Health Research Authority

London - Surrey Borders Research Ethics Committee

Equinox House
City Link
Nottingham
NG2 4LA

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.

03 May 2022

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:	**AM035**
Amendment date:	**12 April 2022**
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:

Document	*Version*	*Date*
Annex 2: Notification of Amendment/Amendment tool [MhraProductsForm_REMAP-CAP AM035 120422]	V1.0	12 April 2022
Completed Amendment Tool [REMAP-CAP AM035 Amendment_Tool_v1_6_LOCKED]	V1.6	12 April 2022
Cover Letter [REMAP-CAP AM035 cover letter 12.04.22]	V1.0	12 April 2022
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [GB_REMAP-CAP_SubjectInsurance_Allianz_Endorsement 2_20210715]	V1.0	15 July 2021
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [GB_REMAP-CAP_SubjectIsurance_Allianz_Endorsement 1_20210125]	V1.0	25 January 2021
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Subject Insurance Certificate]	V1.0	25 January 2021
Other [Cysteamine_Nylexa IMPD_V3.0_08 Apr 2022_Final]	V3.0	08 April 2022
Other [Cysteamine_Nylexa IMPD_V3.0_08 Apr 2022_track changed]	V3.0	08 April 2022

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

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, Imperial College London*

London - Surrey Borders Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 21 April 2022

Committee Members:

Name	*Profession*	*Present*	*Notes*
Mr Tobias Davis	Medical Device Expert	Yes	
Mrs Holly Jordan	Clinical Trial Setup	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Mr Adam Mannion	Approvals Administrator