

Elizabeth Fagbodun

UK REMAP-CAP Management Team

Imperial College London / ICNARC

Tel: 020 7831 6878

Mobile: 075 480 94320

Email: ukremap-cap@icnarc.org

22/12/23

Re: Study Title: Randomized, Embedded, Multi-factorial, Adaptive Platform Trial for community - Acquired Pneumonia (REMAP-CAP)

REC reference: 18/Io/0660

EudraCT number: 2015-002340-14

IRAS project ID: 237150

Substantial Amendment 40 (AM40)

I am submitting substantial amendment AM040 for the REMAP-CAP study. It involves:

The submission of the Immune Modulation Domain Specific Appendices and the addition of tocilizumab and baricitinib interventions for both adults and children with influenza.

We added 2 IMP products to the MHRA CTA

Tocilizumab

Baricitinib

Submission of adult and children IS_CF

1. The wording on all (adult + children) PIS' has been updated to include tocilizumab and baricitinib as a treatment option to flu patients in the PIS.
2. The telephone consent form has been updated so it can be used for both personal legal representatives and patients.
3. Hydrocortisone has been removed from the children's PIS as it is not an option for paediatric participants.
4. The 'fixed course hydrocortisone' has been removed from the PIS as an intervention for adults.
5. The anticoagulation domain has been removed from the PIS as an intervention for adults
6. There are minor typographical corrections to all (adult + children) PIS documents.

Closure of the fixed course hydrocortisone intervention and the anticoagulation and antiplatelet domains

We have closed recruitment to the 'fixed-course hydrocortisone' intervention of the Corticosteroid Domain as it has reached a prespecified statistical trigger for futility. The anticoagulation and antiplatelet domains have also been closed due operational futility.

We are also requesting approval for sites to post the consent form to patients in order to gain retrospective consent, if the site wishes to do so.

The below documents are included in this submission:

REMAP-CAP AM040 Amendment_Tool_v1_6_LOCKED

REMAP-CAP Immune Modulation Influenza DSA - V1.0 Adult + Paediatric patients - 29 September 2023

REMAP-CAP Immune Modulation Influenza DSA - V1.1 Adult patients only - 29 September 2023

Olumiant 2 mg Film-Coated Tablets - Summary of Product Characteristics (SmPC)

RoActemra 20mg/ml Concentrate for Solution for Infusion - Summary of Product Characteristics (SmPC)

REMAP-CAP_YoungChild_PIS_ICF v1.3 2023.12.13_Clean

REMAP-CAP_YoungChild_PIS_ICF v1.3 2023.12.13_Tracked
REMAP-CAP_Child_10-15_PIS_ICF v1.4 2023.11.16_Clean
REMAP-CAP_Child_10-15_PIS_ICF v1.4 2023.11.16_tracked
REMAP-CAP_Child_16-17_PIS_ICF v1.2 2023.11.16_Clean
REMAP-CAP_Child_16-17_PIS_ICF v1.2 2023.11.16_Tracked
REMAP-CAP_PerLIS_ICF v1.16_2023.11.16_Clean
REMAP-CAP_PerLIS_ICF v1.16_2023.11.16_Tracked
REMAP-CAP_PerLR Sum_ICF v1.4_2023.11.16_Clean
REMAP-CAP_PerLR Sum_ICF v1.4_2023.11.16_Tracked
REMAP-CAP_PIS_ICF v1.16_2023.11.16_Clean
REMAP-CAP_PIS_ICF v1.16_2023.11.16_Tracked
REMAP-CAP_ProLR Sum_ICF v1.8_2023.11.16_Clean
REMAP-CAP_ProLR Sum_ICF v1.8_2023.11.16_Tracked
REMAP-CAP_Tel v2.0 2023.11.16_Clean
REMAP-CAP_Tel v2.0 2023.11.16_Tracked
REMAP-CAP letter to sites - Anticoagulation and Antiplatelet Domain - 30 November 2023
REMAP-CAP letter to sites - Corticosteroid Domain_06 December 2023
REMAP-CAP pharmacy guide - Version 4 - 26 October 2023

Many Thanks
Elizabeth

Elizabeth Fagbodun MSc
UK REMAP-CAP Management Team
Imperial College London / ICNARC
Mobile: 075 480 94320
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 anzicrc@med.monash.edu