Health Research Authority

Annual Progress Report to Research Ethics Committee

Clinical Trial of an Investigational Medicinal Product (CTIMP)

To be completed and submitted by the Chief Investigator or sponsor. Please email this report to the REC. For questions with Yes/No options please indicate answer in bold type.

1. Details of the Chief Investigator

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2. Details of Study

Full title of study:	Randomised Evaluation of COVID-19 Therapy (RECOVERY)
Name of REC:	Cambridge East
IRAS ID:	281712
REC reference number:	20/EE/0101
Date of favourable ethical opinion:	17-Mar-2021
Sponsor:	University of Oxford
EudraCT Number:	2020-001113-21

3. Commencement and termination dates

3.1 Has the study started in the UK?	**Yes** / No
3.2 If yes, what was the actual start date in the UK?	19-Mar-2020
If no, what are the reasons for the study not commencing in the UK? What is the expected start date? Please note, if the study will not start within 24 months of the REC Favourable Opinion date the REC may review its' opinion.	
Has the study finished? If yes, complete and submit "Declaration of end of trial" form at Annex 3 to ENTR/CT1, available on the Gov.UK Website	Yes / **No**
If no, what is the expected completion date? If you expect the study to overrun the planned completion date, what are the reasons for this?	Uncertain as it will depend on recruitment to COVID-19 and influenza comparisons
If you do not expect the study to be completed, give reason(s)	

4. Registration

Has the trial been registered?	**Yes** / No

If yes, please provide the name of the registry and registration number?	Registration number: ISRCTN50189673 Clinical Trials.gov: NCT04381936
If no:	a) What is the reason for non-registration? b) What are your intentions for registration?

5. Site Information

Number of UK research sites proposed in original application: Number of UK research sites recruited to date:	1 177
Do you plan to increase the total number of UK sites proposed for the study? Please note, the addition of any new sites not listed in the original applications to the REC and the MHRA should be notified to both bodies by submitting an amendment in IRAS.	Yes / **No**

6. Recruitment of Participants

*Number of participants recruited:	Proposed in original application: n/a Actual number recruited to date: Global: 48,550 UK: 46,980
*Number of participants completing trial:	Actual number completed to date: 0 (follow up continues via linkage to routine electronic records)

***Number of withdrawals from trial date due to:**

(a) withdrawal of consent	293
(b) loss to follow-up	0
(c) death (where not the primary outcome)	n/a
Total study withdrawals:	293

***Number of treatment failures to date (prior to reaching primary outcome) due to:**

(a) adverse events	0
(b) lack of efficacy	0
Total treatment failures:	0

* In the case of international trials, please provide separate figures for UK and non-UK participants.

Have there been any serious difficulties in recruiting participants ?	Yes / **No**
If yes, give details:	
Do you plan to increase the planned recruitment of participants into the study? Please note, any increase in planned recruitment or changes to the recruitment methodology should be notified to the REC as a substantial amendment for ethical review.	Yes / **No**

7. Safety Reports

Have there been any Suspected Unexpected Serious Adverse Reactions (SUSARs) in this trial in the UK and have they been notified to the Committee?	**Yes** / No
Has the Development Safety Update Report (DSUR) been submitted? Sponsors are required to submit a DSUR within one year of the Development International Birth Date (DIBD – the date of first authorisation of a clinical trial in any country worldwide) and provide annual DSUR submissions until all open clinical studies have ended (the final clinical study is completed and its study report has been submitted).	**Yes** / No / Not yet due (submitted with this report)

8. Amendments

Have any substantial amendments been made to the trial during the year?	**Yes** / No
If yes, please give the date and amendment number for each substantial amendment made.	29 – 15 Oct 2022 30 – 5 May 2023

9. Serious breaches of the protocol or Good Clinical Practice

Have any serious breaches of the protocol or GCP occurred in relation to this trial during the year? Under the Clinical Trials Regulations, all serious breaches must be notified to the MHRA GCP inspectors within 7 days of the matter coming to the sponsor's attention.	Yes / **No**
If yes, please give the date of each notification to the MHRA. Please provide the REC with a copy of each notification for information (unless previously notified).	

10. Other issues

Are there any other developments in the trial that you wish to report to the Committee?	Yes / **No**

11. Declaration

*Signature/Electronic authorisation of Chief Investigator or Sponsor representative: *Please print name below and insert electronic signature, if possible	
Print name:	Peter Horby
Date of submission:	12-Jun-2023