UKALL14

FAX MESSAGE

REGISTRATION AND B/T RANDOMISATION REQUEST

STUDY ENTRY

DATE (dd/mm/yyyy): ☐☐ ☐☐ ☐☐☐☐

ATTENTION: UKALL14 TRIAL TEAM

UKALL14 FAX No: 0207 679 9861

Number of pages (including cover sheet): ☐☐

RESEARCH CONTACT:	
PHONE NO:	
FAX NO:	

PHARMACY CONTACT:	
PHONE NO:	
FAX NO:	

Centre	
Consultant	
Patient Initials	
Date of Birth	

UKALL14 Patient Initials [ ] NHS Number [ ]

UKALL14 Registration at Study Entry (1/9)

Patient Details

Patient Initials [ ]

NHS Number [ ][ ][ ] [ ][ ][ ] [ ][ ][ ][ ]

Date of Birth *(dd/mm/yyyy)* [ ][ ] [ ][ ] [ ][ ][ ][ ]

Sex *(1=Male, 2=Female)* [ ]

Date of ALL Diagnosis *(dd/mm/yyyy)* [ ][ ] [ ][ ] [ ][ ][ ][ ]

Disease Type: [ ]

1= Precursor-B cell Disease

2= T-cell disease

Centre [ ]

Consultant [ ]

Has steroid pre-phase started? *(1=Yes, 2=No)* [ ]

If yes, steroid pre-phase start date *(dd/mm/yyyy)* [ ][ ] [ ][ ] [ ][ ][ ][ ]

Proposed start date of Induction Phase 1 *(dd/mm/yyyy)* [ ][ ] [ ][ ] [ ][ ][ ][ ]

REMINDER
Pegylated-Asparaginase is an IMP

Protocol Section 7.2.3—Phase 1 Induction

All patients will receive Phase 1 Induction regardless of phenotype.

Please ensure sufficient drug supply is available to treat Philadelphia Negative patients.

Office use only:
Date form received: _____ Date form entered: _____ Initials: _____

UKALL14 Patient Initials _____ NHS Number _____

UKALL14 Registration at Study Entry (2/9)

Eligibility Checklist

ANSWERS TO THE FOLLOWING QUESTIONS MUST BE YES

	Inclusion Criteria for STUDY ENTRY	Yes	No
a	Aged ≥ 25 and ≤ 65 years at registration **OR** aged ≥ 19 and ≤ 65 years with Philadelphia Chromosome present.		
b	Newly diagnosed and previously untreated ALL - Acute Lymphoblastic Leukaemia. A steroid pre-phase of 5-7 days is required and can be started prior to registration.		
c	Written informed consent.		

ANSWERS TO THE FOLLOWING QUESTIONS MUST BE NO

	Exclusion Criteria for STUDY ENTRY	Yes	No
a	Known HIV infection.		
b	Hepatitis B infection (defined as positive HBsAg and/or HBcAb). Note: Antibodies to Hep B surface antigen only is acceptable.		
c	Hepatitis C infection (antibodies against hepatitis C or PCR evaluation which is positive for hepatitis C DNA).		
d	Pregnant or lactating woman.		
e	Blast transformation of CML.		
f	Mature B-cell leukaemia i.e. Burkitt's lymphoma t(8;14)(q24 ;q32) and variant c-myc translocations e.g. t(2;8)(p12 ;q24), t(8;22)(q24;q11).		

Viral Serology

Test Date (dd/mm/yyyy):	Positive	Negative
Hep B surface antigen (HBsAg)		
Hep C antibodies **or** Hep C DNA (HCV DNA)		
Hep B core antibody (HBcAb)	*	

*Eligibility confirmed by treating clinician (name): _____ Date (dd/mm/yyyy) ☐☐ ☐☐ ☐☐☐☐

REMINDER

Protocol section 8.2.1—Schedule of testing for MRD and correlative science testing.

Please send baseline samples and begin tissue typing of patient and any siblings.

If there is not a matched sibling donor available, please initiate the search for a donor as soon as possible to avoid unnecessary delays.

Office use only:
Date form received: _____ Date form entered: _____ Initials: _____

UKALL14 Patient Initials _____ NHS Number _____

UKALL14 Registration at Study Entry (3/9)

Pre-registration & Pre-1st Randomisation Evaluations

Patient Assessments

Date of assessments *(dd/mm/yyyy)* ☐☐ ☐☐ ☐☐☐☐

Height *(cm)* ☐☐☐ Weight *(kg)* ☐☐☐•☐ ECOG Performance Status ☐

Medical History – Cardiac*

Has the patient been diagnosed with a serious cardiac condition? *(1=Yes, 2=No)* ☐

If yes, please specify below (1=Yes, 2=No)

Angina ☐ Myocardial Infarction ☐ Heart failure ☐

Other (specify) ☐ _____

Medical History – Mental Health*

Any history of mental health issues pre ALL diagnosis? *(1=Yes, 2=No)* ☐

If Yes, please complete below (1=Yes, 2=No):

