



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

16/12/2020

Dear Ms Heather House,

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

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|------------------------------------|---|
| Our Reference: | CTA 21584/0423/001-0012 |
| Eudract Number: | 2020-001113-21 |
| Product: | Hydrocortisone, RoActemra, Methylprednisolone, Intravenous immunoglobulin, REGN10933+REGN10987, Aspirin, Colchicine |
| Protocol number: | NDPHRECOVERY |
| Substantial Amendment Code Number: | Substantial Amendment 12, 15 December 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 15/12/2020.

MEDICAL - Remarks: It is assumed that the children will meet the main Recovery eligibility, although this has not been specifically stated.

The Sponsor is reminded that substantial amendments require a robust scientific rationale and justification (provided in a cover letter or the protocol). This has not been provided on this occasion (rather the information provided is sparse). In future substantial amendments, if this MHRA requirement is not met and an assessor has significant questions or safety concerns then a substantial amendment may be rejected.

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