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02/08/2023

Dear Mr Ali Alshukry

NOTIFICATION OF ADMINISTRATIVE AMENDMENT

Our Reference:	CTA 03057/0074/001-0004
Eudract Number:	2021-001050-62
Product:	Cyklokapron
Protocol Number:	21022
Substantial Amendment Code Number:	change to the sponsor contact

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

Thank you for your notification received on 01/08/2023. The information you provided has been recorded.

You should ensure that, where applicable, your trial details have been updated on the database in which 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:

- o Import of IMPs from listed countries to GB:*

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

- o Supply of IMPs to Northern Ireland:*

<https://www.gov.uk/guidance/supplying-investigational-medicinal-products-to-northern-ireland>

- o 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.

Please quote the above reference numbers in all communications.

Yours sincerely

Submissions
MHRA