



Clinical trial results:

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

Summary

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

Results information

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

Trial information

Trial identification

Sponsor protocol code	EORTC55994
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Additional study identifiers

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

Notes:

Sponsors

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

Notes:

Paediatric regulatory details

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

Notes:

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: 71-78; 1999.
- Girinsky T., Rey A., Roche B., Haie C., Gerbaulet A., Randrianarivello H. Overall treatment time in advanced cervical carcinomas : a critical parameter in treatment outcome. Int. J. Radiat. Oncol. Biol. Phys. 27 : 1051-6 ; 1993.
- Lanciano R., Thomas G., Eifel PG. Over 20 years of progression in radiation oncology: Cervical Cancer. Semin Radiat Oncol 7:121-126, 1997.
- Nag S, Erickson B, Thomadsen B, Orton C, Demanes JD, Petereit D: the American Brachytherapy Society recommendations for High Dose Rate brachytherapy for carcinoma of the Cervix.
- Perez CA, Grigsby PW, Castro Vita H, Lockett MA. Carcinoma of the uterine cervix. I. Impact of prolongation of overall treatment time and timing of brachytherapy on outcome of radiation therapy. Int J Radiat Oncol Biol Phys 32:1275-1288, 1995.

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
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Arm description:

In the CCRT (concomitant chemoradiotherapy) arm cisplatin was to be given with 5 or 6 weekly doses of 40 mg/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
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Investigational medicinal product name	cisplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Concomitant chemotherapy with an initial dose of at least 40 mg/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
Lack of efficacy	14	-
Protocol deviation	7	6

Baseline characteristics

Reporting groups

Reporting group title	NACTS
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Reporting group description:

In the NACTS arm, chemotherapy consisted of cisplatin-based chemotherapy. Several chemotherapy regimens were allowed according to the policy of the institute. The minimum cumulative cisplatin dose was set at 225 mg/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
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Reporting group description:

In the CCRT (concomitant chemoradiotherapy) arm cisplatin was to be given with 5 or 6 weekly doses of 40 mg/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/m ² with a minimum dose of cisplatin of 75 mg/m ² per 3 weeks, irrespectively whether cycles were scheduled weekly or over 10 or 21 days, thus reflecting the daily practice of the majority of the centers. Radical hysterectomy was required within 6 weeks after completion of neoadjuvant chemotherapy and consisted of a Piver-Rutledge type III-V radical hysterectomy, with lymphadenectomy of pelvic-infra-mesenteric with or without high para-aortal lymph nodes).	
Reporting group title	CCRT
Reporting group description:	
In the CCRT (concomitant chemoradiotherapy) arm cisplatin was to be given with 5 or 6 weekly doses of 40 mg/m ² 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 w/o 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
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	20
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Reporting groups

Reporting group title	NACTS
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Reporting group description:

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

Reporting group title	CCRT
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Reporting group description:

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

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

DEEP VEIN THROMBOSIS alternative dictionary used: MedDRA 20 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 300 (0.00%) 0 / 0 0 / 0	1 / 291 (0.34%) 0 / 1 0 / 0	
HYPOTENSION alternative dictionary used: MedDRA 20 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 300 (0.00%) 0 / 0 0 / 0	1 / 291 (0.34%) 1 / 1 0 / 0	
THROMBOSIS alternative dictionary used: MedDRA 20 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 300 (0.00%) 0 / 0 0 / 0	2 / 291 (0.69%) 2 / 2 0 / 0	
General disorders and administration site conditions CHEST PAIN alternative dictionary used: MedDRA 20 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 300 (0.33%) 0 / 1 0 / 0	0 / 291 (0.00%) 0 / 0 0 / 0	
FATIGUE alternative dictionary used: MedDRA 20 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	2 / 300 (0.67%) 2 / 2 0 / 0	1 / 291 (0.34%) 1 / 1 0 / 0	
GENERAL PHYSICAL HEALTH DETERIORATION alternative dictionary used: MedDRA 20 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 300 (0.33%) 1 / 1 0 / 0	0 / 291 (0.00%) 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 occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 300 (0.33%) 0 / 1 0 / 0	0 / 291 (0.00%) 0 / 0 0 / 0	
PANCREATITIS ACUTE alternative dictionary used: MedDRA 20 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 300 (0.33%) 0 / 1 0 / 0	0 / 291 (0.00%) 0 / 0 0 / 0	
PROCTALGIA alternative dictionary used: MedDRA 20 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 300 (0.00%) 0 / 0 0 / 0	1 / 291 (0.34%) 1 / 1 0 / 0	
RETROPERITONEAL HAEMATOMA alternative dictionary used: MedDRA 20 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 300 (0.33%) 1 / 1 0 / 0	0 / 291 (0.00%) 0 / 0 0 / 0	
STOMATITIS alternative dictionary used: MedDRA 20 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	2 / 300 (0.67%) 2 / 2 0 / 0	0 / 291 (0.00%) 0 / 0 0 / 0	
VOMITING alternative dictionary used: MedDRA 20 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	13 / 300 (4.33%) 13 / 13 0 / 0	4 / 291 (1.37%) 6 / 6 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 occurrences (all)	1 / 300 (0.33%) 1	0 / 291 (0.00%) 0	
HEAVY LEGS alternative dictionary used: CTC 2 subjects affected / exposed occurrences (all)	1 / 300 (0.33%) 5	0 / 291 (0.00%) 0	
Immune system disorders ALLERGY alternative dictionary used: CTC 2 subjects affected / exposed occurrences (all)	33 / 300 (11.00%) 40	21 / 291 (7.22%) 27	
URTICARIA alternative dictionary used: CTC 2 subjects affected / exposed occurrences (all)	1 / 300 (0.33%) 1	0 / 291 (0.00%) 0	
Reproductive system and breast disorders FISSURE VAGINAL alternative dictionary used: CTC 2 subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	1 / 291 (0.34%) 1	
IRREGULAR MENSES alternative dictionary used: CTC 2 subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	1 / 291 (0.34%) 1	
ITCH VAGINAL alternative dictionary used: CTC 2 subjects affected / exposed occurrences (all)	1 / 300 (0.33%) 1	0 / 291 (0.00%) 0	
MUC DISCHARGE UTEROUS alternative dictionary used: CTC 2 subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	1 / 291 (0.34%) 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 PRURITUS		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	1
VAGINAL PRURITUS		
alternative dictionary used: CTC 2		
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)
occurrences (all)	0	2
VULVAR EDEMA		
alternative dictionary used: CTC 2		

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

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 THROMBOSIS 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
DEHYDRATION DRY 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 HEMOROİDS		
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
RADIOCYSTITIS		
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 FREQUENCY 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	
MUSCLE WEAKNESS			
alternative dictionary used: CTC 2			

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

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	
HYPOKALIEMIA			
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/m ² providing a minimum dose of platinum of 75 mg/m ² 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: