



UKALL14 Christmas Newsletter 2014

A randomised trial for adults with newly diagnosed acute lymphoblastic leukaemia



As you all know there have been big changes here at the CTC within the UKALL14 trial team, so thank you very much for bearing with us during the transition period. From the middle of January our team should be back up to full strength and ready to take on the new year!

I would like to extend a personal thanks to everyone for welcoming me to the UKALL14, and for all your help and support whilst I have been finding my feet.

Warm Christmas Wishes - Emma, Trial Coordinator; Tel: 0207 6799873 Email: ctc.ukall14@ucl.ac.uk

DRUG ORDERING: OVER THE CHRISTMAS PERIOD

- ◆ **RITUXIMAB**—Drug orders can be received up to 3pm on Friday 19th December and will be processed and delivered within the normal 1-2 working days.
- ◆ **NELARABINE**—Drug orders can be received up to Monday 22nd December for delivery on the 24th December.
- ◆ **PEGYLATED ASPARAGINASE** — Drug orders need to be received by Friday 19th December, and will be dispatched normally on 22nd December.
- ◆ **PALIFERMIN**— Last order date for **UK Mainland** requests for guaranteed delivery before Christmas is Thursday 18th December (Ireland was 15th Dec)

UKALL14 Christmas Top Ten !

| Site Name | Patient Accrual |
|---|-----------------|
| St Bartholomew's Hospital | 26 |
| Royal Marsden Hospital London | 21 |
| Nottingham City Hospital | 20 |
| University College London Hospital | 20 |
| Royal Hallamshire Hospital | 19 |
| St James' University Hospital | 17 |
| Belfast City Hospital | 13 |
| Christie Hospital | 13 |
| Royal Free Hospital | 13 |
| Bristol Haematology and Oncology Centre | 12 |
| Queen Elizabeth Hospital Birmingham | 12 |
| University Hospital Wales | 12 |

Safety Reporting

We have been conducting QC checks on SAEs reported for UKALL14 and have generated multiple requests to resolve and update the SAEs. We appreciate the enormous effort those of you involved have gone to in order to retrospectively look back at patient notes and fill in the gaps. We would like to extend a big thank you for assisting us in this task.

A few important points to note:

- * Careful checks of notes for patient admission and other serious adverse events must be undertaken when completing the CRFs for each phase of treatment; to avoid late reporting of SAEs
- * Remember to include non-IMP ALL treatment (e.g chemo & steroid pre-phase) on the con med page
- * All SAEs which occur between informed consent & 30 days post IMP, or 30 days post transplant (or after this date if the investigator feels there is a causal relationship to the IMP) refer to protocol section 12.2.2

Data Returns - impact of not providing data

- Please continue to send in CRFs and answer data queries within the specified timelines given - when data is not present within trial reports there is a risk of trial closure due to committees drawing the wrong conclusions
- Related papers are written throughout the trial duration, if data is not provided regularly the papers are not written.
- The IDMC have asked us to collect more detail on types of infection and organisms in infection related deaths—a new AE CRF will be coming soon to capture this data
- Death forms—please fax through within 24 hours of becoming aware of a patients death

