 (1.62%)
occurrences causally related to treatment / all	1 / 5	2 / 2	1 / 4
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Autoimmune nephritis			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Azotaemia			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrogenic diabetes insipidus			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephropathy toxic			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	1 / 391 (0.26%)	3 / 391 (0.77%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Tubulointerstitial nephritis			

subjects affected / exposed	1 / 391 (0.26%)	1 / 391 (0.26%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal vascular thrombosis			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureterolithiasis			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
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			
Hypercalcaemia of malignancy			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Autoimmune thyroiditis			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Autoimmune hypothyroidism			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adrenal insufficiency			
subjects affected / exposed	1 / 391 (0.26%)	10 / 391 (2.56%)	6 / 185 (3.24%)
occurrences causally related to treatment / all	1 / 1	9 / 10	7 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperparathyroidism secondary			

subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Hyperthyroidism			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Hypophysitis			
subjects affected / exposed	0 / 391 (0.00%)	5 / 391 (1.28%)	2 / 185 (1.08%)
occurrences causally related to treatment / all	0 / 0	6 / 6	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypothyroidism			
subjects affected / exposed	1 / 391 (0.26%)	1 / 391 (0.26%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	1 / 1	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypopituitarism			
subjects affected / exposed	1 / 391 (0.26%)	5 / 391 (1.28%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	1 / 1	5 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Primary adrenal insufficiency			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Secondary adrenocortical insufficiency			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated hypophysitis			

subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 391 (0.26%)	1 / 391 (0.26%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune arthritis			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	2 / 391 (0.51%)	1 / 391 (0.26%)	3 / 185 (1.62%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			
subjects affected / exposed	1 / 391 (0.26%)	2 / 391 (0.51%)	2 / 185 (1.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flank pain			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertrophic osteoarthropathy			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			

subjects affected / exposed	1 / 391 (0.26%)	1 / 391 (0.26%)	0 / 185 (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
Musculoskeletal chest pain			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Myalgia			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myopathy			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myositis			
subjects affected / exposed	1 / 391 (0.26%)	1 / 391 (0.26%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	1 / 1	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	1 / 391 (0.26%)	1 / 391 (0.26%)	0 / 185 (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
Osteonecrosis			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis of jaw			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			

subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pathological fracture			
subjects affected / exposed	1 / 391 (0.26%)	1 / 391 (0.26%)	0 / 185 (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
Polyarthritis			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Polymyalgia rheumatica			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rheumatoid arthritis			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Rhabdomyolysis			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Infections and infestations			
Abscess			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess limb			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal abscess			

subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspergillus infection			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Appendicitis			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial diarrhoea			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	1 / 391 (0.26%)	3 / 391 (0.77%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 1	1 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial infection			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Catheter site infection			

subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic foot infection			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Dermo-hypodermitis			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Enteritis infectious			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Empyema			

subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis intestinal perforated			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Enterocolitis infectious			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Gastrointestinal infection			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	2 / 185 (1.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile infection			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Groin infection			

subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infectious pleural effusion			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Injection site infection			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella urinary tract infection			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Large intestine infection			

subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	1 / 391 (0.26%)	1 / 391 (0.26%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung abscess			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasopharyngitis			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Neutropenic infection			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic sepsis			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	2 / 185 (1.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis viral			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Metapneumovirus infection			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Myelitis			

subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Parainfluenzae virus infection			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ophthalmic herpes zoster			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal candidiasis			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	2 / 185 (1.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	29 / 391 (7.42%)	40 / 391 (10.23%)	18 / 185 (9.73%)
occurrences causally related to treatment / all	2 / 32	1 / 43	0 / 22
deaths causally related to treatment / all	0 / 4	0 / 6	0 / 5
Pleural infection			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Pneumonia adenoviral			

subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
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 bacterial			
subjects affected / exposed	1 / 391 (0.26%)	1 / 391 (0.26%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	2 / 391 (0.51%)	1 / 391 (0.26%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pneumonia influenzal			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
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 klebsiella			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia necrotising			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomembranous colitis			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia viral			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pulmonary sepsis			

subjects affected / exposed	3 / 391 (0.77%)	1 / 391 (0.26%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal abscess			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary tuberculosis			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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 tract infection			
subjects affected / exposed	5 / 391 (1.28%)	4 / 391 (1.02%)	4 / 185 (2.16%)
occurrences causally related to treatment / all	0 / 7	1 / 4	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Respiratory tract infection viral			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Salmonellosis			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			

subjects affected / exposed	3 / 391 (0.77%)	3 / 391 (0.77%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 2	0 / 0
Septic shock			
subjects affected / exposed	4 / 391 (1.02%)	2 / 391 (0.51%)	4 / 185 (2.16%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 1
Skin infection			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal infection			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic candida			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombophlebitis septic			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Tooth infection			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			

subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral pericarditis			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular device infection			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	2 / 391 (0.51%)	4 / 391 (1.02%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
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			
Acidosis			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adult failure to thrive			

subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Decreased appetite			
subjects affected / exposed	2 / 391 (0.51%)	1 / 391 (0.26%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	4 / 391 (1.02%)	2 / 391 (0.51%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic metabolic decompensation			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Failure to thrive			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrolyte imbalance			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Hypercalcaemia			
subjects affected / exposed	4 / 391 (1.02%)	3 / 391 (0.77%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			

subjects affected / exposed	0 / 391 (0.00%)	2 / 391 (0.51%)	3 / 185 (1.62%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Hypermagnesaemia			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperuricaemia			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (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
Hypokalaemia			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	2 / 185 (1.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypomagnesaemia			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (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
Hypoproteinaemia			

subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	3 / 391 (0.77%)	3 / 391 (0.77%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	1 / 3	2 / 3	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Ketoacidosis			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 1 diabetes mellitus			
subjects affected / exposed	1 / 391 (0.26%)	3 / 391 (0.77%)	1 / 185 (0.54%)
occurrences causally related to treatment / all	1 / 1	3 / 3	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
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-Arm C: Chemotherapy	Part 1-Arm G: Nivo + Chemo	Part 1-Arm F: Chemotherapy
Total subjects affected by serious adverse events			
subjects affected / exposed	213 / 387 (55.04%)	112 / 172 (65.12%)	91 / 183 (49.73%)
number of deaths (all causes)	339	157	174
number of deaths resulting from adverse events	97	52	50
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma gastric			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenocarcinoma of colon			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Acute leukaemia			
subjects affected / exposed	0 / 387 (0.00%)	1 / 172 (0.58%)	0 / 183 (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
Basal cell carcinoma			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign breast neoplasm			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder transitional cell carcinoma			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (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
Cancer pain			
subjects affected / exposed	3 / 387 (0.78%)	1 / 172 (0.58%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangiocarcinoma			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon cancer			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic myeloid leukaemia			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extranodal marginal zone B-cell lymphoma (MALT type)			

subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (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
Haemangioma			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric neoplasm			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Female reproductive neoplasm			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematological malignancy			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic cancer			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
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 cancer			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (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
Infected neoplasm			
subjects affected / exposed	0 / 387 (0.00%)	1 / 172 (0.58%)	0 / 183 (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
Intestinal adenocarcinoma			

subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
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 metastasis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
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 neoplasm malignant			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
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 cancer metastatic			
subjects affected / exposed	0 / 387 (0.00%)	1 / 172 (0.58%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung adenocarcinoma			
subjects affected / exposed	0 / 387 (0.00%)	1 / 172 (0.58%)	0 / 183 (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
Lymphangiosis carcinomatosa			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	1 / 183 (0.55%)
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 meninges			
subjects affected / exposed	1 / 387 (0.26%)	1 / 172 (0.58%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Metastases to central nervous system			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
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 bone			

subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
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 adrenals			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm progression			
subjects affected / exposed	87 / 387 (22.48%)	48 / 172 (27.91%)	41 / 183 (22.40%)
occurrences causally related to treatment / all	0 / 92	0 / 53	0 / 43
deaths causally related to treatment / all	0 / 73	0 / 39	0 / 37
Metastases to pleura			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraneoplastic syndrome			
subjects affected / exposed	0 / 387 (0.00%)	1 / 172 (0.58%)	0 / 183 (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
Oncologic complication			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm progression			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm malignant			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastasis			

subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
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 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
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 compression			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (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
Tumour haemorrhage			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
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 invasion			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
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 pseudoprogression			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
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 pain			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour necrosis			

subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
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			
Arterial thrombosis			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (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
Aortic thrombosis			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (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
Arteritis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extremity necrosis			
subjects affected / exposed	0 / 387 (0.00%)	1 / 172 (0.58%)	0 / 183 (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
Embolism			
subjects affected / exposed	2 / 387 (0.52%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	2 / 387 (0.52%)	0 / 172 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Circulatory collapse			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematoma			

subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemic shock			
subjects affected / exposed	0 / 387 (0.00%)	1 / 172 (0.58%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Hypotension			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive crisis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (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
Infarction			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral embolism			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery stenosis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral arterial occlusive disease			

subjects affected / exposed	1 / 387 (0.26%)	1 / 172 (0.58%)	0 / 183 (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
Orthostatic hypotension			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral ischaemia			
subjects affected / exposed	0 / 387 (0.00%)	1 / 172 (0.58%)	0 / 183 (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
Shock			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subclavian vein thrombosis			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superficial vein thrombosis			
subjects affected / exposed	0 / 387 (0.00%)	1 / 172 (0.58%)	0 / 183 (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
Superior vena cava occlusion			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior vena cava syndrome			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (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
Thrombosis			

subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vasculitis			
subjects affected / exposed	0 / 387 (0.00%)	1 / 172 (0.58%)	0 / 183 (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
Vena cava thrombosis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous thrombosis			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (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
Venous thrombosis limb			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Pregnancy			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	5 / 387 (1.29%)	2 / 172 (1.16%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	1 / 5	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adverse drug reaction			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Death			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	3 / 183 (1.64%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 3
Complication associated with device			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chills			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug withdrawal syndrome			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest discomfort			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	1 / 387 (0.26%)	4 / 172 (2.33%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 1	2 / 5	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Face oedema			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			

subjects affected / exposed	3 / 387 (0.78%)	1 / 172 (0.58%)	4 / 183 (2.19%)
occurrences causally related to treatment / all	1 / 3	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthermia			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (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
Generalised oedema			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucosal inflammation			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (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
Malaise			
subjects affected / exposed	1 / 387 (0.26%)	1 / 172 (0.58%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Influenza like illness			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inflammation			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypothermia			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			

subjects affected / exposed	5 / 387 (1.29%)	3 / 172 (1.74%)	3 / 183 (1.64%)
occurrences causally related to treatment / all	2 / 5	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Performance status decreased			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	1 / 387 (0.26%)	1 / 172 (0.58%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden death			
subjects affected / exposed	0 / 387 (0.00%)	1 / 172 (0.58%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Swelling			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			

subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaphylactic shock			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug hypersensitivity			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (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
Contrast media reaction			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contrast media allergy			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related hypersensitivity reaction			
subjects affected / exposed	0 / 387 (0.00%)	1 / 172 (0.58%)	0 / 183 (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
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intermenstrual bleeding			

subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic pain			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal prolapse			
subjects affected / exposed	0 / 387 (0.00%)	1 / 172 (0.58%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	3 / 387 (0.78%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Apnoea			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspiration			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atelectasis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial haemorrhage			

subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial obstruction			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (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
Chronic obstructive pulmonary disease			
subjects affected / exposed	1 / 387 (0.26%)	5 / 172 (2.91%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 1	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Cough			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
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	8 / 387 (2.07%)	1 / 172 (0.58%)	2 / 183 (1.09%)
occurrences causally related to treatment / all	0 / 8	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Emphysema			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	7 / 387 (1.81%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 8	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Hypercapnia			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			

subjects affected / exposed	0 / 387 (0.00%)	1 / 172 (0.58%)	0 / 183 (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
Interstitial lung disease			
subjects affected / exposed	1 / 387 (0.26%)	1 / 172 (0.58%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Immune-mediated lung disease			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung disorder			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (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
Lung infiltration			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Lung opacity			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant pleural effusion			
subjects affected / exposed	1 / 387 (0.26%)	1 / 172 (0.58%)	4 / 183 (2.19%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mediastinal disorder			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstructive airways disorder			

subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagobronchial fistula			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Organising pneumonia			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (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
Pleurisy			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	1 / 387 (0.26%)	3 / 172 (1.74%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 1	1 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	4 / 387 (1.03%)	5 / 172 (2.91%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	2 / 4	6 / 6	1 / 1
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Productive cough			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (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
Pneumothorax			
subjects affected / exposed	2 / 387 (0.52%)	0 / 172 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 2	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pulmonary embolism			

subjects affected / exposed	5 / 387 (1.29%)	6 / 172 (3.49%)	2 / 183 (1.09%)
occurrences causally related to treatment / all	1 / 6	1 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Pulmonary haemorrhage			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (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 hilum mass			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
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 venous thrombosis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory alkalosis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	5 / 387 (1.29%)	3 / 172 (1.74%)	3 / 183 (1.64%)
occurrences causally related to treatment / all	1 / 7	2 / 4	0 / 3
deaths causally related to treatment / all	0 / 1	1 / 1	0 / 3
Wheezing			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Anxiety			

subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bipolar disorder			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Confusional state			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Completed suicide			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disorientation			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	1 / 387 (0.26%)	2 / 172 (1.16%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide attempt			

subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device dislocation			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
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 physical property issue			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
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			
Acute hepatic failure			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune hepatitis			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (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
Bile duct stone			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis acute			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary obstruction			

subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholestasis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug-induced liver injury			
subjects affected / exposed	0 / 387 (0.00%)	1 / 172 (0.58%)	0 / 183 (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
Hepatitis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic function abnormal			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (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
Hepatorenal failure			

subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatotoxicity			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocholecystis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
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 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertransaminasaemia			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated hepatic disorder			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated hepatitis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice cholestatic			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver disorder			

subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver injury			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
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			
Amylase increased			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 387 (0.00%)	2 / 172 (1.16%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
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 glucose increased			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
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 creatinine increased			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatine phosphokinase increased			

subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
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 calcium decreased			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical condition abnormal			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eosinophil count increased			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
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 potassium decreased			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphocyte count decreased			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test increased			

subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test abnormal			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipase increased			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutrophil count decreased			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic enzyme increased			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	3 / 387 (0.78%)	0 / 172 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	3 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic enzymes increased			
subjects affected / exposed	0 / 387 (0.00%)	1 / 172 (0.58%)	0 / 183 (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
Transaminases increased			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight decreased			

subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin increased			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
White blood cell count decreased			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
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			
Acetabulum fracture			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Accidental overdose			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle fracture			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contusion			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Forearm fracture			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			

subjects affected / exposed	1 / 387 (0.26%)	1 / 172 (0.58%)	0 / 183 (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
Femoral neck fracture			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral nerve injury			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	1 / 387 (0.26%)	1 / 172 (0.58%)	0 / 183 (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
Infusion related reaction			
subjects affected / exposed	0 / 387 (0.00%)	1 / 172 (0.58%)	0 / 183 (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
Humerus fracture			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	0 / 387 (0.00%)	1 / 172 (0.58%)	2 / 183 (1.09%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
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			

subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fracture displacement			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple fractures			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (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
Lumbar vertebral fracture			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb injury			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament sprain			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle strain			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			

subjects affected / exposed	2 / 387 (0.52%)	0 / 172 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural complication			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haemorrhage			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pain			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (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
Radiation pneumonitis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radiation oesophagitis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal fracture			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			

subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (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
Wound dehiscence			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Tracheo-oesophageal fistula			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (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
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute left ventricular failure			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute coronary syndrome			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina pectoris			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Angina unstable			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (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
Arrhythmia			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriosclerosis coronary artery			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 387 (0.00%)	1 / 172 (0.58%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradycardia			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block complete			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			

