Cancer Research UK & UCL Cancer Trials Centre ARISTOTLE **ADVERSE EVENT FORM**

Trial No: ARI - ☐☐☐☐ **Initials:** ☐☐☐

Treatment Week *(please circle)*: **1 2 3 4 5 6 10**

Adverse Event *(Use term listed in CTCAE v4.2)*	**Severity Grade**[1] *(Grades 0-5)*	**Date of Onset** *d d m m y y y y*	**Causally related to radiotherapy**[2]	**Causally related to capecitabine**[2]	**Causally related to irinotecan**[2]	**Was the event serious?** *0 = No 1 = Yes*[3]
Diarrhoea						
Nausea						
Vomiting						
Abdominal pain						
Stomatitis						
Palmar-plantar erythrodysaesthesia						
Fatigue						
Anorexia						
Cardiotoxicity						
Thrombosis						
Embolism						
Neutropenia						

1) Enter worst grade observed during reporting period / Use CTCAE v4.0 unless stated otherwise
2) Enter code: 0 = Not related; 1 = Unlikely; 2 = Possibly; 3 = Probably; 4 = Definitely
3) If yes, ensure a completed SAE Report has been submitted to the UCL CTC, unless stated in protocol as not required

FORM COMPLETED BY: Print name: _____ **Signature:** _____ **Date:** ☐☐☐☐☐☐☐☐ *d d m m y y y y*

Please return to: ARISTOTLE Trial Coordinator, CR UK & UCL Cancer Trials Centre

For CTC use only: Date form received: _____ Date form entered: _____ Initials: _____

Completion Instructions

- **Record all adverse events (AEs) that occur from informed consent until 30 days post last trial treatment administration whether related to the treatment or not.**
- **Pre-existing events do not qualify as AEs unless they worsen.**
- **All AEs added to the form (not pre-printed) must be added to subsequent forms until they have resolved.**

1) Severity Grade

- **Enter worst grade observed since last follow-up**
- **Use CTCAE v4.02**
- **If no AE occurred enter "0"**

2) Causally related to

- **Use the following options: 0 = Not related; 1 = Unlikely; 2 = Possibly; 3 = Probably; 4 = Definitely**

3) Was the event serious?

- **If yes, ensure a completed SAE Report has been submitted to UCL CTC (this must be done within 1 business day of becoming aware of the SAE), unless stated in protocol as not requiring reporting on an SAE Report**

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Anaemia						
Thrombocytopenia						
Skin ulceration (peri-anal)						
Urinary frequency						

1) Enter worst grade observed during reporting period / Use CTCAE v4.0 unless stated otherwise
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