UKALL14

A randomized trial for adults with newly diagnosed acute lymphoblastic leukaemia

Spring Newsletter 2017

Protocol Amendment (v9.0)

Protocol v9.0 17.02.2017, has been approved and released to sites. **Please note the implementation dates are as follows: for participating NHS organisations in Northern Ireland, Scotland or Wales, 29th March; for participating NHS organisations in England, 4th April.**

The key changes are as follows:

- Recruitment has been extended to replace initial 91 patients who were treated with a different backbone chemotherapy regimen:
  - Recruit a further 78 B-cell and 13 T-cell patients (In total: B-cell = 654 & T-cell = 157).
  - This takes anticipated recruitment duration to 7.5 years. B-cell target projected to be reached by June 2017 & T-cell target projected to be reached by June 2018.
- Drug company take-overs/acquisitions reflected within protocol
- Section 7.2.10 Transplant conditioning regimens has been amended: Where patients have no features predictive of a high risk of relapse, the risks associated with a myeloablative transplant may be considered to outweigh the benefit in terms of disease control. Therefore it was agreed that we will allow these patients to remain on trial if they opt not to proceed to transplant.
- Following the move of the MRD lab from the Royal Free Hospital to UCL Cancer Institute, it is no longer possible to send chimerism samples and MRD samples to a single address. Address clarified in relevant sections.
- Further clarification added to explain the method of obtaining DNA samples for new patients in section 9.7.

Rituximab Biosimilars

We have received some queries about whether rituximab biosimilars can be used on UKALL14. Biosimilars are not permitted. Mabthera is a designated IMP, and is supplied by Roche for UKALL14 trial free of charge. Only this supplied rituximab should be used to treat trial patients.

Remember, all UKALL14 IMPs are supplied specifically for the trial, and must only be used to treat trial patients.

Current Documents

Please us know if you are missing any of the current documents listed below:

Protocol v9.0 17.02.2017
PIS v7.0 17.02.2017
PIS – Genetic Testing – Buccal Swab v1.0 09.09.2015
Pregnant Partner Information Sheet v1.0 01.08.2012
Pregnant Patient Information Sheet v1.0 01.08.2012
GP Letter v1.0 11.11.2009
Sample Request Form v3.0 09.11.2015
CRF Completion Guidelines v4.0 10.03.2016
Consent Form v1.2 29.04.2015
ICF - Genetic Testing – Buccal Swab v1.0 09.09.2015
Pregnant Partner Consent Form v1.0 01.08.2012
Pregnant Patient Consent Form v1.0 01.08.2012
Patient Contact Card v1.0 09.11.2009

CTC Website Re-launch

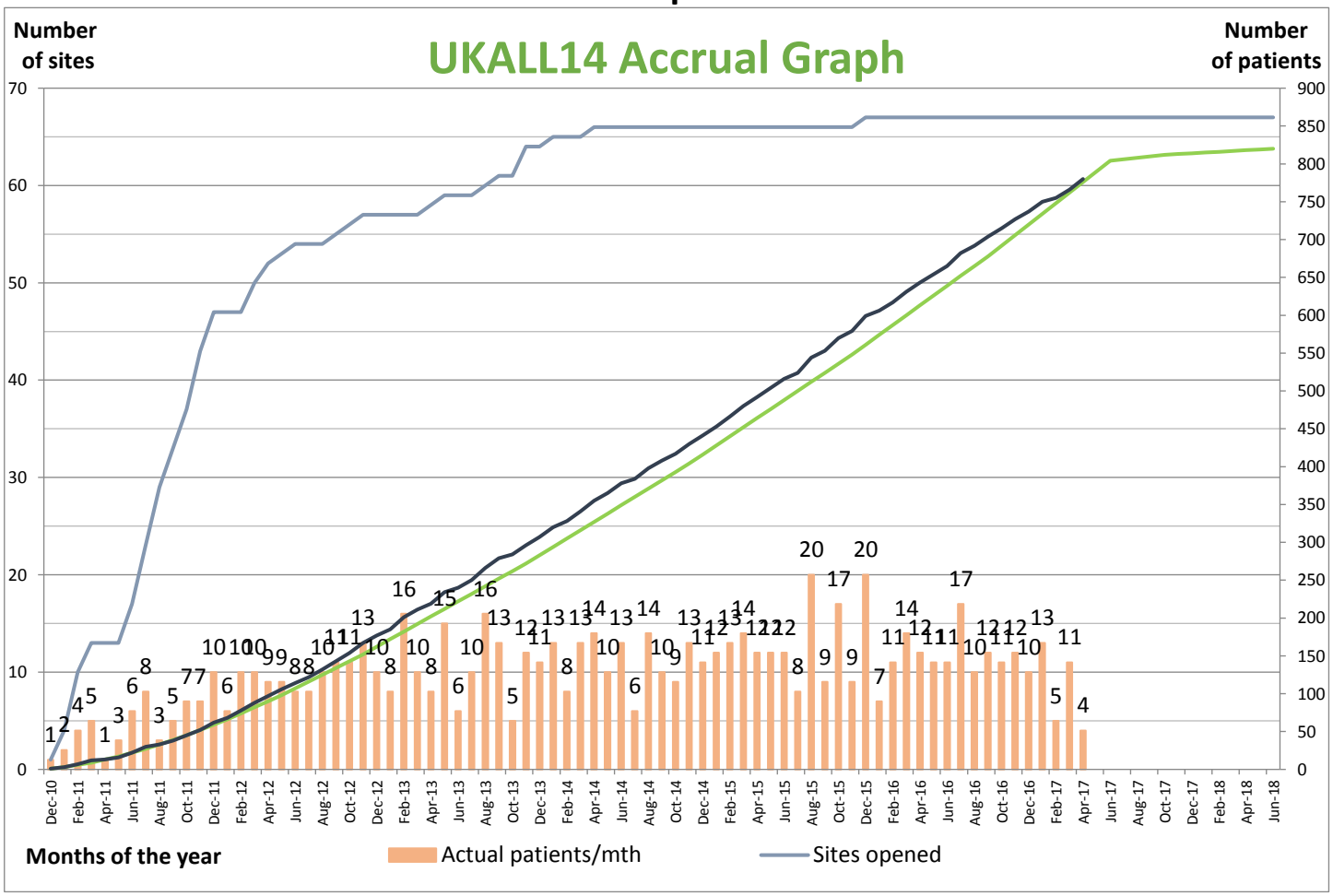
The CTC website (http://www.ctc.ucl.ac.uk) has been overhauled and given a make-over. From the end of April, the CTC website will look quite different and provide much more information to the visitor. Upon launch, users of the website no longer need specific user login details to obtain trial documents. Most documents, including those listed above, will be available on the website for you to download.

