



Centre for Tropical Medicine and Global Health

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

Cambridge East REC
E-submission

9 August 2021

Dear Sir or Madam

Trial: Randomised evaluation of Covid-19 therapy (RECOVERY)
EudraCT: 2020-001113-21
IRAS: 281712
REC ref: 20/EE/0101

Please find enclosed an application for an expedited authorisation of a substantial amendment for the above trial. We are applying for this amendment because after further discussion with experts we wish to strengthen the safety monitoring of participants allocated empagliflozin. We also wish to inform you that we have closed two of the comparisons in the paediatric section of the trial (corticosteroids and intravenous immunoglobulin). Follow-up continues and data analysis will follow.

As described in the previous amendment, a rare side effect of empagliflozin is ketoacidosis. We had mitigated that risk by excluding patients at the highest risk (ie, those with type 1 diabetes). Expert advice has suggested we also exclude other patients at increased risk (ie, those with post-pancreatectomy diabetes, with a history of ketoacidosis or with ketosis at presentation). We have also recommended regular monitoring of ketones so that ketosis can be managed before it progresses to ketoacidosis.

We would like to request that this amendment is **category A**, as per the amendment tool.

I believe all the necessary documentation required for this submission is attached and look forward to hearing the outcome.

Please let us know if you require any further information.





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Yours faithfully

A handwritten signature in blue ink, appearing to read 'Peter Horby', with a long horizontal flourish at the end.

Professor Sir Peter W. Horby

BSc MSc MBBS FRCP FFPH PhD
Chief Investigator, RECOVERY Trial
Professor of Emerging Infectious Diseases and Global Health

Attached files:

1. RECOVERY Protocol V17.0 (tracked and clean)
2. RECOVERY PIS/ICF (adult) V15.0 (tracked and clean)
3. Letter confirming sponsor approval
4. Amendment Tool for SA17

