



## Clinical trial results:

**Randomized phase III study of neoadjuvant chemotherapy followed by surgery vs. concomitant radiotherapy and chemotherapy in FIGO Ib2, IIa > 4 cm or IIb cervical cancer.**

### Summary

EudraCT number	2008-003396-52
Trial protocol	GB FR
Global end of trial date	29 November 2019

### Results information

Result version number	v1 (current)
This version publication date	26 August 2022
First version publication date	26 August 2022

### Trial information

#### Trial identification

Sponsor protocol code	EORTC55994
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#### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00039338
WHO universal trial number (UTN)	-

Notes:

### Sponsors

Sponsor organisation name	EORTC
Sponsor organisation address	Avenue E. Mounier 83/11, Brussels, Belgium, 1200
Public contact	Regulatory Affairs Department, European Organisation for Research and Treatment of Cancer, 0032 02 774 10 54, corneel.coens@eortc.org
Scientific contact	Regulatory Affairs Department, European Organisation for Research and Treatment of Cancer, 0032 02 774 10 54, corneel.coens@eortc.org

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:

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## Results analysis stage

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Analysis stage	Final
Date of interim/final analysis	29 November 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	29 November 2019
Global end of trial reached?	Yes
Global end of trial date	29 November 2019
Was the trial ended prematurely?	No

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Notes:

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## General information about the trial

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Main objective of the trial:

To demonstrate an advantage in overall survival with the use of neoadjuvant chemotherapy followed by radical surgery as compared to the standard approach (concomitant chemotherapy and radiotherapy) in FIGO stage Ib2, IIa > 4 cm, IIb cervical cancer patients.

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Protection of trial subjects:

The study is conducted in agreement with the Declaration of Helsinki (available on the World Medical Association web site (<http://www.wma.net>)) and/or the laws and regulations of the participating countries, whichever provides the greatest protection of the patient. The protocol has been written, and the study conducted according to the ICH Harmonized Tripartite Guideline on Good Clinical Practice. The protocol was approved by the competent ethics committee(s) as required by the applicable national legislation.

Safety data were reviewed within the EORTC Headquarters on a regular basis as part of the Medical Review process. Safety information was included in trial status reports which served as a basis of discussion during EORTC Group meetings.

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Background therapy:

NA

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Evidence for comparator:

Results from 5 randomized phase III trials show an overall survival advantage for cisplatin-based therapy given concurrently with radiation therapy. The patient populations in these studies included women with FIGO stages IB2 to IVA cervical cancer treated with primary radiation therapy and women with FIGO stages Ib to IIA disease found to have poor prognostic factors (metastatic disease in pelvic lymph nodes, disease, or positive surgical margins) at time of primary surgery. Although the trials vary somewhat in terms of stage of disease, dose of radiation, and schedule of cisplatin and radiation, they all demonstrate significant survival benefit for this combined approach. The risk of death from cervical cancer was decreased by 30% to 50% by concurrent chemoradiation.

Ref:

- Gerstner N, Wachter S, Knocke TH, Fellner C, Wambersie A, Potter R. The benefit of Beam's Eye View based 3D treatment planning for cervical cancer. *Radiother. Oncol.* 51: 71-78; 1999.
  - Girinsky T., Rey A., Roche B., Haie C., Gerbaulet A., Randrianarivello H. Overall treatment time in advanced cervical carcinomas : a critical parameter in treatment outcome. *Int. J. Radiat. Oncol. Biol. Phys.* 27 : 1051-6 ; 1993.
  - Lanciano R., Thomas G., Eifel PG. Over 20 years of progression in radiation oncology: Cervical Cancer. *Semin Radiat Oncol* 7:121-126, 1997.
  - Nag S, Erickson B, Thomadsen B, Orton C, Demanes JD, Petereit D: the American Brachytherapy Society recommendations for High Dose Rate brachytherapy for carcinoma of the Cervix.
  - Perez CA, Grigsby PW, Castro Vita H, Lockett MA. Carcinoma of the uterine cervix. I. Impact of prolongation of overall treatment time and timing of brachytherapy on outcome of radiation therapy. *Int J Radiat Oncol Biol Phys* 32:1275-1288, 1995.
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Actual start date of recruitment	25 May 2009
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

## Population of trial subjects

### Subjects enrolled per country

Country: Number of subjects enrolled	Italy: 188
Country: Number of subjects enrolled	Netherlands: 182
Country: Number of subjects enrolled	Belgium: 80
Country: Number of subjects enrolled	Poland: 56
Country: Number of subjects enrolled	United Kingdom: 48
Country: Number of subjects enrolled	Spain: 36
Country: Number of subjects enrolled	Portugal: 24
Country: Number of subjects enrolled	Austria: 6
Country: Number of subjects enrolled	Norway: 4
Country: Number of subjects enrolled	France: 2
Worldwide total number of subjects	626
EEA total number of subjects	578

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)	570
From 65 to 84 years	56
85 years and over	0

## Subject disposition

### Recruitment

Recruitment details:

According to the protocol, it was planned to recruit 625 patients in total. A total of 626 patients were randomized between 23/05/2002 and 22/01/2014 (11 years and 8 months; 140 months) by 25 institutions from 10 countries to receive either NACT followed by surgery (N=314) or concomitant chemo-radiation (N=312).

### Pre-assignment

Screening details:

Cervical cancer of squamous or adeno(squamous) cell type FIGO stage Ib2, IIa2>4cm or I Ib, WHO performance status 0-2, 18-75 years of age, no prior irradiation or chemotherapy, adequate laboratory values and written informed consent according to ICH/GCP and national/local regulations.

### Period 1

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

Blinding implementation details:

Central randomisation using minimization stratified for institution, FIGO stage, age (18-50; 51-75), histological subtype (adenomatous vs non-adenomatous component). Patients are randomized to receive either neoadjuvant chemotherapy followed by surgery (Arm I) or concomitant chemotherapy and radiotherapy (Arm II, control group) in 1:1 ratio.

### Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	NACTS

Arm description:

In the NACTS arm, chemotherapy consisted of cisplatin-based chemotherapy. Several chemotherapy regimens were allowed according to the policy of the institute. The minimum cumulative cisplatin dose was set at 225 mg/m<sup>2</sup> with a minimum dose of cisplatin of 75 mg/m<sup>2</sup> per 3 weeks, irrespectively whether cycles were scheduled weekly or over 10 or 21 days, thus reflecting the daily practice of the majority of the centers. Radical hysterectomy was required within 6 weeks after completion of neoadjuvant chemotherapy and consisted of a Piver-Rutledge type III-V radical hysterectomy, with lymphadenectomy of pelvic-infra-mesenteric with or without high para-aortal lymph nodes).

Arm type	standard of care
Investigational medicinal product name	cisplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

The minimum cumulative cisplatin dose should be 225 mg/m<sup>2</sup> (except when dose modifications, dose delays or treatment termination are needed). The cisplatin dose should be the equivalent of at least 25 mg/m<sup>2</sup> per week. The final dose to start no later than day 64.

<b>Arm title</b>	CCRT
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Arm description:

In the CCRT (concomitant chemoradiotherapy) arm cisplatin was to be given with 5 or 6 weekly doses of 40 mg/m<sup>2</sup> during radiotherapy. External beam radiotherapy with a dose between 45-50 Gy was given to the pelvis combined with external boost or brachytherapy. A minimal total dose (external radiotherapy with or without external boost + brachytherapy) of 75 Gy EQD2 to point A (or 80 Gy to high risk PTV) was mandatory. Adjuvant hysterectomy was allowed in case of histologically proven residual tumour.

Arm type	standard of care
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Investigational medicinal product name	cisplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Concomitant chemotherapy with an initial dose of at least 40 mg/m<sup>2</sup> cisplatin will be administered weekly with a maximum dose of 80 mg per administration and a maximum of 6 administrations. The chemotherapy must be given weekly during radiotherapy. The total cumulative dose should be between 200-240 mg/m<sup>2</sup> (except when dose modifications, dose delays or treatment termination are allowed by the protocol).

<b>Number of subjects in period 1</b>	NACTS	CCRT
Started	314	312
Completed	223	257
Not completed	91	55
Patient refusal	10	13
Organizational problems	-	2
Physician decision	3	6
Consent withdrawn by subject	-	2
Toxicity + lack of efficacy	1	-
Adverse event, non-fatal	31	23
RTP finished early	-	1
Toxicity + patient refusal	-	1
surgical contraindication	4	-
Progressive disease	21	1
Protocol deviation	7	6
Lack of efficacy	14	-

## Baseline characteristics

### Reporting groups

Reporting group title	NACTS
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Reporting group description:

In the NACTS arm, chemotherapy consisted of cisplatin-based chemotherapy. Several chemotherapy regimens were allowed according to the policy of the institute. The minimum cumulative cisplatin dose was set at 225 mg/m<sup>2</sup> with a minimum dose of cisplatin of 75 mg/m<sup>2</sup> per 3 weeks, irrespectively whether cycles were scheduled weekly or over 10 or 21 days, thus reflecting the daily practice of the majority of the centers. Radical hysterectomy was required within 6 weeks after completion of neoadjuvant chemotherapy and consisted of a Piver-Rutledge type III-V radical hysterectomy, with lymphadenectomy of pelvic-infra-mesenteric with or without high para-aortal lymph nodes).

