

IRAS 237150. Substantial Amendment valid for REC review

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Wed 22/12/2021 15:56

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Cc: Farah Al-Beidh <Farah.Al-Beidh@icnarc.org>; ukremap-cap <ukremap-cap@icnarc.org>

Dear Prof Gordon,

Study title: Randomized, Embedded, Multifactorial, Adaptive Platform trial for Community-Acquired Pneumonia**REC reference: 18/LO/0660****IRAS project ID: 237150****Amendment number: AM032****Amendment date: 17 December 2021**

Thank you for submitting the above amendment, which was received on 17 December 2021. I can confirm that this is a valid notice of a substantial amendment and will be reviewed by the Sub-Committee at its next meeting.

Documents received

The documents to be reviewed are as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Annex 1: Clinical Trial Application Form [REMAP-CAP AM032MhraProductsForm_171221]	V1.0	17 December 2021
Completed Amendment Tool [REMAP-CAP Amendment tool_AM032_20211217]	V1.6	17 December 2021
Cover Letter [REMAP-CAP AM032 cover letter 17.12.21]	v1	17 December 2021
Participant consent form [UK REMAP CAP COVID19 PerLR ICF V1.9 2021.11.26 Scotland CLEAN]	v1.9	26 November 2021
Participant consent form [UK REMAP CAP COVID19 PerLR ICF V1.9 2021.11.26 Scotland TC]	v1.9	26 November 2021
Participant consent form [UK REMAP CAP COVID19 PerLRIS ICF v1.10 2021.11.26 NI CLEAN]	v1.10	26 November 2021
Participant consent form [UK REMAP CAP COVID19 PerLRIS ICF v1.10 2021.11.26 NI TC]	v1.10	26 November 2021
Participant consent form [UK REMAP CAP COVID19 PerLRIS ICF v1.11 2021.11.26 TC]	v1.11	26 November 2021
Participant consent form [UK REMAP CAP COVID19 PIS 2021.11.26 v1.11 CLEAN]	v1.11	26 November 2021
Participant consent form [UK REMAP CAP COVID19 PIS 2021.11.26 v1.11 TC]	v1.11	26 November 2021
Participant consent form [UK REMAP CAP COVID19 PIS ICF V1.9 2021.11.26 Scotland CLEAN]	V1.9	26 November 2021

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Participant consent form [UK REMAP CAP COVID19 Retro PIS ICF v1.11 2021.11.26 TC]	V1.11	26 November 2021
Participant information sheet (PIS) [Brief REMAPCAP ProLR_IS summary v5 261121 CLEAN]	v5	26 November 2021
Participant information sheet (PIS) [Brief REMAPCAP ProLR_IS summary v5 261121 TC]	v5	26 November 2021
Research protocol or project proposal [REMAP-CAP - Monoclonal Antibody DSA V1 - 29 November 2021]	v1	29 November 2021
Research protocol or project proposal [REMAP-CAP COVID-19 Immunoglobulin Therapy Domain-Specific Appendix V3 - 24 November 2021_TC from V1.01]	v3	24 November 2021
Research protocol or project proposal [REMAP-CAP COVID-19 Immunoglobulin Therapy Domain-Specific Appendix V3 - 29 November 2021_CLEAN]	v3	29 November 2021
Summary of product characteristics (SmPC) [revised-gb-spc-ronapreve-clean-120mg-ml12aug2021docx]	v1	12 August 2021

Notification of the Committee's decision

The Committee will issue an ethical opinion on the amendment within a maximum of 35 days from the date of receipt.

Kind regards

Laura Fairman

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