Intensification (Day 1 Intensification to the day before next treatment phase begins)

Has the patient experienced any adverse events during this treatment phase? (1=Yes, 2=No) □

Adverse Event *(Pages 1-2: Please report a maximum severity grade for all adverse events listed)*	**Maximum Severity Grade**[1] *(Grades 0-5)*	**Date of Onset** dd/mm/yyyy	**Causally related to Oncaspar?**[2]	**Causally related to Rituximab?**[2]	**Causally related to Nelarabine?**[2]	**Causally related to Palifermin?**[2]	**Outcome**[3]	**Was the event serious?**[4] *0 = No 1 = Yes 2=Yes, but SAE Report not required*
Anaemia								
Agitation								
Allergic Reaction								
Alopecia								
Anorexia								
Arthralgia								
Depression								
Diarrhoea								
Disseminated Intravascular Coagulation								
Erythema Multiforme								
Febrile Neutropenia								
Fever								

1) Enter maximum severity grade using CTCAE v4.0
2) Enter code: 0 = Not related; 1 = Unlikely; 2 = Possibly; 3 = Probably; 4 = Definitely; 5 = IMP not give prior to date of onset; 6 = >30 post IMP
3) Enter code: 0 = Fatal; 1 = Not resolved; 2 = Resolved; 3 = Resolved with sequelae; 4 = Resolving; 5 = Unknown
4) If response 1 is selected, ensure a completed SAE Report has been submitted to the UCL CTC.

Adverse Event *(Pages 1-2: Please report a maximum severity grade for all adverse events listed)*	Maximum Severity Grade[1] *(Grades 0-5)*	Date of Onset dd/mm/yyyy	Causally related to Oncaspar?[2]	Causally related to Rituximab?[2]	Causally related to Nelarabine?[2]	Causally related to Palifermin?[2]	Outcome[3]	Was the event serious?[4] *0 = No* *1 = Yes* *2=Yes, but SAE Report not required*
Headache								
Serum Amylase Increased								
Hypertriglyceridemia								
White Blood Cell Decreased								
Nausea								
Neutrophil Count Decreased								
Pruritus								
Seizure								
Skin hyperpigmentation								
Stroke								
Thromboembolic event	**If a thromboembolic event has occurred, please report on either a Thromboembolic Event Form or SAE Report as appropriate**							
Weight Loss								

1) Enter maximum severity grade using CTCAE v4.0
2) Enter code: 0 = Not related; 1 = Unlikely; 2 = Possibly; 3 = Probably; 4 = Definitely; 5 = IMP not give prior to date of onset; 6 = >30 post IMP
3) Enter code: 0 = Fatal; 1 = Not resolved; 2 = Resolved; 3 = Resolved with sequelae; 4 = Resolving; 5 = Unknown
4) If response 1 is selected, ensure a completed SAE Report has been submitted to the UCL CTC.

Infection Adverse Events Suspected or Proven *(Page 3: Please report a maximum severity grade for all infection adverse events listed below and use the blank rows to report all other infection adverse events using CTCAE v4.0 terms)*	Maximum Severity Grade[1] (0-5)	Date of onset dd/mm/yyyy	Causally related to Oncaspar?[2]	Causally related to Rituximab?[2]	Causally related to Nelarabine?[2]	Causally related to Palifermin?[2]	Outcome[3]	Was the event serious?[4] *0 = No 1 = Yes 2=Yes, but SAE Report not required*	Organism/Pathogen Involved[5] Please give Code + Pathogen name
Catheter related infection									
Device related infection									
Gum infection									
Lung infection									
Mucosal infection									
Skin infection									
Upper respiratory infection									
Urinary tract infection									
Sepsis									

5) Enter code and pathogen, if not proven, please report this as 'not done' or 'unknown' accordingly.
Bacterial: 1=Coagulase-negative staphylococcus; 2=S. pneumonia; 3=Other gram positive (i.e: other streptococci, staphylococci, listeria…); 4=Haemophilus influenza; 5=Other gram negative (i.e: E.coli, klebsiella, proteus, serratia, pseudomonas); 6=Legionella sp; 7=Mycobacteria sp; 8=Other bacterial infection
Fungal: 9=Candida sp; 10=Aspergillus sp; 11=Pneumocystis carinii; 12=Other fungal infection
Viral: 15=HSV; 16=VZV; 17=EBV; 18=CMV; 19=HHV-6; 20=RSV; 21=Other respiratory virus (influenza, parainfluenza, rhinovirus); 22=Adenovirus; 23=HBV, HCV, HIV; 24=Papovavirus; 25=Parvovirus; 26=Other viral infection

1) Enter maximum severity grade using CTCAE v4.0
2) Enter code: 0 = Not related; 1 = Unlikely; 2 = Possibly; 3 = Probably; 4 = Definitely; 5 = IMP not give prior to date of onset; 6 = >30 post IMP
3) Enter code: 0 = Fatal; 1 = Not resolved; 2 = Resolved; 3 = Resolved with sequelae; 4 = Resolving; 5 = Unknown
4) If response 1 is selected, ensure a completed SAE Report has been submitted to the UCL CTC.

Other Adverse Events *(Page 4: Please report other adverse events using CTCAE v4.0 terms)*	Maximum Severity Grade[1] *(Grades 0-5)*	Date of Onset dd/mm/yy	Causally related to Oncaspar?[2]	Causally related to Rituximab?[2]	Causally related to Nelarabine?[2]	Causally related to Palifermin?[2]	Outcome[3]	Was the event serious?[4] *0 = No 1 = Yes 2= Yes, but SAE Report not required*

FORM COMPLETED BY: **Print name:** _____ **Signature:** _____ **Date:** □□ □□ □□ □□ (*d d m m m y y*)

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

For CTC use only: Date form received: _____ Date form entered: _____ Initials: _____

1) Enter maximum severity grade using CTCAE v4.0
2) Enter code: 0 = Not related; 1 = Unlikely; 2 = Possibly; 3 = Probably; 4 = Definitely; 5 = IMP not give prior to date of onset; 6 = >30 post IMP
3) Enter code: 0 = Fatal; 1 = Not resolved; 2 = Resolved; 3 = Resolved with sequelae; 4 = Resolving; 5 = Unknown
4) If response 1 is selected, ensure a completed SAE Report has been submitted to the UCL CTC.

Completion Guidelines

Please use the form to report the maximum severity grade of all AEs occurring during the specified treatment phase.
If the patient has not experienced any AEs during a treatment phase, report this at the top of page 1; no other data are required.
Pre-existing medical conditions or baseline symptoms, i.e. if date of onset is before date of consent, do not need to be reported as AEs unless they worsen.
All AEs added to the form (not pre-printed) must be reported for subsequent treatment periods until they have resolved (grade 0 or baseline).

1) Severity Grade
- A maximum severity grade **must** be reported for all pre-printed AEs using CTCAE v4.0.
- If an AE did not occur, report "0"; no other data in that row are required.

2) Date of Onset
- Report the date the adverse event first occurred.
- If the maximum severity grade has changed since previous treatment phase, report the date the adverse event worsened or improved.

3) Causally related to…(Causality Assessment)
- Use the key at the bottom of each page to report the causal relationship to each IMP. Causality should be assessed by the PI or a co-investigator.
- Columns relating to IMPs that do not form part of this treatment phase have been greyed-out.
- Columns relating to IMPs that patients may have been given during this phase, or previous phases, must be completed. If the IMP had not been given before the AE occurred, report this as 5=IMP not given prior to the event. If the AE occurred more than 30 days after the most recent dose of IMP, report this as 6=> 30 day post IMP.

4) Was the event serious?
- If the event was serious, an SAE Report **must** be submitted to UCL CTC immediately within 24 hours of becoming aware of the SAE, unless the event does not meet the criteria for SAE reporting. Please refer to the SAE reporting time frames, exemptions and flowchart in protocol section 12.2.2.