



Medicines & Healthcare products
Regulatory Agency



MHRA

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

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

16/04/2021

Dear Ms Heather House,

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

Our Reference:	CTA 21584/0423/001-0016
Eudract Number:	2020-001113-21
Product:	Hydrocortisone, RoActemra, Methylprednisolone, Intravenous immunoglobulin, REGN10933+REGN10987, Olumiant , Kineret , Dexamethasone , Dimethyl fumarate, Prednisolone, Infliximab
Protocol number:	NDPHRECOVERY
Substantial Amendment Code Number:	Substantial Amendment 17

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 14/04/2021.

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.

Yours sincerely,

Clinical Trials Unit



MHRA