

AML15 Summary of Changes and Actions Needed FLAG-Ida Closure, 8th May 2007

Brief description of the changes

1. The Chief Investigator Professor Burnett has notified us that the FLAG-Ida arm in AML15 is to be closed.
2. This change will take effect from Tuesday 8th May 2007.
3. The non-APL induction randomisation for **adults** will be ADE v DA.
4. **Paediatric** patients can be registered at diagnosis, before induction chemotherapy commences, so that they can continue to take part in the 2nd and 3rd AML15 randomisations. Please register paediatric patients in the same way as you have previously randomised paediatric patients into AML15 by either phoning the BCTU randomisation service 0800 953 0274 or using the online system; <https://www.trials.bham.ac.uk/AML15>. Collaborators registering paediatric patients will also need to answer all of the eligibility questions, as previously. Paediatric registrations **must** take place at diagnosis before induction chemotherapy has commenced – later registration will not be permitted.
5. The amended protocol, information sheets and consent forms will be available in due course.
6. Professor Burnett has asked that all AML15 collaborators take care that the patient understands that they will not be able to enter the FLAG-Ida option.
7. Apart from the closure of the FLAG-Ida arm, all other AML15 randomisations remain the same.

Actions Needed

A new Randomisation Notepad has been produced. Please ensure this is completed for all randomisations and registrations from 8th May 2007 and a new copy is added to your site file.

Copies of the Randomisation Notepad can be downloaded from the AML15 website; <http://www.aml15.bham.ac.uk/>.