F1

Radiation Therapy Oncology Group
Phase II Study of IMRT with Concurrent Systemic Therapy Followed with Chemotherapy for Post-op Endometrial Cancer
Follow-up Form

RTOG Study No.0921 Case #

PLACE LABEL HERE

Institution Name Institution No.
Patient Initials RTOG Patient ID

AMENDED DATA ☐

INSTRUCTIONS: Submit this form at the appropriate followup interval and whenever there is a change in the patient's status. Dates are recorded mm-dd-yyyy unless otherwise specified.

1 DATE OF LAST CONTACT OR DEATH
_____-_____-_____(1)

2 VITAL STATUS(2)
1 Alive
2 Dead

3 PRIMARY CAUSE OF DEATH(3)
1 Due to this disease
2 Due to second primary or other malignancy
3 Due to protocol treatment
4 Due to complications of non-protocol treatment
5 Due to other cause, specify_____(4)
9 Unknown

4 HAS THE PATIENT HAD A DOCUMENTED CLINICAL ASSESSMENT FOR THIS CANCER (since submission of the previous follow-up form)?(5)
1 No, skip to Q#7
2 Yes-Date of last clinical assessment
_____-_____-_____(6)
9 Unknown, skip to Q#7

5 CURRENT DISEASE STATUS

Status	Method of Evaluation
1 Disease absent	1 Physical exam
2 Disease present	2 Radiographic
9 Unknown	3 Pathologic
	4 Cytologic

Status	Method of Evaluation
___(7) Local tumor	___(8)
___(9) Pelvic lymph nodes	___(10)
___(11) Para-Aortic Nodes	___(12)
___(13) Distant Metastasis	___(14)
___(15) Second Primary	___(16)

6 EVENTS (Enter all changes in disease status which have occurred during this follow-up period and record the date first observed.)

Event Codes

Primary Pelvic Tumor
15 Recurrence upper 2/3 vagina
16 Recurrence lower 1/3 vagina
17 Central pelvic mass
} **(Biopsy/ Cytology proven)
18 Complete response after recurrence

Pelvic Nodes
21 Obturator
22 External Iliac
23 Internal iliac
24 Common iliac
} **(Biopsy/ Cytology proven)
25 Complete response after recurrence

Other Nodal Recurrence
26 Para Aortic Nodes/Vertebral Body Level
27 Sacral Nodes
} **(Biopsy/ Cytology proven)
28 Complete response after recurrence

Other Events
33 Appearance of distant nodes, specify*
34 Appearance of Lung metastasis
35 Appearance of bone metastasis
36 Appearance of liver metastasis
37 Appearance of other metastasis, specify*

Second Malignancy
40 Appearance of second malignancy, specify*

	Event	**Date (mm-dd-yyyy) (see below)	Specify*
#1	___(17)	_____-_____-_____(18)	_____(19)
#2	___(20)	_____-_____-_____(21)	_____(22)
#3	___(23)	_____-_____-_____(24)	_____(25)
#4	___(26)	_____-_____-_____(27)	_____(28)

****EVENT DATE FOR PRIMARY AND/OR NODAL RECURRENCE MUST BE DATE OF BIOPSY OR POSITIVE CYTOLOGY.**

IF THERE WAS RECURRENCE OF DISEASE, WAS THE RECURRENCE:(29)
1 Inside the treatment field
2 Outside the treatment field

DID THE DISEASE RECURRENCE EXTEND OUT TO THE BONY LANDMARKS?(30)
1 No
2 Yes

F1

Radiation Therapy Oncology Group
Phase II Study of IMRT with Concurrent Systemic Therapy Followed with Chemotherapy for Post-op Endometrial Cancer
Follow-up Form

RTOG Study No.0921 Case #

PLACE LABEL HERE

Institution Name Institution No.
Patient Initials RTOG Patient ID

7 (31)___ **HAS A NEW PRIMARY CANCER OR MDS (MYELODYSPLASTIC SYNDROME) BEEN DIAGNOSED THAT HAS NOT BEEN PREVIOUSLY REPORTED?**

