UKALL14
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 UKALL14 Co-ordinator at the CR UK & UCL Cancer Trials Centre on 020 7679 9861 within 24 hours of becoming aware of the pregnancy.

Trial details			
Trial title	**A randomised trial for adults with newly diagnosed acute lymphoblastic leukaemia**		
Trial acronym	**UKALL14**	**EudraCT number**	**2009-012717-22**

Patient details *(Any information regarding female partners of trial patients should be entered in Other Pregnancy Information section)*				
Patient initials	☐☐☐		**Patient trial number**	**14** - ☐ - ☐☐☐
Report relates to:	☐ Trial Patient	☐ Patient's Partner	**Patient date of birth**	☐☐ ☐☐ ☐☐ d d m m m y y
Hospital			**Treating Clinician**	
B Randomisation: ☐ 0=N/A 1=B1 2=B2 **T Randomisation**: ☐ 0=N/A 1=T1 2=T2 **P Randomisation:** ☐ 0=N/A 1=P1 2=P2				
Type of report	☐ Initial ☐☐ ☐☐ ☐☐ d d m m m y y		☐ Follow up	For all follow up reports, please: • Initial & date all changes throughout the report • Fax to UCL CTC within 24 hours of becoming aware of significant new information
Complete for initial reports only:	Date site notified of pregnancy: ☐☐ ☐☐ ☐☐ d d m m m y y		If reported to UCL CTC more than 24 hours after becoming aware of pregnancy, provide reason:	_____

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CANCER RESEARCH UK

Patient trial number: 14- ☐ - ☐☐☐

Trial 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)
Pegylated asparaginase	**Oncaspar**				☐ Y ☐ N		☐☐ ☐☐☐ ☐☐	☐ Y ☐ N	☐☐ ☐☐☐ ☐☐
Rituximab	**Mabthera**				☐ Y ☐ N		☐☐ ☐☐☐ ☐☐	☐ Y ☐ N	☐☐ ☐☐☐ ☐☐
Nelarabine	**Atriance**				☐ Y ☐ N		☐☐ ☐☐☐ ☐☐	☐ Y ☐ N	☐☐ ☐☐☐ ☐☐
Palifermin	**Kepivance**				☐ Y ☐ N		☐☐ ☐☐☐ ☐☐	☐ Y ☐ N	☐☐ ☐☐☐ ☐☐

Most recent phase of protocol treatment ☐ (1=Phase 1 induction, 2= Phase 2 Induction, 3= Intensification, 4= Consolidation, 5= Maintenance, 6= Myeloablative transplant, 7= Non-Myeloablative transplant)	**Date last treatment given before pregnancy confirmation:**	☐☐ ☐☐☐ ☐☐ (d d m m m y y)	**Last trial drug given before pregnancy confirmation:**	

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	☐☐ ☐☐☐ ☐☐

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Pregnancy Report

Patient trial number: 14- ☐ - ☐☐☐

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 y y	☐☐ ☐☐ ☐☐ d d m m y y		☐☐ ☐☐ ☐☐ d d m m y y	☐ Y ☐ N ☐ Pending *
If consented for pregnancy monitoring:	Date consent signed ☐☐ ☐☐ ☐☐ d d m m y y	PIS version used: ☐ . ☐	Consent form version: ☐ . ☐	
*** If mother has not yet consented for pregnancy monitoring:**	☐ Will be consented at next clinic visit	☐ Other (specify): _____		

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 y y		

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

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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**	**Sex**	**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

Trial Reference: 14-☐ - ☐☐☐ - ☐☐ - P	CTC Reference: PREG☐☐☐	
*Reported to MHRA: ☐☐ ☐☐☐ ☐☐ d d m m m y y	*Reported to Main 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	Checked by clinical reviewer ☐☐ ☐☐☐ ☐☐ d d m m m y y