Medicines & Healthcare products Regulatory Agency

MHRA

MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

gov.uk/mhra

Mr Ali Alshukry
UNIVERSITY OF NOTTINGHAM
E-FLOOR, YANG FUJIA BUILDING,
JUBILEE CAMPUS, WOLLATON ROAD
NOTTINGHAM
NG8 1BB
UNITED KINGDOM

28/08/2024

Dear Mr Ali Alshukry,

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

Our Reference:	CTA 03057/0075/001-0005
Eudract Number:	2021-003853-40
Product:	Metoclopramide
Protocol number:	21051
Substantial Amendment Code Number:	SA-03-24

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 24/07/2024.

MEDICAL - Remarks: *Clinical Remarks:

The following comments are for future consideration / information only and do not affect the approval status of your study. No response is required.

1. Whilst the application is approved, the sponsor is informed that some of the changes between protocol version 1.0 dated 01-09-2021 and version 1.4 dated 06-03-2023 can be considered substantial changes as per current regulations that should not have been implemented without MHRA approval (i.e. changes to eligibility criteria), therefore the MHRA GCP inspectorate has been informed of the sponsor's non-compliance.

In the event of a GCP inspection this should be made clear and measures to avoid future non-compliances should be appropriately documented by the sponsor.

The sponsor is reminded that in the future any similar changes would require approval from the Regulatory Authority. In case of doubt, whether an amendment is substantial or not, the Sponsor is recommended to ask advice from the Regulatory Authority.

Further details on the notion of 'substantial', and examples, can be found in article 3.3 and 3.4 of the detailed guidance CT-1 (Detailed guidance on the request to the competent authorities for authorisation of a clinical trial on a medicinal product for human use, the notification of substantial amendments and the declaration of the end of the trial (2010/C 82/01))

2. The sponsor has not provided tracked-changes version showing the changes between protocol version 1.2 (13th July 2022) and protocol version 1.3 (8th November 2022) as the submitted file labelled as “MAPS-2 Research Protocol v1.3_20221108_tracked changes” is a clean version. Therefore, these changes have not been assessed or approved in the current submission. The sponsor should submit details of changes conducted between version 1.2 (13th July 2022) and protocol version 1.3 (8th November 2022) at the time of the next substantial amendment.

The sponsor is reminded that substantial changes to the protocol can only be implemented after approval by the regulatory agency.

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 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