



## RTOG 1203

Report Based on Data Through: 03/14/2019

### A Randomized Phase III Study Of Standard vs. IMRT Pelvic Radiation For Post-Operative Treatment Of Endometrial And Cervical Cancer (TIME-C)

<b>S</b>	<b><u>XRT Dose</u></b>	<b>R</b>
<b>T</b>	1. 45 Gy	<b>A</b> <b><u>Arm 1</u></b>
<b>R</b>	2. 50.4 Gy	<b>N</b> IMRT pelvic radiation treatment
<b>A</b>	<b><u>Chemotherapy</u></b>	<b>D</b>
<b>T</b>	1. No Chemotherapy	<b>O</b>
<b>I</b>	2. 5 cycles of weekly cisplatin at 40 mg/m <sup>2</sup>	<b>M</b> <b><u>Arm 2</u></b>
<b>F</b>	<b><u>Disease Site</u></b>	<b>I</b> 4-field pelvic radiation treatment
<b>Y</b>	1. Endometrial	<b>Z</b>
	2. Cervix	<b>E</b>

See Section 5.0 of the protocol for pre-registration requirements, Section 6.0 of the protocol for details of radiation therapy, and Section 7.0 of the protocol for details of drug therapy.

<b><u>Study Chairs:</u></b>	Ann Klopp, M.D., Ph.D.	(co-PI/Radiation Oncology)
	Anamaria Yeung, M.D.	(co-PI/Radiation Oncology)
	Shannon N. Westin, M.D., M.P.H.	(Gynecological Oncology)
	Kent Gifford, Ph.D.	(Medical Physics)
	Andre Konski, M.D., M.B.A., M.A., F.A.C.R.	(Cost Analysis)
	Joanne Weidhaas, M.D., Ph.D.	(Translational Research)
	Karen Gil, Ph.D.	(Quality of Life)
	Lari Wenzel, Ph.D.	(Quality of Life)

<b><u>Protocol Statisticians:</u></b>	Stephanie Pugh, Ph.D.
	Snehal Deshmukh, M.S.

<b><u>Research Associate:</u></b>	Roseann Bonanni, C.T.R., C.C.R.P.
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<b><u>Dosimetrist:</u></b>	Denise Manfredi, B.S., R.T. (T)
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<b><u>Activated:</u></b>	11/28/2012
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<b><u>Closed:</u></b>	08/27/2015
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<b><u>Status:</u></b>	Follow-up, primary endpoint published
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- **Study Description**

This is a two-armed randomized phase III study designed to evaluate acute gastrointestinal toxicity with patient reported measure of toxicity, the Expanded Prostate Cancer Index Composite (EPIC) instrument. Patients, 18 years or older, must have pathologically proven diagnosis of endometrial or cervical cancer who require post-operative radiation or chemoradiation and Zubrod performance status 0-2. The primary endpoint for this study is to determine if IMRT reduces acute gastrointestinal toxicity in the 5<sup>th</sup> week i.e. after 23-25 fractions of pelvic radiation as measured with EPIC (bowel domain) as compared to conventional pelvic RT.

- **Patient Accrual**

The study was activated on November 28, 2012 and completed accrual on August 27, 2015 with 289 patients randomized (Table 1). Median time of follow-up for vital status is approximately 3 years.

- **Adverse Events**

Adverse events (AEs) were graded with CTCAE version 4. As of March 14, 2019, there have been 39 patients (31.2%) with grade 3, 3 (2.4%) with grade 4, and 1 (0.8%) with grade 5 events reported on the IMRT arm compared to 32 patients (22.2%) with grade 3 events and 4 (2.8%) with grade 4 events on the 4-Field arm regardless of attribution to treatment (Table 2). Table 3 shows the distribution of patients by highest grade AE and by specific AE term without regard to attribution. This table only includes system organ classes and terms with at least one grade 3, 4, or 5 event. There has been one patient (0.8%) with a grade 4 respiratory failure, 1 (0.8%) with a grade 4 thromboembolic event, 1 (0.8%) with a grade 4 sepsis and Hyperkalemia, and 1 (0.8%) with a grade 4 neutrophil count decreased on the IMRT arm, all reported unrelated to treatment. There has been 1 patient (0.8%) with grade 5 hypotension on IMRT arm unrelated to treatment. One patient had both a grade 4 sepsis and grade 5 hypotension AE on IMRT arm. On the 4-Field arm, there has been 1 patient (0.7%) with a grade 4 intra-abdominal hemorrhage reported unrelated to treatment, 1 (0.7%) with a grade 4 hyperglycemia reported unlikely related to treatment, 1 (0.7%) with a grade 4 other reproductive system and breast disorders event reported probably related to treatment and 1 (0.7%) with a grade 4 dyspnea event reported unrelated to treatment (Table 3).

**Table 1**  
**RTOG 1203 Accrual/Eligibility - Data as of 03/14/2019**

	<b>IMRT Pelvic Radiation Treatment</b>	<b>4 Field Pelvic Radiation Treatment</b>	<b>Total</b>
Randomized	137	152	289
Ineligible	7	3	10
Eligible	130	149	279

Eight patients received no study treatment and are not included in adverse event tables.

**Table 2**  
**Distribution of RTOG 1203 Patients by Highest Grade Adverse Event**  
**by System Organ Class - Data as of 03/14/2019**  
**For All Reported Adverse Events without Regard to Attribution**

System Organ Class	IMRT Pelvic Radiation Treatment (n=125)					4 Field Pelvic Radiation Treatment (n=144)				
	n and (%) of Patients by Grade					n and (%) of Patients by Grade				
	1	2	3	4	5	1	2	3	4	5
Overall Highest Grade	36 (28.8)	44 (35.2)	39 (31.2)	3 (2.4)	1 (0.8)	37 (25.7)	66 (45.8)	32 (22.2)	4 (2.8)	0 (0.0)
Blood and lymphatic system disorders	16 (12.8)	6 (4.8)	5 (4.0)	0 (0.0)	0 (0.0)	12 (8.3)	4 (2.8)	3 (2.1)	0 (0.0)	0 (0.0)
Cardiac disorders	8 (6.4)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	4 (2.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Ear and labyrinth disorders	8 (6.4)	2 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	14 (9.7)	2 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)
Eye disorders	8 (6.4)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	3 (2.1)	3 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)
Gastrointestinal disorders	62 (49.6)	40 (32.0)	12 (9.6)	0 (0.0)	0 (0.0)	66 (45.8)	43 (29.9)	14 (9.7)	1 (0.7)	0 (0.0)
General disorders and administration site conditions	73 (58.4)	25 (20.0)	2 (1.6)	0 (0.0)	0 (0.0)	76 (52.8)	25 (17.4)	3 (2.1)	0 (0.0)	0 (0.0)
Hepatobiliary disorders	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)
Immune system disorders	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)
Infections and infestations	4 (3.2)	20 (16.0)	4 (3.2)	1 (0.8)	0 (0.0)	0 (0.0)	16 (11.1)	4 (2.8)	0 (0.0)	0 (0.0)
Injury, poisoning and procedural complications	11 (8.8)	6 (4.8)	1 (0.8)	0 (0.0)	0 (0.0)	14 (9.7)	8 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)
Investigations	12 (9.6)	14 (11.2)	14 (11.2)	1 (0.8)	0 (0.0)	13 (9.0)	16 (11.1)	9 (6.3)	0 (0.0)	0 (0.0)
Metabolism and nutrition disorders	22 (17.6)	12 (9.6)	8 (6.4)	1 (0.8)	0 (0.0)	28 (19.4)	9 (6.3)	4 (2.8)	1 (0.7)	0 (0.0)
Musculoskeletal and connective tissue disorders	21 (16.8)	12 (9.6)	0 (0.0)	0 (0.0)	0 (0.0)	27 (18.8)	12 (8.3)	2 (1.4)	0 (0.0)	0 (0.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	2	0	0	0	0	0	1	0	0

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**by System Organ Class - Data as of 03/14/2019**  
**For All Reported Adverse Events without Regard to Attribution**

