ASAP Newsletter

Issue 6 July 2014

NIHR CRN Portfolio ID: 15318

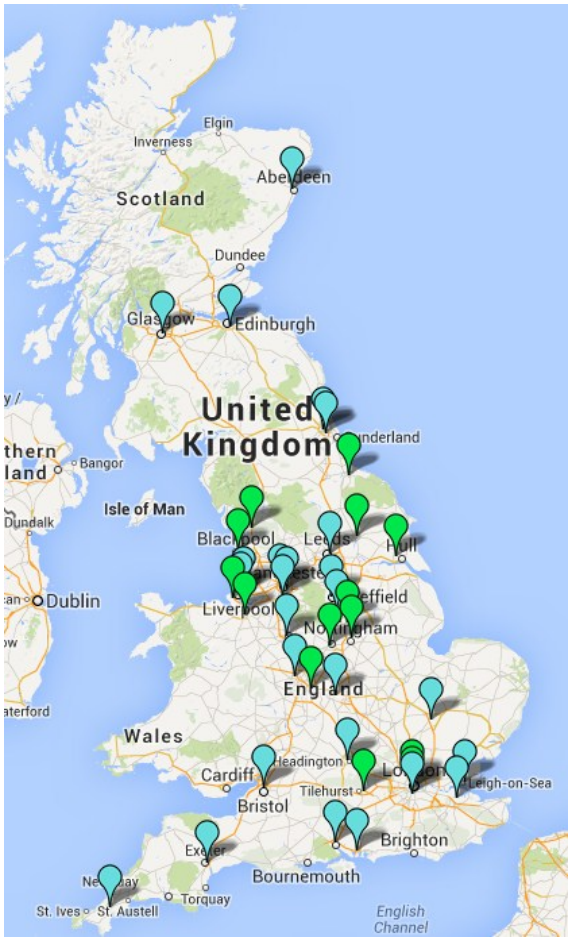
ADJUVANT STEROIDS IN ADULTS WITH PANDEMIC INFLUENZA

R&D approvals for participating sites are continuing to be granted at a steady rate and we now have a third of sites with local R&D approval in place. We are planning for the ASAP trial to enter 'hibernation' at the end of August 2014, therefore we would like to urge all sites that are still working on their local trial set-up to complete and submit their SSIs as soon as possible. Once in hibernation we will continue to provide regular trial updates to keep you informed of what is happening and will perform an annual check of all participating sites to ensure the trial is 'ready-to-go' when a pandemic strikes.

R&D Approvals

We are really pleased to report that 14 sites now have local R&D approval in place for the trial . We would like to say a massive thank you to all those involved at the following sites in helping to set up the trial:

1. ***Royal Berkshire Hospital***
   (PI: Dr Liza Keating)
2. ***Nottingham University Hospitals***
   (PI: Dr Frank Coffey)
3. ***Birmingham Heartland's Hospital***
   (PI: Dr Neil Jenkins)
4. ***Countess of Chester Hospital***
   (PI: Dr Stephen Scott)
5. ***James Cook University Hospital***
   (PI: Prof. Stephen Bonner)
6. ***Blackpool Victoria Hospital***
   (PI: Dr Jason Cuppitt)
7. ***King's Mill Hospital***
   (PI: Dr Mark Roberts)
8. ***York Hospital***
   (PI: Dr John White
9. ***Arrowe Park Hospital***
   (PI: Dr Andrew Wight)
10. ***Chelsea & Westminster Hospital***
    (PI: Dr Hannah Skene)
11. ***Royal Free Hospital***
    (PI: Dr Alison Rodger)
12. ***Royal Lancaster Hospital***
    (PI: Dr Asim Ijaz)
13. ***Castle Hill Hospital***
    (PI: Dr Gavin Barlow)
14. ***Royal Derby Hospital***
    (PI: Dr Tim Bewick)



Green = sites with R&D approval
Blue = site set-up in progress

A further 4 sites have now also submitted their SSIs and we look forward to receiving R&D approval for these sites shortly:

St. George's Hospital,
Royal Liverpool Hospital,
University Hospital Coventry
New Cross Hospital (Wolverhampton).

We are aware that the vast majority of other participating sites are actively working on trial set-up and hope that you will be able to submit your SSIs shortly to help us meet our projected aim of hibernation by the end of August. Please do not hesitate to contact the Trial Manager if you require any help or have any questions.

NOTTINGHAM CLINICAL TRIALS UNIT

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What happens next?

Once R&D approval has been granted at your site and all other required documents have been received (see checklist below) the Trial Manager will prepare a site set-up report. This will document the information which you have provided to us during the set-up phase about how you plan to operate the trial at your site once the trial is activated e.g. where you will store the study drug, location of admission points, how the drug will be prescribed (manual/electronic prescribing) etc. When this report has been completed and agreed by both parties, and all other documentation is in place, your site will be placed into hibernation until a pandemic occurs. We will be in touch regularly (approx. annually) during the hibernation phase to check if any of your procedures have changed since the initial set-up phase.

CHECKLIST FOR SITES IN SET-UP

- ‘Core’ team established (as per Trial Manual)
  - GCP/CVs required
- Confirm receipt of ISF and set-up Pharmacy File
- All involved specialities ((A&E, respiratory, critical care) on board
- Storage area(s) for study drug identified
- Complete and return:
  1) PI protocol signature page
  2) Delegation Log
- Signed site agreement (download from RDMIS)

Useful information for your SSI completion and/or local R&D review

Some useful details (in response to common questions raised by sites) which may help during your local study review are provided below:

- We advise sites NOT to localise the patient information leaflet in advance. We recommend that this be done at the point of trial activation given the potential for a lengthy hibernation period; contact details may change
- To be consistent with the trial end date reported on the ethics form, please use 01-May-2025 as the trial end date on the SSI form
- Study drug will only be sent to sites once the trial has been activated
- Temperature monitoring of the study drugs at the admission points and on the wards is not required.
- A copy of the site agreement should be downloaded from RDMIS; the financial schedule is contained within this.
- Remember, an example SSI is available to help you

Contact Details

Trial Manager—Clare Brittain
✉ asap@nottingham.ac.uk
☎ 0115 884 4952

Chief Investigator—Dr Wei Shen Lim
✉ weishen.lim@nuh.nhs.uk
☎ 0115 9691169 ext 59347

ASAP website http://nuhrise.org/the-asap-trial or type ‘ASAP Flu Trial’ into Google.

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