Reporting group title	CCRT
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Reporting group description:

In the CCRT (concomitant chemoradiotherapy) arm cisplatin was to be given with 5 or 6 weekly doses of 40 mg/m<sup>2</sup> during radiotherapy. External beam radiotherapy with a dose between 45-50 Gy was given to the pelvis combined with external boost or brachytherapy. A minimal total dose (external radiotherapy with or without external boost + brachytherapy) of 75 Gy EQD2 to point A (or 80 Gy to high risk PTV) was mandatory. Adjuvant hysterectomy was allowed in case of histologically proven residual tumour.

Reporting group values	NACTS	CCRT	Total
Number of subjects	314	312	626
Age categorical			
Age			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	287	283	570
From 65-84 years	27	29	56
85 years and over	0	0	0
Age continuous			
Units: years			
median	46	47	
full range (min-max)	23 to 73	23 to 75	-
Gender categorical			
Gender			
Units: Subjects			
Female	314	312	626
Male	0	0	0
WHO PS			
WHO performance status			
Units: Subjects			
PS 0	277	273	550
PS 1	36	39	75
Unknown	1	0	1
Type of cervical carcinoma			

Histological type of the cervical carcinoma			
Units: Subjects			
squamous	266	264	530
adenosquamous	16	11	27
adenocarcinoma	31	35	66
clear cell	0	1	1
Unknown	0	1	1
Missing	1	0	1
FIGO stage			
FIGO stage			
Units: Subjects			
Ib2	83	86	169
IIa > 4 cm	48	47	95
IIb	179	178	357
III	3	0	3
IV	0	1	1
Missing	1	0	1

### Subject analysis sets

Subject analysis set title	ITT
Subject analysis set type	Intention-to-treat
Subject analysis set description: all randomized subjects according to allocated arm	

Reporting group values	ITT		
Number of subjects	626		
Age categorical			
Age			
Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	0		
Adolescents (12-17 years)	0		
Adults (18-64 years)	570		
From 65-84 years	56		
85 years and over	0		
Age continuous			
Units: years			
median			
full range (min-max)			
Gender categorical			
Gender			
Units: Subjects			
Female	626		
Male	0		

WHO PS			
WHO performance status			
Units: Subjects			
PS 0			
PS 1			
Unknown			
Type of cervical carcinoma			
Histological type of the cervical carcinoma			
Units: Subjects			
squamous			
adenosquamous			
adenocarcinoma			
clear cell			
Unknown			
Missing			
FIGO stage			
FIGO stage			
Units: Subjects			
Ib2			
IIa > 4 cm			
IIb			
III			
IV			
Missing			

## End points

### End points reporting groups

Reporting group title	NACTS
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Reporting group description:

In the NACTS arm, chemotherapy consisted of cisplatin-based chemotherapy. Several chemotherapy regimens were allowed according to the policy of the institute. The minimum cumulative cisplatin dose was set at 225 mg/m<sup>2</sup> with a minimum dose of cisplatin of 75 mg/m<sup>2</sup> per 3 weeks, irrespectively whether cycles were scheduled weekly or over 10 or 21 days, thus reflecting the daily practice of the majority of the centers. Radical hysterectomy was required within 6 weeks after completion of neoadjuvant chemotherapy and consisted of a Piver-Rutledge type III-V radical hysterectomy, with lymphadenectomy of pelvic-infra-mesenteric with or without high para-aortal lymph nodes).

Reporting group title	CCRT
-----------------------	------

Reporting group description:

In the CCRT (concomitant chemoradiotherapy) arm cisplatin was to be given with 5 or 6 weekly doses of 40 mg/m<sup>2</sup> during radiotherapy. External beam radiotherapy with a dose between 45-50 Gy was given to the pelvis combined with external boost or brachytherapy. A minimal total dose (external radiotherapy with or without external boost + brachytherapy) of 75 Gy EQD2 to point A (or 80 Gy to high risk PTV) was mandatory. Adjuvant hysterectomy was allowed in case of histologically proven residual tumour.

Subject analysis set title	ITT
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Subject analysis set type	Intention-to-treat
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Subject analysis set description:

all randomized subjects according to allocated arm

### Primary: Overall survival at year 5

End point title	Overall survival at year 5
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End point description:

The main endpoint of the study is the overall survival rate at 5 years. Overall survival is computed from the date of patient randomization to the date of death (any cause) or date of last known to be alive for each patient. The 5 year survival rate is derived using KM estimation.

End point type	Primary
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End point timeframe:

5 years after randomization

End point values	NACTS	CCRT		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	314	312		
Units: percentage alive				
number (confidence interval 95%)	71.7 (66.2 to 76.5)	75.5 (70.2 to 80.0)		

### Statistical analyses

Statistical analysis title	OS difference at year 5
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Comparison groups	NACTS v CCRT
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Number of subjects included in analysis	626
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.291
Method	Chi-squared
Parameter estimate	Risk difference (RD)
Point estimate	3.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.5
upper limit	10.7

<b>Statistical analysis title</b>	OS logrank test
Statistical analysis description: Logrank test of OS	
Comparison groups	NACTS v CCRT
Number of subjects included in analysis	626
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.24
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.64
upper limit	1.12

<b>Secondary: PFS at year 5</b>	
End point title	PFS at year 5
End point description:	
End point type	Secondary
End point timeframe: overall study duration	

<b>End point values</b>	NACTS	CCRT		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	314	312		
Units: percentage alive wo PD				
number (confidence interval 95%)	57.0 (51.1 to 62.4)	65.6 (59.9 to 70.7)		

## Statistical analyses

<b>Statistical analysis title</b>	PFS logrank test
Comparison groups	NACTS v CCRT
Number of subjects included in analysis	626
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.01
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.72
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.57
upper limit	0.93

## Secondary: Complete response

End point title	Complete response
End point description:	complete response versus (partial response, stable disease, progressive disease, non-evaluable)
End point type	Secondary
End point timeframe:	Best response to chemotherapy: best response recorded taking into account all tumor assessments during and after protocol treatment for a maximum of 8 weeks after last chemotherapy or radiotherapy administration.

<b>End point values</b>	NACTS	CCRT		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	314	312		
Units: Subjects	54	138		

## Statistical analyses

No statistical analyses for this end point

### Secondary: Response

End point title	Response
End point description: complete and partial response versus (stable disease, progressive disease, non-evaluable) according to RECIST.	
End point type	Secondary
End point timeframe: Best response to chemotherapy: best response recorded taking into account all tumor assessments during and after protocol treatment for a maximum of 8 weeks after last chemotherapy or radiotherapy administration.	

End point values	NACTS	CCRT		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	314	312		
Units: Subjects	185	206		

### Statistical analyses

No statistical analyses for this end point

### Secondary: Health-related Quality of Life

End point title	Health-related Quality of Life
End point description: Descriptive analysis of the overall health scale (GHQ) of the QLQ-C30	
End point type	Secondary
End point timeframe: QLQ-C30 questionnaires collected at baseline, month 6, month 12, month 18 and month 24	

End point values	NACTS	CCRT		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	229 <sup>[1]</sup>	200 <sup>[2]</sup>		
Units: QLQ-C30 points				
median (inter-quartile range (Q1-Q3))				
month 6	75 (58 to 83)	67 (67 to 83)		
month 12	75 (58 to 83)	75 (58 to 83)		
month 18	67 (58 to 83)	75 (58 to 83)		
month 24	83 (58 to 92)	71 (67 to 83)		

Notes:

[1] - limited to randomized patients with at least one valid questionnaire completed.

[2] - limited to randomized patients with at least one valid questionnaire completed.

## Statistical analyses

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No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Up to 8 weeks after end of protocol treatment. Long term complications were collected until year 5 or progression/start of new treatment.

Adverse event reporting additional description:

Adverse events were collected up to 8 weeks after end of protocol treatment. In addition, long term complication were assessed every 3 months during the year 1 and every 6 months during years 2 until 5. Long term evaluation was also stopped upon progression or start of further antitumoral treatment.

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	20
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### Reporting groups

Reporting group title	NACTS
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Reporting group description:

All 300 patients randomized to the NACTS arm that started allocated treatment regardless of eligibility.

Reporting group title	CCRT
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Reporting group description:

All 300 patients randomized to the CCRTarm that started allocated treatment regardless of eligibility.

Serious adverse events	NACTS	CCRT	
Total subjects affected by serious adverse events			
subjects affected / exposed	59 / 300 (19.67%)	32 / 291 (11.00%)	
number of deaths (all causes)	102	82	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
INTRADUCTAL PROLIFERATIVE BREAST LESION			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
TUMOUR HAEMORRHAGE			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			

DEEP VEIN THROMBOSIS alternative dictionary used: MedDRA 20 subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPOTENSION alternative dictionary used: MedDRA 20 subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
THROMBOSIS alternative dictionary used: MedDRA 20 subjects affected / exposed	0 / 300 (0.00%)	2 / 291 (0.69%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions CHEST PAIN alternative dictionary used: MedDRA 20 subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
FATIGUE alternative dictionary used: MedDRA 20 subjects affected / exposed	2 / 300 (0.67%)	1 / 291 (0.34%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
GENERAL PHYSICAL HEALTH DETERIORATION alternative dictionary used: MedDRA 20 subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MALAISE alternative dictionary used:			

MedDRA 20			
subjects affected / exposed	3 / 300 (1.00%)	0 / 291 (0.00%)	
occurrences causally related to treatment / all	4 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MULTIPLE ORGAN DYSFUNCTION SYNDROME			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
OBSTRUCTION			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PAIN			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PYREXIA			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	3 / 300 (1.00%)	3 / 291 (1.03%)	
occurrences causally related to treatment / all	2 / 3	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
HYPERSENSITIVITY			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	2 / 300 (0.67%)	2 / 291 (0.69%)	
occurrences causally related to treatment / all	0 / 2	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Social circumstances			
SOCIAL PROBLEM			
alternative dictionary used: MedDRA 20			

subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Reproductive system and breast disorders</b>			
VAGINAL HAEMORRHAGE			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	1 / 300 (0.33%)	3 / 291 (1.03%)	
occurrences causally related to treatment / all	0 / 1	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Respiratory, thoracic and mediastinal disorders</b>			
HYPOXIA			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PULMONARY EMBOLISM			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	1 / 300 (0.33%)	1 / 291 (0.34%)	
occurrences causally related to treatment / all	0 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Psychiatric disorders</b>			
ANXIETY			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Investigations</b>			
ELECTROCARDIOGRAM QT PROLONGED			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ELECTROCARDIOGRAM			

REPOLARISATION ABNORMALITY			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HEPATIC ENZYME INCREASED			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
GASTROENTERITIS RADIATION			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
POST PROCEDURAL URINE LEAK			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RADIATION SKIN INJURY			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
URETERIC INJURY			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
WOUND EVISCERATION			
alternative dictionary used: MedDRA 20			

subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Cardiac disorders</b>			
<b>ATRIAL FLUTTER</b>			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>BRADYCARDIA</b>			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>SINUS TACHYCARDIA</b>			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>SUPRAVENTRICULAR TACHYCARDIA</b>			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Nervous system disorders</b>			
<b>CEREBRAL HAEMORRHAGE</b>			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
<b>CEREBRAL ISCHAEMIA</b>			
alternative dictionary used: MedDRA 20			

subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>GENERALISED TONIC-CLONIC SEIZURE</b>			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>PARTIAL SEIZURES</b>			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>PETIT MAL EPILEPSY</b>			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>SUPERIOR SAGITTAL SINUS THROMBOSIS</b>			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>WERNICKE'S ENCEPHALOPATHY</b>			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Blood and lymphatic system disorders</b>			
<b>ANAEMIA</b>			
alternative dictionary used: MedDRA 20			

subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>DISSEMINATED INTRAVASCULAR COAGULATION</b>			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
<b>FEBRILE NEUTROPENIA</b>			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	5 / 300 (1.67%)	0 / 291 (0.00%)	
occurrences causally related to treatment / all	5 / 6	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>NEUTROPENIA</b>			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	2 / 300 (0.67%)	1 / 291 (0.34%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>PANCYTOPENIA</b>			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>THROMBOCYTOPENIA</b>			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	2 / 300 (0.67%)	0 / 291 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Gastrointestinal disorders</b>			
<b>ABDOMINAL PAIN</b>			
alternative dictionary used: MedDRA 20			

subjects affected / exposed	2 / 300 (0.67%)	1 / 291 (0.34%)
occurrences causally related to treatment / all	0 / 2	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>ABDOMINAL PAIN UPPER</b>		
alternative dictionary used: MedDRA 20		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>CONSTIPATION</b>		
alternative dictionary used: MedDRA 20		
subjects affected / exposed	3 / 300 (1.00%)	0 / 291 (0.00%)
occurrences causally related to treatment / all	3 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>DIARRHOEA</b>		
alternative dictionary used: MedDRA 20		
subjects affected / exposed	6 / 300 (2.00%)	1 / 291 (0.34%)
occurrences causally related to treatment / all	7 / 7	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>GASTRITIS</b>		
alternative dictionary used: MedDRA 20		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>NAUSEA</b>		
alternative dictionary used: MedDRA 20		
subjects affected / exposed	14 / 300 (4.67%)	4 / 291 (1.37%)
occurrences causally related to treatment / all	20 / 20	4 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>OESOPHAGEAL HAEMORRHAGE</b>		
alternative dictionary used: MedDRA 20		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

OESOPHAGITIS alternative dictionary used: MedDRA 20 subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PANCREATITIS ACUTE alternative dictionary used: MedDRA 20 subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PROCTALGIA alternative dictionary used: MedDRA 20 subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
RETROPERITONEAL HAEMATOMA alternative dictionary used: MedDRA 20 subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
STOMATITIS alternative dictionary used: MedDRA 20 subjects affected / exposed	2 / 300 (0.67%)	0 / 291 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
VOMITING alternative dictionary used: MedDRA 20 subjects affected / exposed	13 / 300 (4.33%)	4 / 291 (1.37%)	
occurrences causally related to treatment / all	13 / 13	6 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders RASH alternative dictionary used: MedDRA 20			

subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
URTICARIA			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	4 / 300 (1.33%)	0 / 291 (0.00%)	
occurrences causally related to treatment / all	4 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CHRONIC KIDNEY DISEASE			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYDRONEPHROSIS			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
NEPHROPATHY			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RENAL FAILURE			
alternative dictionary used: MedDRA 20			

subjects affected / exposed	3 / 300 (1.00%)	0 / 291 (0.00%)	
occurrences causally related to treatment / all	2 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>RENAL IMPAIRMENT</b>			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	2 / 300 (0.67%)	0 / 291 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>RENAL TUBULAR NECROSIS</b>			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>URINARY RETENTION</b>			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	1 / 300 (0.33%)	1 / 291 (0.34%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Musculoskeletal and connective tissue disorders</b>			
<b>BACK PAIN</b>			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>MYALGIA</b>			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Infections and infestations</b>			
<b>DEVICE RELATED INFECTION</b>			
alternative dictionary used: MedDRA 20			

subjects affected / exposed	2 / 300 (0.67%)	0 / 291 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
DEVICE RELATED SEPSIS		
alternative dictionary used: MedDRA 20		
subjects affected / exposed	2 / 300 (0.67%)	0 / 291 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
ERYSIPELAS		
alternative dictionary used: MedDRA 20		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
ESCHERICHIA SEPSIS		
alternative dictionary used: MedDRA 20		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
GASTROENTERITIS		
alternative dictionary used: MedDRA 20		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
INFECTED LYMPHOCELE		
alternative dictionary used: MedDRA 20		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
INFECTION		
alternative dictionary used: MedDRA 20		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

<b>SALMONELLOSIS</b>			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>SEPSIS</b>			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>SINUSITIS</b>			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>STREPTOCOCCAL INFECTION</b>			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>STREPTOCOCCAL SEPSIS</b>			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>URINARY TRACT INFECTION</b>			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	3 / 300 (1.00%)	3 / 291 (1.03%)	
occurrences causally related to treatment / all	0 / 3	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>UROSEPSIS</b>			
alternative dictionary used: MedDRA 20			

subjects affected / exposed	2 / 300 (0.67%)	0 / 291 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>WOUND INFECTION</b>			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Metabolism and nutrition disorders</b>			
<b>DECREASED APPETITE</b>			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>DEHYDRATION</b>			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	3 / 300 (1.00%)	1 / 291 (0.34%)	
occurrences causally related to treatment / all	3 / 3	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>ELECTROLYTE IMBALANCE</b>			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	2 / 300 (0.67%)	0 / 291 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>HYPERCALCAEMIA</b>			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>HYPOCALCAEMIA</b>			
alternative dictionary used: MedDRA 20			

subjects affected / exposed	1 / 300 (0.33%)	2 / 291 (0.69%)	
occurrences causally related to treatment / all	1 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>HYPOKALAEMIA</b>			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	4 / 300 (1.33%)	2 / 291 (0.69%)	
occurrences causally related to treatment / all	4 / 4	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>HYPOMAGNESAEMIA</b>			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>HYPONATRAEMIA</b>			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>LACTIC ACIDOSIS</b>			
alternative dictionary used: MedDRA 20			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

<b>Non-serious adverse events</b>	NACTS	CCRT	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	298 / 300 (99.33%)	279 / 291 (95.88%)	
Surgical and medical procedures			
BLADDER AND URETHRA			
alternative dictionary used: CTC 2			
subjects affected / exposed	121 / 300 (40.33%)	134 / 291 (46.05%)	
occurrences (all)	338	375	

BONE		
alternative dictionary used: CTC 2		
subjects affected / exposed	20 / 300 (6.67%)	23 / 291 (7.90%)
occurrences (all)	31	36
COLON (NON SIGMOID)		
alternative dictionary used: CTC 2		
subjects affected / exposed	30 / 300 (10.00%)	47 / 291 (16.15%)
occurrences (all)	41	98
CUTANEOUS		
alternative dictionary used: CTC 2		
subjects affected / exposed	26 / 300 (8.67%)	30 / 291 (10.31%)
occurrences (all)	44	41
HEMOPOIETIC TISSUE		
alternative dictionary used: CTC 2		
subjects affected / exposed	12 / 300 (4.00%)	9 / 291 (3.09%)
occurrences (all)	16	16
NON SPECIFIC ABDOMINAL		
alternative dictionary used: CTC 2		
subjects affected / exposed	91 / 300 (30.33%)	92 / 291 (31.62%)
occurrences (all)	214	190
PELVIC SOFT TISSUES		
alternative dictionary used: CTC 2		
subjects affected / exposed	39 / 300 (13.00%)	36 / 291 (12.37%)
occurrences (all)	60	76
PERIPHERAL NERVES		
alternative dictionary used: CTC 2		
subjects affected / exposed	54 / 300 (18.00%)	39 / 291 (13.40%)
occurrences (all)	106	82
RECTUM		
alternative dictionary used: CTC 2		
subjects affected / exposed	56 / 300 (18.67%)	102 / 291 (35.05%)
occurrences (all)	101	260
SIGMOID COLON		
alternative dictionary used: CTC 2		
subjects affected / exposed	38 / 300 (12.67%)	72 / 291 (24.74%)
occurrences (all)	74	163
SMALL BOWEL		

alternative dictionary used: CTC 2			
subjects affected / exposed	26 / 300 (8.67%)	44 / 291 (15.12%)	
occurrences (all)	42	91	
<b>STOMACH AND DUODENUM</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	35 / 300 (11.67%)	38 / 291 (13.06%)	
occurrences (all)	47	47	
<b>URETER</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	34 / 300 (11.33%)	30 / 291 (10.31%)	
occurrences (all)	79	77	
<b>UTERUS-VAGINA-VULVA</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	94 / 300 (31.33%)	157 / 291 (53.95%)	
occurrences (all)	263	598	
<b>VESICULAR</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	31 / 300 (10.33%)	12 / 291 (4.12%)	
occurrences (all)	84	29	
<b>General disorders and administration site conditions</b>			
<b>ASTHENIA</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	11 / 300 (3.67%)	18 / 291 (6.19%)	
occurrences (all)	14	28	
<b>CHILLS</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	1 / 291 (0.34%)	
occurrences (all)	1	1	
<b>COLD FEET</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	1	0	
<b>COMMON MALAISE</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	
occurrences (all)	0	1	

COMMON UNWELLNESS		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
FAGIGUE		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
FATIGUE		
alternative dictionary used: CTC 2		
subjects affected / exposed	124 / 300 (41.33%)	130 / 291 (44.67%)
occurrences (all)	337	307
FEVER		
alternative dictionary used: CTC 2		
subjects affected / exposed	30 / 300 (10.00%)	12 / 291 (4.12%)
occurrences (all)	37	14
FLU		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
FLUE		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
GENERAL FATIGUE		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
GENERAL UNWELLNESS		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
HEAVY LEGS/TIRED LEGS		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
HOT FLASHES		

alternative dictionary used: CTC 2		
subjects affected / exposed	2 / 300 (0.67%)	0 / 291 (0.00%)
occurrences (all)	3	0
<b>LETHARGY</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	2 / 300 (0.67%)	0 / 291 (0.00%)
occurrences (all)	4	0
<b>LOCAL COMPLAINTS</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>MALAISE</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	5 / 300 (1.67%)	3 / 291 (1.03%)
occurrences (all)	8	7
<b>MALAISE GENERAL</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>NIGHT SWEATING</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	3 / 300 (1.00%)	1 / 291 (0.34%)
occurrences (all)	4	1
<b>NIGHT SWEATS</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>SHIVERING</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>SWEATING</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	4 / 291 (1.37%)
occurrences (all)	3	4
<b>WEAKNESS</b>		

alternative dictionary used: CTC 2		
subjects affected / exposed	3 / 300 (1.00%)	1 / 291 (0.34%)
occurrences (all)	3	1
<b>WEIGHT GAIN</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	1 / 291 (0.34%)
occurrences (all)	1	1
<b>WEIGHT LOSS</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	6 / 300 (2.00%)	10 / 291 (3.44%)
occurrences (all)	8	10
<b>BILATERAL ANKLE EDEMA</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>ELECTROLYTE DISTURBANCES</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>GENERAL CONDITION</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>GENERAL DETERIORATION</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>MULTI-ORGAN FAILURE</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>PERIODONTITIS</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>RADIATION CYSTITIS</b>		

alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>SMALL SWELLING LEFT HIP, LIPOMA</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>ABDOMIANL CRAMPS</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>ABDOMINAL</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>ABDOMINAL CRAMPING</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>ABDOMINAL PAIN</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	8 / 291 (2.75%)
occurrences (all)	3	13
<b>ACHE BOWELS</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>ANAL PAIN</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	3 / 291 (1.03%)
occurrences (all)	1	3
<b>ANAL REGION</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>BACK PAIN</b>		

alternative dictionary used: CTC 2		
subjects affected / exposed	5 / 300 (1.67%)	7 / 291 (2.41%)
occurrences (all)	6	12
<b>ARTHRALGIA</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	33 / 300 (11.00%)	24 / 291 (8.25%)
occurrences (all)	48	39
<b>BACKPAIN</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>CERVICAL PAIN</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>CHEST PAIN</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	1 / 291 (0.34%)
occurrences (all)	1	1
<b>COCCYX PAIN</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>COSTA</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>CRAMPS IN LEGS AND TOES</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>DYSPAREUNIA</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	4 / 291 (1.37%)
occurrences (all)	1	4
<b>EPIGASTRIC PAIN</b>		

alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	3 / 291 (1.03%)
occurrences (all)	1	4
<b>FROZEN SHOULDER</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>GROIN PAIN</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>HYPOCHONDRIUM</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>HEAD ACHE</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	25 / 300 (8.33%)	9 / 291 (3.09%)
occurrences (all)	32	12
<b>INGUINAL PAIN</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	1 / 291 (0.34%)
occurrences (all)	1	1
<b>HYPOGASTRIC PAIN</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>LEFT SIDE</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>LOWER ABDOMEN</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>LOWER ABDOMINAL</b>		

alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>LOWER BACK PAIN</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	2 / 300 (0.67%)	1 / 291 (0.34%)
occurrences (all)	2	1
<b>MICTALGIA</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>MYALGIA</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	36 / 300 (12.00%)	12 / 291 (4.12%)
occurrences (all)	51	22
<b>N.O.S.</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	2	0
<b>NECK PAIN</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>NEUROPATHIC: NERVUS ISCHIATICUS</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>PAIN</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	5 / 300 (1.67%)	2 / 291 (0.69%)
occurrences (all)	7	4
<b>PAIN ABDOMEN</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>PAIN ANAL REGION</b>		

alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>PAIN ASS</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>PAIN BACK</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	2 / 300 (0.67%)	2 / 291 (0.69%)
occurrences (all)	4	2
<b>PAIN BACK &amp; LEGS</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>PAIN BUTTOCK RI BY WALKING</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>PAIN DURING URINATING</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>PAIN EAR</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>PAIN GROIN REGION</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>PAIN HEAD</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	2	0
<b>PAIN IN ABDOMEN</b>		

alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	2	0
PAIN IN ANAL REGION		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
PAIN IN GROIN/PUBIC AREA		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
PAIN IN HAND, TOES, FEET		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
PAIN IN THE GENITAL REGION		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
PAIN IN THE GROIN REGION		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
PAIN IN VAGINA		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
PAIN INGUINAL		
alternative dictionary used: CTC 2		
subjects affected / exposed	3 / 300 (1.00%)	0 / 291 (0.00%)
occurrences (all)	3	0
PAIN LEFT FOSSA		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
PAIN LEFT FOSSA + SACCO-ILIACAL		

alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>PAIN LEFT GROIN</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	2
<b>PAIN LEFT HIP/BUTTOCK</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>PAIN LEFT SIDE ABDOMEN</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>PAIN LEFT UPPER LEG</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>PAIN LEGS</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>PAIN LEFT UPPERARM</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>PAIN LOWER BACK</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	1 / 291 (0.34%)
occurrences (all)	1	2
<b>PAIN LOWER ABDOMEN</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	2 / 291 (0.69%)
occurrences (all)	1	3
<b>PAIN NERVES UNDERLEGS (NEUROPATHIC PAIN)</b>		

alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
PAIN NECK		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	2	0
PAIN NOS		
alternative dictionary used: CTC 2		
subjects affected / exposed	2 / 300 (0.67%)	2 / 291 (0.69%)
occurrences (all)	4	6
PAIN PERINEUM AREA		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
PAIN PELVIS		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
PAIN RIGHT FOSSA		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	2 / 291 (0.69%)
occurrences (all)	0	3
PAIN RECTAL		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
PAIN RIGHT HIP		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
PAIN RIGHT LEG		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	2 / 291 (0.69%)
occurrences (all)	0	2
PAIN RIGHT SHOULDER		

alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>PAIN STOMACH</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>PAIN SKIN ABDOMINAL</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>PAIN VULVA</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>PAIN VAGINA</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>PAIN WHOLE BODY</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	1 / 291 (0.34%)
occurrences (all)	1	1
<b>PAIN, NOT DEFINIED</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>PELVIC PAIN BACK PAIN</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>PELVIC PAIN</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	2 / 300 (0.67%)	1 / 291 (0.34%)
occurrences (all)	3	1
<b>PELVIC PAINS</b>		

alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>PELVIS AND GROIN PAIN</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>RECTAL PAIN</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	2 / 291 (0.69%)
occurrences (all)	0	3
<b>RECTAL PAIN (ULCER)</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>RENAL COLICS</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	2
<b>RIGHT FLANK PAIN</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>RIGHT ARM PAIN</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>SKIN SURFACE PAIN</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>SORE THROAT</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>STOMACH ACHE</b>		

alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	2 / 291 (0.69%)
occurrences (all)	0	2
<b>STOMACH PAIN</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	2 / 291 (0.69%)
occurrences (all)	0	2
<b>SUPRA PUBIC PAIN</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	2
<b>SUPRAPUBIC PAIN</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>SWALLOWING</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>THORACAL PAIN</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>THORACIC PAIN</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>THROAT PAIN</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	2 / 300 (0.67%)	1 / 291 (0.34%)
occurrences (all)	2	1
<b>TUMOR PAIN</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	4	0
<b>UNSPECIFIED PAIN</b>		

alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
VAGINAL AND GROIN PAIN		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
VAGINAL EXAMINATION PAINFUL		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
VAGINAL PAIN		
alternative dictionary used: CTC 2		
subjects affected / exposed	2 / 300 (0.67%)	2 / 291 (0.69%)
occurrences (all)	3	4
VULVAR PAIN		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
COMMON COLD		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
FLU ILLNESS		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
FLU LIKE SYNDROME		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	1 / 291 (0.34%)
occurrences (all)	1	1
FLU-LIKE FEELING		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	1 / 291 (0.34%)
occurrences (all)	2	1
FLU-LIKE SYMPTOMS		

<p>alternative dictionary used: CTC 2</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>HEAVY LEGS</p> <p>alternative dictionary used: CTC 2</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 300 (0.33%)</p> <p>1</p> <p>1 / 300 (0.33%)</p> <p>5</p>	<p>0 / 291 (0.00%)</p> <p>0</p> <p>0 / 291 (0.00%)</p> <p>0</p>	
<p>Immune system disorders</p> <p>ALLERGY</p> <p>alternative dictionary used: CTC 2</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>URTICARIA</p> <p>alternative dictionary used: CTC 2</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>33 / 300 (11.00%)</p> <p>40</p> <p>1 / 300 (0.33%)</p> <p>1</p>	<p>21 / 291 (7.22%)</p> <p>27</p> <p>0 / 291 (0.00%)</p> <p>0</p>	
<p>Reproductive system and breast disorders</p> <p>FISSURE VAGINAL</p> <p>alternative dictionary used: CTC 2</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>IRREGULAR MENSES</p> <p>alternative dictionary used: CTC 2</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>ITCH VAGINAL</p> <p>alternative dictionary used: CTC 2</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>MUC DISCHARGE UTEROUS</p> <p>alternative dictionary used: CTC 2</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>MUCOSITIS PORTIO/VAGINA</p> <p>alternative dictionary used: CTC 2</p>	<p>0 / 300 (0.00%)</p> <p>0</p> <p>0 / 300 (0.00%)</p> <p>0</p> <p>1 / 300 (0.33%)</p> <p>1</p> <p>0 / 300 (0.00%)</p> <p>0</p>	<p>1 / 291 (0.34%)</p> <p>1</p> <p>1 / 291 (0.34%)</p> <p>1</p> <p>0 / 291 (0.00%)</p> <p>0</p> <p>1 / 291 (0.34%)</p> <p>1</p>	

subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
PURULENT PV DISCHARGE		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
RADIATION EFFECTS VAGINA		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
SCARTISSUE VAGINA DUE RT		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
SIGNS OF AMENORRHEA		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
SYNECHIA VAGINAL		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
VAGINA AND VULVODYNIA		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
BLEEDING VAGINAL		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
VAGINAL BLOOD LOSS		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
VAGINAL BURNING		
alternative dictionary used: CTC 2		

subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
VAGINAL DISCHARGES		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	1 / 291 (0.34%)
occurrences (all)	2	1
VAGINAL DISCOMFORT		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
VAGINAL DRYNESS		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
VAGINAL FLUID LOSS		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	3 / 291 (1.03%)
occurrences (all)	0	3
VAGINAL ITCHING		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
VAGINAL NARROWING		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
VAGINAL PRURITUS		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
VAGINAL PRURITUS		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	2
VULVAR EDEMA		
alternative dictionary used: CTC 2		

subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	
occurrences (all)	0	1	
<b>VULVITIS</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	
occurrences (all)	0	1	
<b>VULVAR WOUND</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	
occurrences (all)	0	1	
<b>Respiratory, thoracic and mediastinal disorders</b>			
<b>COLD (COMMON)</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	1	0	
<b>A COUGH</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	1	0	
<b>COUGH</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	18 / 300 (6.00%)	9 / 291 (3.09%)	
occurrences (all)	26	11	
<b>DYSPNEA</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	15 / 300 (5.00%)	15 / 291 (5.15%)	
occurrences (all)	23	18	
<b>HOARSENESS</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	
occurrences (all)	0	1	
<b>HYPERVENTILATION</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	1	0	
<b>LABORED BREATHING</b>			

alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	1	0	
<b>PULMONARY</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	13 / 300 (4.33%)	4 / 291 (1.37%)	
occurrences (all)	18	5	
<b>PULMONARY EMBOLISM</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	1 / 291 (0.34%)	
occurrences (all)	1	2	
<b>Cardiac disorders</b>			
<b>BRADYCARDIA</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	
occurrences (all)	0	1	
<b>CARDIOVASCULAR</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	24 / 300 (8.00%)	16 / 291 (5.50%)	
occurrences (all)	36	23	
<b>DEEP VEIN THROMBOSISI LEFT</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	
occurrences (all)	0	1	
<b>DVT</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	
occurrences (all)	0	2	
<b>EDEMA</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	27 / 300 (9.00%)	10 / 291 (3.44%)	
occurrences (all)	31	12	
<b>HEART PALPITATIONS</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	1	0	
<b>HYPERTENSION</b>			

alternative dictionary used: CTC 2		
subjects affected / exposed	23 / 300 (7.67%)	7 / 291 (2.41%)
occurrences (all)	65	17
<b>HYPOTENSION</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	6 / 300 (2.00%)	7 / 291 (2.41%)
occurrences (all)	6	7
<b>PALPITATION</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>PALPITATIONS</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	3 / 300 (1.00%)	0 / 291 (0.00%)
occurrences (all)	4	0
<b>PHLEBITIS</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	2 / 291 (0.69%)
occurrences (all)	1	2
<b>PROLONGED QTC INTERVAL</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>REPOLARISATION DISTURBANCES</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>TACHYCARDIA</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>THROMBOSIS AT SINUS SIGMOID</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>THROMBOSIS LEFT UPPERARM</b>		

alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	1	0	
<b>THROMBOSIS PICC CATHETER</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	
occurrences (all)	0	1	
<b>THROMBOSIS/EMBOLISM</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	1	0	
<b>Nervous system disorders</b>			
<b>ANXIETY</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	2	0	
<b>BALANCE DISTURBANCES</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	1	0	
<b>DEAD FEELING</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	1	0	
<b>DEJECTED</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	1	0	
<b>DEPRESSION</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	
occurrences (all)	0	1	
<b>DISTRESS</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	2	0	
<b>DIZZINESS</b>			

alternative dictionary used: CTC 2		
subjects affected / exposed	5 / 300 (1.67%)	5 / 291 (1.72%)
occurrences (all)	5	5
<b>DIZZY, FAINTING</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>EMOTIONAL DISTURBANCES</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	3 / 300 (1.00%)	2 / 291 (0.69%)
occurrences (all)	3	2
<b>FORGETFUL</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>HALLUCINATIONS</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>HEADACHE</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>INSOMNIA</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	1 / 291 (0.34%)
occurrences (all)	1	2
<b>LIGHT HEADINESS</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>MENTAL DISTRESS</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	4	0
<b>MOOD ALTERATION - ANXIETY</b>		

alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>MOOD ALTERATION AGITATION</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>MOOD ALTERATION: EMOTIONAL DISTURBANCES</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>NERVOSITAS</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	3 / 300 (1.00%)	1 / 291 (0.34%)
occurrences (all)	3	1
<b>NEUROLOGY-OTHER</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	39 / 300 (13.00%)	27 / 291 (9.28%)
occurrences (all)	79	37
<b>NEUROPATHY-MOTOR</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	3 / 300 (1.00%)	0 / 291 (0.00%)
occurrences (all)	3	0
<b>NEUROPATHY-SENSORY</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	62 / 300 (20.67%)	41 / 291 (14.09%)
occurrences (all)	110	59
<b>NUMBNESS GROIN</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>NUMBNESS L HIP</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>PANIC ATTACKS</b>		

alternative dictionary used: CTC 2			
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	
occurrences (all)	0	1	
<b>PETIT MAL</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	2	0	
<b>RESTLESS LEGS</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	2	0	
<b>SENSATION FULLNESS HEAD</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	1	0	
<b>SLEEP DISTURBANCES</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	2 / 300 (0.67%)	0 / 291 (0.00%)	
occurrences (all)	2	0	
<b>SOCIAL PROBLEMS (AT HOME)</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	1	0	
<b>TREMOR</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	2 / 300 (0.67%)	0 / 291 (0.00%)	
occurrences (all)	2	0	
<b>UNSTABLE LEGS</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	2	0	
<b>WERNICKE ENCEPHALOPATHY</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	1	0	
Blood and lymphatic system disorders			