System Organ Class	IMRT Pelvic Radiation Treatment (n=125)					4 Field Pelvic Radiation Treatment (n=144)				
	n and (%) of Patients by Grade					n and (%) of Patients by Grade				
	1	2	3	4	5	1	2	3	4	5
	(0.0)	(1.6)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.7)	(0.0)	(0.0)
Nervous system disorders	28 (22.4)	7 (5.6)	4 (3.2)	0 (0.0)	0 (0.0)	29 (20.1)	9 (6.3)	1 (0.7)	0 (0.0)	0 (0.0)
Psychiatric disorders	20 (16.0)	4 (3.2)	0 (0.0)	0 (0.0)	0 (0.0)	22 (15.3)	11 (7.6)	1 (0.7)	0 (0.0)	0 (0.0)
Renal and urinary disorders	56 (44.8)	18 (14.4)	1 (0.8)	0 (0.0)	0 (0.0)	53 (36.8)	22 (15.3)	3 (2.1)	0 (0.0)	0 (0.0)
Reproductive system and breast disorders	38 (30.4)	8 (6.4)	0 (0.0)	0 (0.0)	0 (0.0)	44 (30.6)	12 (8.3)	3 (2.1)	1 (0.7)	0 (0.0)
Respiratory, thoracic and mediastinal disorders	21 (16.8)	5 (4.0)	1 (0.8)	1 (0.8)	0 (0.0)	15 (10.4)	8 (5.6)	1 (0.7)	1 (0.7)	0 (0.0)
Skin and subcutaneous tissue disorders	22 (17.6)	4 (3.2)	1 (0.8)	0 (0.0)	0 (0.0)	31 (21.5)	7 (4.9)	0 (0.0)	0 (0.0)	0 (0.0)
Surgical and medical procedures	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)
Vascular disorders	14 (11.2)	9 (7.2)	4 (3.2)	1 (0.8)	1 (0.8)	12 (8.3)	7 (4.9)	3 (2.1)	0 (0.0)	0 (0.0)

Adverse events were graded with CTCAE version 4.

**Table 3**  
**Distribution of RTOG 1203 Patients by Highest Grade Adverse Event**  
**by Specific Adverse Event Term - Data as of 03/14/2019**  
**For Selected Adverse Events without Regard to Attribution**

System Organ Class/Term	IMRT Pelvic Radiation Treatment (n=125)					4 Field Pelvic Radiation Treatment (n=144)				
	n and (%) of Patients by Grade					n and (%) of Patients by Grade				
	1	2	3	4	5	1	2	3	4	5
<b>BLOOD AND LYMPHATIC SYSTEM DISORDERS</b>	16 (12.8)	6 (4.8)	5 (4.0)	0 (0.0)	0 (0.0)	12 (8.3)	4 (2.8)	3 (2.1)	0 (0.0)	0 (0.0)
Anemia	15 (12.0)	6 (4.8)	5 (4.0)	0 (0.0)	0 (0.0)	11 (7.6)	4 (2.8)	2 (1.4)	0 (0.0)	0 (0.0)
Febrile neutropenia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)
<b>CARDIAC DISORDERS</b>	8 (6.4)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	4 (2.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Sinus bradycardia	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
<b>EAR AND LABYRINTH DISORDERS</b>	8 (6.4)	2 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	14 (9.7)	2 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)
Hearing impaired	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)
<b>GASTROINTESTINAL DISORDERS</b>	62 (49.6)	40 (32.0)	12 (9.6)	0 (0.0)	0 (0.0)	66 (45.8)	43 (29.9)	14 (9.7)	1 (0.7)	0 (0.0)
Abdominal pain	35 (28.0)	9 (7.2)	2 (1.6)	0 (0.0)	0 (0.0)	43 (29.9)	8 (5.6)	6 (4.2)	0 (0.0)	0 (0.0)
Colitis	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.4)	0 (0.0)	3 (2.1)	0 (0.0)	0 (0.0)
Colonic obstruction	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)
Diarrhea	66 (52.8)	24 (19.2)	6 (4.8)	0 (0.0)	0 (0.0)	74 (51.4)	32 (22.2)	7 (4.9)	0 (0.0)	0 (0.0)
Gastrointestinal disorders - Other	9 (7.2)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	3 (2.1)	5 (3.5)	2 (1.4)	0 (0.0)	0 (0.0)
Ileal obstruction	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)
Intra-abdominal hemorrhage	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
Nausea	39 (31.2)	9 (7.2)	2 (1.6)	0 (0.0)	0 (0.0)	48 (33.3)	11 (7.6)	3 (2.1)	0 (0.0)	0 (0.0)
Proctitis	3 (2.4)	6 (4.8)	1 (0.8)	0 (0.0)	0 (0.0)	5 (3.5)	4 (2.8)	0 (0.0)	0 (0.0)	0 (0.0)

**Table 3**  
**Distribution of RTOG 1203 Patients by Highest Grade Adverse Event**  
**by Specific Adverse Event Term - Data as of 03/14/2019**  
**For Selected Adverse Events without Regard to Attribution**