1 No
2 Yes (Specify below)
9 Unknown

SITE	DATE OF DIAGNOSIS	SPECIFY
(32)___	(33)_____-_____-_____	(34)_____
(35)___	(36)_____-_____-_____	(37)_____

*If new primary is AML/MDS, please report via Adeers

SITE(S) OF NEW PRIMARY

00	None	07	Gastric	14	Squamous-Skin
01	AML/MDS*	08	Liver	15	Prostate
02	BCC	09	Lung	16	Other Hematologic,specify*
03	Bladder	10	Melanoma	17	Other solid, specify*
04	Brain	11	NHL	24	Unknown primary
05	Colorectal	12	Pancreatic		
06	Esophageal	13	Renal		

8 ADDITIONAL NON PROTOCOL TREATMENT

Enter treatment type and date performed for each treatment delivered during the follow-up period. Document details.
IF NO ADDITIONAL TREATMENT, CODE '0' IN THE FIRST BOX.

NON-PROTOCOL THERAPY TYPE	DATE OF NON-PROTOCOL THERAPY	*SPECIFY
___(38)	_____-_____-_____(39)	*_____(40)
___(41)	_____-_____-_____(42)	*_____(43)
___(44)	_____-_____-_____(45)	*_____(46)
___(47)	_____-_____-_____(48)	*_____(49)
___(50)	_____-_____-_____(51)	*_____(52)

NON-PROTOCOL THERAPY TYPE

0	None	4	Chemotherapy
1	Radiation to pelvis	5	Other non-protocol therapy
2	Radiation to other sites, specify*	6	Surgical procedure related to previous RT, specify *
3	Surgery	9	Unknown

F1

Radiation Therapy Oncology Group
Phase II Study of IMRT with Concurrent Systemic Therapy Followed with Chemotherapy for Post-op Endometrial Cancer
Follow-up Form

RTOG Study No.0921 Case #

PLACE LABEL HERE

Institution Name **Institution No.**
Patient Initials **RTOG Patient ID**

9 ☐ **ANY ADVERSE EVENTS?**(53)

1 No
2 Yes
9 Unknown

Adverse Events: Use the CTCAE version 4.0 (**MedDRA 12.0**) to code all events.
Score most severe grade observed during report period (grade 1-5).
Adverse Events of grade 3 or higher require start date.
Assign attribution for each AE and indicate if an SAE report was submitted.
[*If SAE reported, AE grade, start date, and attributions must match on ADEERS report and CRF]
All "other" adverse events must be specified.

A. CTC AE Attribution Code
Any Protocol Treatment
(Including investigational agent)
1 Unrelated
2 Unlikely
3 Possible
4 Probable
5 Definite

B. SAE Report Submitted
1 No
2 Yes
9 Unknown

C. Attribution to Bevacizumab
1 Unrelated
2 Unlikely
3 Possible
4 Probable
5 Definite

MedDRA DISEASE CODE	CTC ADVERSE EVENT TERM	CTC AE GRADE	CTC AE BEGIN DATE	A	B*	C
(301)	(302)	(303)	(304)	(305)	(306)	(609)
(307)	(308)	(309)	(310)	(311)	(312)	(610)
(313)	(314)	(315)	(316)	(317)	(318)	(611)
(319)	(320)	(321)	(322)	(323)	(324)	(612)
(325)	(326)	(327)	(328)	(329)	(330)	(613)
(331)	(332)	(333)	(334)	(335)	(336)	(614)
(337)	(338)	(339)	(340)	(341)	(342)	(615)
(343)	(344)	(345)	(346)	(347)	(348)	(616)
(349)	(350)	(351)	(352)	(353)	(354)	(617)
(355)	(356)	(357)	(358)	(359)	(360)	(618)
(361)	(362)	(363)	(364)	(365)	(366)	(619)
(367)	(368)	(369)	(370)	(371)	(372)	(620)
(373)	(374)	(375)	(376)	(377)	(378)	(621)
(379)	(380)	(381)	(382)	(383)	(384)	(622)
(385)	(386)	(387)	(388)	(389)	(390)	(623)
(391)	(392)	(393)	(394)	(395)	(396)	(624)
(397)	(398)	(399)	(400)	(401)	(402)	(625)
(403)	(404)	(405)	(406)	(407)	(408)	(626)
(409)	(410)	(411)	(412)	(413)	(414)	(627)

COMMENTS_____
_____(601-602)

The reported case report information has been reviewed and confirmed by the principal investigator.

_____(603)
Investigator Signature

_____-_____-_____(604)
Date