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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

08/04/2020

Dear Ms Heather House,

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

| | |
|------------------------------------|---|
| Our Reference: | CTA 21584/0423/001-0003 |
| Eudract Number: | 2020-001113-21 |
| Product: | Lopinavir/ritonavir, Dexamethasone, Hydroxychloroquine, Azithromycin |
| Protocol number: | NDPHRECOVERY |
| Substantial Amendment Code Number: | Code Number: SA2 Version: 1.0 Date: 2020/04/07 |

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 07/04/2020.

PHARMACEUTICAL - Remarks: The following comment is for information only and does not affect the approval status of your study.

1. The CTA application form should be updated to include hydrocortisone and prednisolone as IMPs. Section D.9-1 should also be updated to list the additional IMPs. A copy of the updated form and xml file can be included with the next substantial amendment.

For further information on the above point, please contact Dr Graham McNaughton on 020 3080 6148 or graham.mcnaughton@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