

ASAP Newsletter

Issue 5 May 2014

NIHR CRN Portfolio ID: 15318



ADJUVANT STEROIDS
IN ADULTS WITH
PANDEMIC INFLUENZA

*Much progress has been made over the last month or so in getting the ASAP trial set-up and ready to be activated in a flu pandemic. The study-wide governance checks were completed on 19th March 2014 enabling sites to now proceed with submitting their Site Specific Information (SSI) forms to their local R&D offices to obtain site approval. As advised in earlier communications, this trial is excluded from the NIHR 70-day target for recruitment of first patient. **The trial is scheduled to enter it's hibernation phase in the summer and so it is essential that R&D approval for all sites wanting to participate is obtained within the next couple of months.** We look forward to working with you further to complete the trial set-up phase to time and target.*

R&D approvals/SSIs

Congratulations to the following sites on their rapid completion and submission of their SSI forms:

Nottingham University Hospitals

Royal Berkshire Hospital—1st site to gain R&D approval on 1st May 2014 - well done to all involved!

Royal Free Hospital

We look forward to receiving R&D approval from these sites and having further sites submit their SSIs shortly.

An additional 24 SSIs have been transferred to sites for completion, with the vast majority of these actively working to complete their forms. If you have any questions please do not hesitate to contact the Trial Manager.

UPDATE ON SITE SET-UP ACTIVITIES

- Site files have now been sent out to the majority of sites. Please remember to send back the confirmation slip attached to your file.
- If you have not yet received your file please contact the Trial Manager; site selection documents are still required for a small number of sites
- A 'Core' GCP-trained team needs to be established at each site both for set-up and maintenance of the trial during the hibernation phase. As a minimum this should be the Principal Investigator, Research Nurse/Trial Coordinator and the clinical trials pharmacist. If you have not done so already, please advise us of your core team once this has been determined locally.

And Finally....

- We would like to say a big **thank you** to those sites that have been working hard to coordinate the trial set-up across all involved specialities. Cross-collaboration is really vital to ensuring the success of this trial in a flu pandemic.

Pharmacy

Sites may use their own local templates for constructing their Pharmacy File for the ASAP trial, however this must be constructed in accordance with the instructions provided in the Pharmacy Manual. A zip file containing the Pharmacy Manual and all documents required to construct your Pharmacy File is available from the Trial Manager.

Many thanks to the following sites who have already set-up their pharmacy files :

James Cook University Hospital, King's Mill Hospital, New Cross Hospital (Wolverhampton), Queen Alexandra Hospital (Portsmouth), Queen Elizabeth Hospital (Gateshead), University Hospital Coventry, University Hospital South Manchester, York Hospital

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ASAP website

<http://nuhrise.org/the-asap-trial> or type 'ASAP Flu Trial' into Google.

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