subjects affected / exposed	1 / 387 (0.26%)	1 / 172 (0.58%)	2 / 183 (1.09%)
occurrences causally related to treatment / all	1 / 1	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cardio-respiratory arrest			
subjects affected / exposed	1 / 387 (0.26%)	1 / 172 (0.58%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Cardiac tamponade			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac fibrillation			
subjects affected / exposed	0 / 387 (0.00%)	1 / 172 (0.58%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 387 (0.00%)	1 / 172 (0.58%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure acute			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiogenic shock			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiopulmonary failure			

subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive cardiomyopathy			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated myocarditis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	1 / 387 (0.26%)	1 / 172 (0.58%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Myocarditis			
subjects affected / exposed	0 / 387 (0.00%)	1 / 172 (0.58%)	0 / 183 (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
Myocardial ischaemia			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Palpitations			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion malignant			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			

subjects affected / exposed	2 / 387 (0.52%)	1 / 172 (0.58%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 2	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	0 / 387 (0.00%)	1 / 172 (0.58%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleuropericarditis			
subjects affected / exposed	0 / 387 (0.00%)	1 / 172 (0.58%)	0 / 183 (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
Stress cardiomyopathy			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Right ventricular failure			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular extrasystoles			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachyarrhythmia			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Torsade de pointes			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			

subjects affected / exposed	0 / 387 (0.00%)	1 / 172 (0.58%)	0 / 183 (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
Supraventricular tachycardia			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
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			
Brain oedema			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atonic seizures			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebellar infarction			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	4 / 387 (1.03%)	1 / 172 (0.58%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	1 / 4	1 / 1	0 / 0
deaths causally related to treatment / all	1 / 2	0 / 0	0 / 0
Cerebral haemorrhage			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral ischaemia			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral microangiopathy			

subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	1 / 183 (0.55%)
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	3 / 387 (0.78%)	2 / 172 (1.16%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 2	0 / 0
Dizziness			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular disorder			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysarthria			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (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
Encephalitis autoimmune			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolic cerebral infarction			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			

subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised tonic-clonic seizure			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial paralysis			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic stroke			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic transformation stroke			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoaesthesia			

subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic cerebral infarction			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Ischaemic stroke			
subjects affected / exposed	3 / 387 (0.78%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Lethargy			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar radiculopathy			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (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
Myasthenia gravis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myasthenic syndrome			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nerve compression			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuralgia			

subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuropathy peripheral			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paralysis recurrent laryngeal nerve			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (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
Paraplegia			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (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
Polyneuropathy			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Partial seizures			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sensory loss			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (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
Seizure			

subjects affected / exposed	0 / 387 (0.00%)	1 / 172 (0.58%)	0 / 183 (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
Quadriparesis			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (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
Somnolence			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	2 / 387 (0.52%)	1 / 172 (0.58%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	1 / 387 (0.26%)	1 / 172 (0.58%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 387 (0.00%)	1 / 172 (0.58%)	0 / 183 (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
Vasogenic cerebral oedema			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (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
Vocal cord paralysis			

subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertebrobasilar artery dissection			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
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	9 / 387 (2.33%)	10 / 172 (5.81%)	8 / 183 (4.37%)
occurrences causally related to treatment / all	9 / 11	7 / 11	11 / 13
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune haemolytic anaemia			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	9 / 387 (2.33%)	4 / 172 (2.33%)	7 / 183 (3.83%)
occurrences causally related to treatment / all	7 / 10	1 / 4	5 / 7
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Eosinophilia			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile bone marrow aplasia			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone marrow failure			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukopenia			

subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenopathy			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron deficiency anaemia			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heparin-induced thrombocytopenia			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematotoxicity			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (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
Myelosuppression			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	2 / 387 (0.52%)	1 / 172 (0.58%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	2 / 2	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	2 / 387 (0.52%)	4 / 172 (2.33%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	2 / 2	4 / 5	1 / 1
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Splenic haematoma			

subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (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
Splenic haemorrhage			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (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
Thrombocytopenia			
subjects affected / exposed	5 / 387 (1.29%)	4 / 172 (2.33%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	5 / 5	4 / 4	1 / 1
deaths causally related to treatment / all	2 / 2	0 / 0	0 / 0
Splenic thrombosis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytosis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Sudden hearing loss			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertigo			
subjects affected / exposed	0 / 387 (0.00%)	1 / 172 (0.58%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Cataract			
subjects affected / exposed	1 / 387 (0.26%)	1 / 172 (0.58%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diplopia			

subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (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
Gastrointestinal disorders			
Abdominal hernia			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
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 distension			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
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	2 / 387 (0.52%)	1 / 172 (0.58%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (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
Ascites			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 387 (0.00%)	1 / 172 (0.58%)	0 / 183 (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
Autoimmune colitis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ischaemic			

subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ulcerative			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis microscopic			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	2 / 387 (0.52%)	0 / 172 (0.00%)	3 / 183 (1.64%)
occurrences causally related to treatment / all	1 / 2	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	4 / 387 (1.03%)	1 / 172 (0.58%)	3 / 183 (1.64%)
occurrences causally related to treatment / all	3 / 4	0 / 1	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer haemorrhage			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (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
Duodenal ulcer			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	1 / 387 (0.26%)	1 / 172 (0.58%)	0 / 183 (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
Enterocolitis			

subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erosive oesophagitis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric haemorrhage			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (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
Gastritis			
subjects affected / exposed	0 / 387 (0.00%)	1 / 172 (0.58%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorder			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (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
Gastrointestinal haemorrhage			
subjects affected / exposed	2 / 387 (0.52%)	1 / 172 (0.58%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gingival hypertrophy			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			

subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoids			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated enterocolitis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated gastritis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
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 ischaemia			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated pancreatitis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			

subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant ascites			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal ulcer			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
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 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal stenosis			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (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
Oesophageal ulcer			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal fistula			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Odynophagia			

subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
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	7 / 387 (1.81%)	1 / 172 (0.58%)	4 / 183 (2.19%)
occurrences causally related to treatment / all	4 / 7	1 / 1	3 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
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 ulcer			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
subjects affected / exposed	0 / 387 (0.00%)	1 / 172 (0.58%)	0 / 183 (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
Small intestinal obstruction			
subjects affected / exposed	0 / 387 (0.00%)	1 / 172 (0.58%)	0 / 183 (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
Vomiting			

subjects affected / exposed	7 / 387 (1.81%)	1 / 172 (0.58%)	2 / 183 (1.09%)
occurrences causally related to treatment / all	6 / 7	1 / 1	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Diabetic foot			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune dermatitis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug eruption			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erythema multiforme			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exfoliative rash			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erythema			

subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eczema			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutrophilic dermatosis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pruritus			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash maculo-papular			
subjects affected / exposed	0 / 387 (0.00%)	1 / 172 (0.58%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash vesicular			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash pruritic			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin ulcer			

subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stevens-Johnson syndrome			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxic skin eruption			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
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	4 / 387 (1.03%)	2 / 172 (1.16%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	3 / 4	3 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune nephritis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Azotaemia			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrogenic diabetes insipidus			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephropathy toxic			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			

subjects affected / exposed	2 / 387 (0.52%)	1 / 172 (0.58%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Tubulointerstitial nephritis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
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 vascular thrombosis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureterolithiasis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Hypercalcaemia of malignancy			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune thyroiditis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune hypothyroidism			
subjects affected / exposed	0 / 387 (0.00%)	1 / 172 (0.58%)	0 / 183 (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
Adrenal insufficiency			

subjects affected / exposed	0 / 387 (0.00%)	1 / 172 (0.58%)	0 / 183 (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
Hyperparathyroidism secondary			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthyroidism			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophysitis			
subjects affected / exposed	0 / 387 (0.00%)	1 / 172 (0.58%)	0 / 183 (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
Hypothyroidism			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypopituitarism			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Primary adrenal insufficiency			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Secondary adrenocortical insufficiency			

subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated hypophysitis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
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			
Arthralgia			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (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
Autoimmune arthritis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	1 / 387 (0.26%)	1 / 172 (0.58%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flank pain			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertrophic osteoarthropathy			
subjects affected / exposed	0 / 387 (0.00%)	1 / 172 (0.58%)	0 / 183 (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
Intervertebral disc protrusion			

subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal chest pain			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (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
Myalgia			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myopathy			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myositis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis of jaw			

subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pathological fracture			
subjects affected / exposed	1 / 387 (0.26%)	1 / 172 (0.58%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polyarthritis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polymyalgia rheumatica			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rheumatoid arthritis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhabdomyolysis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abscess			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess limb			

subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal abscess			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspergillus infection			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial diarrhoea			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	1 / 387 (0.26%)	1 / 172 (0.58%)	0 / 183 (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
Bacterial infection			

subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	2 / 183 (1.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Catheter site infection			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic foot infection			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermo-hypodermitis			
subjects affected / exposed	0 / 387 (0.00%)	1 / 172 (0.58%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	1 / 387 (0.26%)	4 / 172 (2.33%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 2	1 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis infectious			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			

subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Empyema			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis intestinal perforated			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis infectious			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (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 infection			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile infection			

subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Groin infection			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (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
Infection			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infectious pleural effusion			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 387 (0.00%)	1 / 172 (0.58%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injection site infection			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (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
Klebsiella urinary tract infection			

subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine infection			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	1 / 387 (0.26%)	3 / 172 (1.74%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung abscess			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasopharyngitis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic infection			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic sepsis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Meningitis viral			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metapneumovirus infection			

subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelitis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ophthalmic herpes zoster			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal candidiasis			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (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
Peritonitis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	31 / 387 (8.01%)	15 / 172 (8.72%)	8 / 183 (4.37%)
occurrences causally related to treatment / all	2 / 33	3 / 19	0 / 8
deaths causally related to treatment / all	0 / 7	0 / 3	0 / 2
Pleural infection			

subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
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 adenoviral			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 387 (0.00%)	1 / 172 (0.58%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	2 / 183 (1.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia influenzal			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia klebsiella			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
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 necrotising			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pseudomembranous colitis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
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 viral			

subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary sepsis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal abscess			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
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 tuberculosis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	3 / 387 (0.78%)	2 / 172 (1.16%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 3	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Respiratory tract infection viral			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (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
Salmonellosis			

subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	3 / 387 (0.78%)	1 / 172 (0.58%)	4 / 183 (2.19%)
occurrences causally related to treatment / all	3 / 3	0 / 1	0 / 4
deaths causally related to treatment / all	2 / 2	0 / 0	0 / 1
Septic shock			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	2 / 183 (1.09%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Skin infection			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal infection			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic candida			
subjects affected / exposed	0 / 387 (0.00%)	1 / 172 (0.58%)	0 / 183 (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
Thrombophlebitis septic			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth infection			

subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	5 / 387 (1.29%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	1 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral pericarditis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
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 device infection			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	1 / 387 (0.26%)	1 / 172 (0.58%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	4 / 387 (1.03%)	1 / 172 (0.58%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Wound infection			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	1 / 183 (0.55%)
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			
Acidosis			

subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adult failure to thrive			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (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
Decreased appetite			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	1 / 387 (0.26%)	1 / 172 (0.58%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Diabetes mellitus			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic metabolic decompensation			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrolyte imbalance			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			

subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (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
Hyperglycaemia			
subjects affected / exposed	1 / 387 (0.26%)	0 / 172 (0.00%)	0 / 183 (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
Hypermagnesaemia			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperuricaemia			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
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 / 387 (0.00%)	1 / 172 (0.58%)	0 / 183 (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
Hypoglycaemia			
subjects affected / exposed	0 / 387 (0.00%)	1 / 172 (0.58%)	0 / 183 (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
Hypomagnesaemia			

subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoproteinaemia			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	2 / 387 (0.52%)	1 / 172 (0.58%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	1 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ketoacidosis			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 1 diabetes mellitus			
subjects affected / exposed	0 / 387 (0.00%)	1 / 172 (0.58%)	0 / 183 (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
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
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 - Arm H: Nivolumab + Chemotherapy	Part 2 - Arm I: Chemotherapy	Part 3 -Arm J: Nivolumab + Ipilimumab
Total subjects affected by serious adverse events			
subjects affected / exposed	240 / 375 (64.00%)	180 / 371 (48.52%)	78 / 126 (61.90%)
number of deaths (all causes)	314	335	95
number of deaths resulting from adverse events	112	86	29
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma gastric			

subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	0 / 126 (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
Adenocarcinoma of colon			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Acute leukaemia			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal cell carcinoma			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Benign breast neoplasm			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder transitional cell carcinoma			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
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 / 375 (0.27%)	5 / 371 (1.35%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 1	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Cholangiocarcinoma			
subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	0 / 126 (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
Colon cancer			

subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic myeloid leukaemia			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extranodal marginal zone B-cell lymphoma (MALT type)			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemangioma			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric neoplasm			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Female reproductive neoplasm			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Haematological malignancy			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic cancer			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
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 cancer			

subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected neoplasm			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
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 adenocarcinoma			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
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 metastasis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
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 neoplasm malignant			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
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 cancer metastatic			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
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 adenocarcinoma			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphangiosis carcinomatosa			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
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 meninges			

subjects affected / exposed	1 / 375 (0.27%)	1 / 371 (0.27%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Metastases to central nervous system			
subjects affected / exposed	2 / 375 (0.53%)	0 / 371 (0.00%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to bone			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
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 adrenals			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm progression			
subjects affected / exposed	81 / 375 (21.60%)	78 / 371 (21.02%)	18 / 126 (14.29%)
occurrences causally related to treatment / all	0 / 90	0 / 81	1 / 18
deaths causally related to treatment / all	0 / 70	0 / 66	1 / 15
Metastases to pleura			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraneoplastic syndrome			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oncologic complication			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Neoplasm progression			

subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm malignant			
subjects affected / exposed	1 / 375 (0.27%)	1 / 371 (0.27%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Metastasis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
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	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Tumour compression			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
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 haemorrhage			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
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 invasion			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Tumour pseudoprogression			

subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
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 pain			
subjects affected / exposed	2 / 375 (0.53%)	1 / 371 (0.27%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Tumour necrosis			
subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Arterial thrombosis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic thrombosis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteritis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extremity necrosis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	1 / 375 (0.27%)	1 / 371 (0.27%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			

subjects affected / exposed	4 / 375 (1.07%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Circulatory collapse			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematoma			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemic shock			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive crisis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infarction			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral embolism			

subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Peripheral artery stenosis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral arterial occlusive disease			
subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	0 / 126 (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
Orthostatic hypotension			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Peripheral ischaemia			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Shock			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subclavian vein thrombosis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superficial vein thrombosis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior vena cava occlusion			

subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior vena cava syndrome			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Thrombosis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vasculitis			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Vena cava thrombosis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous thrombosis			
subjects affected / exposed	0 / 375 (0.00%)	2 / 371 (0.54%)	0 / 126 (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
Venous thrombosis limb			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Pregnancy			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			

