



Centre for Tropical Medicine and Global Health

Nuffield Department of Medicine
Nuffield Department of Medicine Research Building
University of Oxford
Old Road Campus, Roosevelt Drive
Headington
OXFORD
OX3 7FZ

Clinical Trials Unit
Medicines Healthcare Regulatory Agency
E-submission
30 September 2024

Dear Sir or Madam

Trial:	Randomised evaluation of Covid-19 therapy (RECOVERY)
EudraCT:	2020-001113-21
IRAS number:	281712
PO number:	H62017838
Submission ID:	100825186

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 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.

1. Cover letter
- 2a-d. Proposed baloxavir marboxil box and blister labelling
- 3a-s. GMP documentation for new baloxavir marboxil supply
4. Updated CTA form with changes highlighted (these are in sections A4, B1, C1-4, and D9-2 only)
5. Amendment Tool
6. Sponsor approval

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 faithfully

Professor Sir Peter W. Horby

FRCP FFPH PhD FMedSci

Chief Investigator, RECOVERY Trial

Moh Family Foundation Professor of Emerging Infectious Diseases and Global Health