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Re: Study Title: Randomized, Embedded, Multi-factorial, Adaptive Platform Trial for community - Acquired Pneumonia

REC reference: 18/Io/0660

EudraCT number: 2015-002340-14

IRAS project ID: 237150

Substantial amendment 26 (AM02) Expedited Approval

I am submitting substantial amendment AM026 for the REMAP-CAP study.

This involves the addition of the RECOVER funding agreement (since the PREPARE agreement funding ended).

The addition of the DMX-200 intervention (ACE2/RAS domain) to the Participant information sheets as well as the addition of DMX-200 documentation

ACE2 RAS domain

The addition of the ACE2 / RAS domain specific appendix was part of AM025.

Within the current ACE2 RAS domain specific appendix there is the DMX-200 intervention, a chemokine receptor-2 (CCR2) inhibitor that can be used in combination with an ARB.

DMX-200 is a novel drug that will be supplied as a clinical trial IMP with clinical trial labelling.

This intervention is now being added as part of AM026.

I have also made the below changes to the MHRA CTA.

We added 1 IMP product to the MHRA CTA:

DMX-200

Many Thanks

Farah

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