



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

27/01/2021

Dear Ms Heather House,

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

Our Reference:	CTA 21584/0423/001-0013
Eudract Number:	2020-001113-21
Product:	Hydrocortisone, RoActemra, Methylprednisolone, Intravenous immunoglobulin, REGN10933+REGN10987, Aspirin, Colchicine, Olumiant , Kineret , Dexamethasone
Protocol number:	NDPHRECOVERY
Substantial Amendment Code Number:	Substantial Amendment 13, 26 January 2021

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 26/01/2021.

MEDICAL - Remarks: Remark;

The Sponsor is reminded that as per the SmPC's for Baracitinib and Anakinra, women of childbearing potential must use effective contraception and for Baracitinib contraceptive use must continue for at least one week after treatment.

This advice must be provided to patients as and where/when appropriate.

For further information email; lisa.campbell@mhra.gov.uk

TOXICOLOGY

PHARMACEUTICAL

This amendment may therefore be made.

You are reminded that where it is appropriate, the Ethics Committee should also be notified of amendments.



Yours sincerely,

Clinical Trials Unit
MHRA