Asthenia			
subjects affected / exposed	2 / 375 (0.53%)	3 / 371 (0.81%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	2 / 2	2 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adverse drug reaction			
subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	0 / 126 (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
Death			
subjects affected / exposed	1 / 375 (0.27%)	1 / 371 (0.27%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Complication associated with device			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chills			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug withdrawal syndrome			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest discomfort			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Fatigue			

subjects affected / exposed	1 / 375 (0.27%)	2 / 371 (0.54%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Face oedema			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	1 / 375 (0.27%)	3 / 371 (0.81%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthermia			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised oedema			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucosal inflammation			
subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	0 / 126 (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
Malaise			
subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza like illness			
subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inflammation			

subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypothermia			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	6 / 375 (1.60%)	5 / 371 (1.35%)	6 / 126 (4.76%)
occurrences causally related to treatment / all	1 / 6	2 / 7	4 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Performance status decreased			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Pain			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	3 / 375 (0.80%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden death			
subjects affected / exposed	6 / 375 (1.60%)	2 / 371 (0.54%)	4 / 126 (3.17%)
occurrences causally related to treatment / all	0 / 6	0 / 2	1 / 4
deaths causally related to treatment / all	0 / 6	0 / 2	1 / 4
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Swelling			

subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	0 / 126 (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
Anaphylactic shock			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Hypersensitivity			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Drug hypersensitivity			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contrast media reaction			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contrast media allergy			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related hypersensitivity reaction			

subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Intermenstrual bleeding			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic pain			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Vaginal prolapse			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Apnoea			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Aspiration			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Asthma			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atelectasis			
subjects affected / exposed	0 / 375 (0.00%)	2 / 371 (0.54%)	0 / 126 (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
Bronchial haemorrhage			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial obstruction			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	0 / 126 (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
Cough			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
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	4 / 375 (1.07%)	5 / 371 (1.35%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	1 / 5	0 / 5	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Emphysema			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Haemoptysis			

subjects affected / exposed	2 / 375 (0.53%)	1 / 371 (0.27%)	4 / 126 (3.17%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercapnia			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial lung disease			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	3 / 126 (2.38%)
occurrences causally related to treatment / all	1 / 1	0 / 0	4 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated lung disease			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 0	0 / 0	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung disorder			
subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infiltration			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
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 opacity			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant pleural effusion			

subjects affected / exposed	2 / 375 (0.53%)	2 / 371 (0.54%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mediastinal disorder			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Obstructive airways disorder			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Oesophagobronchial fistula			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Organising pneumonia			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleurisy			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	7 / 375 (1.87%)	5 / 371 (1.35%)	3 / 126 (2.38%)
occurrences causally related to treatment / all	0 / 7	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	14 / 375 (3.73%)	1 / 371 (0.27%)	11 / 126 (8.73%)
occurrences causally related to treatment / all	11 / 14	1 / 1	11 / 12
deaths causally related to treatment / all	2 / 3	0 / 0	2 / 2
Productive cough			

subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	5 / 375 (1.33%)	1 / 371 (0.27%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	1 / 6	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	9 / 375 (2.40%)	5 / 371 (1.35%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	1 / 9	1 / 5	0 / 0
deaths causally related to treatment / all	0 / 4	0 / 0	0 / 0
Pulmonary haemorrhage			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Pulmonary hilum mass			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
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 venous thrombosis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory alkalosis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
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	6 / 375 (1.60%)	3 / 371 (0.81%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	1 / 6	0 / 3	0 / 0
deaths causally related to treatment / all	1 / 5	0 / 3	0 / 0
Wheezing			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bipolar disorder			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Confusional state			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Completed suicide			
subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	0 / 126 (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
Disorientation			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Depression			

subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Mental status changes			
subjects affected / exposed	2 / 375 (0.53%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide attempt			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device dislocation			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
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 physical property issue			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
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			
Acute hepatic failure			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune hepatitis			
subjects affected / exposed	2 / 375 (0.53%)	0 / 371 (0.00%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	2 / 2	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile duct stone			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Cholangitis acute			

subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Biliary obstruction			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	2 / 375 (0.53%)	0 / 371 (0.00%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholestasis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug-induced liver injury			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic function abnormal			

subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Hepatic failure			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatorenal failure			
subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	0 / 126 (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
Hepatotoxicity			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Hydrocholecystis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
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 / 375 (0.00%)	0 / 371 (0.00%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertransaminasaemia			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Immune-mediated hepatic disorder			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated hepatitis			

subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	7 / 126 (5.56%)
occurrences causally related to treatment / all	1 / 1	0 / 0	7 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Jaundice cholestatic			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver disorder			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Liver injury			
subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	0 / 126 (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
Investigations			
Amylase increased			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
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 glucose increased			

subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	0 / 126 (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 creatinine increased			
subjects affected / exposed	3 / 375 (0.80%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	4 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood calcium decreased			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical condition abnormal			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eosinophil count increased			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
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 potassium decreased			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrocardiogram QT prolonged			

subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphocyte count decreased			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test increased			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test abnormal			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipase increased			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutrophil count decreased			
subjects affected / exposed	2 / 375 (0.53%)	3 / 371 (0.81%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	2 / 2	3 / 3	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Hepatic enzyme increased			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	6 / 375 (1.60%)	2 / 371 (0.54%)	3 / 126 (2.38%)
occurrences causally related to treatment / all	6 / 6	3 / 3	2 / 3
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Pancreatic enzymes increased			

subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transaminases increased			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight decreased			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Troponin increased			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
White blood cell count decreased			
subjects affected / exposed	3 / 375 (0.80%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	3 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Acetabulum fracture			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Accidental overdose			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle fracture			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contusion			

subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Forearm fracture			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral neck fracture			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral nerve injury			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Infusion related reaction			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Humerus fracture			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			

subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Head injury			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
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			
subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	0 / 126 (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
Fracture displacement			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple fractures			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar vertebral fracture			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Limb injury			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Ligament sprain			
subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	0 / 126 (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
Muscle strain			

subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			
subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural complication			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haemorrhage			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pain			
subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	0 / 126 (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
Radiation pneumonitis			
subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	0 / 126 (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
Radiation oesophagitis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			

subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal fracture			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	2 / 375 (0.53%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound dehiscence			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Tracheo-oesophageal fistula			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	2 / 375 (0.53%)	0 / 371 (0.00%)	0 / 126 (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
Acute left ventricular failure			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Acute coronary syndrome			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina pectoris			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina unstable			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriosclerosis coronary artery			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	3 / 375 (0.80%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	0 / 126 (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
Bradycardia			

subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block complete			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	2 / 375 (0.53%)	0 / 371 (0.00%)	0 / 126 (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
Cardio-respiratory arrest			
subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Cardiac tamponade			
subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	0 / 126 (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 fibrillation			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure acute			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiogenic shock			

subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Coronary artery disease			
subjects affected / exposed	1 / 375 (0.27%)	1 / 371 (0.27%)	0 / 126 (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
Cardiopulmonary failure			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive cardiomyopathy			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated myocarditis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	2 / 126 (1.59%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Myocardial infarction			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Myocarditis			
subjects affected / exposed	3 / 375 (0.80%)	1 / 371 (0.27%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	3 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	2 / 2	0 / 0	0 / 0
Myocardial ischaemia			
subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	0 / 126 (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
Palpitations			

subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion malignant			
subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	0 / 126 (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
Pericardial effusion			
subjects affected / exposed	0 / 375 (0.00%)	3 / 371 (0.81%)	2 / 126 (1.59%)
occurrences causally related to treatment / all	0 / 0	1 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pericarditis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleuropericarditis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress cardiomyopathy			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Right ventricular failure			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular extrasystoles			
subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	0 / 126 (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
Supraventricular tachyarrhythmia			

subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Torsade de pointes			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	2 / 375 (0.53%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Brain oedema			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Atonic seizures			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebellar infarction			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haemorrhage			

subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral ischaemia			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Cerebral microangiopathy			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
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	1 / 375 (0.27%)	3 / 371 (0.81%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Dizziness			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular disorder			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysarthria			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis autoimmune			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolic cerebral infarction			

subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	2 / 375 (0.53%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised tonic-clonic seizure			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial paralysis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Haemorrhagic stroke			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic transformation stroke			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			

subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoaesthesia			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic cerebral infarction			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	1 / 375 (0.27%)	1 / 371 (0.27%)	0 / 126 (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
Lethargy			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar radiculopathy			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myasthenia gravis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myasthenic syndrome			

subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Nerve compression			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuralgia			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuropathy peripheral			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paralysis recurrent laryngeal nerve			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraplegia			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Polyneuropathy			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Partial seizures			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Presyncope			

subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sensory loss			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Quadriparesis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Spinal cord compression			
subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	0 / 126 (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
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 375 (0.00%)	2 / 371 (0.54%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			

subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vasogenic cerebral oedema			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vocal cord paralysis			
subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	0 / 126 (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
Vertebrobasilar artery dissection			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
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	14 / 375 (3.73%)	10 / 371 (2.70%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	13 / 17	8 / 13	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune haemolytic anaemia			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	16 / 375 (4.27%)	6 / 371 (1.62%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	17 / 18	8 / 8	0 / 0
deaths causally related to treatment / all	2 / 2	0 / 0	0 / 0
Eosinophilia			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile bone marrow aplasia			

subjects affected / exposed	2 / 375 (0.53%)	2 / 371 (0.54%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	2 / 2	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone marrow failure			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Leukopenia			
subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	0 / 126 (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
Lymphadenopathy			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron deficiency anaemia			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heparin-induced thrombocytopenia			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematotoxicity			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelosuppression			
subjects affected / exposed	1 / 375 (0.27%)	1 / 371 (0.27%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			

subjects affected / exposed	1 / 375 (0.27%)	1 / 371 (0.27%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	5 / 375 (1.33%)	4 / 371 (1.08%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	6 / 6	5 / 5	0 / 0
deaths causally related to treatment / all	2 / 2	0 / 0	0 / 0
Splenic haematoma			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic haemorrhage			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
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	2 / 375 (0.53%)	2 / 371 (0.54%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	2 / 2	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic thrombosis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytosis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Sudden hearing loss			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertigo			

subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diplopia			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal hernia			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
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 distension			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
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	4 / 375 (1.07%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	2 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Colitis			

subjects affected / exposed	4 / 375 (1.07%)	1 / 371 (0.27%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	5 / 5	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune colitis			
subjects affected / exposed	2 / 375 (0.53%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ischaemic			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Colitis ulcerative			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis microscopic			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	6 / 375 (1.60%)	2 / 371 (0.54%)	4 / 126 (3.17%)
occurrences causally related to treatment / all	5 / 6	2 / 2	3 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer haemorrhage			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer			

subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Enterocolitis			
subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	0 / 126 (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
Erosive oesophagitis			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Gastric haemorrhage			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Gastric ulcer			
subjects affected / exposed	1 / 375 (0.27%)	1 / 371 (0.27%)	0 / 126 (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
Gastritis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorder			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			

subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gingival hypertrophy			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoids			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated enterocolitis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Ileus			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated gastritis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal ischaemia			

subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	0 / 126 (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
Immune-mediated pancreatitis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant ascites			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	1 / 375 (0.27%)	1 / 371 (0.27%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Large intestinal ulcer			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Intestinal obstruction			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Oesophageal stenosis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal ulcer			

subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	0 / 126 (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
Oesophageal fistula			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Odynophagia			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
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	2 / 375 (0.53%)	4 / 371 (1.08%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	2 / 2	5 / 5	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	2 / 375 (0.53%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal ulcer			
subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	0 / 126 (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
Stomatitis			

subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	0 / 126 (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 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
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	5 / 375 (1.33%)	4 / 371 (1.08%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	3 / 5	3 / 4	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	0 / 126 (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
Skin and subcutaneous tissue disorders			
Diabetic foot			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune dermatitis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug eruption			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erythema multiforme			

subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exfoliative rash			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erythema			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eczema			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutrophilic dermatosis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	2 / 126 (1.59%)
occurrences causally related to treatment / all	1 / 1	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pruritus			
subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	0 / 126 (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
Rash maculo-papular			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash vesicular			

subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Rash pruritic			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin ulcer			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Stevens-Johnson syndrome			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Toxic skin eruption			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
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	2 / 375 (0.53%)	2 / 371 (0.54%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	2 / 2	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune nephritis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Azotaemia			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Nephrogenic diabetes insipidus			

subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	0 / 126 (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
Nephropathy toxic			
subjects affected / exposed	2 / 375 (0.53%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	3 / 375 (0.80%)	3 / 371 (0.81%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	2 / 3	2 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Tubulointerstitial nephritis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
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 vascular thrombosis			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Ureterolithiasis			
subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
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			
Hypercalcaemia of malignancy			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune thyroiditis			

subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune hypothyroidism			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adrenal insufficiency			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Hyperparathyroidism secondary			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthyroidism			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophysitis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	2 / 126 (1.59%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypothyroidism			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Hypopituitarism			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inappropriate antidiuretic hormone secretion			

subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Primary adrenal insufficiency			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Secondary adrenocortical insufficiency			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Immune-mediated hypophysitis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
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			
Arthralgia			
subjects affected / exposed	2 / 375 (0.53%)	0 / 371 (0.00%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune arthritis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	2 / 375 (0.53%)	0 / 371 (0.00%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flank pain			

subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Hypertrophic osteoarthropathy			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal chest pain			
subjects affected / exposed	1 / 375 (0.27%)	1 / 371 (0.27%)	0 / 126 (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
Myalgia			
subjects affected / exposed	1 / 375 (0.27%)	1 / 371 (0.27%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myopathy			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myositis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			

subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis of jaw			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Pain in extremity			
subjects affected / exposed	1 / 375 (0.27%)	2 / 371 (0.54%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pathological fracture			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polyarthritis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polymyalgia rheumatica			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Rheumatoid arthritis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhabdomyolysis			

subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abscess			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Abscess limb			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Anal abscess			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Aspergillus infection			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	4 / 375 (1.07%)	0 / 371 (0.00%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial diarrhoea			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Bronchopulmonary aspergillosis			

subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	5 / 375 (1.33%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Bacterial infection			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Catheter site infection			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic foot infection			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermo-hypodermitis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	3 / 375 (0.80%)	4 / 371 (1.08%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 4	1 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			

subjects affected / exposed	2 / 375 (0.53%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis infectious			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Empyema			
subjects affected / exposed	1 / 375 (0.27%)	1 / 371 (0.27%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis intestinal perforated			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Enterocolitis infectious			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
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 infection			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			

subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile infection			
subjects affected / exposed	1 / 375 (0.27%)	1 / 371 (0.27%)	0 / 126 (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
Groin infection			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	1 / 375 (0.27%)	1 / 371 (0.27%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Infectious pleural effusion			
subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	0 / 126 (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
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			

subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injection site infection			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella urinary tract infection			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine infection			
subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	2 / 375 (0.53%)	2 / 371 (0.54%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung abscess			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasopharyngitis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic infection			
subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic sepsis			

subjects affected / exposed	2 / 375 (0.53%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis viral			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metapneumovirus infection			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelitis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	0 / 126 (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
Parainfluenzae virus infection			
subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	0 / 126 (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
Ophthalmic herpes zoster			
subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	0 / 126 (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
Oesophageal candidiasis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			

subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
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	34 / 375 (9.07%)	29 / 371 (7.82%)	11 / 126 (8.73%)
occurrences causally related to treatment / all	8 / 46	5 / 34	1 / 14
deaths causally related to treatment / all	0 / 4	0 / 2	0 / 1
Pleural infection			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
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 adenoviral			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
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 bacterial			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Pneumonia influenzal			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
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 klebsiella			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
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 necrotising			

subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomembranous colitis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
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 viral			
subjects affected / exposed	2 / 375 (0.53%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary sepsis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal abscess			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
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 tuberculosis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			

subjects affected / exposed	1 / 375 (0.27%)	3 / 371 (0.81%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 1	1 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection viral			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salmonellosis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
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	7 / 375 (1.87%)	2 / 371 (0.54%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	3 / 8	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	1 / 375 (0.27%)	1 / 371 (0.27%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	1 / 1	0 / 1	0 / 0
Skin infection			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal infection			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic candida			

subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombophlebitis septic			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth infection			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral pericarditis			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Viral infection			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
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 device infection			
subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	0 / 126 (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
Urosepsis			
subjects affected / exposed	0 / 375 (0.00%)	2 / 371 (0.54%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			

subjects affected / exposed	2 / 375 (0.53%)	3 / 371 (0.81%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
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			
Acidosis			
subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	0 / 126 (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
Adult failure to thrive			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Decreased appetite			
subjects affected / exposed	4 / 375 (1.07%)	3 / 371 (0.81%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	2 / 4	3 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	1 / 375 (0.27%)	1 / 371 (0.27%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus			
subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic metabolic decompensation			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			

subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrolyte imbalance			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 375 (0.00%)	2 / 371 (0.54%)	0 / 126 (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
Hyperglycaemia			
subjects affected / exposed	4 / 375 (1.07%)	1 / 371 (0.27%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypermagnesaemia			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Hyperuricaemia			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			
subjects affected / exposed	1 / 375 (0.27%)	1 / 371 (0.27%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
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	1 / 375 (0.27%)	1 / 371 (0.27%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypomagnesaemia			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoproteinaemia			
subjects affected / exposed	1 / 375 (0.27%)	0 / 371 (0.00%)	0 / 126 (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
Hyponatraemia			
subjects affected / exposed	6 / 375 (1.60%)	1 / 371 (0.27%)	3 / 126 (2.38%)
occurrences causally related to treatment / all	1 / 6	1 / 1	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Ketoacidosis			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 1 diabetes mellitus			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 375 (0.00%)	1 / 371 (0.27%)	0 / 126 (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 3 - Arm K: Chemotherapy		

