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MHRA

Dear Graham and Kirsty,

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 18 (AM018) Expedited Approval

I am submitting substantial amendment AM016 for the REMAP-CAP study, I have made the below changes to the MHRA CTA.

We are adding 2 IMP releasing sites to section D9 of the MHRA CTA.

1. The addition of manufacturer (Sanofi Montpelier) will be providing the study with both licenced and unlicensed product for use in REMAP-CAP.
Sarilumab will be supplied to trial sites through PHE authorised distribution sites
2. The addition of manufacturer Aesica UK for provision of Kaletra Oral Solution Kaletra 80mg/20mg Oral Solution.
Kaletra oral solution will be supplied to trial sites through PHE authorised distribution sites

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