

IRAS 237150. Substantial Amendment valid for REC review

surreyborders.rec@hra.nhs.uk <noreply@harp.org.uk>

Thu 02/12/2021 13:20

To: anthony.gordon@imperial.ac.uk <anthony.gordon@imperial.ac.uk>

Cc: Farah Al-Beidh <Farah.Al-Beidh@icnarc.org>; ukremap-cap <ukremap-cap@icnarc.org>

Dear Prof Gordon,

Study title: Randomized, Embedded, Multifactorial, Adaptive Platform trial for Community-Acquired Pneumonia**REC reference: 18/LO/0660****IRAS project ID: 237150****Amendment number: AM030****Amendment date: 01 December 2021**

Thank you for submitting the above amendment, which was received on 01 December 2021. I can confirm that this is a valid notice of a substantial amendment and will be reviewed by the Sub-Committee at its next meeting.

Documents received

The documents to be reviewed are as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Annex 1: Clinical Trial Application Form [MhraProductsForm_AM030 011221]	v1	01 December 2021
Completed Amendment Tool [Amendment tool_AM030_20211201 updated.pdf]	v1.5	01 December 2021
Cover Letter [REMAP-CAP AM030 cover letter 30.11.21]	v1.0	30 November 2021
Investigator Brochure/SmPC [TRV027 IMPD v4.0 26Aug2021]	V4	26 August 2021
Investigator Brochure/SmPC [TRV027 IMPD v4.0 Signature page]	V4	26 August 2021
Investigator Brochure/SmPC [TRV027 IB Ed 7 30Nov2021]	v7	30 November 2021
Other [Summary of changes to ACE2 RAS Domain-Specific Appendix V1.0 - 16 Nov 2021]	V1	16 November 2021
Other [TRV027 Vial Carton Label version3 REMAP-CAP 19Jul21]	V3	19 July 2021
Participant consent form [UK REMAP CAP COVID19 PerLR ICF V1.9 2021.11.26 Scotland CLEAN]	v1.9	26 November 2021
Participant consent form [UK REMAP CAP COVID19 PerLR ICF V1.9 2021.11.26 Scotland TC]	v1.9	26 November 2021

Participant consent form [UK REMAP CAP COVID19 PerLRIS ICF v1.11 2021.11.26 CLEAN]	v1.11	26 November 2021
Participant consent form [UK REMAP CAP COVID19 PerLRIS ICF v1.10 2021.11.26 NI TC]	v1.10	26 November 2021
Participant consent form [UK REMAP CAP COVID19 PerLRIS ICF v1.10 2021.11.26 NI CLEAN]	v1.10	26 November 2021
Participant consent form [UK REMAP CAP COVID19 PerLRIS ICF v1.11 2021.11.26 TC]	v1.11	26 November 2021
Participant consent form [UK REMAP CAP COVID19 PIS ICF V1.9 2021.11.26 Scotland CLEAN]	v1.9	26 November 2021
Participant consent form [UK REMAP CAP COVID19 PIS ICF V1.9 2021.11.26 Scotland TC]	v1.9	26 November 2021
Participant consent form [UK REMAP CAP COVID19 PIS ICF V1.10 2021.11.26 NI CLEAN]	v1.10	26 November 2021
Participant consent form [UK REMAP CAP COVID19 PIS ICF V1.10 2021.11.26 NI TC]	v1.10	26 November 2021
Participant consent form [UK REMAP CAP COVID19 PIS 2021.11.26 v1.11 CLEAN]	v1.11	26 November 2021
Participant consent form [UK REMAP CAP COVID19 PIS 2021.11.26 v1.11 TC]	v1.11	26 November 2021
Participant consent form [UK REMAP CAP COVID19 Retro PIS ICF V1.9 2021.11.26 Scotland CLEAN]	v1.9	26 November 2021
Participant consent form [UK REMAP CAP COVID19 Retro PIS ICF V1.9 2021.11.26 Scotland TC]	v1.9	26 November 2021
Participant consent form [UK REMAP CAP COVID19 Retro PIS ICF V1.10 2021.11.26 NI CLEAN]	v1.10	26 November 2021
Participant consent form [UK REMAP CAP COVID19 Retro PIS ICF V1.10 2021.11.26 NI TC]	v1.10	26 November 2021
Participant consent form [UK REMAP CAP COVID19 Retro PIS ICF v1.11 2021.11.26 CLEAN]	v1.11	26 November 2021
Participant consent form [UK REMAP CAP COVID19 Retro PIS ICF v1.11 2021.11.26 TC]	v1.11	26 November 2021
Participant information sheet (PIS) [Brief REMAPCAP	v5	26 November 2021

ProLR_IS summary v5 261121 CLEAN]		
Participant information sheet (PIS) [Brief REMAPCAP ProLR_IS summary v5 261121 TC]	v5	26 November 2021
Participant information sheet (PIS) [REMAP-CAP - Monoclonal Antibody DSA V1 - 29 November 2021]	v1	29 November 2021
Research protocol or project proposal [REMAP-CAP - ACE2 RAS DSA - V2 - 14 Oct 2021]	V2	14 October 2021
Research protocol or project proposal [REMAP-CAP - ACE2 RAS DSA - V2 - 14 Oct 2021_TC]	V2	14 October 2021
Research protocol or project proposal [REMAP-CAP COVID-19 Immunoglobulin Therapy Domain-Specific Appendix V3 - 24 November 2021]	V3	24 November 2021
Research protocol or project proposal [REMAP-CAP COVID-19 Immunoglobulin Therapy Domain-Specific Appendix V3 - 24 November 2021_TC from V1.01]	V3	24 November 2021
Summary of product characteristics (SmPC) [revised-gb-spc-ronapreve- clean-120mg- ml12aug2021docx]	V1.0	12 August 2021

Notification of the Committee's decision

The Committee will issue an ethical opinion on the amendment within a maximum of 35 days from the date of receipt.

Kind regards

Laura Fairman

The Old Chapel | Royal Standard Place | HRA | NG1 6FS

T. 02071048181

E. surreyboundaries.rec@hra.nhs.uk

W. www.hra.nhs.uk

Sign up to receive our newsletter [HRA Latest](#).

This email has been scanned by the Symantec Email Security.cloud service.
For more information please visit <http://www.symanteccloud.com>

