UKALL14 News from The CTC trials Team
May 2015

The trial is recruiting really well and we would like to thank you all for your continued efforts.
We now have 495 patients recruited and 66 sites activated.

Since the last newsletter, we have updated many trial documents and reviewed our trial specific procedures in order to improve the ways in which we disseminate information to sites, deal with enquiries, collect missing data and resolve data discrepancies. We hope this newsletter will be helpful in clarifying the major changes as well as highlighting recurring issues with recommendations on how to solve them to make your lives (and ours) easier.

CONTAINS IMPORTANT TRIAL INFORMATION: PLEASE READ ON

CLINICAL QUERIES FROM SITES

UCL CTC receives many requests for assistance about UKALL14 from site staff involved in this complex trial. We do our best to deal with the majority of your questions but we are not clinically qualified so there are some question we are not in a position to answer. If you have questions about how best to manage the clinical care of your patients:

- Please check the protocol or supporting documents for guidance
- If there is no guidance in the protocol, please address your queries to ctc.ukall14@ucl.ac.uk and we will forward them to our clinically qualified colleagues in the Trial Management Group.

Sites must adhere to the protocol wherever possible in order to maintain the quality of the research. We recognise that protocol deviations are sometimes necessary in order to serve the patient's best interests, but any such deviations should be agreed in advance wherever possible, and the reasoning clearly explained in the CRF.

SAE REPORTING

Please remember that not every hospital admission has to be reported within 24 hours on an SAE Report form.

Before submitting an SAE, please check section 12.2.2 of the protocol to ensure that the event meets the criteria for reporting. This section specifies the reporting timeframes, lists events that are, by definition, exempt from immediate reporting, and includes a handy flowchart to help you decide what to do. Reports that do not meet the criteria for SAE reporting will be downgraded. Familiarising yourself with this section of the protocol will save you the time and effort of completing an SAE report unnecessarily.

IMPROVING OUR DATA MANAGEMENT PROCESSES

We are sure that you are all very aware that we have recently pushed hard for submission of missing CRFs and return of data queries. We are very happy to report that data return is at an all-time high of 90% CRF compliance, and the data quality has also greatly improved. Thank you again for all for your hard work.

We do appreciate that you are very busy people with many commitments in addition to UKALL14 and we are doing our best to improve our processes to ensure that:

- Fewer data discrepancies are raised
- Duplication of data queries does not happen
- Requests for trial data are directed to the correct site when a patient transfers elsewhere (eg for transplant)

To accomplish this, we have:

- Updated the UKALL14 CRFs
- Updated our registration for transplant procedure to ensure that both the diagnosing and transplant sites are aware of a patient's status on the trial, and which CRFs they are/will be responsible for completing
- Updated the system for sending out data discrepancy reports

NEW CRFs

The UKALL14 CRFs have had a major make-over; all but four of the CRFs have been updated. The new set of CRFs was circulated to sites for use from 20 April 2015; we have received acknowledgement of receipt from nearly every site now, which is much appreciated.

We are happy to report that the initial response from sites has been positive. We hope that the changes to the CRFs, along with the updated CRF Completion Guidelines (a work in progress to be circulated as soon as possible) will result in a reduction in the number of discrepancies and streamline the data collection process overall. We would be grateful for any feedback on the CRFs or completion guidelines – if something doesn't make sense, let us know and we will do our best to address the issue – we want to help make CRF completion as straightforward as possible for you!

TRANSFERRING PATIENTS TO NEW SITE

Often patients are diagnosed and initially randomised at one hospital, but their care is later transferred to another hospital (either temporarily for transplant or permanently). To effectively follow a patient through the trial and to direct requests for CRFs and data queries to the correct site, it is very important that you keep us informed when a patient transfers to a different site. Please follow these guidelines:

Transfer to new site for transplant

- Complete the Registration for Transplant Form with contact details for both the diagnosing and transplant sites
- Registration for transplant will be confirmed to both the diagnosing and transplant sites along with guidelines regarding CRF submission responsibilities
- Follow the steps below for transfer to an activated UKALL14 site
- The same steps should be followed if a patient's care is transferred back to their original site after transplant.

Transfer of care to a site activated on the UKALL14 trial

- Complete the Centre Transfer Form and submit to CTC
- On receipt, we will aim to address all outstanding data issues with the 'old' site as quickly as possible. The 'old' site is responsible for all data up to the date of transfer.
- The new site will be responsible for submission of CRFs and resolution of queries relating to visits after the date of transfer.
- Please send the new site a copy of the patient's CRF up to the point of transfer for their information. It contains data they may need for SAE reporting purposes.

