



Medicines & Healthcare products
Regulatory Agency



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

09/03/2021

Dear Prof C Butler,

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

Our Reference:	CTA 21584/0426/001-0011
Eudract Number:	2020-001209-22
Product:	Plaquenil-Hydroxychloroquine, Azithromycin, Doxycycline, Pulmicort Turbohaler 400, Colchicine, Favipiravir (Avigan)
Protocol number:	PRINCIPLE
Substantial Amendment Code Number:	SA 13, 22 February 2021

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 09/03/2021.

MEDICAL

TOXICOLOGY - Remarks: Nonclinical remark (no response required) - it is noted that the Investigator's brochure is dated 20 March 2020 and, therefore, a revision will be expected soon.

PHARMACEUTICAL

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