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

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:

Results analysis stage

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

Notes:

General information about the trial

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.

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.

Background therapy:

NA

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: 7I-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 carciunoma 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.

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 IIb, 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
Arm title	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/m² with a minimum dose of cisplatin of 75 mg/m² 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/m2 (except when dose modifications, dose delays or treatment termination are needed). The cisplatin dose should be the equivalent of at least 25 mg/m2 per week. The final dose to start no later than day 64.

Arm title	CCRT

Arm description:

In the CCRT (concomitant chemoradiotherapy) arm cisplatin was to be given with 5 or 6 weekly doses of 40 mg/m2 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

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/m2 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/m² (except when dose modifications, dose delays or treatment termination are allowed by the protocol).

Number of subjects in period 1	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

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/m² with a minimum dose of cisplatin of 75 mg/m² 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/m2 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

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/m² with a minimum dose of cisplatin of 75 mg/m² 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/m2 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
Subject analysis set type	Intention-to-treat

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

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

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
Comparison groups	NACTS v CCRT

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

Statistical analysis title	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

Secondary: PFS at year 5

End point title	PFS at year 5
End point description:	

End point type	Secondary
End point timeframe: overall study duration	

End point values	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

Statistical analysis title	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.

End point values	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[1]	200[2]		
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

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

Dictionary used

Dictionary name	MedDRA
Dictionary version	20

Reporting groups

Reporting group title	NACTS

Reporting group description:

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

Reporting group title	CCRT

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	
Reproductive system and breast disorders			
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	
Respiratory, thoracic and mediastinal disorders			
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	
Psychiatric disorders			
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	
Investigations			
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	
Cardiac disorders			
ATRIAL FLUTTER			
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	
BRADYCARDIA			
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	
SINUS TACHYCARDIA			
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	
SUPRAVENTRICULAR TACHYCARDIA			
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	
Nervous system disorders			
CEREBRAL 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 / 1	0 / 0	
CEREBRAL ISCHAEMIA			
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	
GENERALISED TONIC-CLONIC SEIZURE			
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	
PARTIAL SEIZURES			
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	
PETIT MAL EPILEPSY			
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	
SUPERIOR SAGITTAL SINUS 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	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
WERNICKE'S ENCEPHALOPATHY			
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	
Blood and lymphatic system disorders			
ANAEMIA			
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	
DISSEMINATED INTRAVASCULAR COAGULATION			
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	
FEBRILE NEUTROPENIA			
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	
NEUTROPENIA			
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	
PANCYTOPENIA			
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	
THROMBOCYTOPENIA			
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	
Gastrointestinal disorders			
ABDOMINAL PAIN			
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	
ABDOMINAL PAIN UPPER			
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	
CONSTIPATION			
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	
DIARRHOEA			
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	
GASTRITIS			
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	
NAUSEA			
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	
OESOPHAGEAL 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	

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	
RENAL IMPAIRMENT			
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	
RENAL TUBULAR NECROSIS			
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	
URINARY RETENTION			
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	
Musculoskeletal and connective tissue disorders			
BACK 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	
MYALGIA			
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	
Infections and infestations			
DEVICE RELATED INFECTION			
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	

SALMONELLOSIS			
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	
SEPSIS			
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	
SINUSITIS			
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	
STREPTOCOCCAL 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	
STREPTOCOCCAL SEPSIS			
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	
URINARY TRACT INFECTION			
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	
UROSEPSIS			
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	
WOUND 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	
Metabolism and nutrition disorders			
DECREASED APPETITE			
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	
DEHYDRATION			
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	
ELECTROLYTE IMBALANCE			
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	
HYPERCALCAEMIA			
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	
HYPOCALCAEMIA			
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	
HYPOKALAEMIA			
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	
HYPOMAGNESAEMIA			
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	
HYPONATRAEMIA			
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	
LACTIC ACIDOSIS			
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 %

Non-serious adverse events	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	
STOMACH AND DUODENUM			
alternative dictionary used: CTC 2			
subjects affected / exposed	35 / 300 (11.67%)	38 / 291 (13.06%)	
occurrences (all)	47	47	
URETER			
alternative dictionary used: CTC 2			
subjects affected / exposed	34 / 300 (11.33%)	30 / 291 (10.31%)	
occurrences (all)	79	77	
UTERUS-VAGINA-VULVA			
alternative dictionary used: CTC 2			
subjects affected / exposed	94 / 300 (31.33%)	157 / 291 (53.95%)	
occurrences (all)	263	598	
VESICULAR			
alternative dictionary used: CTC 2			
subjects affected / exposed	31 / 300 (10.33%)	12 / 291 (4.12%)	
occurrences (all)	84	29	
General disorders and administration site conditions			
ASTHENIA			
alternative dictionary used: CTC 2			
subjects affected / exposed	11 / 300 (3.67%)	18 / 291 (6.19%)	
occurrences (all)	14	28	
CHILLS			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	1 / 291 (0.34%)	
occurrences (all)	1	1	
COLD FEET			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	1	0	
COMMON MALAISE			
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	
LETHARGY			
alternative dictionary used: CTC 2			
subjects affected / exposed	2 / 300 (0.67%)	0 / 291 (0.00%)	
occurrences (all)	4	0	
LOCAL COMPLAINTS			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	1	0	
MALAISE			
alternative dictionary used: CTC 2			
subjects affected / exposed	5 / 300 (1.67%)	3 / 291 (1.03%)	
occurrences (all)	8	7	
MALAISE GENERAL			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	1	0	
NIGHT SWEATING			
alternative dictionary used: CTC 2			
subjects affected / exposed	3 / 300 (1.00%)	1 / 291 (0.34%)	
occurrences (all)	4	1	
NIGHT SWEATS			
alternative dictionary used: CTC 2			
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	
occurrences (all)	0	1	
SHIVERING			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	1	0	
SWEATING			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	4 / 291 (1.37%)	
occurrences (all)	3	4	
WEAKNESS			