System Organ Class/Term	IMRT Pelvic Radiation Treatment (n=125)					4 Field Pelvic Radiation Treatment (n=144)				
	n and (%) of Patients by Grade					n and (%) of Patients by Grade				
	1	2	3	4	5	1	2	3	4	5
Small intestinal obstruction	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)
Vomiting	13 (10.4)	2 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	20 (13.9)	6 (4.2)	3 (2.1)	0 (0.0)	0 (0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	73 (58.4)	25 (20.0)	2 (1.6)	0 (0.0)	0 (0.0)	76 (52.8)	25 (17.4)	3 (2.1)	0 (0.0)	0 (0.0)
Fatigue	71 (56.8)	18 (14.4)	2 (1.6)	0 (0.0)	0 (0.0)	70 (48.6)	22 (15.3)	2 (1.4)	0 (0.0)	0 (0.0)
Flu like symptoms	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	4 (2.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pain	15 (12.0)	5 (4.0)	0 (0.0)	0 (0.0)	0 (0.0)	18 (12.5)	2 (1.4)	1 (0.7)	0 (0.0)	0 (0.0)
HEPATOBIILIARY DISORDERS	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)
Gallbladder pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)
IMMUNE SYSTEM DISORDERS	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)
Allergic reaction	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)
INFECTIONS AND INFESTATIONS	4 (3.2)	20 (16.0)	4 (3.2)	1 (0.8)	0 (0.0)	0 (0.0)	16 (11.1)	4 (2.8)	0 (0.0)	0 (0.0)
Appendicitis	0 (0.0)	0 (0.0)	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Device related infection	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Infections and infestations - Other	1 (0.8)	3 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (2.1)	1 (0.7)	0 (0.0)	0 (0.0)
Sepsis	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Upper respiratory infection	0 (0.0)	4 (3.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.4)	1 (0.7)	0 (0.0)	0 (0.0)
Urinary tract infection	0	13	0	0	0	0	9	1	0	0

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**For Selected Adverse Events without Regard to Attribution**

System Organ Class/Term	IMRT Pelvic Radiation Treatment (n=125)					4 Field Pelvic Radiation Treatment (n=144)				
	n and (%) of Patients by Grade					n and (%) of Patients by Grade				
	1	2	3	4	5	1	2	3	4	5
	(0.0)	(10.4)	(0.0)	(0.0)	(0.0)	(0.0)	(6.3)	(0.7)	(0.0)	(0.0)
Wound infection	0	0	1	0	0	0	0	1	0	0
	(0.0)	(0.0)	(0.8)	(0.0)	(0.0)	(0.0)	(0.0)	(0.7)	(0.0)	(0.0)
<b>INJURY, POISONING AND PROCEDURAL COMPLICATIONS</b>	11	6	1	0	0	14	8	0	0	0
	(8.8)	(4.8)	(0.8)	(0.0)	(0.0)	(9.7)	(5.6)	(0.0)	(0.0)	(0.0)
Fall	0	0	1	0	0	1	0	0	0	0
	(0.0)	(0.0)	(0.8)	(0.0)	(0.0)	(0.7)	(0.0)	(0.0)	(0.0)	(0.0)
<b>INVESTIGATIONS</b>	12	14	14	1	0	13	16	9	0	0
	(9.6)	(11.2)	(11.2)	(0.8)	(0.0)	(9.0)	(11.1)	(6.3)	(0.0)	(0.0)
Creatinine increased	3	1	1	0	0	1	0	0	0	0
	(2.4)	(0.8)	(0.8)	(0.0)	(0.0)	(0.7)	(0.0)	(0.0)	(0.0)	(0.0)
Lymphocyte count decreased	1	6	7	0	0	3	6	8	0	0
	(0.8)	(4.8)	(5.6)	(0.0)	(0.0)	(2.1)	(4.2)	(5.6)	(0.0)	(0.0)
Lymphocyte count increased	0	0	0	0	0	0	0	1	0	0
	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.7)	(0.0)	(0.0)
Neutrophil count decreased	0	5	2	1	0	2	3	3	0	0
	(0.0)	(4.0)	(1.6)	(0.8)	(0.0)	(1.4)	(2.1)	(2.1)	(0.0)	(0.0)
Platelet count decreased	8	2	1	0	0	4	1	1	0	0
	(6.4)	(1.6)	(0.8)	(0.0)	(0.0)	(2.8)	(0.7)	(0.7)	(0.0)	(0.0)
Weight gain	1	1	1	0	0	1	0	0	0	0
	(0.8)	(0.8)	(0.8)	(0.0)	(0.0)	(0.7)	(0.0)	(0.0)	(0.0)	(0.0)
Weight loss	5	4	1	0	0	6	3	0	0	0
	(4.0)	(3.2)	(0.8)	(0.0)	(0.0)	(4.2)	(2.1)	(0.0)	(0.0)	(0.0)
White blood cell decreased	8	5	8	0	0	3	10	3	0	0
	(6.4)	(4.0)	(6.4)	(0.0)	(0.0)	(2.1)	(6.9)	(2.1)	(0.0)	(0.0)
<b>METABOLISM AND NUTRITION DISORDERS</b>	22	12	8	1	0	28	9	4	1	0
	(17.6)	(9.6)	(6.4)	(0.8)	(0.0)	(19.4)	(6.3)	(2.8)	(0.7)	(0.0)
Anorexia	18	7	1	0	0	20	7	0	0	0
	(14.4)	(5.6)	(0.8)	(0.0)	(0.0)	(13.9)	(4.9)	(0.0)	(0.0)	(0.0)
Dehydration	0	5	1	0	0	0	2	1	0	0
	(0.0)	(4.0)	(0.8)	(0.0)	(0.0)	(0.0)	(1.4)	(0.7)	(0.0)	(0.0)
Hyperglycemia	7	0	3	0	0	10	4	1	1	0
	(5.6)	(0.0)	(2.4)	(0.0)	(0.0)	(6.9)	(2.8)	(0.7)	(0.7)	(0.0)
Hyperkalemia	4	0	1	1	0	0	0	0	0	0

