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

22/04/2024

Dear Mr Ali Alshukry,

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

Our Reference:	CTA 03057/0074/001-0005
Eudract Number:	2021-001050-62
Product:	Cyklokapron
Protocol number:	21022
Substantial Amendment Code Number:	SA_06_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 19/03/2024.

MEDICAL - Remarks: Remarks regarding eligibility checklist:

The following comments are for information only. No response is required:

The eligibility checklist is not formally reviewed by MHRA. However, for information, a typographical error is noted in the 4th exclusion criterion: it is assumed that “+10mls” should be “+/-10%” in line with updates to the protocol, although within the protocol the update to “60 ml +/-10%” has been applied to the explanatory text but not the eligibility criterion itself.

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