Medicines & Healthcare products Regulatory Agency

MHRA

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

18/09/2020

Dear Ms Heather House,

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

Our Reference:	CTA 21584/0423/001-0009
Eudract Number:	2020-001113-21
Product:	Hydrocortisone, Hydroxychloroquine, Azithromycin, RoActemra, Methylprednisolone, Intravenous immunoglobulin, REGN10933+REGN10987
Protocol number:	NDPHRECOVERY
Substantial Amendment Code Number:	Substantial Amendment 8, 10 September 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 15/09/2020.

MEDICAL - Remarks: Remark (for information only);
The Sponsor is asked to consider adding the following to the PIL and protocol post approval of the substantial amendment;
Pregnant women that are administered mAb's (REGN10933 and REGN10987) in the RECOVERY trial must be advised that live vaccines should be avoided in children with in utero exposure to biologics for at least the first 6 months of life.
For further information contact Dr Lisa Campbell by 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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