Total subjects affected by serious adverse events			
subjects affected / exposed	60 / 123 (48.78%)		
number of deaths (all causes)	94		
number of deaths resulting from adverse events	15		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma gastric			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Adenocarcinoma of colon			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acute leukaemia			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Basal cell carcinoma			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Benign breast neoplasm			
subjects affected / exposed	1 / 123 (0.81%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bladder transitional cell carcinoma			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cancer pain			
subjects affected / exposed	1 / 123 (0.81%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cholangiocarcinoma			

subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colon cancer				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chronic myeloid leukaemia				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Extranodal marginal zone B-cell lymphoma (MALT type)				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemangioma				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastric neoplasm				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Female reproductive neoplasm				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haematological malignancy				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatic cancer				

subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary cancer				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infected neoplasm				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intestinal adenocarcinoma				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intestinal metastasis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung neoplasm malignant				
subjects affected / exposed	1 / 123 (0.81%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Lung cancer metastatic				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung adenocarcinoma				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lymphangiosis carcinomatosa				

subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metastases to meninges			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metastases to central nervous system			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metastases to bone			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metastases to adrenals			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Malignant neoplasm progression			
subjects affected / exposed	9 / 123 (7.32%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 9		
Metastases to pleura			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Paraneoplastic syndrome			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oncologic complication			

subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neoplasm progression				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neoplasm malignant				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metastasis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Prostate cancer				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tumour associated fever				
subjects affected / exposed	1 / 123 (0.81%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Tumour compression				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tumour haemorrhage				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tumour invasion				

subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tumour pseudoprogression				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tumour pain				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tumour necrosis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vascular disorders				
Arterial thrombosis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Aortic thrombosis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Arteritis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Extremity necrosis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Embolism				

subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Deep vein thrombosis			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Circulatory collapse			
subjects affected / exposed	1 / 123 (0.81%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Haematoma			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypovolaemic shock			
subjects affected / exposed	1 / 123 (0.81%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Hypotension			
subjects affected / exposed	1 / 123 (0.81%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypertensive crisis			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypertension			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infarction			

subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peripheral embolism				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peripheral artery stenosis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peripheral arterial occlusive disease				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Orthostatic hypotension				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peripheral ischaemia				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Shock				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Subclavian vein thrombosis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Superficial vein thrombosis				

subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Superior vena cava occlusion				
subjects affected / exposed	1 / 123 (0.81%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Superior vena cava syndrome				
subjects affected / exposed	1 / 123 (0.81%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Thrombosis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vasculitis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vena cava thrombosis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Venous thrombosis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Venous thrombosis limb				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pregnancy, puerperium and perinatal conditions				
Pregnancy				

subjects affected / exposed	1 / 123 (0.81%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Adverse drug reaction			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Death			
subjects affected / exposed	1 / 123 (0.81%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Complication associated with device			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chills			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chest pain			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Drug withdrawal syndrome			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chest discomfort			

subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fatigue				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Face oedema				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General physical health deterioration				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperthermia				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Generalised oedema				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mucosal inflammation				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Malaise				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Influenza like illness				

subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Inflammation				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypothermia				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyrexia				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Performance status decreased				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pain				
subjects affected / exposed	1 / 123 (0.81%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Non-cardiac chest pain				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sudden death				
subjects affected / exposed	1 / 123 (0.81%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Multiple organ dysfunction syndrome				

subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Swelling				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Systemic inflammatory response syndrome				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Immune system disorders				
Anaphylactic reaction				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anaphylactic shock				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypersensitivity				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Drug hypersensitivity				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Contrast media reaction				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Contrast media allergy				

subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infusion related hypersensitivity reaction			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intermenstrual bleeding			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pelvic pain			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vaginal prolapse			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Apnoea			

subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Aspiration				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Asthma				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atelectasis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchial haemorrhage				
subjects affected / exposed	1 / 123 (0.81%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Bronchial obstruction				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chronic obstructive pulmonary disease				
subjects affected / exposed	1 / 123 (0.81%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cough				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dyspnoea				

subjects affected / exposed	1 / 123 (0.81%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Emphysema				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemoptysis				
subjects affected / exposed	1 / 123 (0.81%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypercapnia				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypoxia				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Interstitial lung disease				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Immune-mediated lung disease				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung disorder				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung infiltration				

subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung opacity				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Malignant pleural effusion				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mediastinal disorder				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Obstructive airways disorder				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oesophagobronchial fistula				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Organising pneumonia				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pleurisy				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pleural effusion				

subjects affected / exposed	1 / 123 (0.81%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Pneumonitis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Productive cough				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumothorax				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary embolism				
subjects affected / exposed	1 / 123 (0.81%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Pulmonary haemorrhage				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary hilum mass				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary venous thrombosis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory alkalosis				

subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory distress				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory failure				
subjects affected / exposed	1 / 123 (0.81%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Wheezing				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Psychiatric disorders				
Anxiety				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bipolar disorder				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Delirium				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Confusional state				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Completed suicide				

subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Disorientation				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Depression				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mental status changes				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Suicide attempt				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Product issues				
Device dislocation				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Device physical property issue				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				
Acute hepatic failure				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Autoimmune hepatitis				

subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bile duct stone				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cholangitis acute				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cholangitis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Biliary obstruction				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cholecystitis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cholelithiasis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cholestasis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Drug-induced liver injury				

subjects affected / exposed	3 / 123 (2.44%)			
occurrences causally related to treatment / all	3 / 4			
deaths causally related to treatment / all	0 / 0			
Hepatitis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatic function abnormal				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatic failure				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatorenal failure				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatotoxicity				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hydrocholecystis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperbilirubinaemia				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypertransaminasaemia				

subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Immune-mediated hepatic disorder				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Immune-mediated hepatitis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Jaundice cholestatic				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Liver disorder				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Liver injury				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Investigations				
Amylase increased				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Alanine aminotransferase increased				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Aspartate aminotransferase increased				

subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood alkaline phosphatase increased				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood glucose increased				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood creatinine increased				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood creatine phosphokinase increased				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood calcium decreased				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General physical condition abnormal				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gamma-glutamyltransferase increased				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Eosinophil count increased				

subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood potassium decreased				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Electrocardiogram QT prolonged				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lymphocyte count decreased				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Liver function test increased				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Liver function test abnormal				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lipase increased				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neutrophil count decreased				
subjects affected / exposed	4 / 123 (3.25%)			
occurrences causally related to treatment / all	4 / 5			
deaths causally related to treatment / all	0 / 0			
Hepatic enzyme increased				

subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Platelet count decreased				
subjects affected / exposed	8 / 123 (6.50%)			
occurrences causally related to treatment / all	8 / 9			
deaths causally related to treatment / all	0 / 0			
Pancreatic enzymes increased				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Transaminases increased				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Weight decreased				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Troponin increased				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
White blood cell count decreased				
subjects affected / exposed	2 / 123 (1.63%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
Acetabulum fracture				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Accidental overdose				

subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ankle fracture				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Contusion				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Forearm fracture				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fall				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Femoral neck fracture				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Femoral nerve injury				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Femur fracture				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infusion related reaction				

subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Humerus fracture				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hip fracture				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Head injury				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Injury				
subjects affected / exposed	1 / 123 (0.81%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Fracture displacement				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Multiple fractures				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lumbar vertebral fracture				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Limb injury				

subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ligament sprain				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Muscle strain				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pelvic fracture				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Overdose				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Post procedural complication				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Post procedural haemorrhage				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Procedural pain				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Radiation pneumonitis				

subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Radiation oesophagitis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rib fracture				
subjects affected / exposed	1 / 123 (0.81%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Spinal fracture				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Spinal compression fracture				
subjects affected / exposed	1 / 123 (0.81%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Subdural haematoma				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Wound dehiscence				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Congenital, familial and genetic disorders				
Tracheo-oesophageal fistula				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				

Acute myocardial infarction				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Acute left ventricular failure				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Acute coronary syndrome				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Angina pectoris				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Angina unstable				
subjects affected / exposed	1 / 123 (0.81%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Arrhythmia				
subjects affected / exposed	1 / 123 (0.81%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Arteriosclerosis coronary artery				
subjects affected / exposed	1 / 123 (0.81%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Atrial fibrillation				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atrial flutter				

subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac arrest				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bradycardia				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atrioventricular block complete				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac failure				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardio-respiratory arrest				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac tamponade				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac fibrillation				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac failure congestive				

subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac failure acute			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiogenic shock			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Coronary artery disease			
subjects affected / exposed	1 / 123 (0.81%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiopulmonary failure			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypertensive cardiomyopathy			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune-mediated myocarditis			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myocardial infarction			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myocarditis			

subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myocardial ischaemia				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Palpitations				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pericardial effusion malignant				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pericardial effusion				
subjects affected / exposed	1 / 123 (0.81%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pericarditis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pleuropericarditis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Stress cardiomyopathy				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Right ventricular failure				

subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Supraventricular extrasystoles				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Supraventricular tachyarrhythmia				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Torsade de pointes				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tachycardia				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Supraventricular tachycardia				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
Brain oedema				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atonic seizures				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebellar infarction				

subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebral infarction			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebral haemorrhage			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebral ischaemia			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebral microangiopathy			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebrovascular accident			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dizziness			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebrovascular disorder			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dysarthria			

subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Encephalitis autoimmune				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Embolic cerebral infarction				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Encephalopathy				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Epilepsy				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Generalised tonic-clonic seizure				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Facial paralysis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemorrhage intracranial				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemorrhagic stroke				

subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemorrhagic transformation stroke				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Headache				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hemiparesis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypoaesthesia				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemorrhagic cerebral infarction				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ischaemic stroke				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lethargy				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lumbar radiculopathy				

subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myasthenia gravis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myasthenic syndrome				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nerve compression				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neuralgia				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neuropathy peripheral				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Paralysis recurrent laryngeal nerve				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Paraplegia				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Polyneuropathy				

subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Partial seizures				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Presyncope				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sensory loss				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Seizure				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Quadriparesis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Somnolence				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Spinal cord compression				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Subarachnoid haemorrhage				

subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Syncope				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Transient ischaemic attack				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vasogenic cerebral oedema				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vocal cord paralysis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vertebrobasilar artery dissection				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood and lymphatic system disorders				
Anaemia				
subjects affected / exposed	2 / 123 (1.63%)			
occurrences causally related to treatment / all	2 / 2			
deaths causally related to treatment / all	0 / 0			
Autoimmune haemolytic anaemia				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Febrile neutropenia				

subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Eosinophilia				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Febrile bone marrow aplasia				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bone marrow failure				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Leukopenia				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lymphadenopathy				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Iron deficiency anaemia				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Heparin-induced thrombocytopenia				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haematotoxicity				

subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myelosuppression				
subjects affected / exposed	7 / 123 (5.69%)			
occurrences causally related to treatment / all	7 / 7			
deaths causally related to treatment / all	0 / 0			
Neutropenia				
subjects affected / exposed	1 / 123 (0.81%)			
occurrences causally related to treatment / all	2 / 2			
deaths causally related to treatment / all	0 / 0			
Pancytopenia				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Splenic haematoma				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Splenic haemorrhage				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Thrombocytopenia				
subjects affected / exposed	2 / 123 (1.63%)			
occurrences causally related to treatment / all	2 / 2			
deaths causally related to treatment / all	0 / 0			
Splenic thrombosis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Thrombocytosis				

subjects affected / exposed	1 / 123 (0.81%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ear and labyrinth disorders			
Sudden hearing loss			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vertigo			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Cataract			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diplopia			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal hernia			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal distension			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal pain			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Abdominal pain upper				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ascites				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colitis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Autoimmune colitis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colitis ischaemic				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colitis ulcerative				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colitis microscopic				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Constipation				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diarrhoea				

subjects affected / exposed	2 / 123 (1.63%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
Duodenal ulcer haemorrhage				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Duodenal ulcer				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dysphagia				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Enterocolitis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Erosive oesophagitis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastric haemorrhage				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastric ulcer				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastritis				

subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorder			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gingival hypertrophy			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haematemesis			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemorrhoids			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune-mediated enterocolitis			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ileus			

subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Immune-mediated gastritis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intestinal ischaemia				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Immune-mediated pancreatitis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Melaena				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Malignant ascites				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Large intestine perforation				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Large intestinal ulcer				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intestinal obstruction				

subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oesophageal stenosis			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oesophageal ulcer			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oesophageal fistula			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Odynophagia			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oesophagitis			
subjects affected / exposed	1 / 123 (0.81%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nausea			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancreatitis acute			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancreatitis			

subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rectal ulcer				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Stomatitis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Small intestinal obstruction				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vomiting				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Subileus				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Upper gastrointestinal haemorrhage				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin and subcutaneous tissue disorders				
Diabetic foot				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Autoimmune dermatitis				

subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Drug eruption				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Erythema multiforme				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Exfoliative rash				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Erythema				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Eczema				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neutrophilic dermatosis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rash				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pruritus				

subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rash maculo-papular				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rash vesicular				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rash pruritic				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin ulcer				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Stevens-Johnson syndrome				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Toxic skin eruption				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal and urinary disorders				
Acute kidney injury				
subjects affected / exposed	1 / 123 (0.81%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Autoimmune nephritis				

subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Azotaemia				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nephrogenic diabetes insipidus				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nephropathy toxic				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal failure				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tubulointerstitial nephritis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal vascular thrombosis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ureterolithiasis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary retention				

subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Endocrine disorders			
Hypercalcaemia of malignancy			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Autoimmune thyroiditis			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Autoimmune hypothyroidism			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Adrenal insufficiency			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyperparathyroidism secondary			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyperthyroidism			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypophysitis			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypothyroidism			

subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypopituitarism				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Inappropriate antidiuretic hormone secretion				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Primary adrenal insufficiency				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Secondary adrenocortical insufficiency				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Immune-mediated hypophysitis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue disorders				
Arthralgia				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Autoimmune arthritis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Back pain				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bone pain				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Flank pain				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypertrophic osteoarthropathy				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intervertebral disc protrusion				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Muscular weakness				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal chest pain				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myalgia				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myopathy				

subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myositis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Osteoarthritis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Osteonecrosis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Osteonecrosis of jaw				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pain in extremity				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pathological fracture				
subjects affected / exposed	1 / 123 (0.81%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Polyarthritis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Polymyalgia rheumatica				

subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rheumatoid arthritis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rhabdomyolysis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Abscess				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Abscess limb				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anal abscess				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bacteraemia				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Aspergillus infection				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Appendicitis				

subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bacterial diarrhoea			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchitis			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bacterial infection			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Catheter site infection			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diabetic foot infection			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dermo-hypodermitis			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Clostridium difficile infection			

subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cellulitis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diverticulitis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Enteritis infectious				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Encephalitis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Empyema				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diverticulitis intestinal perforated				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Enterocolitis infectious				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Erysipelas				

subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal infection				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis viral				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Febrile infection				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Groin infection				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Herpes zoster				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infection				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infectious pleural effusion				

subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infective exacerbation of chronic obstructive airways disease				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Influenza				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Injection site infection				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Klebsiella urinary tract infection				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Large intestine infection				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lower respiratory tract infection				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung abscess				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nasopharyngitis				

subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neutropenic infection				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neutropenic sepsis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Meningitis viral				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metapneumovirus infection				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myelitis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Osteomyelitis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Parainfluenzae virus infection				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ophthalmic herpes zoster				

subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oesophageal candidiasis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peritonitis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	8 / 123 (6.50%)			
occurrences causally related to treatment / all	1 / 8			
deaths causally related to treatment / all	0 / 0			
Pleural infection				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia adenoviral				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia bacterial				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia aspiration				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia influenzal				

subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia klebsiella				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia necrotising				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pseudomembranous colitis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia viral				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary sepsis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory syncytial virus infection				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rectal abscess				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis				

subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary tuberculosis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory tract infection				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory tract infection viral				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Salmonellosis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Septic shock				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin infection				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Soft tissue infection				

subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Staphylococcal infection			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Systemic candida			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thrombophlebitis septic			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tooth infection			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Upper respiratory tract infection			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Viral pericarditis			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Viral infection			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular device infection			

subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urosepsis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				
subjects affected / exposed	1 / 123 (0.81%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Wound infection				
subjects affected / exposed	1 / 123 (0.81%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Acidosis				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Adult failure to thrive				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Decreased appetite				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dehydration				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diabetes mellitus				

subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diabetic metabolic decompensation				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Failure to thrive				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Electrolyte imbalance				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypercalcaemia				
subjects affected / exposed	2 / 123 (1.63%)			
occurrences causally related to treatment / all	1 / 3			
deaths causally related to treatment / all	0 / 0			
Hyperglycaemia				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypermagnesaemia				
subjects affected / exposed	0 / 123 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperuricaemia				
subjects affected / exposed	1 / 123 (0.81%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Hypocalcaemia				

subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyperkalaemia			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypokalaemia			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypoglycaemia			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypomagnesaemia			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypoproteinaemia			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyponatraemia			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ketoacidosis			
subjects affected / exposed	1 / 123 (0.81%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Type 1 diabetes mellitus			

subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Part 1-Arm A: Nivolumab	Part 1-Arm B: Nivo + Ipi	Part 1-Arm D: Nivo + Ipi
Total subjects affected by non-serious adverse events			
subjects affected / exposed	356 / 391 (91.05%)	366 / 391 (93.61%)	172 / 185 (92.97%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	18 / 391 (4.60%)	9 / 391 (2.30%)	5 / 185 (2.70%)
occurrences (all)	19	9	5
Vascular disorders			
Hypertension			
subjects affected / exposed	15 / 391 (3.84%)	21 / 391 (5.37%)	8 / 185 (4.32%)
occurrences (all)	18	24	15
Hypotension			
subjects affected / exposed	13 / 391 (3.32%)	16 / 391 (4.09%)	6 / 185 (3.24%)
occurrences (all)	14	18	7
General disorders and administration site conditions			
Chest discomfort			
subjects affected / exposed	3 / 391 (0.77%)	4 / 391 (1.02%)	2 / 185 (1.08%)
occurrences (all)	3	4	2
Asthenia			
subjects affected / exposed	78 / 391 (19.95%)	93 / 391 (23.79%)	40 / 185 (21.62%)
occurrences (all)	104	125	48
Malaise			
subjects affected / exposed	13 / 391 (3.32%)	11 / 391 (2.81%)	7 / 185 (3.78%)
occurrences (all)	16	14	9
Fatigue			

subjects affected / exposed	88 / 391 (22.51%)	107 / 391 (27.37%)	38 / 185 (20.54%)
occurrences (all)	102	143	43
Chest pain			
subjects affected / exposed	18 / 391 (4.60%)	19 / 391 (4.86%)	4 / 185 (2.16%)
occurrences (all)	19	20	4
Mucosal inflammation			
subjects affected / exposed	12 / 391 (3.07%)	13 / 391 (3.32%)	3 / 185 (1.62%)
occurrences (all)	12	14	3
Pyrexia			
subjects affected / exposed	57 / 391 (14.58%)	74 / 391 (18.93%)	32 / 185 (17.30%)
occurrences (all)	80	105	39
Pain			
subjects affected / exposed	6 / 391 (1.53%)	6 / 391 (1.53%)	6 / 185 (3.24%)
occurrences (all)	6	6	6
Oedema peripheral			
subjects affected / exposed	26 / 391 (6.65%)	49 / 391 (12.53%)	18 / 185 (9.73%)
occurrences (all)	28	55	21
Non-cardiac chest pain			
subjects affected / exposed	20 / 391 (5.12%)	16 / 391 (4.09%)	17 / 185 (9.19%)
occurrences (all)	22	20	22
Respiratory, thoracic and mediastinal disorders			
Hiccups			
subjects affected / exposed	10 / 391 (2.56%)	7 / 391 (1.79%)	6 / 185 (3.24%)
occurrences (all)	11	7	9
Haemoptysis			
subjects affected / exposed	26 / 391 (6.65%)	34 / 391 (8.70%)	17 / 185 (9.19%)
occurrences (all)	33	41	20
Epistaxis			
subjects affected / exposed	9 / 391 (2.30%)	3 / 391 (0.77%)	3 / 185 (1.62%)
occurrences (all)	12	4	3
Dyspnoea			
subjects affected / exposed	93 / 391 (23.79%)	98 / 391 (25.06%)	47 / 185 (25.41%)
occurrences (all)	106	111	53
Cough			

subjects affected / exposed	82 / 391 (20.97%)	75 / 391 (19.18%)	31 / 185 (16.76%)
occurrences (all)	102	89	37
Pneumonitis			
subjects affected / exposed	23 / 391 (5.88%)	22 / 391 (5.63%)	6 / 185 (3.24%)
occurrences (all)	31	24	9
Productive cough			
subjects affected / exposed	30 / 391 (7.67%)	28 / 391 (7.16%)	12 / 185 (6.49%)
occurrences (all)	36	32	13
Psychiatric disorders			
Insomnia			
subjects affected / exposed	32 / 391 (8.18%)	43 / 391 (11.00%)	23 / 185 (12.43%)
occurrences (all)	33	45	31
Anxiety			
subjects affected / exposed	12 / 391 (3.07%)	22 / 391 (5.63%)	5 / 185 (2.70%)
occurrences (all)	14	22	5
Investigations			
Bilirubin conjugated increased			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	37 / 391 (9.46%)	47 / 391 (12.02%)	27 / 185 (14.59%)
occurrences (all)	49	72	35
Amylase increased			
subjects affected / exposed	22 / 391 (5.63%)	30 / 391 (7.67%)	18 / 185 (9.73%)
occurrences (all)	33	37	32
Alanine aminotransferase increased			
subjects affected / exposed	40 / 391 (10.23%)	43 / 391 (11.00%)	31 / 185 (16.76%)
occurrences (all)	49	58	37
Blood alkaline phosphatase increased			
subjects affected / exposed	13 / 391 (3.32%)	21 / 391 (5.37%)	13 / 185 (7.03%)
occurrences (all)	13	21	16
Blood glucose increased			
subjects affected / exposed	2 / 391 (0.51%)	2 / 391 (0.51%)	1 / 185 (0.54%)
occurrences (all)	3	2	1
Blood lactate dehydrogenase increased			

subjects affected / exposed	5 / 391 (1.28%)	3 / 391 (0.77%)	4 / 185 (2.16%)
occurrences (all)	5	3	5
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	3 / 391 (0.77%)	5 / 391 (1.28%)	2 / 185 (1.08%)
occurrences (all)	3	5	2
Lipase increased			
subjects affected / exposed	27 / 391 (6.91%)	31 / 391 (7.93%)	25 / 185 (13.51%)
occurrences (all)	49	44	38
Gamma-glutamyltransferase increased			
subjects affected / exposed	7 / 391 (1.79%)	6 / 391 (1.53%)	5 / 185 (2.70%)
occurrences (all)	7	7	6
Blood creatinine increased			
subjects affected / exposed	15 / 391 (3.84%)	23 / 391 (5.88%)	13 / 185 (7.03%)
occurrences (all)	23	39	26
Blood bilirubin increased			
subjects affected / exposed	5 / 391 (1.28%)	5 / 391 (1.28%)	3 / 185 (1.62%)
occurrences (all)	6	7	3
Blood thyroid stimulating hormone increased			
subjects affected / exposed	6 / 391 (1.53%)	10 / 391 (2.56%)	3 / 185 (1.62%)
occurrences (all)	7	10	5
Lymphocyte count decreased			
subjects affected / exposed	4 / 391 (1.02%)	7 / 391 (1.79%)	2 / 185 (1.08%)
occurrences (all)	4	9	11
Neutrophil count decreased			
subjects affected / exposed	11 / 391 (2.81%)	9 / 391 (2.30%)	2 / 185 (1.08%)
occurrences (all)	14	26	5
Neutrophil count increased			
subjects affected / exposed	1 / 391 (0.26%)	1 / 391 (0.26%)	0 / 185 (0.00%)
occurrences (all)	1	1	0
Platelet count decreased			
subjects affected / exposed	10 / 391 (2.56%)	6 / 391 (1.53%)	2 / 185 (1.08%)
occurrences (all)	19	12	4
Weight decreased			

subjects affected / exposed	20 / 391 (5.12%)	37 / 391 (9.46%)	17 / 185 (9.19%)
occurrences (all)	24	42	21
Weight increased			
subjects affected / exposed	8 / 391 (2.05%)	8 / 391 (2.05%)	1 / 185 (0.54%)
occurrences (all)	9	8	2
White blood cell count decreased			
subjects affected / exposed	5 / 391 (1.28%)	8 / 391 (2.05%)	1 / 185 (0.54%)
occurrences (all)	7	15	1
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	6 / 391 (1.53%)	12 / 391 (3.07%)	3 / 185 (1.62%)
occurrences (all)	7	13	3
Nervous system disorders			
Dysgeusia			
subjects affected / exposed	10 / 391 (2.56%)	14 / 391 (3.58%)	5 / 185 (2.70%)
occurrences (all)	10	16	6
Dizziness			
subjects affected / exposed	21 / 391 (5.37%)	30 / 391 (7.67%)	16 / 185 (8.65%)
occurrences (all)	22	32	16
Headache			
subjects affected / exposed	40 / 391 (10.23%)	54 / 391 (13.81%)	13 / 185 (7.03%)
occurrences (all)	46	72	15
Neuropathy peripheral			
subjects affected / exposed	5 / 391 (1.28%)	1 / 391 (0.26%)	2 / 185 (1.08%)
occurrences (all)	6	1	2
Paraesthesia			
subjects affected / exposed	2 / 391 (0.51%)	14 / 391 (3.58%)	4 / 185 (2.16%)
occurrences (all)	2	16	4
Blood and lymphatic system disorders			
Leukopenia			
subjects affected / exposed	3 / 391 (0.77%)	0 / 391 (0.00%)	1 / 185 (0.54%)
occurrences (all)	3	0	1
Neutropenia			
subjects affected / exposed	7 / 391 (1.79%)	4 / 391 (1.02%)	2 / 185 (1.08%)
occurrences (all)	9	5	2
Anaemia			

subjects affected / exposed	51 / 391 (13.04%)	47 / 391 (12.02%)	25 / 185 (13.51%)
occurrences (all)	76	69	37
Leukocytosis			
subjects affected / exposed	4 / 391 (1.02%)	6 / 391 (1.53%)	4 / 185 (2.16%)
occurrences (all)	4	6	4
Thrombocytopenia			
subjects affected / exposed	7 / 391 (1.79%)	6 / 391 (1.53%)	2 / 185 (1.08%)
occurrences (all)	7	8	2
Eye disorders			
Lacrimation increased			
subjects affected / exposed	1 / 391 (0.26%)	3 / 391 (0.77%)	1 / 185 (0.54%)
occurrences (all)	1	4	1
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	30 / 391 (7.67%)	30 / 391 (7.67%)	9 / 185 (4.86%)
occurrences (all)	37	36	11
Abdominal pain upper			
subjects affected / exposed	16 / 391 (4.09%)	18 / 391 (4.60%)	4 / 185 (2.16%)
occurrences (all)	18	19	4
Constipation			
subjects affected / exposed	70 / 391 (17.90%)	78 / 391 (19.95%)	36 / 185 (19.46%)
occurrences (all)	78	96	47
Diarrhoea			
subjects affected / exposed	88 / 391 (22.51%)	102 / 391 (26.09%)	44 / 185 (23.78%)
occurrences (all)	142	178	70
Dry mouth			
subjects affected / exposed	11 / 391 (2.81%)	17 / 391 (4.35%)	6 / 185 (3.24%)
occurrences (all)	11	19	8
Dyspepsia			
subjects affected / exposed	10 / 391 (2.56%)	15 / 391 (3.84%)	7 / 185 (3.78%)
occurrences (all)	11	18	7
Mouth ulceration			
subjects affected / exposed	0 / 391 (0.00%)	4 / 391 (1.02%)	0 / 185 (0.00%)
occurrences (all)	0	4	0
Stomatitis			

subjects affected / exposed	12 / 391 (3.07%)	25 / 391 (6.39%)	2 / 185 (1.08%)
occurrences (all)	17	29	2
Vomiting			
subjects affected / exposed	41 / 391 (10.49%)	52 / 391 (13.30%)	27 / 185 (14.59%)
occurrences (all)	64	72	46
Nausea			
subjects affected / exposed	81 / 391 (20.72%)	93 / 391 (23.79%)	41 / 185 (22.16%)
occurrences (all)	104	130	66
Hepatobiliary disorders			
Hepatic function abnormal			
subjects affected / exposed	0 / 391 (0.00%)	3 / 391 (0.77%)	1 / 185 (0.54%)
occurrences (all)	0	4	1
Skin and subcutaneous tissue disorders			
Rash maculo-papular			
subjects affected / exposed	13 / 391 (3.32%)	28 / 391 (7.16%)	14 / 185 (7.57%)
occurrences (all)	15	35	26
Rash			
subjects affected / exposed	55 / 391 (14.07%)	93 / 391 (23.79%)	31 / 185 (16.76%)
occurrences (all)	71	136	38
Dry skin			
subjects affected / exposed	14 / 391 (3.58%)	37 / 391 (9.46%)	9 / 185 (4.86%)
occurrences (all)	14	43	13
Alopecia			
subjects affected / exposed	9 / 391 (2.30%)	8 / 391 (2.05%)	3 / 185 (1.62%)
occurrences (all)	9	8	3
Pruritus			
subjects affected / exposed	44 / 391 (11.25%)	92 / 391 (23.53%)	29 / 185 (15.68%)
occurrences (all)	49	122	45
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	30 / 391 (7.67%)	61 / 391 (15.60%)	22 / 185 (11.89%)
occurrences (all)	38	65	25
Hyperthyroidism			
subjects affected / exposed	18 / 391 (4.60%)	33 / 391 (8.44%)	19 / 185 (10.27%)
occurrences (all)	18	34	19
Musculoskeletal and connective tissue disorders			