Diagnosis of Depression ☐ Attempted suicide/self harm ☐ Psychotic illness ☐ Anxiety ☐

Other (specify) ☐ _____

On anti-depressants now? *(1=Yes, 2=No)* ☐

**This information is needed as a baseline for the late effects assessment at 2yrs post treatment*

Employment status

Employed now? *(1=Yes, 2=No)* ☐ If yes, current occupation _____

Pregnancy Test

Is the patient a female of child bearing age? *(1=Yes, 2=No)* ☐

If yes, NEGATIVE pregnancy test date (dd/mm/yyyy) ☐☐ ☐☐ ☐☐☐☐

Office use only:
Date form received: _____ Date form entered: _____ Initials: _____

UKALL14 Patient Initials [ ] NHS Number [ ]

UKALL14 Registration at Study Entry (4/9)

Pre-registration & Pre-1st Randomisation Evaluation

CNS Involvement

Lumbar Puncture is only required at baseline if CNS involvement suspected, otherwise should be avoided until the first dose of intrathecal methotrexate is due

Does the patient have suspected CNS involvement? *(1=Yes 2=No)* [ ]

If Yes above then please complete below:

Date of Lumbar Puncture *(dd/mm/yyyy)* [ ][ ] [ ][ ] [ ][ ][ ][ ]

Number of white cells/µL [ ][ ][ ][ ]

Number of red cells/µL [ ][ ][ ][ ]

Extramedullary involvement

Date of Assessment *(dd/mm/yyyy)* [ ][ ] [ ][ ] [ ][ ][ ][ ]

Does the patient have extramedullary involvement? *(1=Yes 2=No)* [ ]

If yes, please complete all boxes below (1= Involved, 2=Not Involved, 3=Not Applicable)

Liver	[ ]	Is the liver enlarged?	[ ]	*(1= Yes 2=No)*
Spleen	[ ]	Is the spleen enlarged?	[ ]	*(1= Yes 2=No)*
Mediastinum	[ ]	Anterior mediastinal mass on chest X-ray?	[ ]	*(1= Yes 2=No)*
Lymph nodes	[ ]	Any superficial lymph nodes enlarged?	[ ]	*(1= Yes 2=No)*
Testes	[ ]			
Other (specify)	[ ]	[ ]		
Other (specify)	[ ]	[ ]		
Other (specify)	[ ]	[ ]		

Office use only:
Date form received: _____ Date form entered: _____ Initials: _____

UKALL14 Patient Initials [ ] NHS Number [ ]

UKALL14 Registration at Study Entry (5/9)

Haematology & Biochemistry

Test should be from date of diagnosis. If these are not available, results prior to the steroid pre-phase must be given.

Date of Haematology *(dd/mm/yyyy)* [ ][ ] [ ][ ] [ ][ ][ ][ ]

White Blood Cell (WBC) Count x10^9/L [ ][ ][ ] . [ ][ ]

Haemoglobin g/dL OR g/L (circle units) [ ][ ][ ] . [ ]

Neutrophils x 10^9/L [ ][ ] . [ ][ ]

Platelets x 10^9/L [ ][ ][ ][ ]

Is the % Bone Marrow Blasts result available at this time?

Yes [ ] Result [ ][ ][ ]

No [ ] Reason: [ ]
*1—Pending**
*2—Unobtainable***

** Please send in an anonymised diagnosis report confirming ALL. Once the diagnosis sample result is available please update this page and fax to UCL-CTC.*

*** Please send in an anonymised diagnosis report confirming ALL.*

Date of Biochemistry *(dd/mm/yyyy)* [ ][ ] [ ][ ] [ ][ ][ ][ ]

Calcium (mmol/L) [ ][ ] . [ ][ ]

Potassium (mmol/L) [ ][ ] . [ ][ ]

Phosphate (mmol/L) [ ][ ] . [ ][ ]

Urate (mmol/L) [ ][ ] . [ ][ ]

Urea (mmol/L) [ ][ ] . [ ][ ]

Creatinine (µmol/L) [ ][ ] . [ ][ ]

Creatinine Clearance (ml/min) [ ][ ] . [ ][ ]

Glucose (mmol/L) [ ][ ] . [ ][ ]

Office use only:
Date form received: _____ Date form entered: _____ Initials: _____

UKALL14 Registration at Study Entry (6/9)

Liver Function Tests

Test should be from date of diagnosis. If these are not available, results prior to the steroid pre-phase must be given.

Date of Liver Function Tests *(dd/mm/yyyy)* ☐☐ ☐☐ ☐☐☐☐

Albumin (g/L) ☐☐☐

Bilirubin (µmol/L) ☐☐☐

Alkaline Phosphatase (IU/L) ☐☐☐☐

Total Protein (g/L) ☐☐☐

Aspartate Transaminase (IU/L) ☐☐☐

Alanine Transaminase (IU/L) ☐☐☐

Gamma-glutamyltransferase (U/L) ☐☐☐

Office use only:
Date form received: _____ Date form entered: _____ Initials: _____

UKALL14 Patient Initials _____ NHS Number _____

UKALL14 Registration at Study Entry (7/9)

Medical History

Does the patient have a significant medical history or baseline symptoms? *(1=Yes, 2=No)* ☐

If yes, please complete the table below:

Enter details of all significant conditions, past or present, e.g. hypertension, allergies, including **past** malignancies.
Do **not** include **current** malignancy.
If a condition is continuing, e.g. uncontrolled hypertension, please report the CTCAE (v4.0) Grade and enter C as the end date.

	Condition Use the CTCAE (v4.0) adverse event name if possible	**Status** 1=Resolved/ Asymptomatic 2= Continuing	**Onset Date** (dd/mm/yyyy)	**End Date** (dd/mm/yyyy)	**Severity Grade** (0-4)	**Treatment Ongoing** 1=Yes, 2=No
1						
2						
3						
4						
5						
6						

Family History of Cancer

Have any of the patient's first degree relatives (mother, father, sister, brother) had cancer?
(1=Yes, 2=No) If yes, please enter details below. ☐

Relative	**Type and Site of Cancer**	**Age at Diagnosis**

Office use only:
Date form received: _____ Date form entered: _____ Initials: _____

UKALL14 Patient Initials [ ] NHS Number [ ]

UKALL14 Registration at Study Entry (8/9)

Informed Consent

This section should be completed only if all criteria on the Eligibility Checklist have been satisfied

Date Patient Information Sheet given to patient *(dd/mm/yyyy)* [ ][ ] [ ][ ] [ ][ ][ ][ ]

Version number of Patient Information Sheet [ ][ ].[ ]

Date patient signed **Part 1** of the Consent Form *(dd/mm/yyyy)* [ ][ ] [ ][ ] [ ][ ][ ][ ]

Version number of Consent Form [ ][ ].[ ]

Has the patient signed **Part 2** of the Consent Form *(1=Yes, 2=No)*
***N.B. Part 2** is not mandatory* [ ]

Date **Part 2** of the Consent Form signed *(dd/mm/yyyy)* [ ][ ] [ ][ ] [ ][ ][ ][ ]

On **Part 2** of the Consent Form, which boxes did the patient initial? [ ]
1=Only box 1, 2=Only box 2, 3=Both boxes, 4=N/A

The patient has initialled all the boxes on the consent form *(1=Yes, 2=No)* [ ]

The patient has personally signed and dated the consent form *(1=Yes, 2=No)* [ ]

The person taking consent has signed and dated the form on the same date as the patient *(1=Yes, 2=No)* [ ]

The person taking consent has been delegated this role on the delegation log *(1=Yes, 2=No)* [ ]

Name of person taking consent [ ]

Office use only:
Date form received: _____ Date form entered: _____ Initials: _____

UKALL14 Patient Initials [ ] NHS Number [ ]

UKALL14 Registration at Study Entry (9/9)

Informed Consent for Constitutional DNA

Buccal swab collection

Date Patient Information Sheet given to patient *(dd/mm/yyyy)* [ ][ ] [ ][ ] [ ][ ][ ][ ]

Version number of Patient Information Sheet: [ ].[ ]

Has the patient signed the Genetic Testing Consent Form *(1=Yes, 2=No)* [ ] *If yes, please provide details below.*
N.B. Participation is optional

Date patient signed Genetic Testing Buccal Swab Consent Form *(dd/mm/yyyy)* [ ][ ] [ ][ ] [ ][ ][ ][ ]

Version number Consent Form [ ].[ ]

The patient has initialled all the boxes on the consent form *(1=Yes, 2=No)* [ ]

The patient has personally signed and dated the consent form *(1=Yes, 2=No)* [ ]

The person taking consent has signed and dated the form on the same date as the patient *(1=Yes, 2=No)* [ ]

The person taking consent has been delegated this role on the delegation log *(1=Yes, 2=No)* [ ]

Name of person taking consent [ ]

Completed by: [ ]

Signature: [ ]

Date completed: D D M M Y Y Y Y [ ][ ] [ ][ ] [ ][ ][ ][ ]

Trial Information & Randomisation Result

(TO BE COMPLETED BY UCL CTC):

Trial Number 14[ ][ ][ ][ ]

Precursor B – cell ALL [ ]

Key:
B1 = Standard Phase 1 Induction
B2 = Standard Phase 1 Induction + Rituximab

T-cell ALL [ ]

Key:
T1 = Standard Phase 1 & 2 Induction
T2 = Standard Phase 1 & 2 Induction followed by Nelarabine

Randomised by *(UCL CTC)* [ ]

Date of Randomisation *(dd/mm/yyyy)* [ ][ ] [ ][ ] [ ][ ][ ][ ]

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