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

Trial No: ARI - ☐☐☐ **Initials:** ☐☐☐

Treatment Week *(please circle)*: **0 1 2 3 4 5 6 10**

Adverse Event *(Use term listed in CTCAE v4.02)*	**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 v4.02 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 24 hours of becoming aware of the SAE), unless stated in protocol as not requiring reporting on an SAE Report**

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

Trial No: ARI - ☐☐☐ **Initials:** ☐☐☐

Treatment Week *(please circle)*: **0 1 2 3 4 5 6 10**

Adverse Event *(Use term listed in CTCAE v4.02)*	**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]
Anaemia						
Thrombocytopenia						
Skin ulceration (peri-anal)						
Urinary frequency						

1) Enter worst grade observed during reporting period / Use CTCAE v4.02 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 24 hours of becoming aware of the SAE), unless stated in protocol as not requiring reporting on an SAE Report**