

# ASAP Newsletter

Issue 3, January 2014

NIHR CRN Portfolio ID: 15318



ADJUVANT STEROIDS  
IN ADULTS WITH  
PANDEMIC INFLUENZA

*I would firstly like to apologise for the lack of contact recently regarding the progress of the ASAP trial set-up. Unfortunately we encountered some unexpected issues before Christmas and the trial team have been working hard to resolve these. Following the positive response from the Ethics Committee on the use of verbal consent in this important public health emergency research study advice was later received reversing this approval. The latest recommendation after discussions with the MHRA, HRA and NIHR is that written consent will be required prior to enrolment to accord with current legal requirements. The trial team have therefore been working to agree a simple approach using written consent; trial documentation is being amended and this will be submitted shortly for MHRA and REC approval. We will of course keep you informed once full approval has been granted for a second time!*

## Contact Details

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### ASAP website

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

## Site Feasibility Questionnaires

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

Arrowe Park Hospital	Birmingham Heartland's Hospital
Blackpool Victoria Hospital	Castle Hill Hospital
Chelsea & Westminster	City General Hospital, N. Staffs
Countess of Chester Hospital	James Cook University Hospital
John Radcliffe Hospital	King's Mill Hospital
New Cross Hospital	Norfolk & Norwich
Queen Alexandra Hospital, Cosham	QE, Gateshead
Royal Berkshire Hospital	Royal Cornwall
Royal Derby Hospital	Royal Devon & Exeter
Royal Free Hospital	Royal Hallamshire Hospital
Royal Lancaster Infirmary	St James Hospital, Leeds
Sunderland Royal	University Hospital Coventry
Worcestershire Royal	Wythenshawe Hospital
York Hospital	

A further 10 sites have returned part of the required documents and additional sites have expressed an interest: **We would be grateful if you could please return all completed documents as soon as possible.**

## SSI submissions

Due to the unforeseen issues encountered with the consent process we were unable to begin the process of transferring SSIs to sites as advised in our last newsletter.

- SSIs will be transferred to sites once revised study documents have been submitted to the MHRA and REC
- Guidance on the completion of the SSI will be issued to all sites

## Pandemic Studies: Co-enrolment

A number of queries have been raised by sites regarding co-enrolment into other pandemic studies; **the Chief Investigators of the following pandemic studies have all agreed that co-enrolment is permitted:**

### PAINTED

ISARIC biological sampling study

MRC FLU 003 study

ASAP trial

**These studies should not be viewed as being in competition with each other but as complementary.**