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 9871 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	