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System Organ Class/Term	IMRT Pelvic Radiation Treatment (n=125)					4 Field Pelvic Radiation Treatment (n=144)				
	n and (%) of Patients by Grade					n and (%) of Patients by Grade				
	1	2	3	4	5	1	2	3	4	5
	(3.2)	(0.0)	(0.8)	(0.8)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)
Hypokalemia	6	0	1	0	0	4	0	1	0	0
	(4.8)	(0.0)	(0.8)	(0.0)	(0.0)	(2.8)	(0.0)	(0.7)	(0.0)	(0.0)
Hypomagnesemia	9	3	0	0	0	4	0	1	0	0
	(7.2)	(2.4)	(0.0)	(0.0)	(0.0)	(2.8)	(0.0)	(0.7)	(0.0)	(0.0)
Hyponatremia	9	0	1	0	0	7	0	0	0	0
	(7.2)	(0.0)	(0.8)	(0.0)	(0.0)	(4.9)	(0.0)	(0.0)	(0.0)	(0.0)
Obesity	0	0	1	0	0	0	0	0	0	0
	(0.0)	(0.0)	(0.8)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	21	12	0	0	0	27	12	2	0	0
	(16.8)	(9.6)	(0.0)	(0.0)	(0.0)	(18.8)	(8.3)	(1.4)	(0.0)	(0.0)
Muscle weakness lower limb	0	0	0	0	0	1	0	1	0	0
	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.7)	(0.0)	(0.7)	(0.0)	(0.0)
Musculoskeletal and connective tissue disorder - Other	1	3	0	0	0	0	1	1	0	0
	(0.8)	(2.4)	(0.0)	(0.0)	(0.0)	(0.0)	(0.7)	(0.7)	(0.0)	(0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	2	0	0	0	0	0	1	0	0
	(0.0)	(1.6)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.7)	(0.0)	(0.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) - Other	0	2	0	0	0	0	0	1	0	0
	(0.0)	(1.6)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.7)	(0.0)	(0.0)
NERVOUS SYSTEM DISORDERS	28	7	4	0	0	29	9	1	0	0
	(22.4)	(5.6)	(3.2)	(0.0)	(0.0)	(20.1)	(6.3)	(0.7)	(0.0)	(0.0)
Peripheral motor neuropathy	3	0	1	0	0	2	0	0	0	0
	(2.4)	(0.0)	(0.8)	(0.0)	(0.0)	(1.4)	(0.0)	(0.0)	(0.0)	(0.0)
Peripheral sensory neuropathy	5	2	1	0	0	9	3	1	0	0
	(4.0)	(1.6)	(0.8)	(0.0)	(0.0)	(6.3)	(2.1)	(0.7)	(0.0)	(0.0)
Syncope	0	0	3	0	0	0	0	0	0	0
	(0.0)	(0.0)	(2.4)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)



