

**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.**

27 January 2025

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

<b>Study title:</b>	<b>Randomized, Embedded, Multifactorial, Adaptive Platform trial for Community-Acquired Pneumonia</b>
<b>REC reference:</b>	<b>18/LO/0660</b>
<b>EudraCT number:</b>	<b>2015-002340-14</b>
<b>Amendment number:</b>	<b>AM042</b>
<b>Amendment date:</b>	<b>12 December 2024</b>
<b>IRAS project ID:</b>	<b>237150</b>

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.

No ethical issues were raised.

## Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Completed Amendment Tool [237150_AM042_locked]	1.6	12 December 2024
Cover Letter [REMAP-CAP AM42 Cover Letter 12.12.2024]	N/A	12 December 2024
Other [MhraProductsForm]	N/A	13 December 2024
Other [REMAP-CAP - DSMB Letter 2024Nov07]	N/A	07 November 2024
Other [GxP-0556697_MV43976_TOCI_200MG_10ML_BX_39029772]	N/A	08 March 2024
Other [GxP-0556698_MV43976_TOCI_200MG_10ML_BX_39029772_BFP]	N/A	08 March 2024
Other [GxP-0556699_MV43976_TOCI_200MG_10ML_VL_39029773]	N/A	06 March 2024
Other [GxP-0556700_MV43976_TOCI_200MG_10ML_VL_39029773_BFP]	N/A	06 March 2024
Other [QP Declaration Tocilizumab GxP-0370888[60]]	N/A	31 October 2023
Other [FM-0061 Regulatory Compliance Confirmation Letter CTR switch MV43976]	N/A	22 August 2024
Other [GxP-0566740]	N/A	22 July 2024
Other [MV43976_BALO_2G_40MG_20ML_BX_39030769]	N/A	01 October 2024
Other [MV43976_BALO_2G_40MG_20ML_BX_39030769_BFP]	N/A	03 October 2024
Other [MV43976_BALO_2G_40MG_20ML_VL_39030770]	N/A	01 October 2024
Other [MV43976_BALO_2G_40MG_20ML_VL_39030770_BFP]	N/A	03 October 2024
Participant information and informed consent form [REMAP-CAP-PIS-ICF-UK-v1.20]	1.20	17 January 2025
Participant information and informed consent form [REMAP-CAP-PIS-ICF-UK-v1.20 TC]	1.20	17 January 2025
Participant information and informed consent form [REMAP-CAP-Child 0-9-PIS-ICF TC]	1.6	17 January 2025
Participant information and informed consent form [REMAP-CAP-Child 10-15-PIS-ICF TC]	1.7	17 January 2025
Participant information and informed consent form [REMAP-CAP-Child 16-17-PIS-ICF]	1.5	17 January 2025
Participant information sheet (PIS) [REMAP-CAP-Privacy-Notice-v1.2-25.11.2024 TC]	1.2	25 November 2024
Participant information sheet (PIS) [REMAP-CAP-Privacy-Notice-v1.2-25.11.2024 clean]	1.2	25 November 2024
Participant information sheet (PIS) [REMAP-CAP-Patient-Video-CF-v1.2-13.11.2024 Clean]	1.2	13 November 2024
Participant information sheet (PIS) [REMAP-CAP-Patient-Video-CF-v1.2-13.11.2024 TC]	1.2	13 November 2024
Participant information sheet (PIS) [REMAP-CAP-PerLRIS-ICF-v1.19-13.11.2024 Clean]	1.19	13 November 2024
Participant information sheet (PIS) [REMAP-CAP-PerLRIS-ICF-v1.19-13.11.2024 TC]	1.19	13 November 2024
Participant information sheet (PIS) [REMAP-CAP-PerLR-Sum-ICF-v1.7-13.11.2024 Clean]	1.7	13 November 2024
Participant information sheet (PIS) [REMAP-CAP-PerLR-Sum-ICF-v1.7-13.11.2024 TC]	1.7	13 November 2024
Participant information sheet (PIS) [REMAP-CAP-PerLR-Video-CF-v1.2-13.11.2024 Clean]	1.2	13 November 2024
Participant information sheet (PIS) [REMAP-CAP-PerLR-Video-CF-v1.2-13.11.2024 TC]	1.2	13 November 2024