Pain in extremity			
subjects affected / exposed	24 / 391 (6.14%)	17 / 391 (4.35%)	7 / 185 (3.78%)
occurrences (all)	25	21	7
Myalgia			
subjects affected / exposed	22 / 391 (5.63%)	23 / 391 (5.88%)	9 / 185 (4.86%)
occurrences (all)	28	24	9
Back pain			
subjects affected / exposed	36 / 391 (9.21%)	42 / 391 (10.74%)	28 / 185 (15.14%)
occurrences (all)	41	48	33
Arthralgia			
subjects affected / exposed	62 / 391 (15.86%)	72 / 391 (18.41%)	26 / 185 (14.05%)
occurrences (all)	77	93	30
Infections and infestations			
Bronchitis			
subjects affected / exposed	11 / 391 (2.81%)	17 / 391 (4.35%)	9 / 185 (4.86%)
occurrences (all)	12	18	11
Nasopharyngitis			
subjects affected / exposed	23 / 391 (5.88%)	27 / 391 (6.91%)	9 / 185 (4.86%)
occurrences (all)	32	33	13
Upper respiratory tract infection			
subjects affected / exposed	17 / 391 (4.35%)	14 / 391 (3.58%)	7 / 185 (3.78%)
occurrences (all)	23	17	9
Pneumonia			
subjects affected / exposed	20 / 391 (5.12%)	21 / 391 (5.37%)	12 / 185 (6.49%)
occurrences (all)	22	23	15
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	97 / 391 (24.81%)	130 / 391 (33.25%)	61 / 185 (32.97%)
occurrences (all)	119	174	64
Hyperglycaemia			
subjects affected / exposed	16 / 391 (4.09%)	24 / 391 (6.14%)	9 / 185 (4.86%)
occurrences (all)	20	30	13
Hyperkalaemia			
subjects affected / exposed	12 / 391 (3.07%)	10 / 391 (2.56%)	6 / 185 (3.24%)
occurrences (all)	15	13	6
Hyponatraemia			

subjects affected / exposed	17 / 391 (4.35%)	39 / 391 (9.97%)	14 / 185 (7.57%)
occurrences (all)	19	59	21
Hypomagnesaemia			
subjects affected / exposed	7 / 391 (1.79%)	12 / 391 (3.07%)	10 / 185 (5.41%)
occurrences (all)	15	14	13
Hypokalaemia			
subjects affected / exposed	16 / 391 (4.09%)	27 / 391 (6.91%)	13 / 185 (7.03%)
occurrences (all)	26	33	29
Hypochloraemia			
subjects affected / exposed	0 / 391 (0.00%)	1 / 391 (0.26%)	0 / 185 (0.00%)
occurrences (all)	0	1	0
Hypermagnesaemia			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	16 / 391 (4.09%)	25 / 391 (6.39%)	9 / 185 (4.86%)
occurrences (all)	17	33	17
Hyperuricaemia			
subjects affected / exposed	3 / 391 (0.77%)	1 / 391 (0.26%)	2 / 185 (1.08%)
occurrences (all)	3	1	3
Hypertriglyceridaemia			
subjects affected / exposed	1 / 391 (0.26%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences (all)	1	0	0
Hypocalcaemia			
subjects affected / exposed	9 / 391 (2.30%)	12 / 391 (3.07%)	5 / 185 (2.70%)
occurrences (all)	11	13	5
Hypoproteinaemia			
subjects affected / exposed	0 / 391 (0.00%)	0 / 391 (0.00%)	0 / 185 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	10 / 391 (2.56%)	14 / 391 (3.58%)	5 / 185 (2.70%)
occurrences (all)	16	20	9

Non-serious adverse events	Part 1-Arm C: Chemotherapy	Part 1-Arm G: Nivo + Chemo	Part 1-Arm F: Chemotherapy
Total subjects affected by non-serious adverse events			
subjects affected / exposed	361 / 387 (93.28%)	167 / 172 (97.09%)	165 / 183 (90.16%)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	11 / 387 (2.84%)	9 / 172 (5.23%)	2 / 183 (1.09%)
occurrences (all)	13	9	2
Vascular disorders			
Hypertension			
subjects affected / exposed	13 / 387 (3.36%)	12 / 172 (6.98%)	8 / 183 (4.37%)
occurrences (all)	14	15	11
Hypotension			
subjects affected / exposed	9 / 387 (2.33%)	10 / 172 (5.81%)	8 / 183 (4.37%)
occurrences (all)	11	11	8
General disorders and administration site conditions			
Chest discomfort			
subjects affected / exposed	3 / 387 (0.78%)	3 / 172 (1.74%)	0 / 183 (0.00%)
occurrences (all)	3	4	0
Asthenia			
subjects affected / exposed	66 / 387 (17.05%)	35 / 172 (20.35%)	42 / 183 (22.95%)
occurrences (all)	90	44	61
Malaise			
subjects affected / exposed	17 / 387 (4.39%)	13 / 172 (7.56%)	11 / 183 (6.01%)
occurrences (all)	29	27	16
Fatigue			
subjects affected / exposed	101 / 387 (26.10%)	54 / 172 (31.40%)	50 / 183 (27.32%)
occurrences (all)	132	71	59
Chest pain			
subjects affected / exposed	13 / 387 (3.36%)	6 / 172 (3.49%)	12 / 183 (6.56%)
occurrences (all)	13	7	14
Mucosal inflammation			
subjects affected / exposed	12 / 387 (3.10%)	13 / 172 (7.56%)	13 / 183 (7.10%)
occurrences (all)	16	18	14
Pyrexia			
subjects affected / exposed	38 / 387 (9.82%)	33 / 172 (19.19%)	32 / 183 (17.49%)
occurrences (all)	51	46	45
Pain			
subjects affected / exposed	6 / 387 (1.55%)	6 / 172 (3.49%)	4 / 183 (2.19%)
occurrences (all)	6	6	4

Oedema peripheral			
subjects affected / exposed	37 / 387 (9.56%)	27 / 172 (15.70%)	23 / 183 (12.57%)
occurrences (all)	44	32	26
Non-cardiac chest pain			
subjects affected / exposed	21 / 387 (5.43%)	9 / 172 (5.23%)	12 / 183 (6.56%)
occurrences (all)	22	10	14
Respiratory, thoracic and mediastinal disorders			
Hiccups			
subjects affected / exposed	20 / 387 (5.17%)	9 / 172 (5.23%)	14 / 183 (7.65%)
occurrences (all)	22	21	20
Haemoptysis			
subjects affected / exposed	22 / 387 (5.68%)	9 / 172 (5.23%)	11 / 183 (6.01%)
occurrences (all)	24	12	12
Epistaxis			
subjects affected / exposed	13 / 387 (3.36%)	9 / 172 (5.23%)	6 / 183 (3.28%)
occurrences (all)	15	13	7
Dyspnoea			
subjects affected / exposed	61 / 387 (15.76%)	40 / 172 (23.26%)	39 / 183 (21.31%)
occurrences (all)	68	47	45
Cough			
subjects affected / exposed	45 / 387 (11.63%)	45 / 172 (26.16%)	27 / 183 (14.75%)
occurrences (all)	49	56	30
Pneumonitis			
subjects affected / exposed	3 / 387 (0.78%)	7 / 172 (4.07%)	1 / 183 (0.55%)
occurrences (all)	3	7	1
Productive cough			
subjects affected / exposed	15 / 387 (3.88%)	11 / 172 (6.40%)	8 / 183 (4.37%)
occurrences (all)	15	11	9
Psychiatric disorders			
Insomnia			
subjects affected / exposed	30 / 387 (7.75%)	25 / 172 (14.53%)	11 / 183 (6.01%)
occurrences (all)	34	27	12
Anxiety			
subjects affected / exposed	19 / 387 (4.91%)	7 / 172 (4.07%)	6 / 183 (3.28%)
occurrences (all)	20	7	7
Investigations			

Bilirubin conjugated increased			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	21 / 387 (5.43%)	16 / 172 (9.30%)	12 / 183 (6.56%)
occurrences (all)	26	26	16
Amylase increased			
subjects affected / exposed	12 / 387 (3.10%)	17 / 172 (9.88%)	4 / 183 (2.19%)
occurrences (all)	14	31	4
Alanine aminotransferase increased			
subjects affected / exposed	27 / 387 (6.98%)	22 / 172 (12.79%)	15 / 183 (8.20%)
occurrences (all)	34	30	22
Blood alkaline phosphatase increased			
subjects affected / exposed	12 / 387 (3.10%)	7 / 172 (4.07%)	4 / 183 (2.19%)
occurrences (all)	14	11	5
Blood glucose increased			
subjects affected / exposed	3 / 387 (0.78%)	1 / 172 (0.58%)	0 / 183 (0.00%)
occurrences (all)	3	1	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	4 / 387 (1.03%)	2 / 172 (1.16%)	2 / 183 (1.09%)
occurrences (all)	4	3	2
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	0 / 387 (0.00%)	1 / 172 (0.58%)	0 / 183 (0.00%)
occurrences (all)	0	1	0
Lipase increased			
subjects affected / exposed	14 / 387 (3.62%)	12 / 172 (6.98%)	1 / 183 (0.55%)
occurrences (all)	14	16	2
Gamma-glutamyltransferase increased			
subjects affected / exposed	9 / 387 (2.33%)	2 / 172 (1.16%)	7 / 183 (3.83%)
occurrences (all)	12	2	7
Blood creatinine increased			
subjects affected / exposed	21 / 387 (5.43%)	18 / 172 (10.47%)	10 / 183 (5.46%)
occurrences (all)	26	34	15
Blood bilirubin increased			

subjects affected / exposed	3 / 387 (0.78%)	0 / 172 (0.00%)	2 / 183 (1.09%)
occurrences (all)	3	0	3
Blood thyroid stimulating hormone increased			
subjects affected / exposed	3 / 387 (0.78%)	4 / 172 (2.33%)	1 / 183 (0.55%)
occurrences (all)	5	5	1
Lymphocyte count decreased			
subjects affected / exposed	9 / 387 (2.33%)	8 / 172 (4.65%)	4 / 183 (2.19%)
occurrences (all)	13	27	5
Neutrophil count decreased			
subjects affected / exposed	50 / 387 (12.92%)	31 / 172 (18.02%)	20 / 183 (10.93%)
occurrences (all)	100	56	45
Neutrophil count increased			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	31 / 387 (8.01%)	22 / 172 (12.79%)	25 / 183 (13.66%)
occurrences (all)	43	44	41
Weight decreased			
subjects affected / exposed	22 / 387 (5.68%)	14 / 172 (8.14%)	8 / 183 (4.37%)
occurrences (all)	24	14	8
Weight increased			
subjects affected / exposed	3 / 387 (0.78%)	3 / 172 (1.74%)	1 / 183 (0.55%)
occurrences (all)	3	4	1
White blood cell count decreased			
subjects affected / exposed	19 / 387 (4.91%)	17 / 172 (9.88%)	6 / 183 (3.28%)
occurrences (all)	39	39	9
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	2 / 387 (0.52%)	10 / 172 (5.81%)	1 / 183 (0.55%)
occurrences (all)	2	13	2
Nervous system disorders			
Dysgeusia			
subjects affected / exposed	25 / 387 (6.46%)	11 / 172 (6.40%)	9 / 183 (4.92%)
occurrences (all)	26	12	10
Dizziness			

subjects affected / exposed	27 / 387 (6.98%)	18 / 172 (10.47%)	21 / 183 (11.48%)
occurrences (all)	32	22	26
Headache			
subjects affected / exposed	31 / 387 (8.01%)	19 / 172 (11.05%)	8 / 183 (4.37%)
occurrences (all)	33	25	13
Neuropathy peripheral			
subjects affected / exposed	11 / 387 (2.84%)	4 / 172 (2.33%)	3 / 183 (1.64%)
occurrences (all)	13	4	3
Paraesthesia			
subjects affected / exposed	9 / 387 (2.33%)	10 / 172 (5.81%)	5 / 183 (2.73%)
occurrences (all)	10	11	5
Blood and lymphatic system disorders			
Leukopenia			
subjects affected / exposed	21 / 387 (5.43%)	10 / 172 (5.81%)	9 / 183 (4.92%)
occurrences (all)	32	21	16
Neutropenia			
subjects affected / exposed	70 / 387 (18.09%)	45 / 172 (26.16%)	37 / 183 (20.22%)
occurrences (all)	110	80	62
Anaemia			
subjects affected / exposed	159 / 387 (41.09%)	80 / 172 (46.51%)	76 / 183 (41.53%)
occurrences (all)	199	123	93
Leukocytosis			
subjects affected / exposed	1 / 387 (0.26%)	1 / 172 (0.58%)	1 / 183 (0.55%)
occurrences (all)	1	1	1
Thrombocytopenia			
subjects affected / exposed	39 / 387 (10.08%)	17 / 172 (9.88%)	14 / 183 (7.65%)
occurrences (all)	60	27	21
Eye disorders			
Lacrimation increased			
subjects affected / exposed	18 / 387 (4.65%)	9 / 172 (5.23%)	2 / 183 (1.09%)
occurrences (all)	18	11	2
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	21 / 387 (5.43%)	10 / 172 (5.81%)	7 / 183 (3.83%)
occurrences (all)	24	11	7
Abdominal pain upper			

subjects affected / exposed	22 / 387 (5.68%)	5 / 172 (2.91%)	6 / 183 (3.28%)
occurrences (all)	25	5	8
Constipation			
subjects affected / exposed	104 / 387 (26.87%)	63 / 172 (36.63%)	53 / 183 (28.96%)
occurrences (all)	146	86	66
Diarrhoea			
subjects affected / exposed	66 / 387 (17.05%)	38 / 172 (22.09%)	33 / 183 (18.03%)
occurrences (all)	80	55	46
Dry mouth			
subjects affected / exposed	3 / 387 (0.78%)	2 / 172 (1.16%)	0 / 183 (0.00%)
occurrences (all)	3	2	0
Dyspepsia			
subjects affected / exposed	10 / 387 (2.58%)	13 / 172 (7.56%)	6 / 183 (3.28%)
occurrences (all)	28	16	6
Mouth ulceration			
subjects affected / exposed	3 / 387 (0.78%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences (all)	4	0	0
Stomatitis			
subjects affected / exposed	28 / 387 (7.24%)	16 / 172 (9.30%)	11 / 183 (6.01%)
occurrences (all)	37	22	11
Vomiting			
subjects affected / exposed	73 / 387 (18.86%)	33 / 172 (19.19%)	34 / 183 (18.58%)
occurrences (all)	109	50	50
Nausea			
subjects affected / exposed	174 / 387 (44.96%)	79 / 172 (45.93%)	74 / 183 (40.44%)
occurrences (all)	319	145	118
Hepatobiliary disorders			
Hepatic function abnormal			
subjects affected / exposed	1 / 387 (0.26%)	2 / 172 (1.16%)	2 / 183 (1.09%)
occurrences (all)	1	2	3
Skin and subcutaneous tissue disorders			
Rash maculo-papular			
subjects affected / exposed	7 / 387 (1.81%)	9 / 172 (5.23%)	4 / 183 (2.19%)
occurrences (all)	10	15	4
Rash			

subjects affected / exposed	31 / 387 (8.01%)	29 / 172 (16.86%)	13 / 183 (7.10%)
occurrences (all)	33	40	16
Dry skin			
subjects affected / exposed	12 / 387 (3.10%)	11 / 172 (6.40%)	4 / 183 (2.19%)
occurrences (all)	12	11	4
Alopecia			
subjects affected / exposed	34 / 387 (8.79%)	12 / 172 (6.98%)	10 / 183 (5.46%)
occurrences (all)	34	12	11
Pruritus			
subjects affected / exposed	17 / 387 (4.39%)	23 / 172 (13.37%)	5 / 183 (2.73%)
occurrences (all)	20	28	6
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	4 / 387 (1.03%)	9 / 172 (5.23%)	1 / 183 (0.55%)
occurrences (all)	5	10	1
Hyperthyroidism			
subjects affected / exposed	7 / 387 (1.81%)	9 / 172 (5.23%)	0 / 183 (0.00%)
occurrences (all)	7	10	0
Musculoskeletal and connective tissue disorders			
Pain in extremity			
subjects affected / exposed	10 / 387 (2.58%)	14 / 172 (8.14%)	4 / 183 (2.19%)
occurrences (all)	13	18	4
Myalgia			
subjects affected / exposed	9 / 387 (2.33%)	10 / 172 (5.81%)	3 / 183 (1.64%)
occurrences (all)	10	10	3
Back pain			
subjects affected / exposed	31 / 387 (8.01%)	23 / 172 (13.37%)	13 / 183 (7.10%)
occurrences (all)	33	31	14
Arthralgia			
subjects affected / exposed	19 / 387 (4.91%)	28 / 172 (16.28%)	9 / 183 (4.92%)
occurrences (all)	22	31	10
Infections and infestations			
Bronchitis			
subjects affected / exposed	9 / 387 (2.33%)	9 / 172 (5.23%)	8 / 183 (4.37%)
occurrences (all)	12	14	9
Nasopharyngitis			

subjects affected / exposed	22 / 387 (5.68%)	15 / 172 (8.72%)	4 / 183 (2.19%)
occurrences (all)	26	18	5
Upper respiratory tract infection			
subjects affected / exposed	12 / 387 (3.10%)	14 / 172 (8.14%)	6 / 183 (3.28%)
occurrences (all)	15	18	6
Pneumonia			
subjects affected / exposed	17 / 387 (4.39%)	10 / 172 (5.81%)	7 / 183 (3.83%)
occurrences (all)	20	12	9
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	109 / 387 (28.17%)	61 / 172 (35.47%)	52 / 183 (28.42%)
occurrences (all)	161	85	65
Hyperglycaemia			
subjects affected / exposed	14 / 387 (3.62%)	6 / 172 (3.49%)	9 / 183 (4.92%)
occurrences (all)	15	11	13
Hyperkalaemia			
subjects affected / exposed	9 / 387 (2.33%)	11 / 172 (6.40%)	3 / 183 (1.64%)
occurrences (all)	13	26	7
Hyponatraemia			
subjects affected / exposed	20 / 387 (5.17%)	11 / 172 (6.40%)	8 / 183 (4.37%)
occurrences (all)	24	20	10
Hypomagnesaemia			
subjects affected / exposed	21 / 387 (5.43%)	15 / 172 (8.72%)	12 / 183 (6.56%)
occurrences (all)	30	22	12
Hypokalaemia			
subjects affected / exposed	12 / 387 (3.10%)	13 / 172 (7.56%)	9 / 183 (4.92%)
occurrences (all)	13	14	14
Hypochloraemia			
subjects affected / exposed	0 / 387 (0.00%)	1 / 172 (0.58%)	0 / 183 (0.00%)
occurrences (all)	0	1	0
Hypermagnesaemia			
subjects affected / exposed	2 / 387 (0.52%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences (all)	2	0	0
Hypoalbuminaemia			
subjects affected / exposed	14 / 387 (3.62%)	8 / 172 (4.65%)	7 / 183 (3.83%)
occurrences (all)	17	14	7

