

EMBRACE – Follow-up			Patient ID:				
Embrace No.	Time	72	84	96	108	120	
Day							
Month							
Year							
Physician (initials)							
RECTUM/SIGMOID COLON/BOWEL, morbidity scoring CTC v3.0							
1. Diarrhea							
1: Increase of <4 stools per day over baseline; mild increase in ostomy output compared to baseline 2: Increase of 4 – 6 stools per day over baseline; IV fluids indicated <24hrs; moderate increase in colostomy output compared to baseline; not interfering with ADL 3: Increase of ≥7 stools per day over baseline; incontinence; IV fluids ≥24 hrs; hospitalization; severe increase in colostomy output compared to baseline; interfering with ADL 4: Life-threatening consequences (e.g., hemodynamic collapse) 5: Death							
2. Flatulence							
1: Mild 2: Moderate							
3. Incontinence (anal)							
1: Occasional use of pads required 2: Daily use of pads required 3: Interfering with ADL; operative intervention indicated 4: Permanent bowel diversion indicated 5: Death							
4. Proctitis							
1: Rectal discomfort, intervention not indicated 2: Symptoms not interfering with ADL; medical intervention indicated 3: Stool incontinence or other symptoms interfering with ADL; operative intervention indicated 4: Life-threatening consequences (e.g., perforation) 5: Death							
5. Bleeding (hemorrhage GI)		Anus					
		Rectum					
		Sigmoid					
		Colon					
		Small bowel					
1: Mild, intervention (other than iron supplements) not indicated 2: Symptomatic and medical intervention or minor cauterization indicated 3: Transfusion, interventional radiology, endoscopic, or operative intervention indicated; radiation therapy (i.e., hemostasis of bleeding site) 4: Life-threatening consequences; major urgent intervention indicated 5: Death							
6. Stricture/stenosis		Anus					
		Rectum					
		Sigmoid					
		Colon					
		Small bowel					
1: Asymptomatic radiographic findings only 2: Symptomatic; altered GI function (e.g., altered dietary habits, vomiting, bleeding, diarrhea); iv fluids indicated <24 hrs 3: Symptomatic and severely altered GI function (e.g., altered dietary habits, diarrhea, or GI fluid loss); iv fluids, tube feedings, or TPN indicated ≥24 hrs; operative intervention indicated 4: Life-threatening consequences; operative intervention requiring complete organ resection (e.g., total colectomy) 5: Death							
7. Fistula		Anus					
		Rectum					
		Sigmoid					
		Colon					
		Small bowel					
1: Asymptomatic, radiographic findings only 2: Symptomatic; altered GI function (e.g., altered dietary habits, diarrhea, or GI fluid loss); IV fluids indicated <24 hrs 3: Symptomatic and severely altered GI function (e.g., altered dietary habits, diarrhea, or GI fluid loss); IV fluids, tube feedings, or TPN indicated ≥24 hrs 4: Life-threatening consequences 5: Death							
8. Gastro/intestinal other							
Specify category:							

