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UKALL14

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RE: Memorandum to Investigators and Pharmacists – 26.01.2016

In the light of some recently-identified incidents on the UKALL14 trial, we would like to remind you of the following:

Correct prescription of pegylated asparaginase

- Philadelphia positive ALL patients must not receive pegylated asparaginase during any of the treatment phases.
- Philadelphia negative patients aged ≥ 41 years at trial registration only receive one dose of pegylated asparaginase during Phase 1 induction. This is to be given on day 18. The day 4 dose must be omitted.

Please ensure that your prescription templates reflect the above information, and be extra vigilant in checking each patient's age and Philadelphia status when prescribing and dispensing pegylated asparaginase.

If any dosing errors are identified at site, UCL CTC must be informed immediately.

Ordering IMP

Sites are reminded to use the study-specific order forms to place orders for each of the IMPs:

- Rituximab
- Pegylated asparaginase
- Nelarabine
- Palifermin

Detailed guidance regarding drug ordering can be found in the UKALL14 Drug Supply Guidelines. Please ensure that any staff involved in ordering drug for UKALL14 are familiar with the Drug Supply Guidelines and aware of the location of the drug order forms.

Dispensing of supplied IMP to non-trial patients

- Trial stock must only be used to treat patients who are registered on the UKALL14 trial.
- Study drug must not be dispensed to non-trial patients. It is your responsibility to ensure that there is enough commercial hospital stock available to treat non-trial patients.

Please file a copy of this memorandum in the investigator site file and pharmacy site file, and ensure that this information is communicated to all members of your team involved in prescribing or dispensing drug for UKALL14.

Prepared by

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on behalf of the UKALL14 Trial Team