

ASAP Newsletter

Issue 7 August 2015

NIHR CRN Portfolio ID: 15318



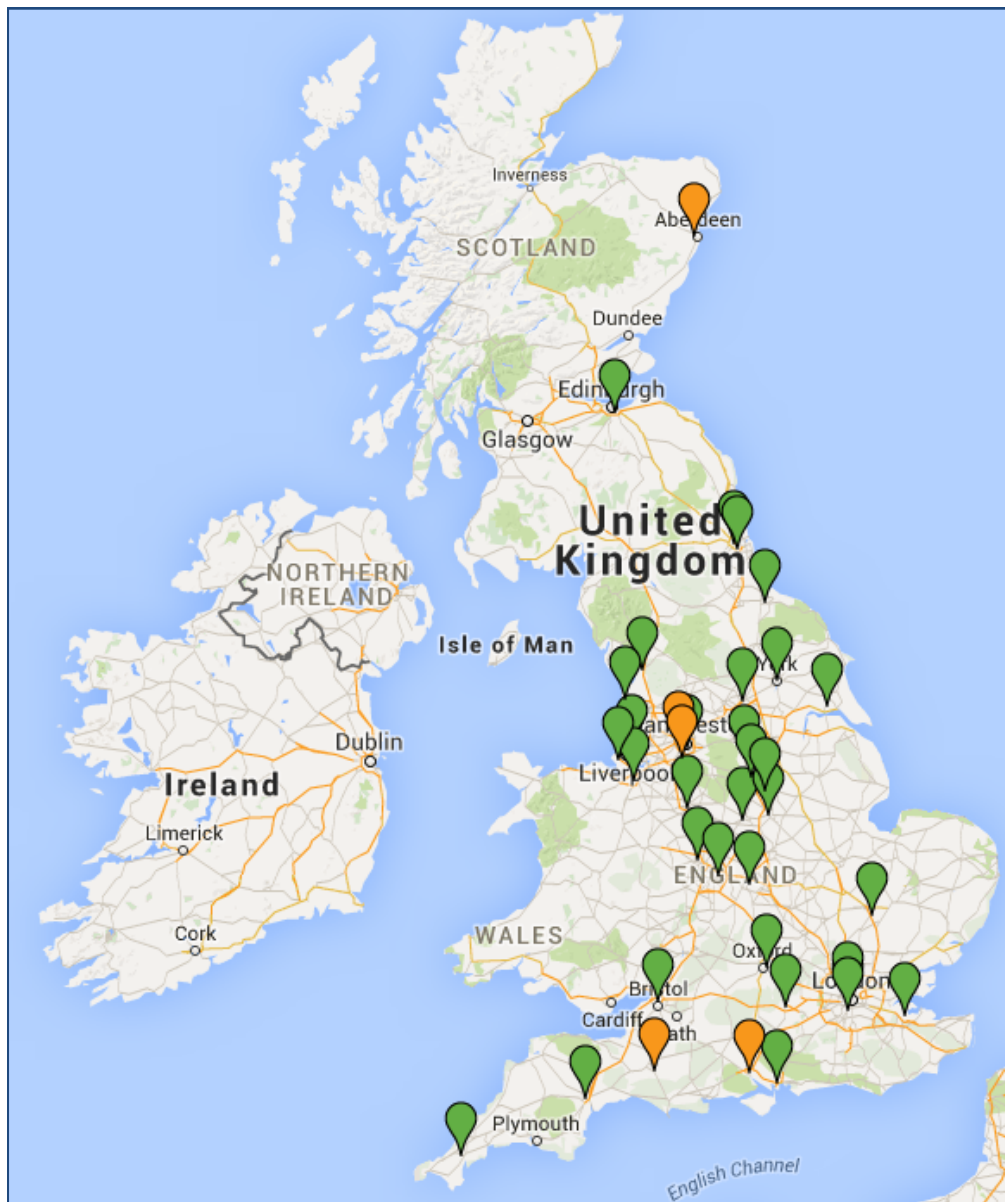
ADJUVANT STEROIDS
IN ADULTS WITH
PANDEMIC INFLUENZA


The trial is now in hibernation!


The ASAP trial has now officially entered its hibernation phase! Thank you to everyone for all their hard work in helping us reach this stage. The hard work now continues to maintain sites during this phase of the trial.

R&D Approvals

We are really pleased to report that **34** sites now have local R&D approval in place for the trial, details of these sites are shown overleaf. Despite being in hibernation, we are continuing to work hard to obtain the final few site approvals.



 Sites with R&D approval

 Sites still awaiting R&D approval

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Thank you to all involved staff at the below sites for working hard to coordinate your R&D approval!

