Dr Farah Al-Beidh

Clinical Trial Manager

Imperial College London / ICNARC

Tel: 020 7831 6878

Mobile: 07714051401

Fax: 020 7831 6879

Email: ukremap-cap@icnarc.org

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 16 (AM016) 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 products to the CTA

1. The addition of unlicensed Sarilumab. The manufacturer (Sanofi Montpelier) will be providing the study with both licenced and unlicensed product for use in REMAP-CAP. The unlicensed product will be provided with clinical trial labels (submitted to MHRA), GMP certification and QP declaration. Sarilumab will be supplied to trial sites through PHE authorised distribution sites

2. The addition of Kaletra 80mg/20mg Oral Solution.
Aesica UK is the manufacture of Kaletra Oral Solution. The Marketing Authorisation Holder is Abbvie. This product will be provided with GMP certification and QP declaration.

Farah Al-Beidh PhD
UK REMAP-CAP Trial Manager
Imperial College London / ICNARC
Tel: 020 7831 6878
Mobile: 07714051401
Fax: 020 7831 6879
Email: ukremap-cap@icnarc.org

REMAP-CAP
Randomized, Embedded, Multifactorial Adaptive Platform trial for Community-Acquired Pneumonia

Coordinating Centers

EUROPE
University Medical Center Utrecht
Heidelberglaan 100
3584 CX
THE NETHERLANDS
Phone **+31 (0) 6 277 444 77**
Email prepare_icu@umcmtrecht.nl

NEW ZEALAND
The Medical Research Institute of New Zealand
Private Bag 7902, Newtown, Wellington 6242,
NEW ZEALAND
Phone +64 4 805 0147
Email anne.turner@mrinz.ac.nz

AUSTRALIA
The Australian and New Zealand Intensive Care Research Centre, Monash University
Level 3, 533 St Kilda Road
Melbourne, Victoria, 3004
AUSTRALIA
Phone +61 3 9903 0247
Email anzicrc@med.monash.edu