

London - Surrey Borders Research Ethics Committee

The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

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.

11 March 2021

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: AM025
Amendment date: 05 March 2021
IRAS project ID: 237150

The above amendment was reviewed by the Sub-Committee 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 2: Notification of Amendment [Amendment tool 237150_AM025__A2 signed]	v1.0	05 March 2021
Completed Amendment Tool [Amendment tool 237150_AM025_signed]	v1.0	05 March 2021
Cover Letter [REMAP-CAP AM025 cover letter 05.03.21 signed]	v1.0	05 March 2021
Other [Summary of changes to COVID19 Anticoagulation Domain Specific Appendix V1.0 03 March 2021]	V1.0	03 March 2021

Other [MhraProductsForm_ AM025]	V1.0	09 March 2021
Other [IRASEudractExport]	V1.0	09 March 2021
Participant information sheet (PIS) [Brief REMAPCAP PIS Summary v2 040321 TC]	V2.0	04 March 2021
Participant information sheet (PIS) [Brief REMAPCAP PIS Summary v2 040321]	V2.0	04 March 2021
Participant information sheet (PIS) [Brief REMAPCAP ProLR_IS summary v3 040321 TC]	V3.0	04 March 2021
Participant information sheet (PIS) [Brief REMAPCAP ProLR_IS summary v3 040321]	V3.0	04 March 2021
Participant information sheet (PIS) [UK REMAP CAP COVID19 PIS v1.8 2021.03.02 TC]	v1.8	02 March 2021
Participant information sheet (PIS) [UK REMAP CAP COVID19 PIS v1.8 2021.03.02 CLEAN]	V1.8	02 March 2021
Participant information sheet (PIS) [UK REMAP CAP COVID19 PerLRIS ICF v1.8 2021.03.02 TC]	v1.8	02 March 2021
Participant information sheet (PIS) [UK REMAP CAP COVID19 PerLRIS ICF v1.8 2021.03.02 CLEAN]	v1.8	02 March 2021
Participant information sheet (PIS) [UK REMAP CAP COVID19 Retro PIS ICF v1.8 2021.03.02 TC]	v1.8	02 March 2021
Participant information sheet (PIS) [UK REMAP CAP COVID19 Retro PIS ICF v1.8 2021.03.02 CLEAN]	v1.8	02 March 2021
Participant information sheet (PIS) [UK REMAP CAP COVID19 PIS ICF V1.6 2021.03.02 Scotland TC]	v1.6	02 March 2021
Participant information sheet (PIS) [UK REMAP CAP COVID19 PIS ICF V1.6 2021.03.02 Scotland CLEAN]	v1.6	02 March 2021
Participant information sheet (PIS) [UK REMAP CAP COVID19 PerLR ICF V1.6 2021.03.02 Scotland TC]	v1.6	02 March 2021
Participant information sheet (PIS) [UK REMAP CAP COVID19 PerLR ICF V1.6 2021.03.02 Scotland CLEAN]	v1.6	02 March 2021
Participant information sheet (PIS) [UK REMAP CAP COVID19 PIS ICF V1.7 2020.03.02 NI TC]	V1.7	02 March 2021
Participant information sheet (PIS) [UK REMAP CAP COVID19 PIS ICF V1.7 2020.03.02 NI CLEAN]	V1.7	02 March 2021
Participant information sheet (PIS) [UK REMAP CAP COVID19 PerLRIS ICF v1.7 2021.03.02 NI TC]	V1.7	02 March 2021
Participant information sheet (PIS) [UK REMAP CAP COVID19 PerLRIS ICF v1.7 2021.03.02 NI CLEAN]	V1.7	02 March 2021
Participant information sheet (PIS) [UK REMAP CAP COVID19 Retro PIS ICF V1.7 2020.03.02 NI TC]	V1.7	02 March 2021
Participant information sheet (PIS) [UK REMAP CAP COVID19 Retro PIS ICF V1.7 2020.03.02 NI CLEAN]	V1.7	02 March 2021
Participant information sheet (PIS) [UK REMAP CAP COVID19 Retro PIS ICF V1.6 2021.03.02 Scotland TC]	V1.6	02 March 2021
Participant information sheet (PIS) [UK REMAP CAP COVID19 Retro PIS ICF V1.6 2021.03.02 Scotland CLEAN]	V1.6	02 March 2021
Research protocol or project proposal [REMAP-CAP - ACE2 RAS DSA - V1 - 08 November 2020]	V1.0	08 November 2020
Research protocol or project proposal [REMAP-CAP - Therapeutic Anticoagulation - V3 - 27 February 2021_CLEAN]	V3.0	27 February 2021
Research protocol or project proposal [REMAP-CAP - Therapeutic Anticoagulation - V3 - 27 February 2021_TC]	V3.0	27 February 2021
Summary of product characteristics (SmPC) [REMAP-CAP_SmPC_Losartan]	v1.0	05 March 2021
Summary of product characteristics (SmPC) [REMAP-CAP_SmPC_Ramipril]	v1.0	05 March 2021
Summary of product characteristics (SmPC) [Candesartan tablets]	v1.0	09 March 2021

SmPC]		
Summary of product characteristics (SmPC) [Captopril Tablets - SmPC]	v1.0	09 March 2021
Summary of product characteristics (SmPC) [Enalapril tablets SmPC]	V1.0	09 March 2021
Summary of product characteristics (SmPC) [Irbesartan film-coated tablets - SmPC]	V1.0	09 March 2021
Summary of product characteristics (SmPC) [Lisinopril Tablet - SmPC]	V1.0	09 March 2021
Summary of product characteristics (SmPC) [Perindopril Tablets - SmPC]	V1.0	09 March 2021
Summary of product characteristics (SmPC) [Valsartan Capsules - SmPC]	V1.0	09 March 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
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Yours sincerely

**Sir Adrian Baillie
Chair**

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

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

Copy to: Prof Anthony Gordon, Imperial College London
Dr Farah Al-Beidh

London - Surrey Borders Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 10 March 2021

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Sir Adrian Baillie	Property Developer	Yes	
Mr Tobias Davis	Medical Device Expert	Yes	
Dr Mike Philpot	Consultant Psychiatrist (Retired)	Yes	