ARISTOTLE

UCL

Serious Adverse Event (SAE) Report

Patient trial number: ARI – ☐☐☐☐

Please complete all sections with details of any SAE occurring from the time of informed consent until 30 days post last trial treatment administration (and later if the event is felt to be a long term side effect). For guidance on which events to report please see trial protocol.

Please fax this form to the ARISTOTLE Co-ordinator at the CR UK & UCL Cancer Trials Centre on 020 7679 9871 within 1 business day of notification of the event.

Trial details

Trial title	A phase III trial comparing standard versus novel CRT as pre-operative treatment for MRI defined locally advanced rectal cancer		
Trial acronym	ARISTOTLE	**EudraCT number**	2008-005782-59

Patient details

Patient initials	☐☐☐	**Patient trial number**		**ARI** – ☐☐☐☐	
NHS number	☐☐☐☐☐☐☐☐☐☐	**Date of birth**		☐☐ ☐☐ ☐☐☐☐ (d d m m y y y y)	
Gender	☐ Male ☐ Female	**Height**	☐☐☐ cm	**Weight**	☐☐☐.☐ kg
Hospital		**Treating Clinician**			
Type of report	☐ First ☐ Update ☐ Final	**Trial arm**	☐ ***Standard***	☐ ***Standard + irinotecan***	

Trial treatment

Treatment / Drug Name	Brand	Dose	Unit	Frequency	Is this full dose?	Route	Start date (d d m m y y y y)	Ongoing?	End date (d d m m y y y y)
Radiotherapy					☐ Y ☐ N		☐☐ ☐☐ ☐☐☐☐	☐ Y ☐ N	☐☐ ☐☐ ☐☐☐☐
Capecitabine					☐ Y ☐ N	Oral	☐☐ ☐☐ ☐☐☐☐	☐ Y ☐ N	☐☐ ☐☐ ☐☐☐☐
Irinotecan					☐ Y ☐ N	IV	☐☐ ☐☐ ☐☐☐☐	☐ Y ☐ N	☐☐ ☐☐ ☐☐☐☐

Most recent cycle number ☐	**Date last treatment given prior to SAE:**	☐☐ ☐☐ ☐☐☐☐ (d d m m y y y y)	**What was last treatment given prior to SAE?**	

Event summary description	*(Give a concise medical description of the event including all relevant symptoms and complete page overleaf for all events that meet the definition of serious)*	Continued on a separate sheet:	☐ **Y** ☐ **N**

No. of events included in this report: ☐	If hospitalisation, please provide: Admission date ☐☐ ☐☐ ☐☐☐☐ (d d m m y y y y)	Discharge date ☐☐ ☐☐ ☐☐☐☐ (d d m m y y y y)	

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COMPLETE A SEPARATE PAGE FOR EACH EVENT THAT MEET THE DEFINITION OF SERIOUS (photocopy this page as necessary for each event)

Name of event (use CTCAE version 4.02)	Grade	Date of onset	Ongoing?	Date resolved
	☐	☐☐ ☐☐ ☐☐☐☐ (d d m m y y y y)	☐ Y ☐ N	☐☐ ☐☐ ☐☐☐☐ (d d m m y y y y)

Why was the event serious? *(choose most serious)*	Outcome
☐ Resulted in death	☐ Fatal
☐ Life-threatening	☐ Not resolved
☐ Required new or prolonged hospitalisation	☐ Resolved
☐ Resulted in persistent or significant disability/incapacity	☐ Resolved with sequelae
☐ Resulted in congenital anomaly/birth defect	☐ Resolving
☐ Other *(specify)* _____	

SAE Assessment

Treatment / Drug Name	Causal relationship to event *(Enter one code only)* 0 = None 1 = Unlikely 2 = Possibly 3 = Probably 4 = Definitely	Action taken *(Enter one code only)* 0 = Dose not changed 1 = Dose reduced 2 = Treatment stopped 3 = Not applicable	Office Use Only: Event expected for the treatment / drug *(Enter one code only)* 1 = Expected 2 = Not Expected
Radiotherapy	☐	☐	☐
Capecitabine	☐	☐	☐
Irinotecan	☐	☐	☐

Office use only

Event No: ARI - ☐☐☐☐-☐☐-☐	Was the event a SUSAR? ☐ *Y ☐ N	Date SAE entered on database ☐☐ ☐☐ ☐☐☐☐ (d d m m y y y y)
*Date reported to MHRA: ☐☐ ☐☐ ☐☐☐☐ (d d m m y y y y)	*Date reported to Main REC ☐☐ ☐☐ ☐☐☐☐ (d d m m y y y y)	*Reported to Principal Investigators ☐ Y
Form checked by (signature)	Date ☐☐ ☐☐ ☐☐☐☐ (d d m m y y y y)	

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Concomitant medications? ☐ Y ☐ N *(Only include drugs given within the last 30 days excluding treatment for SAE. Continue on separate sheet if necessary)* Continued on a separate sheet: ☐ Y ☐ N

Drug Name	Brand	Indication	Dose	Units	Frequency	Route	Start date (d d m m y y y y)	Ongoing?	End date (d d m m y y y y)
								☐ Y ☐ N	
								☐ Y ☐ N	
								☐ Y ☐ N	
								☐ Y ☐ N	

Treatment for SAE? ☐ Y ☐ N *(If yes, please specify below)*

Drug Name	Brand	Indication	Dose	Units	Frequency	Route	Start date (d d m m y y y y)	Ongoing?	End date (d d m m y y y y)
								☐ Y ☐ N	
								☐ Y ☐ N	
								☐ Y ☐ N	
								☐ Y ☐ N	

Any relevant tests / laboratory data? ☐ Y ☐ N *(If yes, please specify below)*

Date (d d m m y y y y)	Test	Results
		Results pending: ☐ Y
		Results pending: ☐ Y
		Results pending: ☐ Y
		Results pending: ☐ Y

Any relevant medical history / concurrent conditions? ☐ Y ☐ N *(If yes, please specify below)*

Was event expected in view of patient's medical history? ☐ Y ☐ N

Signature: PI or other participating clinicians only		**Print name:**		**Date of report:**	☐☐ ☐☐ ☐☐☐☐ (d d m m y y y y)