**Table 3**  
**Distribution of RTOG 1203 Patients by Highest Grade Adverse Event**  
**by Specific Adverse Event Term - Data as of 03/14/2019**  
**For Selected Adverse Events without Regard to Attribution**

System Organ Class/Term	IMRT Pelvic Radiation Treatment (n=125)					4 Field Pelvic Radiation Treatment (n=144)				
	n and (%) of Patients by Grade					n and (%) of Patients by Grade				
	1	2	3	4	5	1	2	3	4	5
PSYCHIATRIC DISORDERS	20 (16.0)	4 (3.2)	0 (0.0)	0 (0.0)	0 (0.0)	22 (15.3)	11 (7.6)	1 (0.7)	0 (0.0)	0 (0.0)
Depression	9 (7.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (4.9)	4 (2.8)	1 (0.7)	0 (0.0)	0 (0.0)
RENAL AND URINARY DISORDERS	56 (44.8)	18 (14.4)	1 (0.8)	0 (0.0)	0 (0.0)	53 (36.8)	22 (15.3)	3 (2.1)	0 (0.0)	0 (0.0)
Renal and urinary disorders - Other	6 (4.8)	3 (2.4)	1 (0.8)	0 (0.0)	0 (0.0)	7 (4.9)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)
Urinary incontinence	16 (12.8)	7 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	12 (8.3)	7 (4.9)	2 (1.4)	0 (0.0)	0 (0.0)
Urinary tract obstruction	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	38 (30.4)	8 (6.4)	0 (0.0)	0 (0.0)	0 (0.0)	44 (30.6)	12 (8.3)	3 (2.1)	1 (0.7)	0 (0.0)
Reproductive system and breast disorders - Other	5 (4.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (4.2)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
Vaginal dryness	4 (3.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (4.9)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)
Vaginal stricture	4 (3.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.4)	4 (2.8)	2 (1.4)	0 (0.0)	0 (0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	21 (16.8)	5 (4.0)	1 (0.8)	1 (0.8)	0 (0.0)	15 (10.4)	8 (5.6)	1 (0.7)	1 (0.7)	0 (0.0)
Cough	11 (8.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	9 (6.3)	2 (1.4)	1 (0.7)	0 (0.0)	0 (0.0)
Dyspnea	14 (11.2)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	9 (6.3)	5 (3.5)	0 (0.0)	1 (0.7)	0 (0.0)
Hypoxia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.7)	0 (0.0)	0 (0.0)
Pleural effusion	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	2 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Respiratory failure	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

**Table 3**  
**Distribution of RTOG 1203 Patients by Highest Grade Adverse Event**  
**by Specific Adverse Event Term - Data as of 03/14/2019**  
**For Selected Adverse Events without Regard to Attribution**

System Organ Class/Term	IMRT Pelvic Radiation Treatment (n=125)					4 Field Pelvic Radiation Treatment (n=144)				
	n and (%) of Patients by Grade					n and (%) of Patients by Grade				
	1	2	3	4	5	1	2	3	4	5
Respiratory, thoracic and mediastinal disorders - Other	1 (0.8)	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)
Sore throat	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	22 (17.6)	4 (3.2)	1 (0.8)	0 (0.0)	0 (0.0)	31 (21.5)	7 (4.9)	0 (0.0)	0 (0.0)	0 (0.0)
Pruritus	7 (5.6)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	9 (6.3)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)
SURGICAL AND MEDICAL PROCEDURES	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)
Surgical and medical procedures - Other	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)
VASCULAR DISORDERS	14 (11.2)	9 (7.2)	4 (3.2)	1 (0.8)	1 (0.8)	12 (8.3)	7 (4.9)	3 (2.1)	0 (0.0)	0 (0.0)
Hot flashes	8 (6.4)	4 (3.2)	1 (0.8)	0 (0.0)	0 (0.0)	7 (4.9)	3 (2.1)	1 (0.7)	0 (0.0)	0 (0.0)
Hypertension	2 (1.6)	3 (2.4)	2 (1.6)	0 (0.0)	0 (0.0)	2 (1.4)	6 (4.2)	0 (0.0)	0 (0.0)	0 (0.0)
Hypotension	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)
Thromboembolic event	0 (0.0)	1 (0.8)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)
Vascular disorders - Other	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Adverse events were graded with CTCAE version 4.

Only includes system organ classes and terms with at least one grade 3, 4, or 5.