UKALL14

Serious Adverse Event (SAE) Report

NOT REQUIRED FOR 'REGISTRATION ONLY' SUB-STUDY PATIENTS (14-3-XXX)

Please complete all sections with details of any SAE occurring during the reporting windows outlined in protocol section 12.2.2 (and outside these timeframes 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 UKALL14 Co-ordinator at the CR UK & UCL Cancer Trials Centre on 020 7679 9861 within 24 hours of becoming aware of the event.

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					
Patient initials	☐☐☐	**Patient trial number** *Randomised patients only 14-**1**-XXX or 14-**2**-XXX* *SAE data not collected for 'Registration only' patients (14-**3**-XXX)*	**14** - ☐ - ☐☐☐		
Sex	☐ Male ☐ Female	**Date of birth**	☐☐/☐☐/☐☐☐☐ (d d m m m y y)		
Hospital		**Treating Clinician**			
Type of report	☐ First ☐ Update ☐ Final	**Height**	☐☐☐ cm	**Weight**	☐☐☐.☐ kg
Trial arm	**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				

Trial treatment ☐ **Tick if no IMPs given to date**

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)	**Start Date of most recent phase of protocol treatment, prior to SAE:**	☐☐/☐☐/☐☐☐☐ (d d m m m y y)	**What was the last IMP given prior to SAE?** (1=Pegylated asparaginase, 2= Rituximab, 3= Nelarabine, 4= Palifermin)	

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Patient trial number: 14- ☐ - ☐☐☐

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

Date site became aware of SAE: ☐☐ ☐☐ ☐☐ (d d m m m y y)	If aware more than 24 hours before submission, reason for late reporting:	
No. of events included in this report: ☐	If hospitalisation, please provide: Admission date ☐☐ ☐☐ ☐☐ (d d m m m y y)	Discharge date ☐☐ ☐☐ ☐☐ (d d m m m y y)

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CANCER RESEARCH UK

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Patient trial number: 14- ☐ - ☐☐☐

Serious Adverse Event (SAE)

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

Name of event (use CTCAE version 4.0)	Grade	Date of onset	Ongoing?	Date resolved
	☐	☐☐ ☐☐ ☐☐☐☐ (d d m m m y y)	☐ Y ☐ N	☐☐ ☐☐ ☐☐☐☐ (d d m m m 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)* _____	☐ Not assessable

SAE Assessment

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 = Drug withdrawn 3 = Not applicable	OFFICE USE ONLY Event expected for the drugs 1 = Expected 2 = Not Expected
Pegylated Asparaginase	☐	☐	☐
Rituximab	☐	☐	☐
Nelarabine	☐	☐	☐
Palifermin	☐	☐	☐

Office use only

Event No: 14 _ ☐ _ ☐☐☐ _ ☐☐ _ ☐☐	Was the event a SUSAR? ☐ *Y ☐ N	Date SAE entered on database ☐☐ ☐☐ ☐☐☐☐ (d d m m m y y)
*Date reported to MHRA: ☐☐ ☐☐ ☐☐☐☐ (d d m m m y y)	*Date reported to Main REC ☐☐ ☐☐ ☐☐☐☐ (d d m m m y y)	*Reported to Principal Investigators ☐ Y
Form checked by (signature)	Date ☐☐ ☐☐ ☐☐☐☐ (d d m m m y y)	Date checked by clinical reviewer ☐☐ ☐☐ ☐☐☐☐ (d d m m m y y)

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Patient trial number: 14- ☐ - ☐☐☐

Concomitant Medications

- *List non-IMP drugs given within the 30 days prior to SAE onset, including non-IMP treatment for ALL.*
- *Do not list IMP treatments or treatment for SAE, as these are recorded elsewhere on the form.*
- *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	☐☐☐☐☐☐☐
							☐☐☐☐☐☐☐	☐ Y ☐ N	☐☐☐☐☐☐☐
							☐☐☐☐☐☐☐	☐ Y ☐ N	☐☐☐☐☐☐☐
							☐☐☐☐☐☐☐	☐ Y ☐ N	☐☐☐☐☐☐☐
							☐☐☐☐☐☐☐	☐ Y ☐ N	☐☐☐☐☐☐☐
							☐☐☐☐☐☐☐	☐ Y ☐ N	☐☐☐☐☐☐☐
							☐☐☐☐☐☐☐	☐ Y ☐ N	☐☐☐☐☐☐☐
							☐☐☐☐☐☐☐	☐ Y ☐ N	☐☐☐☐☐☐☐
							☐☐☐☐☐☐☐	☐ Y ☐ N	☐☐☐☐☐☐☐
							☐☐☐☐☐☐☐	☐ Y ☐ N	☐☐☐☐☐☐☐
							☐☐☐☐☐☐☐	☐ Y ☐ N	☐☐☐☐☐☐☐
							☐☐☐☐☐☐☐	☐ Y ☐ N	☐☐☐☐☐☐☐
							☐☐☐☐☐☐☐	☐ Y ☐ N	☐☐☐☐☐☐☐
							☐☐☐☐☐☐☐	☐ Y ☐ N	☐☐☐☐☐☐☐
							☐☐☐☐☐☐☐	☐ Y ☐ N	☐☐☐☐☐☐☐
							☐☐☐☐☐☐☐	☐ Y ☐ N	☐☐☐☐☐☐☐

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Patient trial number: 14-☐-☐☐☐

Did the patient receive any treatment for this SAE? ☐ Y ☐ N *(If yes, please specify below)* *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	

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

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