



Medicines & Healthcare products
Regulatory Agency



MHRA

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

gov.uk/mhra

Clinical Trials and Research Governance
UNIVERSITY OF OXFORD
CLINICAL TRIALS AND RESEARCH GOVERNANCE, JOINT RESEARCH OFFICE,
1ST FLOOR, BOUNDARY BROOK HOUSE, CHURCHILL DRIVE, HEADINGTON
OXFORD
OX3 7LQ
UNITED KINGDOM

17/11/2023

Dear Clinical Trials and Research Governance,

THE MEDICINES FOR HUMAN USE (CLINICAL TRIALS) REGULATIONS 2004 S.I. 2004/1031

Our Reference:	CTA 21584/0423/001-0032
Eudract Number:	2020-001113-21
Product:	Hydrocortisone, RoActemra, Kineret , Dexamethasone , Prednisolone, Empagliflozin, Oseltamivir, Baloxavir, Sotrovimab, Molnupiravir, Nirmatrelvir/ritonavir
Protocol number:	NDPHRECOVERY
Substantial Amendment Code Number:	Substantial Amendment 33

NOTICE OF ACCEPTANCE OF AMENDMENT

I am writing to inform you that the Licensing Authority accepts the proposed amendment to your clinical trial authorisation (CTA), received on 01/11/2023.

MEDICAL - Remarks: Clinical Remarks.

The following comments are for future consideration / information only and do not affect the approval status of your study. No response is required.

The new sentence (section 8.1) "Previous trials have produced conflicting results on mortality, but have mostly been underpowered for this outcome, and in aggregate they are consistent with no significant effect of corticosteroids on mortality, or with a reduction of a third.(16)" may benefit from clarification in the next protocol amendment.

If you have a query on these comments, please contact Dr Chris Cooper on chris.cooper@mhra.gov.uk

The direct e-mail address for Clinical Trials Helpline is ctdhelpline@mhra.gov.uk

This amendment may therefore be made.

If applicable, you should ensure your trial details have been updated on the database where you have registered your trial.



You are reminded that from 1 January 2022 you will need to comply with the requirements specified in the following guidance, where applicable:

- o Import of IMPs from listed countries to GB:*

<https://www.gov.uk/government/publications/importing-investigational-medicinal-products-into-great-britain-from-approved-countries>

- o Supply of IMPs to Northern Ireland:*

<https://www.gov.uk/guidance/supplying-investigational-medicinal-products-to-northern-ireland>

- o Substantial amendments to clinical trials:*

<https://www.gov.uk/guidance/guidance-on-substantial-amendments-to-a-clinical-trial>

Any required substantial amendment to your Clinical Trial Authorisation should be submitted and approved as soon as possible and before 1 January 2022.

Yours sincerely,

Clinical Trials Unit
MHRA