



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

07/04/2022

Dear Prof C Butler

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

Our Reference: CTA 21584/0452/001-0004

IRAS ID: 1004274

Product: Molnupiravir, Paxlovid

Protocol number: PANORAMIC

Substantial Amendment Code Number: Substantial Amendment 03

NOTICE OF ACCEPTANCE OF AMENDMENT

I am writing to inform you that the Licensing Authority, having reviewed your application in collaboration with the Research Ethics Committee (where applicable), accepts the proposed amendment to your clinical trial authorisation (CTA), received on 05/04/2022.

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.

You are reminded that from 1 January 2022 you will need to comply with the requirements specified in the following guidance, where applicable:





Import of IMPs from listed countries to GB:

 $\underline{https://www.gov.uk/government/publications/importing-investigational-medicinal-products-into-great-britain-from-approved-countries}$

Supply of IMPs to Northern Ireland:

 $\underline{https://www.gov.uk/guidance/supplying-investigational-medicinal-products-to-northern-ireland}$

Substantial amendments to clinical trials:

https://www.gov.uk/guidance/guidance-on-substantial-amendments-to-a-clinical-trial

Any required substantial amendment to your Clinical Trial Authorisation should be submitted and approved as soon as possible and before 1 January 2022.

Yours sincerely,

Clinical Trials Unit MHRA