Hyperuricaemia			
subjects affected / exposed	1 / 387 (0.26%)	1 / 172 (0.58%)	2 / 183 (1.09%)
occurrences (all)	2	1	2
Hypertriglyceridaemia			
subjects affected / exposed	0 / 387 (0.00%)	0 / 172 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	9 / 387 (2.33%)	7 / 172 (4.07%)	3 / 183 (1.64%)
occurrences (all)	13	7	4
Hypoproteinaemia			
subjects affected / exposed	0 / 387 (0.00%)	1 / 172 (0.58%)	0 / 183 (0.00%)
occurrences (all)	0	1	0
Hypophosphataemia			
subjects affected / exposed	11 / 387 (2.84%)	7 / 172 (4.07%)	5 / 183 (2.73%)
occurrences (all)	13	9	7

Non-serious adverse events	Part 2 - Arm H: Nivolumab + Chemotherapy	Part 2 - Arm I: Chemotherapy	Part 3 -Arm J: Nivolumab + Ipilimumab
Total subjects affected by non-serious adverse events			
subjects affected / exposed	357 / 375 (95.20%)	345 / 371 (92.99%)	124 / 126 (98.41%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	12 / 375 (3.20%)	12 / 371 (3.23%)	3 / 126 (2.38%)
occurrences (all)	12	12	3
Vascular disorders			
Hypertension			
subjects affected / exposed	21 / 375 (5.60%)	8 / 371 (2.16%)	8 / 126 (6.35%)
occurrences (all)	28	11	8
Hypotension			
subjects affected / exposed	9 / 375 (2.40%)	8 / 371 (2.16%)	5 / 126 (3.97%)
occurrences (all)	10	9	5
General disorders and administration site conditions			
Chest discomfort			
subjects affected / exposed	6 / 375 (1.60%)	7 / 371 (1.89%)	14 / 126 (11.11%)
occurrences (all)	6	8	16
Asthenia			

subjects affected / exposed	70 / 375 (18.67%)	52 / 371 (14.02%)	17 / 126 (13.49%)
occurrences (all)	105	68	21
Malaise			
subjects affected / exposed	20 / 375 (5.33%)	24 / 371 (6.47%)	12 / 126 (9.52%)
occurrences (all)	36	29	16
Fatigue			
subjects affected / exposed	87 / 375 (23.20%)	80 / 371 (21.56%)	18 / 126 (14.29%)
occurrences (all)	114	115	20
Chest pain			
subjects affected / exposed	16 / 375 (4.27%)	14 / 371 (3.77%)	5 / 126 (3.97%)
occurrences (all)	17	15	5
Mucosal inflammation			
subjects affected / exposed	19 / 375 (5.07%)	12 / 371 (3.23%)	0 / 126 (0.00%)
occurrences (all)	22	14	0
Pyrexia			
subjects affected / exposed	54 / 375 (14.40%)	38 / 371 (10.24%)	40 / 126 (31.75%)
occurrences (all)	82	43	59
Pain			
subjects affected / exposed	7 / 375 (1.87%)	4 / 371 (1.08%)	10 / 126 (7.94%)
occurrences (all)	7	4	10
Oedema peripheral			
subjects affected / exposed	40 / 375 (10.67%)	38 / 371 (10.24%)	10 / 126 (7.94%)
occurrences (all)	50	42	12
Non-cardiac chest pain			
subjects affected / exposed	18 / 375 (4.80%)	9 / 371 (2.43%)	15 / 126 (11.90%)
occurrences (all)	19	9	19
Respiratory, thoracic and mediastinal disorders			
Hiccups			
subjects affected / exposed	13 / 375 (3.47%)	13 / 371 (3.50%)	1 / 126 (0.79%)
occurrences (all)	17	15	2
Haemoptysis			
subjects affected / exposed	19 / 375 (5.07%)	20 / 371 (5.39%)	31 / 126 (24.60%)
occurrences (all)	22	21	43
Epistaxis			

subjects affected / exposed	11 / 375 (2.93%)	9 / 371 (2.43%)	3 / 126 (2.38%)
occurrences (all)	11	9	4
Dyspnoea			
subjects affected / exposed	74 / 375 (19.73%)	55 / 371 (14.82%)	19 / 126 (15.08%)
occurrences (all)	80	58	20
Cough			
subjects affected / exposed	69 / 375 (18.40%)	44 / 371 (11.86%)	30 / 126 (23.81%)
occurrences (all)	80	52	39
Pneumonitis			
subjects affected / exposed	16 / 375 (4.27%)	1 / 371 (0.27%)	7 / 126 (5.56%)
occurrences (all)	19	1	8
Productive cough			
subjects affected / exposed	24 / 375 (6.40%)	15 / 371 (4.04%)	15 / 126 (11.90%)
occurrences (all)	28	15	18
Psychiatric disorders			
Insomnia			
subjects affected / exposed	31 / 375 (8.27%)	23 / 371 (6.20%)	22 / 126 (17.46%)
occurrences (all)	37	26	31
Anxiety			
subjects affected / exposed	9 / 375 (2.40%)	13 / 371 (3.50%)	1 / 126 (0.79%)
occurrences (all)	9	14	3
Investigations			
Bilirubin conjugated increased			
subjects affected / exposed	5 / 375 (1.33%)	0 / 371 (0.00%)	14 / 126 (11.11%)
occurrences (all)	7	0	28
Aspartate aminotransferase increased			
subjects affected / exposed	48 / 375 (12.80%)	25 / 371 (6.74%)	46 / 126 (36.51%)
occurrences (all)	55	44	93
Amylase increased			
subjects affected / exposed	33 / 375 (8.80%)	17 / 371 (4.58%)	24 / 126 (19.05%)
occurrences (all)	50	25	35
Alanine aminotransferase increased			
subjects affected / exposed	48 / 375 (12.80%)	29 / 371 (7.82%)	42 / 126 (33.33%)
occurrences (all)	66	45	70
Blood alkaline phosphatase increased			

subjects affected / exposed	23 / 375 (6.13%)	9 / 371 (2.43%)	18 / 126 (14.29%)
occurrences (all)	29	11	31
Blood glucose increased			
subjects affected / exposed	5 / 375 (1.33%)	1 / 371 (0.27%)	7 / 126 (5.56%)
occurrences (all)	5	1	12
Blood lactate dehydrogenase increased			
subjects affected / exposed	10 / 375 (2.67%)	5 / 371 (1.35%)	11 / 126 (8.73%)
occurrences (all)	22	5	16
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	4 / 375 (1.07%)	0 / 371 (0.00%)	7 / 126 (5.56%)
occurrences (all)	5	0	9
Lipase increased			
subjects affected / exposed	27 / 375 (7.20%)	16 / 371 (4.31%)	15 / 126 (11.90%)
occurrences (all)	44	27	29
Gamma-glutamyltransferase increased			
subjects affected / exposed	17 / 375 (4.53%)	10 / 371 (2.70%)	23 / 126 (18.25%)
occurrences (all)	19	13	34
Blood creatinine increased			
subjects affected / exposed	41 / 375 (10.93%)	29 / 371 (7.82%)	13 / 126 (10.32%)
occurrences (all)	72	38	29
Blood bilirubin increased			
subjects affected / exposed	9 / 375 (2.40%)	0 / 371 (0.00%)	23 / 126 (18.25%)
occurrences (all)	13	0	44
Blood thyroid stimulating hormone increased			
subjects affected / exposed	5 / 375 (1.33%)	1 / 371 (0.27%)	7 / 126 (5.56%)
occurrences (all)	5	1	7
Lymphocyte count decreased			
subjects affected / exposed	3 / 375 (0.80%)	3 / 371 (0.81%)	10 / 126 (7.94%)
occurrences (all)	3	4	25
Neutrophil count decreased			
subjects affected / exposed	52 / 375 (13.87%)	54 / 371 (14.56%)	16 / 126 (12.70%)
occurrences (all)	146	135	34
Neutrophil count increased			

subjects affected / exposed	4 / 375 (1.07%)	1 / 371 (0.27%)	8 / 126 (6.35%)
occurrences (all)	6	1	11
Platelet count decreased			
subjects affected / exposed	38 / 375 (10.13%)	30 / 371 (8.09%)	22 / 126 (17.46%)
occurrences (all)	75	54	28
Weight decreased			
subjects affected / exposed	32 / 375 (8.53%)	31 / 371 (8.36%)	44 / 126 (34.92%)
occurrences (all)	33	35	55
Weight increased			
subjects affected / exposed	10 / 375 (2.67%)	3 / 371 (0.81%)	7 / 126 (5.56%)
occurrences (all)	11	3	10
White blood cell count decreased			
subjects affected / exposed	41 / 375 (10.93%)	39 / 371 (10.51%)	22 / 126 (17.46%)
occurrences (all)	132	100	36
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	8 / 375 (2.13%)	5 / 371 (1.35%)	0 / 126 (0.00%)
occurrences (all)	8	5	0
Nervous system disorders			
Dysgeusia			
subjects affected / exposed	17 / 375 (4.53%)	14 / 371 (3.77%)	0 / 126 (0.00%)
occurrences (all)	18	15	0
Dizziness			
subjects affected / exposed	31 / 375 (8.27%)	18 / 371 (4.85%)	16 / 126 (12.70%)
occurrences (all)	33	18	22
Headache			
subjects affected / exposed	34 / 375 (9.07%)	24 / 371 (6.47%)	12 / 126 (9.52%)
occurrences (all)	44	33	21
Neuropathy peripheral			
subjects affected / exposed	26 / 375 (6.93%)	12 / 371 (3.23%)	1 / 126 (0.79%)
occurrences (all)	27	12	1
Paraesthesia			
subjects affected / exposed	19 / 375 (5.07%)	16 / 371 (4.31%)	0 / 126 (0.00%)
occurrences (all)	20	16	0
Blood and lymphatic system disorders			

Leukopenia			
subjects affected / exposed	19 / 375 (5.07%)	15 / 371 (4.04%)	5 / 126 (3.97%)
occurrences (all)	41	30	9
Neutropenia			
subjects affected / exposed	66 / 375 (17.60%)	58 / 371 (15.63%)	2 / 126 (1.59%)
occurrences (all)	125	103	6
Anaemia			
subjects affected / exposed	174 / 375 (46.40%)	151 / 371 (40.70%)	63 / 126 (50.00%)
occurrences (all)	273	202	125
Leukocytosis			
subjects affected / exposed	4 / 375 (1.07%)	4 / 371 (1.08%)	9 / 126 (7.14%)
occurrences (all)	4	5	12
Thrombocytopenia			
subjects affected / exposed	48 / 375 (12.80%)	31 / 371 (8.36%)	2 / 126 (1.59%)
occurrences (all)	85	42	4
Eye disorders			
Lacrimation increased			
subjects affected / exposed	20 / 375 (5.33%)	10 / 371 (2.70%)	0 / 126 (0.00%)
occurrences (all)	22	10	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	30 / 375 (8.00%)	15 / 371 (4.04%)	7 / 126 (5.56%)
occurrences (all)	41	16	8
Abdominal pain upper			
subjects affected / exposed	22 / 375 (5.87%)	13 / 371 (3.50%)	8 / 126 (6.35%)
occurrences (all)	27	16	12
Constipation			
subjects affected / exposed	84 / 375 (22.40%)	83 / 371 (22.37%)	20 / 126 (15.87%)
occurrences (all)	110	119	23
Diarrhoea			
subjects affected / exposed	79 / 375 (21.07%)	48 / 371 (12.94%)	26 / 126 (20.63%)
occurrences (all)	121	71	35
Dry mouth			
subjects affected / exposed	11 / 375 (2.93%)	5 / 371 (1.35%)	8 / 126 (6.35%)
occurrences (all)	11	5	8
Dyspepsia			

subjects affected / exposed	12 / 375 (3.20%)	8 / 371 (2.16%)	2 / 126 (1.59%)
occurrences (all)	12	11	2
Mouth ulceration			
subjects affected / exposed	2 / 375 (0.53%)	2 / 371 (0.54%)	8 / 126 (6.35%)
occurrences (all)	2	2	9
Stomatitis			
subjects affected / exposed	17 / 375 (4.53%)	10 / 371 (2.70%)	1 / 126 (0.79%)
occurrences (all)	19	12	2
Vomiting			
subjects affected / exposed	55 / 375 (14.67%)	56 / 371 (15.09%)	20 / 126 (15.87%)
occurrences (all)	81	79	25
Nausea			
subjects affected / exposed	126 / 375 (33.60%)	133 / 371 (35.85%)	17 / 126 (13.49%)
occurrences (all)	203	220	18
Hepatobiliary disorders			
Hepatic function abnormal			
subjects affected / exposed	3 / 375 (0.80%)	2 / 371 (0.54%)	8 / 126 (6.35%)
occurrences (all)	3	2	15
Skin and subcutaneous tissue disorders			
Rash maculo-papular			
subjects affected / exposed	10 / 375 (2.67%)	4 / 371 (1.08%)	5 / 126 (3.97%)
occurrences (all)	10	4	8
Rash			
subjects affected / exposed	59 / 375 (15.73%)	32 / 371 (8.63%)	32 / 126 (25.40%)
occurrences (all)	75	33	41
Dry skin			
subjects affected / exposed	7 / 375 (1.87%)	9 / 371 (2.43%)	1 / 126 (0.79%)
occurrences (all)	7	9	1
Alopecia			
subjects affected / exposed	45 / 375 (12.00%)	45 / 371 (12.13%)	3 / 126 (2.38%)
occurrences (all)	47	47	3
Pruritus			
subjects affected / exposed	38 / 375 (10.13%)	11 / 371 (2.96%)	27 / 126 (21.43%)
occurrences (all)	43	11	39
Endocrine disorders			

Hypothyroidism			
subjects affected / exposed	33 / 375 (8.80%)	4 / 371 (1.08%)	27 / 126 (21.43%)
occurrences (all)	35	7	32
Hyperthyroidism			
subjects affected / exposed	11 / 375 (2.93%)	6 / 371 (1.62%)	20 / 126 (15.87%)
occurrences (all)	11	6	24
Musculoskeletal and connective tissue disorders			
Pain in extremity			
subjects affected / exposed	25 / 375 (6.67%)	21 / 371 (5.66%)	7 / 126 (5.56%)
occurrences (all)	29	22	8
Myalgia			
subjects affected / exposed	30 / 375 (8.00%)	21 / 371 (5.66%)	1 / 126 (0.79%)
occurrences (all)	37	24	1
Back pain			
subjects affected / exposed	38 / 375 (10.13%)	29 / 371 (7.82%)	10 / 126 (7.94%)
occurrences (all)	51	31	12
Arthralgia			
subjects affected / exposed	40 / 375 (10.67%)	40 / 371 (10.78%)	17 / 126 (13.49%)
occurrences (all)	51	48	21
Infections and infestations			
Bronchitis			
subjects affected / exposed	18 / 375 (4.80%)	7 / 371 (1.89%)	2 / 126 (1.59%)
occurrences (all)	25	10	2
Nasopharyngitis			
subjects affected / exposed	14 / 375 (3.73%)	12 / 371 (3.23%)	1 / 126 (0.79%)
occurrences (all)	18	13	2
Upper respiratory tract infection			
subjects affected / exposed	25 / 375 (6.67%)	14 / 371 (3.77%)	16 / 126 (12.70%)
occurrences (all)	34	28	16
Pneumonia			
subjects affected / exposed	23 / 375 (6.13%)	27 / 371 (7.28%)	16 / 126 (12.70%)
occurrences (all)	27	30	20
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	105 / 375 (28.00%)	88 / 371 (23.72%)	40 / 126 (31.75%)
occurrences (all)	128	114	53

