ARISTOTLE

Pregnancy Report

Please complete all sections with details of any pregnancy occurring from the time of informed consent until last follow-up visit.
Please fax this form to the ARISTOTLE Co-ordinator at the CR UK & UCL Cancer Trials Centre on 020 7679 9861 within 24 hours 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 *(Any information regarding female partners of trial patients should be entered in Other Pregnancy Information section)*

Patient initials	☐☐☐	**Patient trial number**		ARI - ☐☐☐	
NHS number	☐☐☐☐☐☐☐☐☐☐	**Date of birth**		☐☐ ☐☐☐ ☐☐ d d m m m 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 m y y	Ongoing?	End date d d m m m 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 before pregnancy confirmation:** ☐☐ ☐☐☐ ☐☐ d d m m m y y	**Last treatment given before pregnancy confirmation:**

Pregnancy Report

Patient trial number: ☐☐☐

Concomitant medications? ☐ Y ☐ N

(Only include drugs given during the 30 day period prior to pregnancy confirmation. 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 m y y)	Ongoing?	End date (d d m m m y y)
								☐ Y ☐ N	
								☐ Y ☐ N	
								☐ Y ☐ N	
								☐ Y ☐ N	
								☐ Y ☐ N	
								☐ Y ☐ N	
								☐ Y ☐ N	
								☐ Y ☐ N	

Pregnancy Information

Start date of last menses	Date pregnancy confirmed	Method of diagnosis	Anticipated date of childbirth	Mother consented for pregnancy monitoring
☐☐ ☐☐☐ ☐☐ (d d m m m y y)	☐☐ ☐☐☐ ☐☐ (d d m m m y y)		☐☐ ☐☐☐ ☐☐ (d d m m m y y)	☐ Y ☐ N

Pregnancy Outcome

☐ Not known at this date	☐ Still birth	☐ Induced abortion	☐ Spontaneous abortion
☐ Neonatal death	☐ Uneventful (normal/healthy baby)	☐ Birth defects *(provide details in Other Pregnancy Information section below)*	
Date of Above Outcome:	☐☐ ☐☐☐ ☐☐ (d d m m m y y)		

Date of delivery (d d m m m y y)	Gestation (weeks)	Mode of Delivery	Gender	Weight (kg)	Antenatal Problems	Postnatal Problems
☐☐ ☐☐☐ ☐☐	☐☐		☐ Male ☐ Female	☐.☐		

Pregnancy Report

Patient trial number: ☐☐☐

Other Pregnancy Information *(concurrent conditions, medical history, complications during birth, birth defects etc)*

Past Pregnancy History

Date of delivery (d d m m m y y)	Gestation (weeks)	Mode of Delivery	Gender	Weight (kg)	Antenatal Problems	Postnatal Problems
☐☐ ☐☐☐ ☐☐	☐☐		☐ Male ☐ Female	☐.☐		
☐☐ ☐☐☐ ☐☐	☐☐		☐ Male ☐ Female	☐.☐		
☐☐ ☐☐☐ ☐☐	☐☐		☐ Male ☐ Female	☐.☐		

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

Office use only

*Reported to MHRA: ☐☐ ☐☐☐ ☐☐ (d d m m m y y)	*Reported to REC ☐☐ ☐☐☐ ☐☐ (d d m m m y y)	Entered on database ☐☐ ☐☐☐ ☐☐ (d d m m m y y)	
Form checked by (signature)	Date ☐☐ ☐☐☐ ☐☐ (d d m m m y y)		