Permanent transfer of care to a site not activated on the UKALL14 trial

- Please note that if a patient cannot be referred to a UKALL14 trial site, the existing site remains responsible for submitting CRFs, and will need to liaise with their new hospital in order to collect data.
- If data cannot be obtained from their new hospital, please submit the 'Lost to Follow Up' CRF, documenting the date the patient was last known to be alive, and the date they were withdrawn from trial.
- If the patient is lost to follow up within 2 years of completing trial treatment, the 'Treatment Summary' CRF must also be completed and sent.

DATA DISCREPANCIES

We are aware that there have been some issues at some sites with:

- **Duplication of data discrepancy reports**.
  We apologise wholeheartedly if this happened at your site. We do appreciate that you work hard to complete these queries and it is extremely frustrating to duplicate work when you are already over-stretched. When we generate a discrepancy report, all queries open on the database are compiled and sent to the appropriate site. The queries are closed on the database once we receive a response from site. Theoretically, data queries should not be duplicated except in the occasional event of responses from site getting lost in the post, or human error on our part in failing to close down queries. We have, however, encountered a few glitches on our database which should now be resolved. Going forward, we hope that this will not be an issue, and we would certainly expect and appreciate your feedback if this continues to be a problem.

- **Data discrepancy reports and/or requests for data sent to wrong site**.
  Our database system is able to re-direct data queries if a patient transfers to a new site (see section above) but we do require that you keep us informed when this happens (and also if a patient transfers back to the original site for follow up). The updated Registration for Transplant Forms will enable us to collect contact details for the new site and we have updated our trial specific procedures to ensure that diagnosing sites and transfer sites are copied in to correspondence relating to a trial patient, clarifying which CRFs will be due from which site. Of course, this system only works properly if you tell us who is responsible for the patient's care at any given time, by sending transfer of care forms, as outlined above.
  Please make sure that you complete this information on page 2 of version 2.0 (20Apr15) of the Registration for Transplant Form and send transfer of care forms whenever a patient's care moves to a different trial site.

TREATMENT SUMMARY FORM AND FOLLOW UP

There seems to be some confusion about the time of submission for the Treatment Summary Form and also about the schedule of follow up visits required for patients continuing on trial treatment and those who have stopped trial treatment early. Please see below for the following guidelines:

Treatment Summary Form

This form should be filled out for all patients at one of the following time points:

- At any point during the trial if trial treatment is stopped early.
- Upon completion of 24 months of maintenance therapy (for non-transplant patients).
- Upon completion of 24 months of post-transplant follow up (for transplant patients).

Please note: trial treatment is not complete until after 24 months of post-transplant follow up or 24 months of maintenance.

Annual Follow up form.

This form should be completed annually until death at the following time points:

- The anniversary of last trial treatment if trial treatment is stopped early.
- The anniversary of completion of 24 months of maintenance therapy (for non-transplant patients).
- The anniversary of completion of 24 months of post-transplant follow up (for transplant patients).

2 year additional follow up form.

- This form should be completed at the second annual follow up assessment (2 years after stopping treatment or completing maintenance, or 4 years after stem cell transplant). It contains a few additional pieces of data needed to address study endpoints.
- Please make sure you remember to give the patient the general health questionnaire to complete at this follow up visit.

NEW PROTOCOL v6.1

On 16.03.2015, we released a new protocol (v6.1 dated 27.01.2015) to sites. This should be in use at sites by now. If you have not already done so, please can you confirm receipt of this document and confirmation of required actions (as detailed in the email of 16.03.2015), either via return of email or by completion of the fax receipt attached to the email. For sites where R&D approval is required before the new protocol can be used, please ensure a copy of the R&D approval letter/email is provided to us. If your R&D has not yet approved the protocol please ask them to review it as soon as possible.

DOWNLOADING CURRENT TRIAL DOCUMENTS FROM CTC WEBSITE

Current trial documents can be downloaded from the CTC website. Please register as a user, as this is the best way for you to ensure you have the most up-to-date documents.
If you go to the UCL-CTC website http://www.ctc.ucl.ac.uk you will need to:
>Register/ >Login/ >Go to 'Trials List'/ >Find 'UKALL14' trial/ >Download documents
Please let us know if you have any trouble using this service, access should be granted within 24 hours.

THANK YOU

We hope that this newsletter will be useful in clarifying some uncertain areas, and we look forward to achieving our aims outlined within to enhance our collaborative efforts within the UKALL14 trial.

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