Hyperglycaemia			
subjects affected / exposed	29 / 375 (7.73%)	20 / 371 (5.39%)	18 / 126 (14.29%)
occurrences (all)	44	25	24
Hyperkalaemia			
subjects affected / exposed	12 / 375 (3.20%)	11 / 371 (2.96%)	6 / 126 (4.76%)
occurrences (all)	18	13	7
Hyponatraemia			
subjects affected / exposed	25 / 375 (6.67%)	16 / 371 (4.31%)	47 / 126 (37.30%)
occurrences (all)	39	19	81
Hypomagnesaemia			
subjects affected / exposed	25 / 375 (6.67%)	22 / 371 (5.93%)	10 / 126 (7.94%)
occurrences (all)	39	26	15
Hypokalaemia			
subjects affected / exposed	27 / 375 (7.20%)	21 / 371 (5.66%)	24 / 126 (19.05%)
occurrences (all)	39	26	37
Hypochloraemia			
subjects affected / exposed	5 / 375 (1.33%)	1 / 371 (0.27%)	17 / 126 (13.49%)
occurrences (all)	7	1	25
Hypermagnesaemia			
subjects affected / exposed	0 / 375 (0.00%)	0 / 371 (0.00%)	7 / 126 (5.56%)
occurrences (all)	0	0	11
Hypoalbuminaemia			
subjects affected / exposed	25 / 375 (6.67%)	15 / 371 (4.04%)	41 / 126 (32.54%)
occurrences (all)	29	23	71
Hyperuricaemia			
subjects affected / exposed	7 / 375 (1.87%)	7 / 371 (1.89%)	20 / 126 (15.87%)
occurrences (all)	14	8	51
Hypertriglyceridaemia			
subjects affected / exposed	1 / 375 (0.27%)	1 / 371 (0.27%)	8 / 126 (6.35%)
occurrences (all)	1	1	21
Hypocalcaemia			
subjects affected / exposed	7 / 375 (1.87%)	6 / 371 (1.62%)	14 / 126 (11.11%)
occurrences (all)	9	7	23
Hypoproteinaemia			
subjects affected / exposed	1 / 375 (0.27%)	3 / 371 (0.81%)	15 / 126 (11.90%)
occurrences (all)	1	3	24

Hypophosphataemia			
subjects affected / exposed	10 / 375 (2.67%)	8 / 371 (2.16%)	8 / 126 (6.35%)
occurrences (all)	16	8	13

Non-serious adverse events	Part 3 - Arm K: Chemotherapy		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	121 / 123 (98.37%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	2 / 123 (1.63%)		
occurrences (all)	2		
Vascular disorders			
Hypertension			
subjects affected / exposed	3 / 123 (2.44%)		
occurrences (all)	4		
Hypotension			
subjects affected / exposed	1 / 123 (0.81%)		
occurrences (all)	1		
General disorders and administration site conditions			
Chest discomfort			
subjects affected / exposed	7 / 123 (5.69%)		
occurrences (all)	9		
Asthenia			
subjects affected / exposed	11 / 123 (8.94%)		
occurrences (all)	13		
Malaise			
subjects affected / exposed	13 / 123 (10.57%)		
occurrences (all)	23		
Fatigue			
subjects affected / exposed	23 / 123 (18.70%)		
occurrences (all)	29		
Chest pain			
subjects affected / exposed	3 / 123 (2.44%)		
occurrences (all)	3		
Mucosal inflammation			

subjects affected / exposed	0 / 123 (0.00%)		
occurrences (all)	0		
Pyrexia			
subjects affected / exposed	17 / 123 (13.82%)		
occurrences (all)	19		
Pain			
subjects affected / exposed	4 / 123 (3.25%)		
occurrences (all)	6		
Oedema peripheral			
subjects affected / exposed	4 / 123 (3.25%)		
occurrences (all)	4		
Non-cardiac chest pain			
subjects affected / exposed	12 / 123 (9.76%)		
occurrences (all)	12		
Respiratory, thoracic and mediastinal disorders			
Hiccups			
subjects affected / exposed	6 / 123 (4.88%)		
occurrences (all)	10		
Haemoptysis			
subjects affected / exposed	17 / 123 (13.82%)		
occurrences (all)	20		
Epistaxis			
subjects affected / exposed	1 / 123 (0.81%)		
occurrences (all)	1		
Dyspnoea			
subjects affected / exposed	16 / 123 (13.01%)		
occurrences (all)	16		
Cough			
subjects affected / exposed	18 / 123 (14.63%)		
occurrences (all)	20		
Pneumonitis			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences (all)	0		
Productive cough			

subjects affected / exposed	14 / 123 (11.38%)		
occurrences (all)	15		
Psychiatric disorders			
Insomnia			
subjects affected / exposed	11 / 123 (8.94%)		
occurrences (all)	23		
Anxiety			
subjects affected / exposed	2 / 123 (1.63%)		
occurrences (all)	2		
Investigations			
Bilirubin conjugated increased			
subjects affected / exposed	3 / 123 (2.44%)		
occurrences (all)	3		
Aspartate aminotransferase increased			
subjects affected / exposed	32 / 123 (26.02%)		
occurrences (all)	59		
Amylase increased			
subjects affected / exposed	4 / 123 (3.25%)		
occurrences (all)	6		
Alanine aminotransferase increased			
subjects affected / exposed	36 / 123 (29.27%)		
occurrences (all)	66		
Blood alkaline phosphatase increased			
subjects affected / exposed	8 / 123 (6.50%)		
occurrences (all)	8		
Blood glucose increased			
subjects affected / exposed	7 / 123 (5.69%)		
occurrences (all)	12		
Blood lactate dehydrogenase increased			
subjects affected / exposed	8 / 123 (6.50%)		
occurrences (all)	11		
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences (all)	0		
Lipase increased			

subjects affected / exposed	6 / 123 (4.88%)			
occurrences (all)	9			
Gamma-glutamyltransferase increased				
subjects affected / exposed	16 / 123 (13.01%)			
occurrences (all)	18			
Blood creatinine increased				
subjects affected / exposed	11 / 123 (8.94%)			
occurrences (all)	12			
Blood bilirubin increased				
subjects affected / exposed	10 / 123 (8.13%)			
occurrences (all)	17			
Blood thyroid stimulating hormone increased				
subjects affected / exposed	1 / 123 (0.81%)			
occurrences (all)	1			
Lymphocyte count decreased				
subjects affected / exposed	9 / 123 (7.32%)			
occurrences (all)	20			
Neutrophil count decreased				
subjects affected / exposed	54 / 123 (43.90%)			
occurrences (all)	170			
Neutrophil count increased				
subjects affected / exposed	3 / 123 (2.44%)			
occurrences (all)	3			
Platelet count decreased				
subjects affected / exposed	49 / 123 (39.84%)			
occurrences (all)	96			
Weight decreased				
subjects affected / exposed	19 / 123 (15.45%)			
occurrences (all)	21			
Weight increased				
subjects affected / exposed	10 / 123 (8.13%)			
occurrences (all)	11			
White blood cell count decreased				

subjects affected / exposed	59 / 123 (47.97%)		
occurrences (all)	186		
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Dysgeusia			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences (all)	0		
Dizziness			
subjects affected / exposed	10 / 123 (8.13%)		
occurrences (all)	14		
Headache			
subjects affected / exposed	8 / 123 (6.50%)		
occurrences (all)	8		
Neuropathy peripheral			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences (all)	0		
Paraesthesia			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Leukopenia			
subjects affected / exposed	25 / 123 (20.33%)		
occurrences (all)	77		
Neutropenia			
subjects affected / exposed	16 / 123 (13.01%)		
occurrences (all)	36		
Anaemia			
subjects affected / exposed	93 / 123 (75.61%)		
occurrences (all)	167		
Leukocytosis			
subjects affected / exposed	4 / 123 (3.25%)		
occurrences (all)	4		
Thrombocytopenia			

subjects affected / exposed	14 / 123 (11.38%)		
occurrences (all)	38		
Eye disorders			
Lacrimation increased			
subjects affected / exposed	1 / 123 (0.81%)		
occurrences (all)	1		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	4 / 123 (3.25%)		
occurrences (all)	7		
Abdominal pain upper			
subjects affected / exposed	2 / 123 (1.63%)		
occurrences (all)	2		
Constipation			
subjects affected / exposed	25 / 123 (20.33%)		
occurrences (all)	39		
Diarrhoea			
subjects affected / exposed	8 / 123 (6.50%)		
occurrences (all)	12		
Dry mouth			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences (all)	0		
Dyspepsia			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences (all)	0		
Mouth ulceration			
subjects affected / exposed	1 / 123 (0.81%)		
occurrences (all)	1		
Stomatitis			
subjects affected / exposed	3 / 123 (2.44%)		
occurrences (all)	3		
Vomiting			
subjects affected / exposed	25 / 123 (20.33%)		
occurrences (all)	45		
Nausea			

subjects affected / exposed	30 / 123 (24.39%)		
occurrences (all)	59		
Hepatobiliary disorders			
Hepatic function abnormal			
subjects affected / exposed	9 / 123 (7.32%)		
occurrences (all)	9		
Skin and subcutaneous tissue disorders			
Rash maculo-papular			
subjects affected / exposed	2 / 123 (1.63%)		
occurrences (all)	2		
Rash			
subjects affected / exposed	15 / 123 (12.20%)		
occurrences (all)	17		
Dry skin			
subjects affected / exposed	1 / 123 (0.81%)		
occurrences (all)	1		
Alopecia			
subjects affected / exposed	5 / 123 (4.07%)		
occurrences (all)	5		
Pruritus			
subjects affected / exposed	5 / 123 (4.07%)		
occurrences (all)	5		
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	3 / 123 (2.44%)		
occurrences (all)	3		
Hyperthyroidism			
subjects affected / exposed	3 / 123 (2.44%)		
occurrences (all)	3		
Musculoskeletal and connective tissue disorders			
Pain in extremity			
subjects affected / exposed	4 / 123 (3.25%)		
occurrences (all)	4		
Myalgia			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences (all)	0		

Back pain			
subjects affected / exposed	11 / 123 (8.94%)		
occurrences (all)	11		
Arthralgia			
subjects affected / exposed	7 / 123 (5.69%)		
occurrences (all)	7		
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 123 (0.00%)		
occurrences (all)	0		
Nasopharyngitis			
subjects affected / exposed	1 / 123 (0.81%)		
occurrences (all)	1		
Upper respiratory tract infection			
subjects affected / exposed	11 / 123 (8.94%)		
occurrences (all)	22		
Pneumonia			
subjects affected / exposed	11 / 123 (8.94%)		
occurrences (all)	11		
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	34 / 123 (27.64%)		
occurrences (all)	55		
Hyperglycaemia			
subjects affected / exposed	13 / 123 (10.57%)		
occurrences (all)	26		
Hyperkalaemia			
subjects affected / exposed	5 / 123 (4.07%)		
occurrences (all)	5		
Hyponatraemia			
subjects affected / exposed	18 / 123 (14.63%)		
occurrences (all)	26		
Hypomagnesaemia			
subjects affected / exposed	6 / 123 (4.88%)		
occurrences (all)	11		
Hypokalaemia			

subjects affected / exposed	11 / 123 (8.94%)		
occurrences (all)	14		
Hypochloraemia			
subjects affected / exposed	9 / 123 (7.32%)		
occurrences (all)	12		
Hypermagnesaemia			
subjects affected / exposed	2 / 123 (1.63%)		
occurrences (all)	2		
Hypoalbuminaemia			
subjects affected / exposed	20 / 123 (16.26%)		
occurrences (all)	39		
Hyperuricaemia			
subjects affected / exposed	9 / 123 (7.32%)		
occurrences (all)	15		
Hypertriglyceridaemia			
subjects affected / exposed	9 / 123 (7.32%)		
occurrences (all)	12		
Hypocalcaemia			
subjects affected / exposed	8 / 123 (6.50%)		
occurrences (all)	9		
Hypoproteinaemia			
subjects affected / exposed	14 / 123 (11.38%)		
occurrences (all)	20		
Hypophosphataemia			
subjects affected / exposed	2 / 123 (1.63%)		
occurrences (all)	3		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
21 October 2015	Replacement of Arm E (nivolumab 1 mg/kg Q2W + ipilimumab 1 mg/kg Q6W) with Arm G (nivolumab + chemotherapy) in Part 1b (PD-L1 < 1% subjects). Defined programmed cell death ligand 1 (PD-L1 1%) NSCLC subjects as 'PD-L1 expressing NSCLC subjects' and PD-L1 (< 1%) NSCLC subjects as 'PD-L1 non-expressing NSCLC subjects.' Updated CA209012 data in background sections. Clarified the target population, added dose details for carboplatin when treated with gemcitabine or pemetrexed, clarified aspartate aminotransferase(AST)/alanine aminotransferase(ALT) values when liver metastases were present, and removed cytochrome P450 (CYP)3A4 language throughout the protocol.
17 November 2016	Changes in Part1a (PD-L1 ≥ 1%) Single primary end-point OS for nivolumab +ipilimumabvs chemotherapyin PD-L1≥50% (OS PD-L1≥1% next in hierarchy) Demotion of PFS to secondary end-points Demotion of nivolumabvs chemotherapycomparisons to secondary end-point Increased the sample size from 990 to 1200 to ensure at least 400 subjects with PD-L1 ≥50% were available for the primary endpoint, based on the expected distribution of PD-L1 in first-line NSLC Changes in Part 1b (PD-L1 < 1%) Single primary endpoint of PFS nivolumabvs chemotherapyvs chemotherapy Demotednivolumab +ipilimumabvs chemotherapyendpoints and OSand PFS fornivolumabvs chemotherapyvs chemotherapyto secondary Decreasedsample size to conclude enrolment together with PD-L1≥1% and allowedaddition of Part 2 (nivolumabvs chemotherapyvs chemotherapyin all comers)
27 June 2017	Increased enrolled subjects from 739 to 1153 and increased randomized subjects from 480 to approximately 750 for Part 2 only and modified the statistical considerations and sample size justifications accordingly.
05 October 2017	In May-2017, prior to BMS's decision to amend the CA209227 protocol, preliminary efficacy by TMB results (F1CDx) became available from CA209568 (nivo + ipi). CA209568 studied the same combination dose and regimen (nivolumab 3mg/kg Q2W + ipilimumab 1 mg/kg Q6W) and patient population as CA209227. CA209568 also demonstrated that a clinically meaningful cutoff could be determined to identify the group of patients most likely to benefit from combination immunotherapy over first-line chemotherapy.
01 June 2018	Removed 1 of the 2 interim OS analyses in Part 2, because emerging data with chemo + PD-1 inhibitors showed a consistent delayed benefit, with immuno-oncology (IO)mechanism of action (more pronounced in patients with low or no PD-L1 expressing tumors). Given that there are close to 50% of subjects with PD-L1 non-expressing tumors in Part 2, early evaluation of OS may miss detecting the benefit in terms of OS drivenby nivolumab +chemotherapy. Subjects with squamous histology were enrolled, and in the absence of any survival data with chemo+PD-L1, early evaluation of OS may not be appropriate.

15 August 2018	The main purpose of the Amendment is to adapt the analyses of Part 2 of CA209227 to evolving science, in order to better demonstrate the benefit of nivolumab +chemotherapy in subjects with non-squamous histology subtype NSCLC in the first-line setting.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported