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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 33 (AM03) Expedited Approval

I am submitting substantial amendment AM033 for the REMAP-CAP study.

This involves:

Addition of UK QP oversight of DMX-200 by Fisher Clinical services UK LTD, Langhurstwood road, Horsham, RH12 4QD, UK.

Submission of associated MIA IMP

Submission of Certificate of GMP compliance for Fisher Clinical services, Horsham.

The below documents are included in this submission:

MhraProductsForm_REMAP-CAP AM033 170222

MIA (IMP) 18693 v 41

REMAP-CAP DMX-200 MIA (IMP) Certificate of GMP Compliance 03Nov2021

REMAP-CAP AM033 Amendment_Tool_v1_6_LOCKED

Many Thanks

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