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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

28/12/2022

Dear Prof C Butler

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

Our Reference: IRAS ID: Product: Protocol number: Substantial Amendment Code Number: CTA 21584/0452/001-0007 1004274 Molnupiravir, Paxlovid PANORAMIC Substantial Amendment 6

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 17/11/2022.

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: <u>https://www.gov.uk/government/publications/importing-investigational-medicinal-products-into-great-britain-from-approved-countries</u>

Supply of IMPs to Northern Ireland:

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