ARISTOTLE

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

FOLLOW UP FORM: 4 MONTHS

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

FU4-1/3

INSTRUCTIONS:
If confirmed residual disease or recurrence has been reported prior to this visit, please complete sections1 and 3 **only**.

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

A) ECOG Performance Status: ☐ **OR** ☐ N/A (patient did not attend)

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 ± Surgery
- ☐ N/A - confirmed recurrence reported previously

4. SURGERY

A) Has the patient had surgery for their primary tumour since completing CRT? ☐ Yes ☐ No ☐ N/A - patient had complete response

If the patient has had surgery for their rectal cancer, please submit a Surgery Form and Pathology Form.

If the patient did not have surgery, please submit a Surgery Form documenting reason why surgery was not performed; and a Suspected or Confirmed Residual Disease or Recurrence Form too.

B) Has the patient had surgery for their metastases since completing CRT? ☐ Yes ☐ No ☐ N/A - not mets

¥If the patient has had surgery for their metastases, please submit a Surgery Form

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

ARISTOTLE

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

FOLLOW UP FORM: 4 MONTHS

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5. CHEMOTHERAPY

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

i) If the patient started a new regimen, give start date of chemotherapy: ☐☐/☐☐/☐☐☐☐

ii) If yes, what was the function of the regimen

☐ Adjuvant ☐ Palliative

☐ Other *(please specify)* _____

iii) If yes, give details of the regimen

☐ 5FU ☐ Capecitabine

☐ Oxaliplatin + Capecitabine ☐ Oxaliplatin + 5FU

☐ Other *(please specify)* _____

B) Has the patient stopped any ongoing chemotherapy regimens since the last visit? ☐ Yes ☐ No ☐ Unknown

i) If yes, give date of completion of chemotherapy: ☐☐/☐☐/☐☐☐☐

ii) If yes, give duration of chemotherapy: ☐☐ months

6. RADIOTHERAPY TO PELVIS

A) Has the patient started any radiotherapy to pelvis since the last visit? ☐ Yes ☐ No ☐ Unknown

i) If the patient started a new regimen, give start date of radiotherapy: ☐☐/☐☐/☐☐☐☐

i) If yes, what was the function of the regimen

☐ Adjuvant ☐ Other *(please specify)* _____

B) Has the patient stopped any ongoing radiotherapy regimens since the last visit? ☐ Yes ☐ No ☐ Unknown

i) If yes, give date of completion of radiotherapy: ☐☐/☐☐/☐☐☐☐

ii) If yes, give total number of fractions: ☐☐ Gy

7. 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)* _____

8. 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: _____

ARISTOTLE

FOLLOW UP FORM: 4 MONTHS

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

9. 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: _____