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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 31 (AM031) Expedited Approval

I am submitting substantial amendment AM031 for the REMAP-CAP study.

This involves:

1. IMPD v2.0 dated 13 Dec 2021_track changed
2. IMPD v2.0 dated 13 Dec 2021_Final
3. Cysteamine label v5.0 dated 20 Aug 2021 – Expiry date extended up to Jun 2022

The main changes in the revised IMPD include:

1. Change of AMRI name to Curia (Scotland) Limited – page 101
2. Inclusion of 18m stability report for non-GMP batch and 6month stability report for GMP batch : Section 2.1.P.& Stability – p 171 onwards. This data supports extension of expiry date to Jun 2022
3. Shelf-life extension plan – page 177-178

Many Thanks

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