We hope you will find the website helpful and user friendly!

Recruitment

Current Recruitment: B-cell 633 *(target 654)*, T-cell 133 *(target 157)*

Number of Open Sites: 67



Thank you everyone for all your recruitment efforts!

As you can see from the accrual graph above, recruitment is ahead of the predicted accrual figures. However T-cell accrual is behind our recruitment target, and recruitment into this arm will continue after the B-cell target has been met.

As completion of the B-cell randomisation is fast approaching, we are currently in the process of amending the protocol to include a registration only option, which patients can be entered into once the B-cell and T-cell patient randomisation targets are reached. Once approved, it will allow patients to be registered on UKALL14 for minimal data collection and collection of MRD samples. Treatment will be as per the local clinician's choice, and there will be no IMPs for registration only patients.

Post Induction Treatment Allocation

Please complete and fax to UCL CTC the PITA and the Registration for Treatment (Transplant or Maintenance) Forms as soon as possible once your patient has completed Phase 2 Induction and their treatment pathway is clear. Until we receive these forms, we will not be able to help you track your patient's post-induction treatment pathway and the CRF reporting requirements.

Please note that even if the patient has transferred (or will be transferring) to another hospital for transplant, these forms must be submitted by the registering site. You may not be able to complete the whole registration form but the fax coversheet and page 1 must be completed and submitted as a minimum. We will then pass the form to the transplant site for completion and inform you once the patient has been registered.

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When to complete the Late Effects Form

The '2 year Additional Follow up Form' was renamed the 'Late Effects Form' in March 2016, but still appears as the '2yr additional follow up form' in the Overdue CRF Report.
To ensure we collect late effects data at a consistent timepoint for all patients, regardless of whether they complete trial treatment or stop treatment early, this form is to be completed ***approximately 4.5 to 5 years after study entry*** (rather than with the 2 year annual follow up visit as it was previously).
We require a Late Effects Form for all patients surviving at the 4.5 to 5 years post study entry timepoint, **even if a 2 year additional follow up form has already been submitted**. It would be helpful if Late Effects Forms could be annotated (if necessary) to make it clear if it is superseding any previously submitted '2 Year Additional Follow up' forms.
Please note that Late Effects Forms can be complete retrospectively, but the GHQ-12 questionnaires should not be. Please remember to give out the questionnaire to patients when they attend clinic 4.5-5 years after study entry.

Change of NHS email addresses

We have been informed about an upcoming change to email addresses at some NHS hospitals. Please provide us with a list of the new email addresses for your site as soon as possible to ensure that our records are up to date and reflect the current contact details for your teams.

UKALL14 Trial Team Contacts

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