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

REC reference: 18/lo/0660

EudraCT number: 2015-002340-14

IRAS project ID: 237150

Substantial amendment 24 (AM024) Expedited Approval

I am submitting substantial amendment AM024 for the REMAP-CAP study.
I have made the below changes to the MHRA CTA.

We are adding 1 IMP product to the MHRCTA

1. The addition of Pascorbin (ascorbic acid).

The manufacturer, PASCOE provides the SmPC. The product will be provided with clinical trial labels (submitted to MHRA), GMP certification and QP declaration / Mawdsleys service summary.

Mawdsleys is the Importer and Manufacturer (to allow stock to be brought over from Germany and to cover the secondary activities and final QP) as well as the Sub-contractor for storage and distribution activities.

The label text has been agreed and has been submitted alongside the updated MHRA CTA to receive MHRA approvals. Mawdsleys have provided a service summary document which will detail Mawdsleys responsibilities and the exact label text which is to be applied to the product. Pascorbin will be supplied to trial sites through PHE authorised distribution sites.

Many Thanks

Farah

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