

London - Surrey Borders Research Ethics Committee

The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Tel: 02071048181
Fax: N/A

**Please note: This is the
favourable opinion of the REC
only and does not allow the
amendment to be implemented
at NHS sites in England until
the outcome of the HRA
assessment has been
confirmed.**

06 December 2021

Prof Anthony Gordon
UK Chief Investigator
Imperial College London
11th floor Intensive Care Unit
Charing Cross Hospital
Fulham Palace Road
w6 8rf

Dear Prof Gordon

Study title:	Randomized, Embedded, Multifactorial, Adaptive Platform trial for Community-Acquired Pneumonia
REC reference:	18/LO/0660
EudraCT number:	2015-002340-14
Amendment number:	AM030
Amendment date:	01 December 2021
IRAS project ID:	237150

The above amendment was reviewed at the meeting of the Sub-Committee held on 02 December 2021 in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

<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 ProLR_IS summary v5 261121 CLEAN]	v5	26 November 2021
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_TC from V1.01]	V3	24 November 2021
Research protocol or project proposal [REMAP-CAP COVID-19 Immunoglobulin Therapy Domain-Specific Appendix V3 - 29 November 2021_CLEAN.pdf]	v3	29 November 2021
Summary of product characteristics (SmPC) [revised-gb-spc-ronapreve-clean-120mg-ml12aug2021docx]	V1.0	12 August 2021

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

Amendments related to COVID-19

We will update your research summary for the above study on the research summaries section of our website. During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you have not already done so, please register your study on a public registry as soon as possible and provide the HRA with the registration detail, which will be posted alongside other information relating to your project.

Statement of compliance

This Committee is recognised by the United Kingdom Ethics Committee Authority under the Medicines for Human Use (Clinical Trials) Regulations 2004, and is authorised to carry out the ethical review of clinical trials of investigational medicinal products.

The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: <https://www.hra.nhs.uk/planning-and-improving-research/learning/>

IRAS Project ID - 237150:

Please quote this number on all correspondence

Yours sincerely

Pp. Laura Fairman
Approvals Administrator

Mr Tobias Davis
Chair

E-mail: surreyborders.rec@hra.nhs.uk

Enclosures: List of names and professions of members who took part in the review

Copy to: Dr Farah Al-Beidh

London - Surrey Borders Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 02 December 2021

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Mr Tobias Davis	Medical Device Expert	Yes	Meeting Chair
Miss Holly Shrimpton	Plastic Surgery Service Manager & Vascular Surgery Service Manager	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Mrs Laura Fairman	Approvals Administrator - minutes