

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

22/09/2021

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 29 (AM029) Expedited Approval

I am submitting substantial amendment AM029 for the REMAP-CAP study.

Much of this documentation was submitted as part of AM028, however the MHRA required additional information be provided within the IB and so provided a notice of non-acceptance for AM028. The IMP documentation, supplied as part of AM028, plus the updated IB (track changed and clean) is now being resubmitted as AM029 for review and approval by the MHRA and HRA. All patient facing documentation remains as part of AM028 for review and approval by the REC / HRA.

We added 1 IMP product to the MHRA CTA
Cysteamine Bitartrate

For AM029 I have submitted the below documents:

Amendment_Tool_v1_5_25Mar21 REMAP-CAP AM029 22.09.21 Locked

Cysteamine_Nylexa IMPD_V1.0_18 Aug 2021

Nylexa clinical label_Version4.0_13 Jul 2021

REMAP-CAP - Domain Specific Appendix - Cysteamine - V1.0 - 21 June 2021

REMAP-CAP pharmacy guide - Version 3 - 18 August 2021_CLEAN

MhraProductsForm_AM028 200821

IRASEudractExport

Cysteamine_Nylexa IB_Version1.1_22 Sep 2021_Track changed

Cysteamine_Nylexa IB_Version1.1_22 Sep 2021

Many Thanks
Farah

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

Coordinating Centers

EUROPE

University Medical Center Utrecht
Heidelberglaan 100
3584 CX

THE NETHERLANDS

Phone +31 (0) 6 277 444 77
Email prepare_icu@umcmrecht.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@mrnz.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 anzirc@med.monash.edu