ARISTOTLE

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

CONFIRMATION OF RESIDUAL DISEASE OR RECURRENCE FORM

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

A response is not required for all sections of this CRF - see details below

INSTRUCTIONS:

If a Suspected Residual Disease or Recurrence Form has previously been submitted for this patient:

- complete only section 1 to **confirm** the previously reported suspected disease
- complete only section 2 if the previously reported suspected disease **has not been confirmed** after 6 months.

Otherwise, complete sections 3-5 to report suspected disease **for the first time**.

1. Confirmation of previously reported suspected residual or recurrent disease

If this is to confirm the presence of previously suspected residual or recurrent disease, complete this section only. Otherwise, leave this section blank and go on to section 2.

A) Does the patient have confirmed residual disease? ☐ Yes ☐ No

B) Does the patient have confirmed loco-regional recurrence? ☐ Yes ☐ No

C) Does the patient have confirmed metastatic disease? ☐ Yes ☐ No

D) Method of confirmation *(complete all that apply)*

☐ Biopsy

Date of biopsy: ☐☐ / ☐☐ / ☐☐☐☐

☐ CEA elevation

Date of blood sample: ☐☐ / ☐☐ / ☐☐☐☐

CEA value (μg/mL): ☐☐☐☐

☐ Imaging (locoregional)

Date of scan: ☐☐ / ☐☐ / ☐☐☐☐

Type of scan:
- ☐ MRI pelvis
- ☐ CT scan
- ☐ PET scan
- ☐ Other *(specify)* _____

☐ Imaging (metastatic disease)

Date of scan: ☐☐ / ☐☐ / ☐☐☐☐

Type of scan:
- ☐ MRI pelvis
- ☐ CT scan
- ☐ PET scan
- ☐ Other *(specify)* _____

Site(s) of metastatic disease:
- ☐ Liver
- ☐ Lung
- ☐ Lymph nodes
- ☐ Peritoneum
- ☐ Bone
- ☐ Brain
- ☐ Other *(specify)* _____

☐ Other method of confirmation *(specify)* _____

Date of confirmation: ☐☐ / ☐☐ / ☐☐☐☐

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

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2. Lack of confirmation of previously reported suspected residual or recurrent disease

If this is to report that a suspected residual or recurrent disease was not confirmed after 6 months, complete this section only. Otherwise, leave this section blank and go on to section 3.

Please provide the date of the MDT meeting where it was agreed the suspected disease could not be confirmed:

Date of MDT meeting: ☐☐ / ☐☐ / ☐☐☐☐

3. Residual disease following CRT

A) Does the patient have residual disease following CRT? ☐ Yes ☐ No *If no, go on to question 4*

B) How was residual disease confirmed?

☐ MDT decision that disease is not resectable based on post CRT pelvic MRI

Date of MDT meeting: ☐☐ / ☐☐ / ☐☐☐☐

☐ Decision at laparotomy that disease is not resectable

☐ Incomplete resection of tumour **with** biopsy proof of residual disease
(if no biopsy proof, then this would be "suspected" residual disease and a Suspected Residual Disease or Recurrence form should be completed)

4. Loco-regional recurrence

A) Does the patient have confirmed loco-regional recurrence? ☐ Yes ☐ No *If no, go on to question 5*

B) Method of confirmation:

☐ Clinical recurrence with biopsy proof of recurrence

Date of biopsy: ☐☐ / ☐☐ / ☐☐☐☐

☐ CEA elevation and enlarging or new mass

i. Date of blood sample: ☐☐ / ☐☐ / ☐☐☐☐

CEA value (μg/mL): ☐☐☐☐

ii. Date of scan identifying new or enlarging ☐☐ / ☐☐ / ☐☐☐☐

Type of scan:
☐ MRI pelvis
☐ CT scan
☐ PET scan
☐ Other *(specify)* _____

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

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CONFIRMATION OF RESIDUAL DISEASE OR RECURRENCE FORM

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5. Metastatic disease

A) Does the patient have confirmed metastatic disease? ☐ Yes ☐ No *If no, do not complete the rest of this section*

B) Method of confirmation:

☐ Clinical recurrence with biopsy proof of recurrence

Date of biopsy: ☐☐ / ☐☐ / ☐☐☐☐

☐ CEA elevation and evidence of distant metastases

Date of blood sample: ☐☐ / ☐☐ / ☐☐☐☐

CEA value (μg/mL): ☐☐☐☐

C) Date of scan identifying distant metastases: ☐☐ / ☐☐ / ☐☐☐☐

i) Type of scan:
- ☐ MRI pelvis
- ☐ CT scan
- ☐ PET scan
- ☐ Other *(specify)* _____

ii) Site(s) of metastatic disease:
- ☐ Liver
- ☐ Lung
- ☐ Lymph nodes
- ☐ Peritoneum
- ☐ Bone
- ☐ Brain
- ☐ Other *(specify)* _____

Completed by (print name):	**Signature:**	**Date Completed:**
		☐☐ ☐☐ ☐☐☐☐

Site:

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