



MHRA

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

[gov.uk/mhra](https://www.gov.uk/mhra)

Ms Jennifer Boston
NOTTINGHAM UNIVERSITY HOSPITALS NHS TRUST
RESEARCH & INNOVATION,
QUEEN'S MEDICAL CENTRE, DERBY ROAD
NOTTINGHAM
NG7 2UH
UNITED KINGDOM

15/05/2023

Dear Ms Jennifer Boston

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

| | |
|------------------|-------------------------|
| Our Reference: | CTA 19162/0239/001-0001 |
| IRAS ID: | 1004870 |
| Product: | Mannitol |
| Protocol number: | 22SR001 |

NOTICE OF ACCEPTANCE OF AMENDED REQUEST

I am writing to inform you that the Licensing Authority, having reviewed your application in collaboration with the Research Ethics Committee, accepts your amended request for a clinical trial authorisation (CTA), with effective received date of 21/10/2022.

COMBINED REVIEW MEDICAL

PHARMACEUTICAL

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