

ASAP Newsletter

Issue 2, October 2013, Page 1 of 2

NIHR CRN Portfolio ID: 15318



ADJUVANT STEROIDS
IN ADULTS WITH
PANDEMIC INFLUENZA

*There have been some major developments in the trial since the last newsletter was issued; we are delighted to report that the trial has received **MHRA approval** and a provisional opinion has also been received from the Ethics Committee. We were extremely encouraged by the Ethics Committee's response to the trial and their recognition of the difficulties associated with conducting the trial during a pandemic. As a result, the Ethics Committee recommend that participants that have capacity to consent give **VERBAL CONSENT WITHOUT ANY REQUIREMENT FOR WRITTEN CONSENT**. This is a major breakthrough for the trial and echoes the opinions that we have heard during the various Patient and Public Involvement sessions which we have held to consult the public on this issue.*

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ASAP website

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

Frequently asked questions (FAQs)

A FAQs document has now been placed on the trial website containing answers to the most commonly raised questions. We will continue to update this document as required.

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Trial News

Ethics & Regulatory

- MHRA approval obtained 11th September 2013
- Ethical Review Meeting (South Central—Oxford C REC) took place on 27th September 2013
 - ◇ Protocol and information sheets are being updated and the response is in progress. We anticipate full approval by the end of the month.

CSP/Portfolio

- The trial is proceeding through NIHR CSP
- Trent CLRN are leading; study-wide review is in progress
- Study has been added to NIHR CRN Portfolio (ID: 15318)
<http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=15318>

Site Visits

- Given the unique nature of the ASAP trial, we have started to arrange visits to some sites to discuss and work through the challenges of conducting pandemic flu research.
 - ◇ We hope that the feedback from these visits will help improve the study procedures and provide helpful suggestions for other participating sites.
- The first visits took place on Friday 11th October with members of the Trial Management Group meeting with the research staff at **King's Mill Hospital** and **Royal Derby Hospital** — *we would like to thank staff at both these sites* for spending time talking to us, showing us around their flu admission points and offering suggestions for improvements to trial documentation.

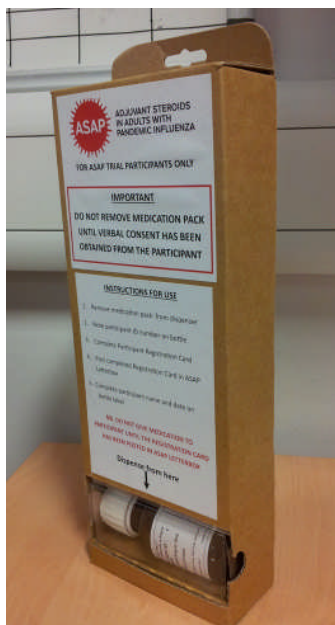
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IMP Treatment Packs

ASAP dispensing cartons contain 6 IMP treatment packs (1 per participant). A draft of the dispensing carton is shown in the picture opposite. Dispensing cartons will need to be distributed from the main pharmacy to the flu admission points. **Please note these will only be delivered to sites once the trial has been activated.**

PLEASE NOTE THAT TEMPERATURE MONITORING AT THE ADMISSION POINTS IS NOT REQUIRED; THIS HAS BEEN APPROVED BY THE MHRA.

Randomisation of participants should be quick and simple. Following verbal consent:

- Remove IMP treatment pack from dispensing carton
- Complete Participant Registration Card—the IMP treatment pack will contain the Participant's ID number
- Post completed Registration Card in ASAP Letterbox (this will be provided by the Trial Office) next to dispensing carton
- Complete participant name and date on bottle label

Local R&D approval/SSI submissions

- Local R&D approval is being sought in advance of a pandemic .
- Once approvals have been obtained, the trial will be placed in 'hibernation' until activated.
- An example SSI will be provided by the NCTU with the site staff roles required for conducting the trial.
- Sites that have returned all feasibility documents and have been approved by NCTU for the trial may begin to draft their SSI applications for local R&D approval.
- Please notify the Trial Manager of the contact person for SSI completion at your site.

Find out more about ASAP at the BTS Winter Meeting

If you would like to find out more about the ASAP trial, the Chief Investigator Dr Wei Shen Lim will be giving a talk about the trial together with an update on the progress of the trial set-up. The talk will be given on the first day of the British Thoracic Society (BTS) Winter meeting:

Date/Time: 4th December 2013 3-4pm.

Venue: Queen Elizabeth II Conference Centre, London.

Look out for further details in the next ASAP Newsletter.

Site Feasibility Questionnaires

Many thanks to the following sites who have returned **both** their site selection and pharmacy questionnaires:

| | |
|----------------------------------|----------------------|
| Arrowe Park Hospital | Castle Hill Hospital |
| Countess of Chester Hospital | King's Mill Hospital |
| New Cross Hospital | Norfolk & Norwich |
| Queen Alexandra Hospital, Cosham | QE, Gateshead |
| Royal Berkshire Hospital | Royal Derby Hospital |
| Royal Devon & Exeter | Royal Free Hospital |
| Royal Lancaster Infirmary | St James' |
| Wythenshawe Hospital | York Hospital |

- A further 27 sites have returned part of the required documents: **We would be grateful if you could please return all completed documents as soon as possible.**

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