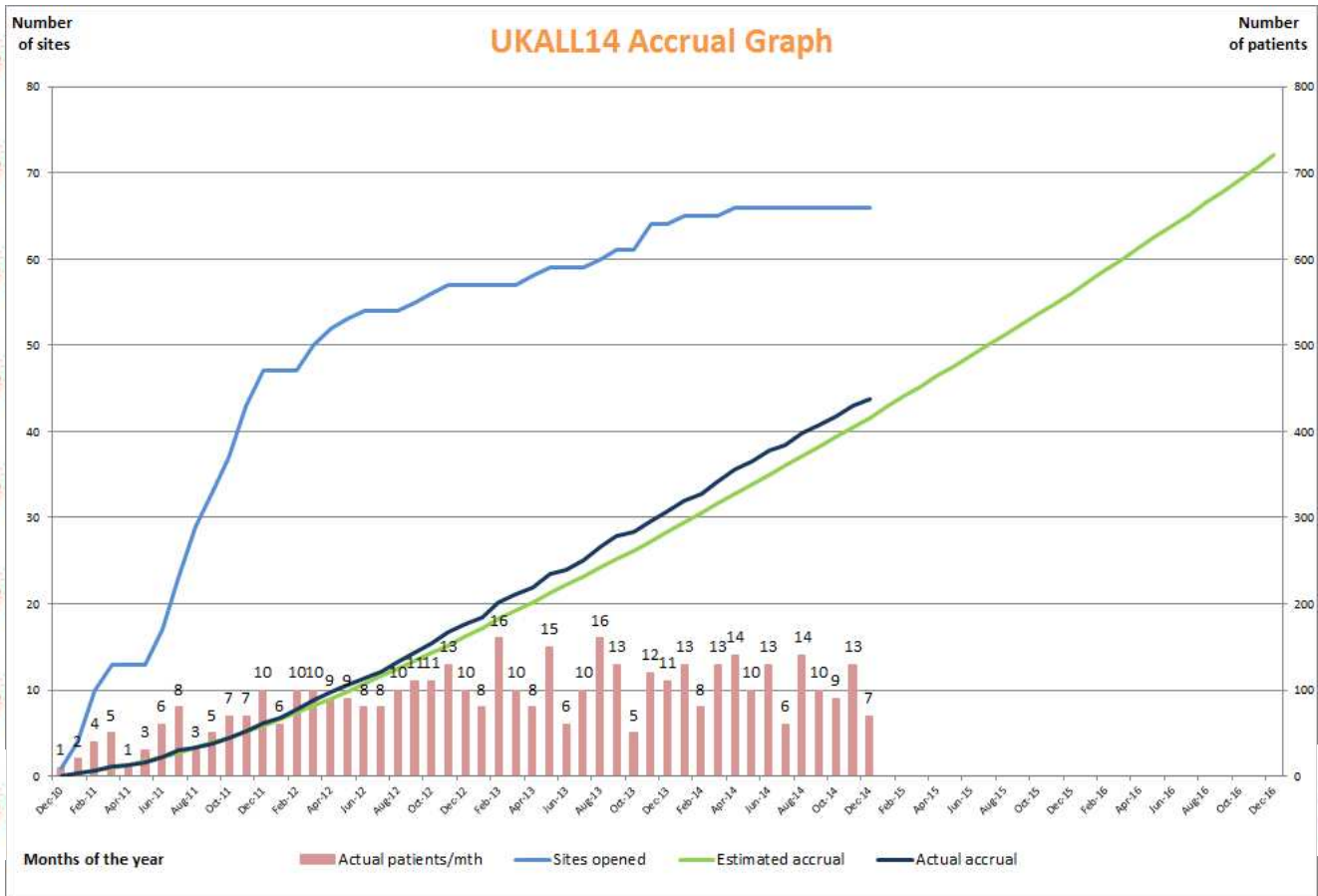
PLEASE FEEL FREE TO CALL THE UKALL14 TRIALS TEAM WITH URGENT & PRIORITY QUERIES. DUE TO THE VOLUME OF INCOMING EMAILS THERE MAY BE A DELAY TO PICKING UP AN EMAIL SO ALWAYS BEST TO FOLLOW-UP WITH A CALL

UKALL14 ARRANGEMENTS OVER CHRISTMAS & NEW YEAR

Please see the calendar below outlining the closure dates and cover for these dates at UCL-CTC.

| Monday | Tuesday | Wednesday | Thursday | Friday |
|--|--|--|-------------------------------------|--|
| 22 nd December Normal Operation 09:00-17:00 | 23 rd December Normal Operation 09:00-17:00 | 24 th December Open - limited cover 10:00-16:00 | 25 th December CLOSED | 26 th December CLOSED |
| 29 th December Open - limited cover 10:00-16:00 | 30 th December Open - limited cover 10:00-16:00 | 31 st December Open - limited cover 10:00-16:00 | 1 st January CLOSED | 2 nd January Open - limited cover 10:00-16:00 |

UKALL14 Current Accrual Graph



| Name | Position | Number/Email | Name | Position | Number |
|------------------------------------|------------------------|--|-----------------|-----------------------|---------------|
| Dr Adele Fielding | Chief Investigator | a.fielding@ucl.ac.uk | Emma Lawrie | Trial Coordinator | 0207 679 9873 |
| Prof David Marks | Transplant Coordinator | 0117 342 8523 | Pip Patrick | Snr Trial Coordinator | 0207 679 9056 |
| General enquiries & randomisations | | 0207 679 9860 | UKALL14 fax no. | | 0207 679 9861 |

| Current Documentation | Version & Date | Current Documentation | Version & Date |
|-----------------------|-----------------|---|-----------------|
| Protocol | v6.0 20/07/2014 | Registration Forms | v4.0 24/07/2014 |
| PIS | v5.1 16/06/2014 | Registration for Transplant/Maintenance | v1.0 08/12/2010 |
| Consent Form | v1.1 03/09/2010 | Drug Supply Guidelines | v2.1 25/02/2014 |



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