



Medicines & Healthcare products
Regulatory Agency



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Prof C Butler
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NUFFIELD DEPARTMENT OF PRIMARY CARE HEALTH SCIENCES,
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30/03/2020

Dear Prof C Butler,

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

Our Reference:	CTA 21584/0426/001-0002
Eudract Number:	2020-001209-22
Product:	Plaquenil-Hydroxychloroquine
Protocol number:	PRINCIPLE
Substantial Amendment Code Number:	Code Number: SA1 Version: Date: 2020/03/27

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 27/03/2020.

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**