



MHRA

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

gov.uk/mhra

Prof C Butler
UNIVERSITY OF OXFORD
NUFFIELD DEPARTMENT OF PRIMARY CARE HEALTH SCIENCES,
RADCLIFFE OBSERVATORY QUARTER, WOODSTOCK ROAD
OXFORD
OX2 6GG
UNITED KINGDOM

28/04/2021

Dear Prof C Butler,

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

Our Reference:	CTA 21584/0426/001-0013
Eudract Number:	2020-001209-22
Product:	Plaquenil-Hydroxychloroquine, Azithromycin, Doxycycline, Pulmicort Turbohaler 400, Colchicine, Favipiravir (Avigan), Ivermectin
Protocol number:	PRINCIPLE
Substantial Amendment Code Number:	SA 15

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 27/04/2021.

MEDICAL - Remarks: The IB contains an RSI section of several pages and only one adverse reaction is serious (Hepatitis), the rest non-serious.

If non-serious adverse reactions are included in the RSI table the Sponsor has to add the following statement in the RSI: "For the purpose of safety reporting in the clinical trials only serious adverse reactions already listed as serious in the above table will be considered expected; Any other serious ADR will be considered unexpected".

This amendment request is therefore approved on the condition that the Sponsor will add the statement above to the IB at the time of the next formal substantial amendment request for the trial (be that for any document).

For further information email; lisa.campbell@mhra.gov.uk

This amendment may therefore be made.

If applicable, you should ensure your trial details have been updated on the database where you have registered your trial.



You are reminded that where it is appropriate, the Ethics Committee should also be notified of amendments.

Yours sincerely,

Clinical Trials Unit
MHRA