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BLADDER, morbidity scoring CTC v3.0							
9. Urinary frequency/urgency							
1: Increase in frequency or nocturia up to 2 x normal; enuresis 2: Increase >2 x normal but <hourly 3: ≥1 x/hr; urgency; catheter indicated							
10. Incontinence, urinary							
1: Occasional (e.g., with coughing, sneezing, etc.), pads not indicated 2: Spontaneous, pads indicated 3: Interfering with ADL; intervention indicated (e.g., clamp, collagen injections) 4: Operative intervention indicated (e.g., cystectomy or permanent urinary diversion)							
11. Cystitis							
1: Asymptomatic 2: Frequency with dysuria; macroscopic hematuria 3: Transfusion; IV pain medications; bladder irrigation indicated 4: Catastrophic bleeding; major non-elective intervention indicated 5: Death							
12. Bladder spasm							
1: Symptomatic, intervention not indicated 2: Symptomatic, antispasmodics indicated 3: Narcotics indicated 4: Major surgical intervention indicated (e.g., cystectomy)							
13. Bleeding (Hemorrhage GU)	Bladder						
	Ureter						
	Urethra						
1: Mild, intervention (other than iron supplements) not indicated 2: Symptomatic and medical intervention or minor cauterization indicated 3: Transfusion, interventional radiology, endoscopic, or operative intervention indicated; radiation therapy (i.e., hemostasis of bleeding site) 4: Life-threatening consequences; major urgent intervention indicated 5: Death							
14. Stenosis/stricture	Bladder						
	Ureter						
	Urethra						
1: Asymptomatic, radiographic or endoscopic findings only 2: Symptomatic but no hydronephrosis, sepsis or renal dysfunction; dilation or endoscopic repair or stent placement indicated 3: Symptomatic and altered organ function (e.g., sepsis or hydronephrosis, or renal dysfunction); operative intervention indicated 4: Life-threatening consequences; organ failure or operative intervention requiring organ resection indicated 5: Death							
15. Fistula	Bladder						
	Ureter						
	Urethra						
1: Asymptomatic, radiographic findings only 2: Symptomatic; noninvasive intervention indicated 3: Symptomatic interfering with ADL; invasive intervention indicated 4: Life-threatening consequences; operative intervention requiring partial or full organ resection; permanent urinary diversion 5: Death							
16. Bladder other							
Specify category:							
VAGINA, morbidity scoring CTC v3.0							
17. Vaginal dryness							
1: Mild 2: Interfering with sexual function; dyspareunia; intervention indicated							
18. Vaginal stenosis/length							
1: Vaginal narrowing and/or shortening not interfering with function 2: Vaginal narrowing and/or shortening interfering with function 3: Complete obliteration; not surgically correctable							
19. Vaginal mucositis							
1: Erythema of the mucosa; minimal symptoms 2: Patchy ulcerations; moderate symptoms or dyspareunia 3: Confluent ulcerations; bleeding with trauma; unable to tolerate vaginal exam, sexual intercourse or tampon placement 4: Tissue necrosis; significant spontaneous bleeding; life-threatening consequences							
20. Bleeding (hemorrhage GU)							
1: Minimal or microscopic bleeding; intervention not indicated 2: Gross bleeding, medical intervention, or urinary tract irrigation indicated 3: Transfusion, interventional radiology, endoscopic, or operative intervention indicated; radiation therapy (i.e., hemostasis of bleeding site) 4: Life-threatening consequences; major urgent intervention indicated 5: Death							

