

London - Surrey Borders Research Ethics Committee

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

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.

08 June 2020

Dr Farah Al-Beidh
ICNARC
Napier House
24 High Holborn
WC1V 6AZ

Dear Dr Al-Beidh

Study title: Randomized, Embedded, Multifactorial, Adaptive Platform trial for Community-Acquired Pneumonia
REC reference: 18/LO/0660
EudraCT number: 2015-002340-14
Amendment number: AM019
Amendment date: 05 June 2020
IRAS project ID: 237150

The above amendment was reviewed at the meeting of the Sub-Committee held 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 |
|----------|---------|------|
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|---|------|--------------|
| Completed Amendment Tool [237150_AM019_05jun2020_Locked05jun20_135918] | v1.0 | 05 June 2020 |
| Cover Letter [REMAP-CAP AM019 cover letter 05.06.20 sig] | v1.0 | 05 June 2020 |
| Other [Summary of changes to Pandemic Appendix to Core Protocol V1.0 - 24 May 2020] | v1.0 | 24 May 2020 |
| Other [REMAP-CAP COVID-19 Immunoglobulin Therapy Domain-Specific Appendix V1.1 - 01 June 2020_TC] | v1.1 | 01 June 2020 |
| Other [REMAP-CAP COVID-19 Immunoglobulin Therapy Domain-Specific Appendix V1.1- 01 June 2020] | v1.1 | 01 June 2020 |
| Other [REMAP-CAP - PATC - V2.0 - 18 May 2020_CLEAN] | v2.0 | 18 May 2020 |
| Other [REMAP-CAP - PATC - V2.0 - 18 May 2020_TC] | v2.0 | 18 May 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/>



**Health Research
Authority**

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|--------------------|---|
| 18/LO/0660: | Please quote this number on all correspondence |
|--------------------|---|

Yours sincerely

Thomas Fairman
HRA Approvals Manager

On behalf of

Mr Tobias Davis
Vice-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



Health Research Authority

London - Surrey Borders Research Ethics Committee

Attendance at Sub-Committee of the REC meeting in correspondence

Committee Members:

| <i>Name</i> | <i>Profession</i> | <i>Present</i> | <i>Notes</i> |
|-----------------|----------------------------------|----------------|--------------|
| Mr Tobias Davis | Medical Device Expert | Yes | |
| Mrs Jill Goss | Regulatory Affairs Consultant | Yes | |

Also in attendance:

| <i>Name</i> | <i>Position (or reason for attending)</i> |
|---------------------|---|
| Mr Thomas Fairman | Approvals Manager |
| Ms Chelsea Phillips | Approvals Administrator |