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

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

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

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

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

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

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

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

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

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

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			

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

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

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

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

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

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

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

alternative dictionary used: CTC 2			
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	
occurrences (all)	0	1	
PETIT MAL			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	2	0	
RESTLESS LEGS			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	2	0	
SENSATION FULLNESS HEAD			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	1	0	
SLEEP DISTURBANCES			
alternative dictionary used: CTC 2			
subjects affected / exposed	2 / 300 (0.67%)	0 / 291 (0.00%)	
occurrences (all)	2	0	
SOCIAL PROBLEMS (AT HOME)			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	1	0	
TREMOR			
alternative dictionary used: CTC 2			
subjects affected / exposed	2 / 300 (0.67%)	0 / 291 (0.00%)	
occurrences (all)	2	0	
UNSTABLE LEGS			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	2	0	
WERNICKE ENCEPHALOPATHY			
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	
LYMPHOPENIA			
alternative dictionary used: CTC 2			
subjects affected / exposed	0 / 300 (0.00%)	2 / 291 (0.69%)	
occurrences (all)	0	6	
NEUTROPENIA			
alternative dictionary used: CTC 2			
subjects affected / exposed	24 / 300 (8.00%)	9 / 291 (3.09%)	
occurrences (all)	35	12	
NEUTROPHILS			
alternative dictionary used: CTC 2			
subjects affected / exposed	31 / 300 (10.33%)	21 / 291 (7.22%)	
occurrences (all)	35	22	
NEUTROPHILS/GRANULOCYTES			
alternative dictionary used: CTC 2			
subjects affected / exposed	3 / 300 (1.00%)	3 / 291 (1.03%)	
occurrences (all)	6	4	
PANCYTOPENIA			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	1 / 291 (0.34%)	
occurrences (all)	1	2	
PLATELETS			
alternative dictionary used: CTC 2			
subjects affected / exposed	4 / 300 (1.33%)	7 / 291 (2.41%)	
occurrences (all)	5	9	
THROMBOCYTOPENIA			
alternative dictionary used: CTC 2			
subjects affected / exposed	11 / 300 (3.67%)	5 / 291 (1.72%)	
occurrences (all)	17	7	
TROMBOCYTOPENIA			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	2 / 291 (0.69%)	
occurrences (all)	1	3	
DISSEMINATED INTRAVASCULAR COAGULATION			

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	1	0	
Endocrine disorders			
FLASHES HOT			
alternative dictionary used: CTC 2			
subjects affected / exposed	0 / 300 (0.00%)	6 / 291 (2.06%)	
occurrences (all)	0	7	
HOT FLUSHES			
alternative dictionary used: CTC 2			
subjects affected / exposed	8 / 300 (2.67%)	11 / 291 (3.78%)	
occurrences (all)	11	13	
HYPERTHYROIDISM			
alternative dictionary used: CTC 2			
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	
occurrences (all)	0	1	
Musculoskeletal and connective tissue disorders			
ARTHRITIS			
alternative dictionary used: CTC 2			
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	
occurrences (all)	0	3	
DISCOMFORT RIGHT ILIAC FOSSA			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	1	0	
HNP			
alternative dictionary used: CTC 2			
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	
occurrences (all)	0	4	
INTERMITTENT LOW BACK PAIN			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	1	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	0 / 300 (0.00%)	1 / 291 (0.34%)	
occurrences (all)	0	1	
WOUND INFECTED			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	1	0	
Metabolism and nutrition disorders			
DECREASE CREATININE CLEARANCE			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	1	0	
HYPERGLYCEMIA			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	1	0	
HYPERKALEMIA			
alternative dictionary used: CTC 2			
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	
occurrences (all)	0	1	
HYPOCALCEMIA			
alternative dictionary used: CTC 2			
subjects affected / exposed	5 / 300 (1.67%)	2 / 291 (0.69%)	
occurrences (all)	7	4	
HYPO-KALEMIA			
alternative dictionary used: CTC 2			
subjects affected / exposed	9 / 300 (3.00%)	6 / 291 (2.06%)	
occurrences (all)	12	10	
HYPOKALIEMA			
alternative dictionary used: CTC 2			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	
occurrences (all)	1	0	
HYPO-MAGNESEMIA			
alternative dictionary used: CTC 2			
subjects affected / exposed	11 / 300 (3.67%)	2 / 291 (0.69%)	
occurrences (all)	22	5	
HYPONATREMIA			
alternative dictionary used: CTC 2			

subjects affected / exposed	4 / 300 (1.33%)	1 / 291 (0.34%)	
occurrences (all)	5	1	
HYPOPHOSHATEMIA 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/m² providing a minimum dose of platinum of 75 mg/m² 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: - Change of primary end-point: from overall survival to overall survival at 5 years. - Secondary end-point: overall survival has been added - Total number of pts has been lowered from 686 to 625 - Eligibility criteria: addition of criteria about pregnancy test, contraception, breast feeding and hypersensitivity to component(s) of chemotherapeutics to be used or cisplatin contraindication. - Statistics chapters have been updated to reflect changes of end-points and number of patients. - The TR chapter has been completely revised to incorporate up-to-date rationale & 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. - A standard chapter about HBM collection has been added. - The dummy run procedure for RTQA and PVU section have been updated - The PIS/IC has also been updated.

Notes:

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: