UKALL14 | Trial Number: 14 | Patient Initials:

Non-Myeloablative Conditioning Regimen (1/1)

Date started (dd/mm/yyyy) (Day –7) ☐☐ ☐☐ ☐☐☐☐

BSA (m^2) ☐ **Weight (kg)** ☐☐☐.☐

Please enter the daily dose given in the table below:

Day	Fludarabine (mg)	Melphalan (mg)	Alemtuzumab (mg)
-7			
-6			
-5			
-4			
-3			
-2			
-1			

Completed by:

Signature:

Date completed: d d m m y y y y

Please return to: UKALL14 Trial Coordinator, CR UK & UCL Cancer Trials Centre, 90 Tottenham Court Road, London, W1T 4TJ

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

UKALL14 Trial Number 14 Patient Initials

Myeloablative Conditioning Regimen (1/2)

Date myeloablative conditioning started (dd/mm/yyyy) (Day–7) ☐☐ ☐☐ ☐☐☐☐

BSA (m^2) ☐ **Weight (kg)** ☐☐☐.☐

Please enter the daily dose given in the table below:

Day	Etoposide (mg)		Cyclophosphamide (mg)		Fractionated TBI (daily dose) (cGY)
-7					
-6					
-5		**OR**			
-4					
-3					
-2					
-1					

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

UKALL14 | Trial Number: 14 | Patient Initials:

Myeloablative Conditioning Regimen (2/2)

GvHD Prevention

Did the patient receive Methotrexate for GvHD prevention? (1=Yes, 2=No) ☐

Drug	No of doses given
Methotrexate	

T-cell depletion

Was T-cell depletion considered necessary? (1=Yes, 2=No) ☐

If yes, was T-cell depletion given as recommended in the protocol? (1=Yes, 2=No) ☐

If No, please complete the table below. Please specify the day of the conditioning regimen (e.g Day –2) and the dose given)

Day	Alemtuzumab (mg)

Completed by:

Signature:

Date completed: d d m m y y y y

Please return to: UKALL14 Trial Coordinator, CR UK & UCL Cancer Trials Centre, 90 Tottenham Court Road, London, W1T 4TJ

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

UKALL14 | Trial Number: 14 | Patient Initials:

Palifermin Form (1/1)

Myeloablative Conditioning Regimen - Palifermin Randomisation:

Randomisation

Patients ≤ 40 years of age being treated with the Myeloablative Conditioning regimen. ☐

Key:
Dose of Palifermin:
P1 = Standard
P2 = Collapsed

Weight (kg) ☐☐☐.☐

Date started (dd/mm/yyyy) (Day –10) ☐☐☐☐☐☐☐☐

Date finished (dd/mm/yyyy) (Day 4) ☐☐☐☐☐☐☐☐

Please enter the daily dose given in the table below, and indicate any reduction/delay/ omission.

Day	Palifermin (µg)	Reduction[1]	Delay[1]	Omission[1]
-10				
-9				
-8				
0				
2				
4				

[1] 0=No reduction/delay/omission, 1=Neurotoxicity, 2=Hepatotoxicity, 3=Cardiotoxicity 4=Haematological Toxicity 5=Infusion-related toxicity 6=Pancreatitis 7=Patient Choice, 8=Clinician Choice, 9=Administrative, 10=Other (specify below):

Day	10 = OTHER Reason for Reduction/Delay/Omission
-10	
-9	
-8	
0	
2	
4	

Completed by:

Signature:

Date completed: d d m m y y y y

Please return to: UKALL14 Trial Coordinator, CR UK & UCL Cancer Trials Centre, 90 Tottenham Court Road, London, W1T 4TJ

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

UKALL14 | Trial Number: 14 | Patient Initials:

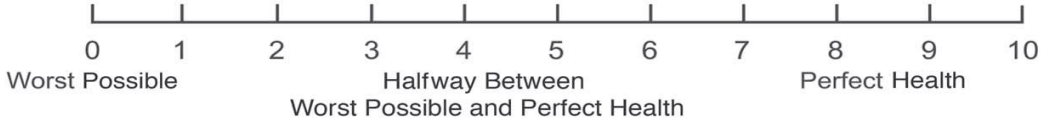
Oral Daily Mucositis Questionnaire (1/1)

ODMQ

To be completed daily by all patients receiving a myeloablative transplant, during in-patient therapy from day -12 until day 28 or date of discharge (whichever is sooner)

Date of Assessment (dd/mm/yyyy) ☐☐ ☐☐ ☐☐☐☐

1. How would you rate your OVERALL HEALTH during the LAST 24 HOURS? (*circle one number*)



2. During the LAST 24 HOURS, how much MOUTH AND THROAT SORENESS did you have? (*circle one number*)

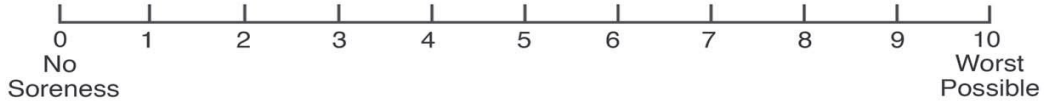
No soreness ---------- 0
A little soreness ---------- 1
Moderate soreness ---------- 2
Quite a lot of soreness ---------- 3
Extreme soreness ---------- 4

If you circled 0, please skip to question 5

3. During the LAST 24 HOURS, how much did MOUTH AND THROAT SORENESS limit you in each of the following activities? (*circle one number*)

	Not Limited	Limited A Little	Limited Some	Limited A Lot	Unable To Do
a. Swallowing	0	1	2	3	4
b. Drinking	0	1	2	3	4
c. Eating	0	1	2	3	4
d. Talking	0	1	2	3	4
e. Sleeping	0	1	2	3	4

4. On a scale of 1 to 10, how would you rate your OVERALL MOUTH AND THROAT SORENESS during the LAST 24 HOURS? (*circle one number*)

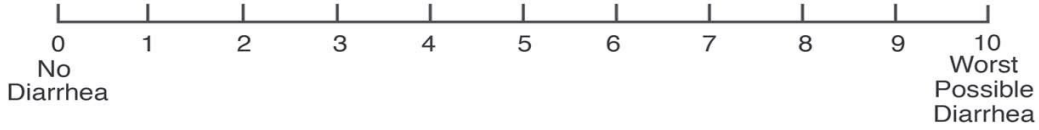


5. During the LAST 24 HOURS, how much DIARRHEA did you have? (*circle one number*)

No diarrhea ---------- 0
A little diarrhea ---------- 1
Moderate diarrhea ---------- 2
Quite a lot of diarrhea ---------- 3
Severe diarrhea ---------- 4

If you circled 0, STOP here

6. On a scale of 1 to 10, how would you rate your OVERALL DIARRHEA during the LAST 24 HOURS? (*circle one number*)



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

UKALL14 | Trial Number: 14 | Patient Initials:

Transplant Form (1/1)

Haematopoietic Stem Cell Transplant

Transplant date ☐☐ ☐☐ ☐☐☐☐

Source of stem cells

Source of stem cells
(1=peripheral blood, 2=bone marrow, 3=peripheral blood and bone marrow, 4=cord blood) ☐

Please complete the total Number of cells infused for the source of stem cells given above:

Peripheral Blood CD34+ (cells/kg) ☐☐☐

AND/OR

Bone Marrow CD34+ (cells/kg) ☐☐☐

Donor details

Type of donor
(1=sibling, 2=8/8 MUD, 3=7/8 MMUD, 4=cord blood) ☐

Donor sex (1=male, 2=female) ☐

Donor CMV status (1=positive 2=negative) ☐

Completed by:

Signature:

Date completed: d d m m y y y y

Please return to: UKALL14 Trial Coordinator, CR UK & UCL Cancer Trials Centre, 90 Tottenham Court Road, London, W1T 4TJ

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

UKALL14 | Trial Number: 14 | Patient Initials:

Day 100 Form (1/2)

Transplant Outcome

Day 100 (dd/mm/yyyy) ☐☐☐☐☐☐☐☐

Remission Status

Remission Status ☐ (1=Complete remission 2=Not in remission)

If not in remission, please complete a relapse form.

Graft versus Host Disease

Has the patient experienced GvHD post transplant? (1=Yes, 2=No) ☐

If yes above, please complete a GvHD form.

Engraftment

Neutrophil count of 0.5 x 10^9/L reached? (1=Yes, 2=No, 3=Never below this level) ☐

If Yes, please specify the date:

Date Neutrophil count reached 0.5 x 10^9/L (first of 3 consecutive days) ☐☐☐☐☐☐☐☐

IF NO, PLEASE COMPLETE A GRAFT FAILURE FORM

Platelet count of 20 x 10^9/L reached? (1=Yes, 2=No, 3=Never below this level) ☐

If Yes, please specify the date:

Date platelet count reached 20 x 10^9/L (first of 3 consecutive days) ☐☐☐☐☐☐☐☐

IF NO, PLEASE COMPLETE A GRAFT FAILURE FORM

Infection

Radiological evidence of pneumonia (1=Yes, 2=No) ☐

Please document any infections that occurred during Transplant Treatment on the AE form

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

UKALL14 | Trial Number: 14 | Patient Initials:

Day 100 Form (2/2)

Other Complications of Transplant

Did the patient experience any of the complications listed below during inpatient stay (1=Yes, 2=No) ☐

If Yes, please specify which complication below:(1=Yes, 2=No)

Veno-occlusive disease (VOD) ☐ Diffuse Alveolar Damage (DAD) ☐ Creatinine >200 ☐

Was dialysis required? (1=Yes, 2=No) ☐ Was ITU admission required? (1=*Yes, 2=No) ☐

If yes, was this EXEMPT from SAE reporting? (1=Yes, 2=No) ☐
(*See SAE reporting time frames, exemptions and flowchart in protocol section 12.2.2)

If NO, an SAE report is required

Please document any other non infection related complications that occurred during Transplant Treatment on the AE form

Discharge

Has the patient been discharged from hospital? (1=Y, 2=N) ☐

If yes above, please complete the date of discharge below

Date of discharge ☐☐☐☐☐☐☐☐

Completed by:

Signature:

Date completed: d d m m y y y y

Please return to: UKALL14 Trial Coordinator, CR UK & UCL Cancer Trials Centre, 90 Tottenham Court Road, London, W1T 4TJ

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

UKALL14 | Trial Number: 14 | Patient Initials:

GvHD Form (1/2)

GvHD Assessment

This form should be completed for each separate episode of GvHD that the patient experiences. The form should be updated as necessary until the episode resolves. (please initial and date any changes). Report separate episodes on a new form.

Date of onset of this episode of GvHD (dd/mm/yyyy) ☐☐☐☐☐☐☐☐

Has this episode of GvHD resolved? (1=Yes, 2=No) ☐

If yes, Date of resolution of this episode of GvHD: ☐☐☐☐☐☐☐☐

GvHD Assessment

Please indicate the type of GvHD ☐

1=Acute GvHD within 100 days of transplant, 2=Acute GvHD > 100 days due to DLI,
3=Chronic GvHD > 100 days after transplant , 4=Chronic GvHD arising from Acute GvHD

Please complete either the Acute or Chronic section below and the treatment section overleaf

Acute GvHD

Stage: Skin ☐ (0-4) Liver ☐ (0-4) Gut ☐ (0-4) **Maximum Grade** ☐

Chronic GvHD

Grade ☐ 1=limited, 2=extensive Platelet count less than 100 x 10^9/L ☐ 1=Yes, 2=No

Organs Affected

Skin ☐ *(0=not affected, 1=localised, 2=generalised)*

Liver ☐ *(0=not affected, 1=general dysfunction, 2=histology showing chronic aggressive hepatitis/bridging necrosis /cirrhosis)*

Lungs ☐ *(0=not affected, 1=Bronchiolitis obliterans)*

Gut ☐ *(0=not affected, 1=affected)* Mouth ☐ *(0=not affected, 1=affected)* Eyes ☐ *(0=not affected, 1=affected)*

Genitourinary ☐ *(0=not affected, 1=affected)* Other ☐ *(0=not affected, 1=affected)*

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

UKALL14 | Trial Number: 14 | Patient Initials:

GvHD Form (2/2)

GvHD Assessment

Treatment for GvHD

Please specify the treatment given below:(1=Yes, 2=No)

Topical therapy (including topical steroids)	☐	
Calcineurin inhibitors	☐	
Systemic Steroids	☐	
Pentostatin	☐	
Thalidomide	☐	
Rituximab	☐	
ECP	☐	
MMF	☐	
Other monoclonal antibody	☐	
Other (specify)	☐	

Completed by:

Signature:

Date completed: d d m m y y y y

Please return to: UKALL14 Trial Coordinator, CR UK & UCL Cancer Trials Centre, 90 Tottenham Court Road, London, W1T 4TJ

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

UKALL14 | Trial Number: 14 | Patient Initials:

Graft Failure Form (1/1)

Graft Failure

Date graft failure confirmed (dd/mm/yyyy) ☐☐ ☐☐ ☐☐☐☐

Number of days post transplant ☐☐

Please indicate the type of graft failure (1=Primary, 2=Secondary) ☐

PRIMARY GRAFT FAILURE

Day 28 Neutrophil count ☐☐.☐☐ X 10^9/L

Most recently recorded % donor chimerism:

% PMBC ☐☐ % T-cell ☐☐ % Granulocyte ☐☐

SECONDARY GRAFT FAILURE

Date primary engraftment achieved (dd/mm/yyyy) ☐☐ ☐☐ ☐☐☐☐

Date secondary graft failure recorded (dd/mm/yyyy) ☐☐ ☐☐ ☐☐☐☐

Neutrophil count at secondary graft failure ☐☐.☐☐ X 10^9/L

% donor chimerism when secondary graft failure recorded:

% PMBC ☐☐ % T cell ☐☐ % Granulocyte ☐☐

Completed by:

Signature:

Date completed: d d m m y y y y

Please return to: UKALL14 Trial Coordinator, CR UK & UCL Cancer Trials Centre, 90 Tottenham Court Road, London, W1T 4TJ

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

UKALL14 | Trial Number: 14 | Patient Initials:

Post Transplant Assessment Form (1/1)

Date of Assessment (dd/mm/yyyy) ☐☐ ☐☐ ☐☐☐☐

Assessment Month ☐☐ *6/9/12/15/18/21/24 Months post transplant*

Discharge *Please only complete for patients who had not been discharged from hospital by Day 100.*

Has the patient been discharged from hospital? (1=Yes, 2=No) ☐ *If Yes, please complete date below*

Date of discharge ☐☐ ☐☐ ☐☐ ☐☐

Patient status

Please indicate patient status (1=Alive 2=Dead) ☐

Has the patient relapsed? (1=Yes, 2=No) ☐ Has the patient been diagnosed with a second cancer (1=Yes, 2=No) ☐

Please ensure the relevant Death, Relapse or Second Cancer Form is also completed.

Donor Lymphocyte Infusion

Has the patient been given DLI? (1=Yes,2=No) ☐ **If yes, please enter DLI details below:**

Number of DLI doses given? ☐

Date DLI given (dd/mm/yyyy)	**CD3 dose/kg**	**Reason for giving DLI** *(1=mixed chimerism 2=continued or progressive minimal residual disease 3=Both)*

Graft versus Host Disease

Has the patient experienced GvHD since the last assessment? (1=Yes, 2=No) ☐

If yes, a new GvHD form should be completed for any new episodes of GvHD, ensuring any previous forms have been updated. If this episode of GvHD is ongoing from the last assessment, please ensure the current GvHD form is updated with any new information.

Completed by:

Signature:

Date completed: d d m m y y y y

Please return to: UKALL14 Trial Coordinator, CR UK & UCL Cancer Trials Centre, 90 Tottenham Court Road, London, W1T 4TJ

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