- The Royal Berkshire NHS Foundation Trust**
Dr Liza Keating
- Nottingham University Hospitals NHS Foundation Trust**
Dr Frank Coffey
- Heart of England NHS Foundation Trust**
Dr Neil Jenkins
- Countess of Chester Hospital NHS Foundation Trust**
Dr Stephen Scott
- South Tees NHS Foundation Trust**
Prof. Stephen Bonner
- Blackpool Teaching Hospitals NHS Foundation Trust**
Dr Jason Cupitt
- Sherwood Forest Hospitals NHS Foundation Trust**
Dr Mark Roberts
- York Teaching Hospitals NHS Foundation Trust**
Dr John White
- Wirral University Teaching Hospitals NHS Foundation Trust**
Dr Andrew Wight
- Chelsea and Westminster Hospital NHS Foundation Trust**
Dr Hannah Skene
- The Royal Free London NHS Foundation Trust**
Dr Alison Rodger
- University Hospitals of Morecambe Bay NHS Foundation Trust**
Dr Asim Ijaz
- Hull and East Yorkshire Hospitals NHS Trust**
Dr Gavin Barlow
- Derby Hospitals NHS Foundation Trust**
Dr Tom Bewick
- University Hospitals of North Midlands NHS Trust**
Dr Mohammed Harris
- Royal Cornwall Hospitals NHS Trust**
Dr Jonathan Paddle
- St George's University Hospitals NHS Foundation Trust**
Professor Emma Baker
- University Hospitals Coventry and Warwickshire NHS Trust**
Dr Magdy Sakr
- Gateshead Health NHS Foundation Trust**
Dr Helen Curtis
- Royal Liverpool and Broadgreen University Hospital NHS Trust**
Dr Andrea Collins
- The Newcastle-upon-Tyne Hospitals NHS Foundation Trust**
Dr Ashley Price
- Leeds Teaching Hospitals NHS Trust**
Dr Jane Minton
- The Royal Wolverhampton Hospitals NHS Trust**
Dr Andrew MacDuff
- Portsmouth Hospitals NHS Trust**
Dr Anoop Chauhan
- Central Manchester University Hospitals NHS Foundation Trust**
Dr Mark Woodhead
- Oxford University Hospitals NHS Foundation Trust**
Dr Matthew Scarborough
- Chesterfield Royal Hospital NHS Foundation Trust**
Dr Anthony Darby
- Royal Devon and Exeter NHS Foundation Trust**
Dr Bip Patel
- Kent and Medway NHS and Social Care Partnership Trust**
Dr Alasdair Stewart
- Sheffield Teaching Hospitals NHS Foundation Trust**
Professor David Dockrell
- Cambridge University Hospitals NHS Foundation Trust**
Dr Raz Mahroof
- Aintree University Hospitals NHS Foundation Trust**
Dr Rob Parker
- North Bristol NHS Trust**
Dr Nick Maskell
- NHS Lothian**
Dr Adam Hill

**NOTTINGHAM
CLINICAL
TRIALS
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Hibernation Phase Checks

During the hibernation phase of the trial, the ASAP trial team will be carrying out annual checks of each site, in order to ensure that all information and documentation is up to date in anticipation of trial activation. The following information will be checked:

- | | |
|--|---|
|  Core staff details |  IMP storage at admission points |
|  CV and GCP updates |  Prescribing procedure established |
|  Delegation log check |  TTO procedure established |
|  Lead clinicians identified at admission points |  Current Pandemic Flu Plan |
|  Access to trial database | |

We will require a prompt response to all hibernation phase checks!

Dummy Site Activation

In order to ensure trial resilience, the decision has been made to carry out several dummy site activations annually to test the trial procedures, documents and systems that have been put in place. Our first dummy activation is scheduled to take place in October 2015 at Derby Hospitals NHS Foundation Trust. Thank you to Dr Tom Bewick and the team for agreeing to be our first test subjects!

Training Material

An online training package has been developed for both clinical and pharmacy staff, we plan to release these to sites over the coming months. They will be available directly through the ASAP website. We request that all Core Team members complete an annual refresher of this training during throughout hibernation.

New ASAP Website Launch!

The ASAP trial team have been working hard to develop a new ASAP website. This website will give you access to:

- Background information
- Current version of ASAP documents
- ASAP newsletters
- Training Material
- Pharmacy/IMP information and documentation
- Relevant publications
- ASAP trial contact information

Please take time to visit our website at:

www.asaptrial.org

**NOTTINGHAM
CLINICAL
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UNIT**



ASAP Mechanistic Sub-Study

Approval has now been granted for the ASAP sub-study. The sub-study aims to address the following key questions in the treatment of influenza:

- A) For each patient, what was the point in the natural history of influenza infection at which admission occurred?
- B) What effect does steroid have on the natural history of influenza infection defined by clinical phenotype and RNA transcriptomic pattern?
- C) Does comparison of the transcriptomic pattern in placebo versus steroid treatment arm suggest pro-inflammatory mechanisms are both altered?

The mechanistic sub-study will recruit a total of 200 ASAP trial participants from the below sites **ONLY**:

Aintree University Hospital, Liverpool

City Hospital, Nottingham

Manchester Royal Infirmary

Queen's Medical Centre, Nottingham

Royal Liverpool University Hospital

Southampton General Hospital

We will be working closely with the above sites to ensure that logistics are in place for conducting the sub-study.

IMP/Placebo

- All IMP/Placebo packaging has been finalised.
- ASAP placebo/IMP has now been manufactured by Rosemont® and is ready for distribution upon activation.
- Further details will be provided in our next newsletter.

Contact Details

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ASAP website

www.asaptrial.org