Medicines & Healthcare products Regulatory Agency

MHRA

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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

23/11/2020

Dear Ms Heather House,

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

Our Reference:	CTA 21584/0423/001-0011
Eudract Number:	2020-001113-21
Product:	Hydrocortisone, RoActemra, Methylprednisolone, Intravenous immunoglobulin, REGN10933+REGN10987, Aspirin, Colchicine
Protocol number:	NDPHRECOVERY
Substantial Amendment Code Number:	Substantial Amendment 11, 19 November 2020

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 20/11/2020.

MEDICAL - Remarks:
Blood dyscrasias has not been included as a contraindication (as per the SmPC for Colchicine), the Sponsor is asked to address this by contacting Dr Lisa Campbell (lisa.campbell@mhra.gov.uk) and addressing this at the time of a subsequent substantial amendment as appropriate.
For future IMP additions to RECOVERY the Sponsor is reminded to provide a scientific rationale to support the use of the IMP in the treatment of COVID -19, this can be provided either in the protocol or the application cover letter. The choice of dosing regimens should also be justified.
For further information email lisa.campbell@mhra.gov.uk

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

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