



**MHRA**

10 South Colonnade  
Canary Wharf  
London  
E14 4PU  
United Kingdom

[gov.uk/mhra](https://gov.uk/mhra)

Ms Heather House  
UNIVERSITY OF OXFORD  
CLINICAL TRIALS AND RESEARCH GOVERNANCE, JOINT RESEARCH OFFICE,  
1ST FLOOR, BOUNDARY BROOK HOUSE, CHURCHILL DRIVE, HEADINGTON  
OXFORD  
OX3 7LQ  
UNITED KINGDOM

13/08/2021

Dear Ms Heather House,

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

Our Reference:	CTA 21584/0423/001-0018
Eudract Number:	2020-001113-21
Product:	Hydrocortisone, RoActemra, Methylprednisolone, Intravenous immunoglobulin, REGN10933+REGN10987, Olumiant , Kineret , Dexamethasone , Dimethyl fumarate, Prednisolone, Infliximab, Empagliflozin
Protocol number:	NDPHRECOVERY
Substantial Amendment Code Number:	Substantial Amendment 19

**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 09/08/2021.

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 where it is appropriate, the Ethics Committee should also be notified of amendments.

*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