

**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.**

04 June 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:** AM026  
**Amendment date:** Jun 2 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>
Completed Amendment Tool [237150_AM026_Locked]	V1.5	02 June 2021
Cover Letter [REMAP-CAP AM026 cover letter 010621]	V1.0	02 June 2021
Financial Arrangements [Grant Agreement-101003589-RECoVER_FE]	V1.0	12 March 2021
Investigator Brochure/SmPC [DMX-200 COVID-19 IMPD v2.0 April 2021]	V2.0	01 April 2021
Investigator Brochure/SmPC [DMX-200 ARDS IB v3.0 SIGNED]	V3.0	31 May 2021

Other [DIL2501 REMAP CAP label Proof english & dutch 20210505]	V1.0	05 May 2021
Other [DMX-200_REMAP_CAP_label_proof_Part_2_sign_of 20210506]	V1.0	06 May 2021
Other [MIA_Fisher_DE_BW_01_MIA_2021_0022_DE+ EN]	V1.0	05 March 2021
Other [QP Declaration REMAP CAP_27May2021]	V1.0	27 May 2021
Other [Site GMP Certificate FDA EU and Registration Database Reference 2020 Signed]	V1.0	15 May 2021
Participant information sheet (PIS) [UK REMAP CAP COVID19 PerLR ICF V1.7 2021.06.01 Scotland TC]	V1.7	01 June 2021
Participant information sheet (PIS) [UK REMAP CAP COVID19 PerLRIS ICF v1.8 2021.06.01 NI TC]	V1.8	01 June 2021
Participant information sheet (PIS) [UK REMAP CAP COVID19 PerLRIS ICF v1.9 2021.06.01 TC]	1.9	01 June 2021
Participant information sheet (PIS) [UK REMAP CAP COVID19 PIS ICF V1.7 2021.06.01 Scotland TC]	1.7	01 June 2021
Participant information sheet (PIS) [UK REMAP CAP COVID19 PIS ICF V1.8 2020.06.01 NI TC]	V1.8	01 June 2021
Participant information sheet (PIS) [UK REMAP CAP COVID19 PIS v1.9 2021.06.01 TC]	V1.9	01 June 2021
Participant information sheet (PIS) [UK REMAP CAP COVID19 Retro PIS ICF V1.7 2021.06.01 Scotland TC]	1.7	01 June 2021
Participant information sheet (PIS) [UK REMAP CAP COVID19 Retro PIS ICF V1.8 2020.06.01 NI TC]	V1.8	01 June 2021
Participant information sheet (PIS) [UK REMAP CAP COVID19 Retro PIS ICF v1.9 2021.06.01 TC]	V1.9	01 June 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

**Sir Adrian Baillie  
Chair**

E-mail: [surreyborders.rec@hra.nhs.uk](mailto: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

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**Attendance at Sub-Committee of the REC meeting on 04 June 2021**