

Clinical Trials Unit
Medicines Healthcare Regulatory Agency
E-submission
31 July 2025

Dear Sir or Madam,

Trial:	Randomised evaluation of Covid-19 therapy (RECOVERY)
EudraCT:	2020-001113-21
IRAS number:	281712
PO number:	H62017838
Submission ID:	100901485

Please find enclosed an application for authorisation of substantial amendment 37 for the above trial. This is to remove two COVID-19 comparisons that have closed, and to make several other less significant changes as described in the Amendment Tool.

Note that the dexamethasone and prednisolone dosing information in the Clinical Trial Authorisation form has been updated to reflect the current total dose allowed by the protocol, which has reduced now the high-dose corticosteroid comparison for COVID-19 has closed. These total doses had previously been entered incorrectly in the CTA form. There has been no change to dosing in either of the current corticosteroid comparisons (for influenza and community-acquired pneumonia) between protocol V27.0 and V28.0.

1. Cover letter
- 2a-b. Protocol V28.0 (tracked and clean)
- 3a-b. Clinical Trial Authorisation form (xml and pdf)
4. Baloxavir marboxil SmPC V2 (EU-1-20-1500-001 2025-06-02)
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,



Sir Peter Horby

Director, Pandemic Sciences Institute

Moh Family Foundation Professor of Emerging Infectious Diseases

Nuffield Department of Medicine