ALAT		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	2
ANEMIA		
alternative dictionary used: CTC 2		
subjects affected / exposed	19 / 300 (6.33%)	11 / 291 (3.78%)
occurrences (all)	35	18
ASAT		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	2
CREATININE ELEVATED		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
GRANULOCYTOPENIA		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
HEMATOLOGICAL		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
HEMOGLOBIN		
alternative dictionary used: CTC 2		
subjects affected / exposed	69 / 300 (23.00%)	51 / 291 (17.53%)
occurrences (all)	103	114
HYPOMAGNESEMIA		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
LEUCOPENIA		
alternative dictionary used: CTC 2		
subjects affected / exposed	14 / 300 (4.67%)	7 / 291 (2.41%)
occurrences (all)	21	11
LEUKOCYTES		

alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	2	0
<b>LYMPHOPENIA</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	2 / 291 (0.69%)
occurrences (all)	0	6
<b>NEUTROPENIA</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	24 / 300 (8.00%)	9 / 291 (3.09%)
occurrences (all)	35	12
<b>NEUTROPHILS</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	31 / 300 (10.33%)	21 / 291 (7.22%)
occurrences (all)	35	22
<b>NEUTROPHILS/GRANULOCYTES</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	3 / 300 (1.00%)	3 / 291 (1.03%)
occurrences (all)	6	4
<b>PANCYTOPENIA</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	1 / 291 (0.34%)
occurrences (all)	1	2
<b>PLATELETS</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	4 / 300 (1.33%)	7 / 291 (2.41%)
occurrences (all)	5	9
<b>THROMBOCYTOPENIA</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	11 / 300 (3.67%)	5 / 291 (1.72%)
occurrences (all)	17	7
<b>TROMBOCYTOPENIA</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	2 / 291 (0.69%)
occurrences (all)	1	3
<b>DISSEMINATED INTRAVASCULAR COAGULATION</b>		

alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>ABDOMINAL HEMATOMA</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	2	0
<b>BLEEDING</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	73 / 300 (24.33%)	0 / 291 (0.00%)
occurrences (all)	73	0
<b>BLOOD LOSS</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>EPISTAXIS</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	4 / 300 (1.33%)	0 / 291 (0.00%)
occurrences (all)	8	0
<b>ESOPHAGAL BLEEDING</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>HEMATOMA NAVEL</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>HEMATOMA RETRO PERITONEAL</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>HEMATURIA</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	3 / 300 (1.00%)	3 / 291 (1.03%)
occurrences (all)	3	4
<b>HEMORRHAGE/BLEEDING</b>		

alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	1	0	
<b>IRREGULAR BLOOD LOSS</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	1 / 291 (0.34%)	
occurrences (all)	1	1	
<b>NOSE BLEEDING</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	1	0	
<b>BLEEDING RECTAL</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	
occurrences (all)	0	1	
<b>UTERINE BLEEDING</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	1	0	
<b>VAGINAL BLEEDING</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	25 / 300 (8.33%)	51 / 291 (17.53%)	
occurrences (all)	32	79	
<b>Ear and labyrinth disorders</b>			
<b>AUDITORY</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	59 / 300 (19.67%)	35 / 291 (12.03%)	
occurrences (all)	139	66	
<b>HEARING LOSS</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	2 / 300 (0.67%)	0 / 291 (0.00%)	
occurrences (all)	4	0	
<b>INNER EAR/HEARING</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	3 / 300 (1.00%)	1 / 291 (0.34%)	
occurrences (all)	4	1	
<b>Eye disorders</b>			

AMBLYOPIA		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
BLURRED VISION		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
BLURRED VISION LEFT EYE		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
CONJUNCTIVIS LEFT		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
CONJUNCTIVITIS		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	2	0
DECLINE VISUS		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
DOUBLE VISION		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
DOUBLE VISION - PAPILLEDEMA		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
DRY EYES		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	2 / 291 (0.69%)
occurrences (all)	0	4
HAZY SIGHT (SEEING(?))		

alternative dictionary used: CTC 2			
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	
occurrences (all)	0	1	
<b>INTRA-OCULAR PRESSURE</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	
occurrences (all)	0	1	
<b>OPTIC DISC EDEMA</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	
occurrences (all)	0	1	
<b>VISION LOSS</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	1	0	
<b>VISION:FLASHING LIGHTS</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	1	0	
<b>VISUAL DISTURBANCE</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	
occurrences (all)	0	2	
<b>VISUS DECREASE</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	3	0	
<b>Gastrointestinal disorders</b>			
<b>ABDOMINAL DISTENSION</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	1	0	
<b>PAIN ABDOMINAL</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	79 / 300 (26.33%)	89 / 291 (30.58%)	
occurrences (all)	137	147	
<b>ACUTE PANCREATITIS</b>			

alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	2	0
<b>ALTERED TASTE</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	3	0
<b>ANOREXIA</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	3 / 300 (1.00%)	9 / 291 (3.09%)
occurrences (all)	3	12
<b>CONSTIPATION</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	121 / 300 (40.33%)	78 / 291 (26.80%)
occurrences (all)	212	114
<b>DECREASED APPETITE</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	2 / 300 (0.67%)	1 / 291 (0.34%)
occurrences (all)	3	1
<b>DEHYDRATION</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>DEHYDRATION DRY SKIN AND MUCOSA</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>DIARRHEA</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	64 / 300 (21.33%)	191 / 291 (65.64%)
occurrences (all)	91	398
<b>DISGEUSIA</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>DRY MOUTH</b>		

alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>DYSGEUSIA</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	2 / 291 (0.69%)
occurrences (all)	0	2
<b>DYSOSMIA</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>DYSPEPSIA</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	2 / 300 (0.67%)	0 / 291 (0.00%)
occurrences (all)	3	0
<b>DYSPEPSIA/HEARTBURN</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	2
<b>DYSPHAGIA</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>FLATULENCE</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>GASTROINTESTINAL</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	100 / 300 (33.33%)	81 / 291 (27.84%)
occurrences (all)	193	145
<b>GASTROINTESTINAL HEMOROÏDS</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>ILEUS</b>		

alternative dictionary used: CTC 2		
subjects affected / exposed	3 / 300 (1.00%)	0 / 291 (0.00%)
occurrences (all)	3	0
LOSS OF APPETITE		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
MUCOSITIS ANAL		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
MUCOSITIS ORAL		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
MUCOSITIS/STOMATITIS		
alternative dictionary used: CTC 2		
subjects affected / exposed	2 / 300 (0.67%)	0 / 291 (0.00%)
occurrences (all)	3	0
NASTY TASTE		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
NAUSEA		
alternative dictionary used: CTC 2		
subjects affected / exposed	220 / 300 (73.33%)	173 / 291 (59.45%)
occurrences (all)	466	397
ODYNOPHAGIA		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
OESOPHAGITIS		
alternative dictionary used: CTC 2		
subjects affected / exposed	2 / 300 (0.67%)	0 / 291 (0.00%)
occurrences (all)	2	0
OLFACTORY LOSS		

alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	1 / 291 (0.34%)
occurrences (all)	1	1
<b>OPERATIVE INJURY</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>ORAL CAVITY MUCOSITIS</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>ORAL MUCOSITIS</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>PHARYNGAL - MUCOSITIS</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>PHARYNGITIS</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>PYROSIS</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	2 / 300 (0.67%)	0 / 291 (0.00%)
occurrences (all)	2	0
<b>RECTAL BLEEDING</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	7 / 300 (2.33%)	7 / 291 (2.41%)
occurrences (all)	8	7
<b>RUCTUS</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	2	0
<b>SENSE OF SMELL DISTURBANCE</b>		

