



REMAP-CAP

AUTUMN NEWSLETTER

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ISSUE 16

Reminders & Updates

UKCCRG Conference

We look forward to seeing many of you at UKCCRG. Prof Tony Gordon will be giving an update from the NIHR on day 1 at **09:35** and a REMAP-CAP update on day 1 at **14:20**.

Protocol v4.0 transition

We have now transitioned 37 sites to protocol v4.0, thank you for all your hard work! There are only 10 sites left to transition. After 31st August 2026 sites will no longer be able to recruit to protocol v3.1.

Any staff at transitioned sites that have not completed their training have been locked out of the database until this is completed.

Flu Season

Ahead of the next flu season we will be holding a refresher session. An invite will be sent out soon. Please come along and ask any questions!

Influenza Antiviral Domain

The antiviral domain has now been switched back on for all sites. The following changes have been made following the recent Oseltamivir results:

- **Severely ill adults/adolescents:** only open to baloxavir day 1 and 4, and 'no treatment'. **We encourage sites to take part to help us get an answer!**
- **Moderately ill adults/adolescents:** no longer open to 10 day options
- **Paediatrics** - no changes, available interventions remain as they are

Site Versioning

The site version number on the PIS/CFs should start at v1.0 for each amendment with the date of localisation. If any changes are made to the same PIS/CF version (e.g. the PI changes, a contact number changes) the version number should then be updated to v2.0.

Substantial Amendment 45

Substantial AM45 will be submitted soon which includes:

- 5 year extension until December 2031
- Closure of IG domain & removal from PIS/CFs
- Exemption for trial labelling of IMP from hospital stock
- Protocol v4.1
- Updated SmPCs

Website

We are aware there are issues with the documents page on the website and we're working hard on a solution.

Training

We are developing shorter training modules specific to certain roles on the trial. We hope this will make training new staff quicker and easier.

Recruitment

491 flu patients recruited!

