Medicines & Healthcare products Regulatory Agency

MHRA

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Dr P Bath
UNIVERSITY OF NOTTINGHAM
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UNITED KINGDOM

18/05/2021

Dear Dr P Bath,

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

Our Reference:	CTA 03057/0073/001-0001
Eudract Number:	2021-000185-15
Product:	Ciclesonide, Niclosamide Ethanolamine
Protocol number:	21001

NOTICE OF ACCEPTANCE OF AMENDED REQUEST

I am writing to inform you that the Licensing Authority accepts your amended request for a clinical trial authorisation (CTA), received on 28/04/2021.

The authorisation is effective from the date of this letter although your trial may be suspended or terminated at any time by the Licensing Authority in accordance with regulation 31. You must notify the Licensing Authority within 90 days of the trial ending.

You are reminded that a favourable opinion from the Ethics Committee is also required before this trial can proceed, changes made as part of your amended request may need to be notified to the Ethics Committee. If not already provided, please follow the guidance on our website on informing us of the registration status of your trial (where applicable).

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:***

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

- ***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