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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 REC and MHRA

On the 20th March 2026 we informed you both of some protocol planned changes to the REMAP-CAP trial.

We would now like to formalise these changes and submit an amendment which includes updated consent forms. Our independent Data and Safety Monitoring Board (DSMB) has recently recommended that we close recruitment to the oseltamivir interventions (5 and 10 days) as they have been reported as inferior in critically ill adult patients.

The International Trial Steering Committee (ITSC) have agreed with this recommendation, and we have now 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 recommends that for participants in the severe state who have been allocated to one of these interventions, administration should discontinue. We are working to analyse and report the full data 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 interventions in severe state patients (critically ill).

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

We have currently paused recruitment to the whole domain while we update 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 have now completed.

We are submitting these revised documents to you for review, as described in the amendment tool. The following has been added in the adult/paediatrics full PISs, in the section where side effects are described:

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

Best wishes

Janis

Submitted documents:

Document Title	Version
Amendment tool: 237150_SA044	v1.8, 31.03.2026
REMAP-CAP letter to sites - Pause of Influenza Antiviral Domain - 14 MAR 2026	14.03.2026
REMAP-CAP-PIS-ICF-UK-v4.0 25.03.2026_TC	v4.0 25.03.2026 TC
REMAP-CAP-PIS-ICF-UK-v4.0 25.03.2026_clean	v4.0 25.03.2026 clean
REMAP-CAP-PIS-Sum-ICF-v4.0-25.03.2026_TC	v4.0 25.03.2026 TC
REMAP-CAP-PIS-Sum-ICF-v4.0-25.03.2026_clean	v4.0 25.03.2026 clean
REMAP-CAP-PerLRIS-ICF-v4.0-26.03.2026_TC	v4.0 25.03.2026 TC
REMAP-CAP-PerLRIS-ICF-v4.0-26.03.2026_clean	v4.0 25.03.2026 clean
REMAP-CAP-PerLR-Sum-ICF-v4.0 25.03.2026_TC	v4.0 25.03.2026 TC
REMAP-CAP-PerLR-Sum-ICF-v4.0 25.03.2026_clean	v4.0 25.03.2026 clean
REMAP-CAP-Patient-Video-CF-v4.0-25.03.2026_TC	v4.0 25.03.2026 TC
REMAP-CAP-Patient-Video-CF-v4.0-25.03.2026_clean	v4.0 25.03.2026 clean
REMAP-CAP-PerLR-Video-CF-v4.0-25.03.2026_TC	v4.0 25.03.2026 TC
REMAP-CAP-PerLR-Video-CF-v4.0-25.03.2026_clean	v4.0 25.03.2026 clean
REMAP-CAP-ProLR-Sum-ICF-v4.0-25.03.2026_TC	v4.0 25.03.2026 TC
REMAP-CAP-ProLR-Sum-ICF-v4.0-25.03.2026_clean	v4.0 25.03.2026 clean
REMAP-CAP-Tel-CF-v5.0-25.03.2026_TC	v5.0 25.03.2026 TC
REMAP-CAP-Tel-CF-v5.0-25.03.2026_clean	v5.0 25.03.2026 clean

REMAP-CAP-ChildrenYoungPpl 0-17-PIS-ICF-v4.0-25.03.2026_TC	v4.0 25.03.2026 TC
REMAP-CAP-ChildrenYoungPpl 0-17-PIS-ICF-v4.0-25.03.2026_clean	v4.0 25.03.2026 clean
REMAP-CAP-ChildrenYoungPpl 0-17-ProLR-Sum-ICF-v4.0-25.03.2026_TC	v4.0 25.03.2026 TC
REMAP-CAP-ChildrenYoungPpl 0-17-ProLR-Sum-ICF-v4.0-25.03.2026_clean	v4.0 25.03.2026 clean
REMAP-CAP-ChildrenYoungPpl 0-17-Video-CF-v4.0-25.03.2026_TC	v4.0 25.03.2026 TC
REMAP-CAP-ChildrenYoungPpl 0-17-Video-CF-v4.0-25.03.2026_clean	v4.0 25.03.2026 clean
REMAP-CAP-ChildrenYoungPpl 0-17 Tel-CF-v4.0-25.03.2026_TC	v4.0 25.03.2026 TC
REMAP-CAP-ChildrenYoungPpl 0-17 Tel-CF-v4.0-25.03.2026_clean	v4.0 25.03.2026 clean

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