Participant information sheet (PIS) [REMAP-CAP-PIS-Sum-ICF-v1.0-20.11.2024]	1	20 November 2024
Participant information sheet (PIS) [REMAP-CAP-ProLR-Sum-ICF-v1.11-13.11.2024 Clean]	1.11	13 November 2024
Participant information sheet (PIS) [REMAP-CAP-ProLR-Sum-ICF-v1.11-13.11.2024 TC]	1.11	13 November 2024
Participant information sheet (PIS) [REMAP-CAP-Tel-CF-v2.1-13.11.2024 Clean]	2.1	13 November 2024
Participant information sheet (PIS) [REMAP-CAP-Tel-CF-v2.1-13.11.2024 TC]	2.1	13 November 2024
Participant information sheet (PIS) [REMAP-CAP-Child 0-15-Video-CF-v1.0-20.11.2024]	1	20 November 2024
Participant information sheet (PIS) [REMAP-CAP-Child 0-17 Tel-CF-v1.0-20.11.2024]	1	20 November 2024
Participant information sheet (PIS) [REMAP-CAP-Child 0-17-ProLR-Sum-ICF-v1.0-13.11.2024]	1	13 November 2024
Participant information sheet (PIS) [REMAP-CAP-Child 16-17-Video-CF-v1.0-20.11.2024]	1	20 November 2024
Schedule of Events or SoECAT [REMAP-CAP SoECAT v1.0]	1	28 September 2022
Schedule of Events or SoECAT [REMAP-CAP SoECAT v2.0]	2	28 September 2022
Summary of product characteristics (SmPC) [REMAP-CAP_SmPC_Dexamethasone Tablet_20220814_current]	N/A	14 August 2022
Summary of product characteristics (SmPC) [REMAP-CAP_SmPC_Dexamethasone Injection_20220225_current]	N/A	25 February 2022
Summary of product characteristics (SmPC) [REMAP-CAP_SmPC_Hydrocortisone_20230607_current]	N/A	12 June 2023
Summary of product characteristics (SmPC) [REMAP-CAP_SmPC_Amoxicillin-Clavulanate_20200303_current]	N/A	03 March 2020
Summary of product characteristics (SmPC) [REMAP-CAP_SmPC_Ceftriaxone_20230221_current]	N/A	06 July 2023
Summary of product characteristics (SmPC) [REMAP-CAP_SmPC_Levofloxacin_20221102_current]	N/A	12 December 2022
Summary of product characteristics (SmPC) [REMAP-CAP_SmPC_Moxifloxacin_20201109_current]	N/A	09 November 2020
Summary of product characteristics (SmPC) [REMAP-CAP_SmPC_Piperacillin-Tazobactam_20221219_current]	N/A	03 January 2023
Summary of product characteristics (SmPC) [REMAP-CAP_SmPC_Baloxavir_20210107_granules]	N/A	07 January 2021
Summary of product characteristics (SmPC) [REMAP-CAP_SmPC_Baloxavir_20230615_tablets]	N/A	20 June 2023
Summary of product characteristics (SmPC) [REMAP-CAP_SmPC_Oseltamivir (Tamiflu)_20210525_current]	N/A	25 May 2021
Summary of product characteristics (SmPC) [REMAP-CAP_SmPC_Azithromycin powder_20220622_current]	N/A	28 June 2022
Summary of product characteristics (SmPC) [REMAP-CAP_SmPC_Azithromycin tablet_20220519_current]	N/A	09 June 2022
Summary of product characteristics (SmPC) [REMAP-CAP_SmPC_Clarithromycin powder_20230127_current]	N/A	01 August 2023
Summary of product characteristics (SmPC) [REMAP-CAP_SmPC_Clarithromycin tablet_20230715_current]	N/A	21 July 2023
Summary of product characteristics (SmPC) [REMAP-CAP_SmPC_Erythromycin powder_20220622_current]	N/A	22 June 2022
Summary of product characteristics (SmPC) [REMAP-CAP_SmPC_Erythromycin tablet_20230702_current]	N/A	19 July 2023
Summary of product characteristics (SmPC) [REMAP-CAP_SmPC_Roxithromycin_202005XX_current]	N/A	01 May 2020

Summary of product characteristics (SmPC) [REMAP-CAP_SmPC_Baricitinib (Olumiant)_20230925_current]	N/A	29 September 2023
Summary of product characteristics (SmPC) [REMAP-CAP_SmPC_Tocilizumab (RoActemra)_20221122_current]	N/A	29 November 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
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Yours sincerely



pp

**Mr Tobias Davis**  
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: Dr Farah Al-Beidh, Imperial College London*

**London - Surrey Borders Research Ethics Committee**

**Attendance at Sub-Committee of the REC meeting on 26 December 2024**

**Committee Members:**

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Mr Michael John Adams	Retired, Medicines Development Director	Yes	
Mr Tobias Davis	Medical Device Expert	Yes	(chaired the meeting)

**Also in attendance:**

<i>Name</i>	<i>Position (or reason for attending)</i>
Mr Matthew Mills	Approvals Administrator