

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 11 (AM11) Expedited Approval

Please find enclosed a substantial amendment AM11 that adds 2 additional immune modulatory agent, Tocilizumab and Sarilumab to the COVID immune modulation domain of the REMAP-CAP trial. We will evaluate these agents on their own. These drugs are used to treat rheumatoid arthritis and inflammatory diseases. Other minor changes to this DSA include a change to statistical methods to facilitate more rapid evaluation of interventions. All changes to this DSA have been outlined in a summary of changes, which includes a rationale for each change. We added these interventions into the information sheets and made a few minor changes to make some of the terminology more lay friendly.

New documentation attached and uploaded onto IRAS:

REMAP-CAP - COVID-19 Immune Modulation Domain-Specific Appendix V2.0 - 07 April 2020_CLEAN

REMAP-CAP - COVID-19 Immune Modulation Domain-Specific Appendix V2.0 - 07 April 2020_TC

SmPC Sarilumab (Kevzara)

SmPC Tocilizumab (RoActemra)

Summary of changes to COVID19 Immune Modulation Therapy Domain Specific Appendix V1.0 - 08 April 2020

UK REMAP CAP COVID19 PIS ICF V1.3 2020.04.09 TC

UK REMAP CAP COVID19 Retro PIS ICF V1.3 2020.04.09 TC

UK REMAPCAP COVID19 PerLRIS ICF v1.3 2020.04.09 TC

UK REMAP CAP COVID19 PIS ICF V1.1 2020.04.09 – Scotland TC
UK REMAP CAP COVID19 Retro PIS ICF V1.1 2020.04.09 Recovered Capacity – Scotland TC
UK REMAPCAP COVID19 PerLRIS ICF v1.1 2020.04.09 Attorney Guardian Relative – Scotland TC

UK REMAP CAP COVID19 PerLRIS ICF v1.2 2020.04.09_NI TC
UK REMAP CAP COVID19 PIS ICF V1.2 2020.04.09_NI TC
UK REMAP CAP COVID19 Retro PIS ICF V1.2 2020.04.09_NI 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