



Centre for Tropical Medicine and Global Health

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Cambridge East REC
E-submission
30 September 2024

Dear Dr Lamont

Trial:	Randomised evaluation of Covid-19 therapy (RECOVERY)
EudraCT:	2020-001113-21
IRAS number:	281712
REC ref:	20/EE/0101
Amendment:	Substantial Amendment 36 (30-Sep-2024)

Please find enclosed an application for authorisation of substantial amendment 36 for the above trial. This is to change the supply arrangements for baloxavir marboxil, to facilitate the introduction of this comparison at international sites. This involves changing to a clinical trial formulation without UK marketing authorisation, supplied by Roche Global. This will be used identically to the current commercial baloxavir marboxil supply. We will continue to use the baloxavir marboxil SmPC as the RSI and as a simplified IMPD for the trial.

Included with this submission are:

1. CTA form with changes highlighted (these are in sections A4, B1, C1-4, and D9-2 only)
2. Amendment Tool
3. Sponsor approval

Please note that our numbering of substantial amendments includes those not related to the UK, so amendment numbers for UK submissions are non-consecutive (e.g. substantial amendment 35 related to the addition of new sites in the EU).

I believe this all the necessary documentation required for this submission and look forward to hearing the outcome. Thank you very much for your assessment.

Yours sincerely,

Professor Sir Peter W. Horby

FRCP FFPH PhD FMedSci

Chief Investigator, RECOVERY Trial

Moh Family Foundation Professor of Emerging Infectious Diseases and Global Health