ARISTOTLE

Trial Number: A R I — ☐☐☐ **Patient Initials:** ☐☐☐

FOLLOW UP FORM: 4 MONTHS

NB *All dates should be in DD-MM-YYYY format*

1. DATE OF LAST CONTACT

A) Date patient last known to be alive: ☐☐ / ☐☐ / ☐☐☐☐

i) How was this information obtained? *(tick one box only)*

☐ Patient attended for clinic visit ☐ Telephone call with patient ☐ Via GP ☐ Via local hospital

☐ Via hospice ☐ Other *(please specify)* _____

If the patient has died since the last visit please submit a death form

2. PHYSICAL EXAMINATION

☐ N/A (patient did not attend)

A) Weight (kg): ☐☐☐.☐

B) ECOG Performance Status: ☐

3. DISEASE STATUS

A) Has the patient's disease recurred since the last visit *(tick one box only)*?

☐ Yes—suspected *(complete a Suspected Residual Disease or Recurrence form)*

☐ Yes—confirmed *(complete a Confirmed Residual Disease or Recurrence form)*

☐ No

☐ Unknown

☐ N/A—patient had residual disease after CRT

☐ N/A—confirmed recurrence reported previously

4. ADJUVANT CHEMOTHERAPY

A) Has the patient started any new adjuvant chemotherapy since the last visit? ☐ Yes ☐ No ☐ Unknown

i) If yes, give details of the regimen

☐ 5FU ☐ Capecitabine

☐ Oxaliplatin + Capecitabine ☐ Oxaliplatin + 5FU

☐ Other *(please specify)* _____

ii) If yes, give start date of chemotherapy: ☐☐ / ☐☐ / ☐☐☐☐

5. SURGERY FOR LATE EFFECTS OF RADIOTHERAPY

A) Has the patient required surgery for late effects of radiotherapy since the last visit? ☐ Yes ☐ No ☐ Unknown

i) If yes, date of surgery: ☐☐ / ☐☐ / ☐☐☐☐

ii) If yes, was this for:

☐ Bleeding

☐ Blockage (stricture)

☐ Other *(please specify)* _____

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____

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6. SECOND (UNRELATED) MALIGNANCY

A) Has the patient developed a second unrelated malignancy since the last visit? ☐ Yes ☐ No

i) If yes, specify type: _____

ii) Is there histological evidence? ☐ Yes ☐ No

Please send a copy of the pathology report to the Trials Centre if available.

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____

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FOLLOW UP FORM: 4 MONTHS

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7. ADVERSE EVENTS

Record the worst grade experienced *since surgery* for each AE listed below, and for any other surgical complications. If patient did not have surgery, tick this box: ☐

FU4-3/3

System Organ Class *(Use SOC as listed in CTCAE v4.02. You do not need to record the SOC if the AE term in the next column is listed in CTCAEv4.02. You must record the SOC if you are using the "other" CTCAE term.)*	**Adverse Event Term** *(Use term as listed in CTCAE v4.02. If a suitable CTCAE term does not exist, use the "other" term under the appropriate SOC and use free text to describe the AE.)*	**Severity Grade**[1] *(Grades 0-5)*	**Continued from previous reporting period** *(Y/N)*	**Date of Onset** *(required only if AE commenced during this reporting period)* dd—mm—yyyy (e.g. 30 – 01 – 2011)	**Outcome**[2]	**Causally related to protocol treatment**[3]	**Seriousness Criteria**[4]	**SAE Report Submitted** *(Y[5]/N)*
Cardiac disorders	Myocardial infarction							
Infections and infestations Infections and infestations	Pelvic infection							
	Wound infection (Abdominal)							
	Other (specify)							
Injury, poisoning and procedural complications Injury, poisoning and procedural complications	Gastrointestinal anastomotic leak							
	Wound dehiscence (perineal)							
	Anastomotic dehiscence							
Nervous system disorders	Stroke							
Vascular disorders	Thromboembolic event							

1) Enter worst grade observed during reporting period. Use CTCAE v4.02 unless stated otherwise

2) Enter code: 0 = Fatal; 1 = Not resolved; 2 = Resolved; 3 = Resolved with sequelae; 4 = Resolving; 5 = Unknown

3) Enter code: 0 = Not related; 1 = Unlikely; 2 = Possibly; 3 = Probably; 4 = Definitely

4) Enter code: 0 = not serious; 1 = resulted in death; 2 = life threatening; 3 = required hospitalisation; 4 = resulted in disability/ incapacity; 5 = congenital anomaly or birth defect; 6 = other medically significant

5) For all serious AEs, an SAE Report must be submitted to the UCL CTC, unless stated in protocol as exempt. Complete this row for serious events ONLY.

Completed by (print name): _____ **Signature:** _____ **Date Completed:** d d m m y y y y

Site: _____

For UCL CTC use only:

Date Checked: _____ Initials: _____

Date entered: _____ Initials: _____