



UK REMAP-CAP Management Team

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Re: Multi-factorial, Adaptive Platform Trial for Community Acquired Pneumonia (REMAP-CAP)

REC reference: 18/LO/0660

EudraCT number: 2015-002340-14

IRAS project ID: 237150

Substantial Amendment 44 (AM044)

Dear MHRA

On the 20th March 2026 we informed you of some planned protocol changes to the REMAP-CAP trial. We then proceeded to submit Am44 to the REC and believed also to have submitted to the MHRA at the same time. However, there appears to have been an error and Am44 was not received by the MHRA - this came to light on 15th June. After discussing with Louisa (senior safety officer from the MHRA) we have been asked to submit this as a modification at present.

Our independent Data and Safety Monitoring Board (DSMB) had recommended in mid-March that we close recruitment to the oseltamivir interventions (5 and 10 days) in critically ill adults, as these have been reported as inferior in critically ill adult patients.

The International Trial Steering Committee (ITSC) agreed with this recommendation, and we have closed the following interventions in the **severe state only (critically ill adults)**:

- Oseltamivir 5 days duration
- Oseltamivir 10 days duration

As per the attached letter, the ITSC recommended that for participants in the severe state who had been allocated to one of these interventions, administration should discontinue. We are still working to analyse and report the full data in a peer-reviewed manuscript as soon as possible.

Our results have shown monotherapy of oseltamivir in severe patients is ineffective, and until we have more information, we also propose that we pause the combination of interventions (oseltamivir & baloxavir) in severe state adult patients (critically ill).

Separate to this, as 10 days of oseltamivir is not a typical treatment for moderately ill adults on the ward, as they do not remain in hospital long enough to receive this, we believe this option is redundant, and we plan to continue to pause this in adults in the moderate state.

We paused recruitment to the whole domain while we updated our patient information sheets. After discussion with our PPI group, they fed back to us that it was important that we should include this emerging information as part of our consent process, which we completed. The REC provided their favourable opinion for this on 24th April.

The following has been added in the adult/paediatrics full PISs, in the treatment section:

‘In this trial we have found Oseltamivir to be ineffective in seriously ill adult patients in ICU and it is possibly associated with worse outcomes. However, it has been shown to help patients outside of hospital who are mildly ill feel better more quickly. We currently don’t know its effect on moderately ill adult patients in general wards, or its effects in children.’

We have attached the full PIS/CFs for adults and paediatrics for reference.

We look forward to hearing from you and please do not hesitate to contact us if you need any further information.

Kind regards

Aisha

Submitted documents:

Document Title	Version
Modification Tool_237150_SA044 to MHRA	V2.1, 24.04.2026
REMAP-CAP letter to sites - Pause of Influenza Antiviral Domain - 14 MAR 2026	14.03.2026
REMAP-CAP-PIS-ICF-UK-v4.1 22.04.2026_TC	V4.1, 22.04.2026
REMAP-CAP-PerLRIS-ICF-v4.1-22.04.2026_TC	V4.1, 22.04.2026
REMAP-CAP-ChildrenYoungPpl 0-17-PIS-ICF-v4.1-22.04.2026_TC	V4.1, 22.04.2026