

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

Barbara Cuddon
REC Manager
Health Research Authority
Skipton House, 80 London Road, London SE1 6LH

Dear Barbara,

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 10 (AM10) Expedited Approval

Please find enclosed a substantial amendment AM10 that adds an additional antiviral agent, hydroxychloroquine to the COVID anti-viral domain of the REMAP-CAP trial. We will evaluate this agent on its own and also in combination with kaletra. This drug is commonly used to treat malaria and various rheumatoid illnesses and has anti-viral effects. It is being evaluated in several other clinical trials for COVID-19. We have also updated our analytical plan to include a combined analysis of all anti-viral agents compared to the current standard of care. We added this intervention into the information sheets and made a few minor semantic changes to make some of the terminology more lay friendly.

New documentation attached and uploaded onto IRAS:

REMAP-CAP - COVID-19 Antiviral Domain-Specific Appendix V2.0 - 01 April 2020_CLEAN

REMAP-CAP - COVID-19 Antiviral Domain-Specific Appendix V2.0 - 01 April 2020_CLEAN

SmPC_Hydroxychloroquine_English

Summary of changes to COVID19 Antiviral Therapy Domain Specific Appendix V1.0 - 02 April 2020

UK REMAP CAP COVID19 PIS ICF V1.2 2020.04.06 TC

UK REMAP CAP COVID19 Retro PIS ICF V1.2 2020.04.06 TC

UK REMAPCAP COVID19 PerLRIS ICF v1.2 2020.04.06 TC

Thank you for your prompt review of these changes

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