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VAGINA continued, morbidity scoring CTC v3.0							
21. Fistula (Vagina cont.)							
1: Asymptomatic, radiographic findings only 2: Symptomatic; noninvasive intervention indicated 3: Symptomatic interfering with ADL; invasive intervention indicated 4: Life-threatening consequences; operative intervention requiring partial or full organ resection; permanent urinary diversion 5: Death							
22. Vaginal other							
Specify category							
23. Hormonal therapy							
0: no 1: oral 2: vaginal 3: oral + vaginal 9: unknown							
24. Regular vaginal dilatation							
0: no 1: yes 9: unknown							
MUSCLE/SOFT TISSUE/BONE, morbidity scoring CTC v3.0							
25. Fibrosis	Pelvic left						
– deep connective	Pelvic right						
1: Increased density, “spongy” feel 2: Increased density with firmness or tethering 3: Increased density with fixation of tissue; operative intervention indicated; interfering with ADL 4: Life-threatening; disabling; loss of limb; interfering with vital organ function 5: Death							
26. Fracture	Pelvic ring						
- insufficiency	Femoral head						
1: Asymptomatic, radiographic findings only (e.g., asymptomatic rib fracture on plain x-ray, pelvic insufficiency fracture on MRI, etc.) Symptomatic but nondisplaced; immobilization indicated 2: Symptomatic but non-displaced; immobilization indicated 3: Symptomatic and displaced or open wound with bone exposure; operative intervention indicated 4: Disabling; amputation indicated 5: Death							
27. Muscle/soft tissue/bone other							
Specify category:							
LYMPHATICS, morbidity scoring CTC v3.0							
28. Edema: limb							
1: 5 – 10% inter-limb discrepancy in volume or circumference at point of greatest visible difference; swelling or obscuration of anatomic architecture on close inspection; pitting edema 2: >10 – 30% inter-limb discrepancy in volume or circumference at point of greatest visible difference; readily apparent obscuration of anatomic architecture; obliteration of skin folds; readily apparent deviation from normal anatomic contour 3: >30% inter-limb discrepancy in volume; lymphorrhea; gross deviation from normal anatomic contour; interfering with ADL 4: Progression to malignancy (i.e., lymphangiosarcoma); amputation indicated; disabling 5: Death							
29. Edema: trunk/genital							
1: Swelling or obscuration of anatomic architecture on close inspection; pitting edema 2: Readily apparent obscuration of anatomic architecture; obliteration of skin folds; readily apparent deviation from normal anatomic contour 3: Lymphorrhea; interfering with ADL; gross deviation from normal anatomic contour 4: Progression to malignancy (i.e., lymphangiosarcoma); disabling 5: Death							
OTHER, NOT COVERED ABOVE, morbidity scoring CTC v3.0							
30. Fatigue							
1: Mild fatigue over baseline 2: Moderate or causing difficulty performing some ADL 3: Severe fatigue interfering with ADL 4: Disabling							
31. Insomnia							
REMARK: If pain or other symptoms interfere with sleep do not grade as insomnia. Grade primary event(s) causing Insomnia 1: Occasional difficulty sleeping, not interfering with function 2: Difficulty sleeping, interfering with function but not interfering with ADL 3: Frequent difficulty sleeping, interfering with ADL 4: Disabling							

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32. Hot flashes								
1: Mild								
2: Moderate								
3: Interfering with ADL								
33. Other, specify category and grade								
a)								
b)								
c)								
d)								
e)								
f)								

ADL: Activities of daily living. The tasks of everyday life. Basic ADLs include eating, dressing, getting into or out of a bed or chair, taking a bath or shower, and using the toilet. Instrumental activities of daily living (IADL) are activities related to independent living and include preparing meals, managing money, shopping, doing housework, and using a telephone. Also called activities of daily living.

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TUMOR STATUS							
1. Gynaecological Examination							
0: No tumor 1: Tumor present (<i>If present please fill out "Follow-Up CRF"</i>) 9: Gyn. Exam. not performed							
2. Biopsy from cervix							
0: Negative 1: Positive 9: Not done							
3. MRI primary tumor							
0: No tumor 1: Tumor present (<i>If present please fill out "Follow-Up CRF"</i>) 2: Uncertain 9: MRI not performed							
4. Imaging Regional/Systemic Status		regional					
		systemic					
0: No nodes/mets. 1: Node/mets present (<i>If present please fill out "Follow-Up CRF"</i>) 2: Uncertainty 9: Investigations not performed							
4a. Hydronephrosis							
0: no 1: left 2: right 3: bilat 9: NA							
4b. Insufficiency Fracture							
0: no 1: yes 9: NA							
4c. Other relevant findings							
Specify category:							
5. Overall Disease Status							
0: Local control 1: Persistent Disease 2: Local recurrence 9: Not evaluated	Local recurrence						
1: Clinical 2: Imaging 3: Biopsy	Level of confirmation						
0: Regional control 1: Persistent disease 2: Regional recurrence 9: Not evaluated	Regional recurrence						
1: Clinical 2: Imaging 3: Biopsy	Level of confirmation						
0: Systemic control 1: Systemic progression before first FUP 2: Systemic recurrence 9: Not evaluated	Systemic recurrence						
1: Clinical 2: Imaging 3: Biopsy	Level of confirmation						