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

05/05/2020

Dear Ms Heather House,

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

Our Reference:	CTA 21584/0423/001-0005
Eudract Number:	2020-001113-21
Product:	Lopinavir/ritonavir, Dexamethasone, Hydroxychloroquine, Azithromycin
Protocol number:	NDPHRECOVERY
Substantial Amendment Code Number:	Code Number: SA4 Version: 1.0 Date: 2020/04/24

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 28/04/2020.

MEDICAL - Remarks: Clinical Conditions of approval
1. Inclusion of children to all study arms can be approved provided the DSMB has specific and regular oversight of emerging data from the paediatric population. This must include safety as well as efficacy, both for paediatric data and paediatric and adult data combined. There should be a low threshold for taking action.
If these conditions are met, the trial amendment is authorised and you do not need to respond to this letter. If your trial does not meet these conditions, your trial does not have authorisation and therefore you cannot proceed with the trial. You must inform the MHRA immediately if the trial does not meet the above conditions. All changes to the terms and conditions of this trial must be made as a request for a substantial amendment to this clinical trial authorisation.
If you have a query on these comments, please contact Dr Kirsty Wydenbach on 020 3080 6859 or Kirsty.wydenbach@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

Medicines and Healthcare Products Regulatory Agency