UKALL14 Trial Number 14 Patient Initials

FAX MESSAGE

# Adverse Event of Special Interest
# Thromboembolic Event Urgent Event Form

**DATE** (dd/mm/yyyy): ☐☐ ☐☐ ☐☐☐☐

**ATTENTION:** UKALL14 TRIAL TEAM

**FAX No:** 0207 679 9861

**Number of pages (including cover sheet):** ☐☐

| | |
|---|---|
| **RESEARCH CONTACT:** | |
| **PHONE NO:** | |
| **Centre** | |
| **Patient's Consultant** | |

## Radiological Reports / Lab Results

Please submit anonymised copies of relevant tests results carried out at the time of the event. Please write the patient's initials and trial number on each page. Please indicate which reports/results are included with this fax by ticking the boxes in the table below.

| | | | |
|---|---|---|---|
| FBC | | Anti-thrombin levels | |
| PT/PTT | | Ultrasound report | |
| Fibrinogen | | Cross sectional imaging | |

**Thromboembolic events occurring outside the SAE reporting window must be reported within 7 calendar days of becoming aware of the event**

UKALL14 | Trial Number: 14- | Patient Initials:

# UKALL14 Thromboembolic Event Urgent Event Form (1/1)

**Thromboembolic events occurring outside the SAE reporting window must be reported within 7 calendar days of becoming aware of the event**

**Use this form to report venous thromboembolisms occurring outside the SAE reporting window only. (See Protocol section 12.2.2 and 12.3)**

## Adverse Event: Thromboembolic Event

| | |
|---|---|
| Most recent phase UKALL14 trial treatment started<br>1=Phase 1 Induction; 2= Phase 2 Induction; 3=Intensification; 4=Consolidation; 5=Maintenance; 6=Conditioning; 7=Transplant; 8=24 month post-SCT follow-up period | |
| Start date most recent phase trial treatment (dd/mm/yyyy) | |
| Maximum severity grade (0-5)<br>Enter maximum severity grade using CTCAE v4.0 | |
| Date of Onset (dd/mm/yyyy) | |
| Causally related to Oncaspar?[1] | Causally related to Rituximab?[1] |
| Causally related to Nelarabine?[1] | Causally related to Palifermin?[1] |
| Outcome[2] | |
| Site of thrombosis<br>1=Central Venous Catheter (specify line site); 2=Pulmonary Vein; 3=Deep Vein Thrombosis; 4=Central Nervous System; 5=Other, specify | Specify line site if applicable |
| Was the patient receiving prophylactic anticoagulants prior to the event?<br>0=No; 1-Yes | If Yes, Specify: |
| Did the patient receive any treatment for this VTE?<br>0=No; 1-Yes | If Yes, Specify: |

1) Enter code: 0 = Not related; 1 = Unlikely; 2 = Possibly; 3 = Probably; 4 = Definitely; 5=IMP not given prior to date of onset
2) Enter code: 0 = Fatal; 1 = Not resolved; 2 = Resolved; 3 = Resolved with sequelae; 4 = Resolving; 5 = Unknown

**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: _____