alternative dictionary used: CTC 2			
subjects affected / exposed	3 / 300 (1.00%)	2 / 291 (0.69%)	
occurrences (all)	3	3	
<b>SENSE OF TASTE</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	1	0	
<b>STOMACH DISTURBANCE</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	
occurrences (all)	0	1	
<b>STOMACH ULCERATION</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	
occurrences (all)	0	2	
<b>STOMATITIS</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	2 / 300 (0.67%)	2 / 291 (0.69%)	
occurrences (all)	3	3	
<b>TASTE DISTURBANCE</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	2 / 300 (0.67%)	1 / 291 (0.34%)	
occurrences (all)	2	2	
<b>VOMITING</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	132 / 300 (44.00%)	89 / 291 (30.58%)	
occurrences (all)	218	151	
<b>LOSS OF WEIGHT</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	1 / 291 (0.34%)	
occurrences (all)	1	1	
<b>Hepatobiliary disorders</b>			
<b>ALAT VALUE</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	2 / 300 (0.67%)	2 / 291 (0.69%)	
occurrences (all)	5	4	
<b>ALKALINE PHOSPHATASIS</b>			

alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
ALT		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
ASAT VALUE		
alternative dictionary used: CTC 2		
subjects affected / exposed	2 / 300 (0.67%)	2 / 291 (0.69%)
occurrences (all)	4	2
BILIRUBIN		
alternative dictionary used: CTC 2		
subjects affected / exposed	11 / 300 (3.67%)	31 / 291 (10.65%)
occurrences (all)	15	58
GGT		
alternative dictionary used: CTC 2		
subjects affected / exposed	2 / 300 (0.67%)	2 / 291 (0.69%)
occurrences (all)	4	6
GGT INCREASED		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
HYPERTRANSAMINASE		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	3 / 291 (1.03%)
occurrences (all)	1	4
HYPOKALEMIA		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
INCREASE OF CRP		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
INCREASE OF GAMMA GT-LEVEL		

alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	1	0	
<b>INCREASED LIVER ENZYMES</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	1	0	
<b>LDH</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	1	0	
<b>LIVER DYSFUNCTION/FAILURE</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	
occurrences (all)	0	1	
<b>LIVER FUNCTION (ASAT/ALAT)</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	2 / 300 (0.67%)	0 / 291 (0.00%)	
occurrences (all)	2	0	
<b>SGOT (AST)</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	23 / 300 (7.67%)	29 / 291 (9.97%)	
occurrences (all)	28	45	
<b>SGPT (ALT)</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	21 / 300 (7.00%)	44 / 291 (15.12%)	
occurrences (all)	27	79	
<b>Skin and subcutaneous tissue disorders</b>			
<b>ABDOMINAL WOUND</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	
occurrences (all)	0	1	
<b>ACNE</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	1	0	
<b>ALLOPECIA</b>			

alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>ALOPECIA</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	82 / 300 (27.33%)	13 / 291 (4.47%)
occurrences (all)	164	17
<b>BURN BACKSIDE/GROIN</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>CUTANEOUS-RASH REACTION</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>DECUBITUS</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>DERMATITIS</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>DESQUAMATION</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>DIASTHESIS</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>DRY SKIN</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	5 / 300 (1.67%)	4 / 291 (1.37%)
occurrences (all)	9	5
<b>ECZEMA</b>		

alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	1 / 291 (0.34%)
occurrences (all)	1	2
<b>EPIDERMIOLYSIS LABIA/PERIANAL</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>ERYTHEMA</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	2 / 300 (0.67%)	1 / 291 (0.34%)
occurrences (all)	2	1
<b>EXANTHEMA</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	2 / 300 (0.67%)	0 / 291 (0.00%)
occurrences (all)	2	0
<b>EXCORIATION</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>FLUSHING</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>HAIRLOSS</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>HAND-FOOT REACTION</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	2 / 300 (0.67%)	1 / 291 (0.34%)
occurrences (all)	2	1
<b>HYPERPIGMENTATION</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>INGUINAL</b>		

alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	2
<b>INJECTION SITE REACTION</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	2 / 300 (0.67%)	0 / 291 (0.00%)
occurrences (all)	4	0
<b>IRRITATION OF THE BACK</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>ITCHING</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	2 / 300 (0.67%)	1 / 291 (0.34%)
occurrences (all)	2	1
<b>ITCHY SKIN</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>NAIL CHANGES</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	2 / 291 (0.69%)
occurrences (all)	0	3
<b>PIGMENTATION CHANGES</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	2
<b>PRURITUS</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	4 / 291 (1.37%)
occurrences (all)	1	4
<b>PSORIASIS</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	2 / 300 (0.67%)	0 / 291 (0.00%)
occurrences (all)	2	0
<b>RADIATION DERMATITIS</b>		

alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	2 / 291 (0.69%)
occurrences (all)	0	2
<b>RADIATION DERMATITIS VULVAR</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>RASH</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	3 / 300 (1.00%)	4 / 291 (1.37%)
occurrences (all)	4	6
<b>RASH/DESQUAMATION</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	2
<b>SKIN</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>SKIN DRY</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	2	0
<b>SKIN PAIN</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>SKIN RADIATION</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>SKIN RASH</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	7 / 300 (2.33%)	10 / 291 (3.44%)
occurrences (all)	11	12
<b>SKIN REACTION</b>		

alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>SKIN REDNESS</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>URTICARIA</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>VITILIGO LOWER LEGS</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>VULVA</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	2
<b>WOUND CELLULITIS</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>WOUND DEHISCENCE</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>WOUND FINGER</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>WOUND INFECTION</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>WOUND PROBLEM</b>		

alternative dictionary used: CTC 2			
subjects affected / exposed	0 / 300 (0.00%)	2 / 291 (0.69%)	
occurrences (all)	0	2	
<b>Renal and urinary disorders</b>			
<b>ACUTE PRERENAL FAILURE</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	1	0	
<b>ACUTE RENAL INSUFFICIENCY</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	1	0	
<b>URETHRA AND BLADDER</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	1	0	
<b>CREATINE ELEVATION</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	1	0	
<b>BLADDER DYSFUNCTION</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	1	0	
<b>CREATININE</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	12 / 300 (4.00%)	3 / 291 (1.03%)	
occurrences (all)	16	8	
<b>CREATININE CLEARANCE</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	2 / 300 (0.67%)	0 / 291 (0.00%)	
occurrences (all)	3	0	
<b>CREATININE CLEARANCE DECREASE</b>			
alternative dictionary used: CTC 2			
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	
occurrences (all)	0	1	
<b>CREATININE ELEVATION</b>			

alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>CREATININE INCREASE</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	4 / 300 (1.33%)	0 / 291 (0.00%)
occurrences (all)	4	0
<b>CYSTITIS</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	4 / 300 (1.33%)	9 / 291 (3.09%)
occurrences (all)	4	12
<b>CREATININE INCREASED</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>DECREASED RENAL FUNCTION</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>DECLINE OF RENAL FUNCTION</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>DEHISCENCE OF VAGINAL CUFF SURGICAL REPAIR</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>DYSURIA</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	32 / 291 (11.00%)
occurrences (all)	0	47
<b>DIFFICULTY URINATING</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>DYSURIA (PAINFUL URINATION)</b>		

alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>ELECTROLYTE DISTURBANCE</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	2 / 300 (0.67%)	0 / 291 (0.00%)
occurrences (all)	2	0
<b>FISTULA</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	3 / 300 (1.00%)	0 / 291 (0.00%)
occurrences (all)	3	0
<b>ERYTHEMA GENITALIA</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>HYDRONEPHROSIS</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>HYDRO-URETERO-NEPHROSIS</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>INCONTINENCY</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>INCONTINENCE</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	1 / 291 (0.34%)
occurrences (all)	1	1
<b>INCREASE CREATININE</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>INCREASED CREATININE VALUE</b>		

alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>INCREASED CREATININE LEVEL</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>KIDNEY FAILURE</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	2 / 300 (0.67%)	0 / 291 (0.00%)
occurrences (all)	2	0
<b>INJURY TO URETER</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>KIDNEY FUNCTION DECREASE</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>MICTALGIA PAIN</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>MICTURATION PAIN</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	4
<b>MUCOSITIS CERVIX</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>MUCOSITIS VAGINAL</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>NEPHROPATHY</b>		

alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	3	0
<b>NOCTURIA</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	2 / 291 (0.69%)
occurrences (all)	0	2
<b>NYCTURIA</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	2 / 291 (0.69%)
occurrences (all)	2	3
<b>OPERATION INJURY</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	10 / 300 (3.33%)	0 / 291 (0.00%)
occurrences (all)	10	0
<b>OPERATIVE INJURY TO URETER</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>PAIN + DYSURIA</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>PAINFUL URINATION</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	2 / 291 (0.69%)
occurrences (all)	0	2
<b>POLLAKISURIA</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	4 / 291 (1.37%)
occurrences (all)	1	5
<b>PRE-RENAL KIDNEY DISTURBANCE</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>RADIATION VULVO VAGINITIS</b>		

alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>RADIOCYSTITIS</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>RENAL CLEARANCES REDUCTION</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>RENAL FUNCTION</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>RENAL FUNCTION DECREASING</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>RENAL IMPAIRMENT</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>RENAL INSUFFICIENCY</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	3 / 300 (1.00%)	0 / 291 (0.00%)
occurrences (all)	3	0
<b>RIGHT URETER LEAKAGE</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>SENSITIVE BLADDER</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>STRESS INCONTINENCE</b>		

alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	2 / 291 (0.69%)
occurrences (all)	1	2
<b>SUPRAPUBIC CATHETER</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>URETERAL OBSTRUCTION</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>URGE INCONTINENCE</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	2 / 300 (0.67%)	4 / 291 (1.37%)
occurrences (all)	2	5
<b>URGENCY OF MICTURITION</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>URINARY DISTURBANCES</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>URINARY FREQUENCE INCREASE</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>URINARY FREQUENCY</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	5 / 291 (1.72%)
occurrences (all)	1	6
<b>URINARY FREQUENCY NOCTURIA</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>URINARY INCONTINENCE</b>		

alternative dictionary used: CTC 2		
subjects affected / exposed	2 / 300 (0.67%)	1 / 291 (0.34%)
occurrences (all)	2	1
<b>URINARY OBSTRUCTION</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
<b>URINARY RETENTION</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	12 / 300 (4.00%)	2 / 291 (0.69%)
occurrences (all)	16	2
<b>URINARY TRACT INFECTED</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>UTERUS PERFORATION</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>VAGINAL DISCHARGE</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	1 / 291 (0.34%)
occurrences (all)	3	2
<b>VAGINAL ITCH</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>VAGINAL WARTS</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
<b>VAGINITIS</b>		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	3 / 291 (1.03%)
occurrences (all)	0	3
<b>VESICO-VAGINAL FISTULA</b>		

alternative dictionary used: CTC 2 subjects affected / exposed occurrences (all)	1 / 300 (0.33%) 1	0 / 291 (0.00%) 0	
Endocrine disorders FLASHES HOT alternative dictionary used: CTC 2 subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	6 / 291 (2.06%) 7	
HOT FLUSHES alternative dictionary used: CTC 2 subjects affected / exposed occurrences (all)	8 / 300 (2.67%) 11	11 / 291 (3.78%) 13	
HYPERTHYROIDISM alternative dictionary used: CTC 2 subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	1 / 291 (0.34%) 1	
Musculoskeletal and connective tissue disorders ARTHRITIS alternative dictionary used: CTC 2 subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	1 / 291 (0.34%) 3	
DISCOMFORT RIGHT ILIAC FOSSA alternative dictionary used: CTC 2 subjects affected / exposed occurrences (all)	1 / 300 (0.33%) 1	0 / 291 (0.00%) 0	
HNP alternative dictionary used: CTC 2 subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	1 / 291 (0.34%) 4	
INTERMITTENT LOW BACK PAIN alternative dictionary used: CTC 2 subjects affected / exposed occurrences (all)	1 / 300 (0.33%) 1	0 / 291 (0.00%) 0	
MUSLE WEAKNESS alternative dictionary used: CTC 2			

subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
OSTEOARTHRITIS		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
SEROMA		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
STIFFNESS		
alternative dictionary used: CTC 2		
subjects affected / exposed	2 / 300 (0.67%)	0 / 291 (0.00%)
occurrences (all)	3	0
Infections and infestations		
A COLD		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
ABSCESS RIGHT SHOULDER		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
BLADDER		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
CANDIDIASIS		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
COLD SORE		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
COLD/RHINITIS		
alternative dictionary used: CTC 2		

subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
CYSTITIS INFECTION		
alternative dictionary used: CTC 2		
subjects affected / exposed	2 / 300 (0.67%)	1 / 291 (0.34%)
occurrences (all)	2	1
EPIDERMOLYSE		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	2
EPIDERMOLYSIS BUTTOCK		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
ERYSIPELAS R ARM		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
FEBRILE NEUTROPENIA		
alternative dictionary used: CTC 2		
subjects affected / exposed	8 / 300 (2.67%)	2 / 291 (0.69%)
occurrences (all)	9	2
HEPATITIS		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
HERPES		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
HERPETIC LIP		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
INFECTED LYMPHOCELE		
alternative dictionary used: CTC 2		

subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
INFECTION		
alternative dictionary used: CTC 2		
subjects affected / exposed	44 / 300 (14.67%)	32 / 291 (11.00%)
occurrences (all)	50	36
INFECTION ANC		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
INFECTION OF THE PICC		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
INFECTION PORT A CATH		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
ORAL HERPES		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
PERINEAL FUNGALINFECTION		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
PICC CATHETER INFECTION R ARM		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
RENAL URINARY TRACT INFECTION		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
SALMONELLA AND CANDIDA INFECTION		
alternative dictionary used: CTC 2		

subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
SEPSIS		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
SKIN INFECTION		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	2	0
STREPTOCOCCUS PNEUMONIA INFECTION		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
TONSILLITIS		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
URINARY INFECTION		
alternative dictionary used: CTC 2		
subjects affected / exposed	2 / 300 (0.67%)	2 / 291 (0.69%)
occurrences (all)	2	2
URINARY TRACT INFECTION		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	1 / 291 (0.34%)
occurrences (all)	1	2
UROLOGIC INFECTION		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
UROSEPSIS		
alternative dictionary used: CTC 2		
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)
occurrences (all)	1	0
VIRAL INFECTION		
alternative dictionary used: CTC 2		

subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	1 / 291 (0.34%) 1	
WOUND INFECTED alternative dictionary used: CTC 2			
subjects affected / exposed occurrences (all)	1 / 300 (0.33%) 1	0 / 291 (0.00%) 0	
Metabolism and nutrition disorders			
DECREASE CREATININE CLEARANCE alternative dictionary used: CTC 2			
subjects affected / exposed occurrences (all)	1 / 300 (0.33%) 1	0 / 291 (0.00%) 0	
HYPERGLYCEMIA alternative dictionary used: CTC 2			
subjects affected / exposed occurrences (all)	1 / 300 (0.33%) 1	0 / 291 (0.00%) 0	
HYPERKALEMIA alternative dictionary used: CTC 2			
subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	1 / 291 (0.34%) 1	
HYPOCALCEMIA alternative dictionary used: CTC 2			
subjects affected / exposed occurrences (all)	5 / 300 (1.67%) 7	2 / 291 (0.69%) 4	
HYPO-KALEMIA alternative dictionary used: CTC 2			
subjects affected / exposed occurrences (all)	9 / 300 (3.00%) 12	6 / 291 (2.06%) 10	
HYPOKALIEMIA alternative dictionary used: CTC 2			
subjects affected / exposed occurrences (all)	1 / 300 (0.33%) 1	0 / 291 (0.00%) 0	
HYPO-MAGNESEMIA alternative dictionary used: CTC 2			
subjects affected / exposed occurrences (all)	11 / 300 (3.67%) 22	2 / 291 (0.69%) 5	
HYPONATREMIA alternative dictionary used: CTC 2			

subjects affected / exposed	4 / 300 (1.33%)	1 / 291 (0.34%)	
occurrences (all)	5	1	
HYPOPHOSATEMIA			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	1	0	
LACTATE ACIDOSIS			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	1	0	

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
02 September 2003	This amendment allowed incorporating tissue of the patients of the trial in the virtual tumor bank; adapting the document to reflect the EORTC policy for publication; and changing the requirement for the neo-adjuvant treatment arm. The minimum platinum dose was set at 225 mg/m <sup>2</sup> providing a minimum dose of platinum of 75 mg/m <sup>2</sup> per cycle irrespectively whether cycles are scheduled weekly or over 10 days, thus reflecting the daily practice of the majority of the centers.
19 February 2014	Following an EORTC Board meeting, a statistical analysis (to compare the two arms) was performed by an independent statistician according to EORTC procedures. It appears that there is a better survival, in contrast to what was expected in the protocol. Event rates for the primary endpoint are therefore lower than expected, negating any advantage of longer follow-up times currently achieved. Therefore, the recommendation of the independent statistician was to re-design the study. This major amendment included: <ul style="list-style-type: none"><li>- Change of primary end-point: from overall survival to overall survival at 5 years.</li><li>- Secondary end-point: overall survival has been added</li><li>- Total number of pts has been lowered from 686 to 625</li><li>- Eligibility criteria: addition of criteria about pregnancy test, contraception, breast feeding and hypersensitivity to component(s) of chemotherapeutics to be used or cisplatin contraindication.</li><li>- Statistics chapters have been updated to reflect changes of end-points and number of patients.</li><li>- The TR chapter has been completely revised to incorporate up-to-date rationale &amp; proposals: genetic profile in cervical cancer; STAT(6)-expression for platinum-sensitivity in cervical cancer; influence of the tumor microenvironment on STAT phosphorylation; interaction between microenvironment, protein-expression and (epi)genetic alterations.</li><li>- A standard chapter about HBM collection has been added.</li><li>- The dummy run procedure for RTQA and PVU section have been updated</li><li>- The PIS/IC has also been updated.</li></ul>

Notes:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

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

The trial took almost 12 years (11 years + 8 months) to complete. The type of disease but also the difficulty of presenting patients with a randomized choice between surgery or radiotherapy played a role.

Notes: