

London - Surrey Borders Research Ethics Committee

Research Ethics Committee (REC) London Centre
Ground Floor
Skipton House
80 London Road
London
SE1 6LH

12 October 2020

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: AM022
Amendment date: 05 October 2020
IRAS project ID: 237150

The above amendment was reviewed 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 1: Clinical Trial Application Form [AM022 Amendment tool_PDF]	1.0	05 October 2020
Annex 2: Notification of Amendment [AM022 Annex2_PDF]	1.0	05 October 2020
Cover Letter [REMAP-CAP AM022 cover letter 01.10.20 COVID-19 expedite signed]	1.0	05 October 2020
Other [MhraProductsForm_AM022 COVID-19 expedite review 05.10.20]	1.0	05 October 2020
Other [MHRA AM022Notice of acceptance of Amendment]		07 October 2020
Participant information sheet (PIS) [UK REMAP CAP COVID19 PerLR ICF V1.5 2020.10.01 Scotland CLEAN]	1.5	01 October 2020

Participant information sheet (PIS) [UK REMAP CAP COVID19 PerLR ICF V1.5 2020.10.01 Scotland TC]	1.5	01 October 2020
Participant information sheet (PIS) [UK REMAP CAP COVID19 PerLRIS ICF v1.6 2020.10.01 NI CLEAN]	1.6	01 October 2020
Participant information sheet (PIS) [UK REMAP CAP COVID19 PerLRIS ICF v1.6 2020.10.01 NI TC]	1.6	01 October 2020
Participant information sheet (PIS) [UK REMAP CAP COVID19 PIS ICF V1.5 2020.10.01 Scotland CLEAN]	1.5	01 October 2020
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Participant information sheet (PIS) [UK REMAP CAP COVID19 PIS ICF V1.6 2020.10.01 NI TC]	1.6	01 October 2020
Participant information sheet (PIS) [UK REMAP CAP COVID19 PIS ICF V1.7 2020.10.01 CLEAN]	1.7	01 October 2020
Participant information sheet (PIS) [UK REMAP CAP COVID19 PIS ICF V1.7 2020.10.01 TC]	1.7	01 October 2020
Participant information sheet (PIS) [UK REMAP CAP COVID19 Retro PIS ICF V1.5 2020.10.01 Scotland CLEAN]	1.5	01 October 2020
Participant information sheet (PIS) [UK REMAP CAP COVID19 Retro PIS ICF V1.5 2020.10.01 Scotland TC]	1.5	01 October 2020
Participant information sheet (PIS) [UK REMAP CAP COVID19 Retro PIS ICF V1.6 2020.10.01 NI CLEAN]	1.6	01 October 2020
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Participant information sheet (PIS) [UK REMAPCAP COVID19 Retro PIS ICF v1.7 2020.10.01 TC]	1.7	01 October 2020
Participant information sheet (PIS) [SmPC_Prasugrel Mylan_Eng]	1.0	05 October 2020
Research protocol or project proposal [REMAP-CAP - Antiplatelet DSA - V1.0 - 24 August 2020]	1.0	24 August 2020
Summary of product characteristics (SmPC) [SmPC_Aspirin_75mg]	1.0	05 October 2020
Summary of product characteristics (SmPC) [SmPC_Brilique INN-ticagrelor_Eng]	1.0	05 October 2020
Summary of product characteristics (SmPC) [SmPC_clopidogrel-ratiopharm-EMA-English]	1.0	05 October 2020

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: Dr Farah Al-Beidh

London - Surrey Borders Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 22 October 2020

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Sir Adrian Baillie	Property Developer	Yes	
Miss Holly Shrimpton	RAF Medical Support Officer	Yes	