Medicines & Healthcare products Regulatory Agency

MHRA

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Louise Ner
NHS GREATER GLASGOW & CLYDE AND UNIVERSITY OF GLASGOW
CLINICAL RESEARCH AND DEVELOPMENT CENTRAL OFFICE,
WARD 11, DYKEBAR HOSPITAL, GRAHAMSTON ROAD
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UNITED KINGDOM

14/04/2025

Dear Louise Ner,

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

Our Reference:	CTA 24712/0060/001-0004
Eudract Number:	2021-006886-39
Product:	Noradrenaline (Norepinephrine), Plasma-Lyte® 148, Compound Sodium Lactate Solution for Infusion BP
Protocol number:	GN20AE342
Substantial Amendment Code Number:	SA_09

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 13/03/2025.

MEDICAL - Remarks: *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 trial application is approved, the sponsor is reminded that the impact in the study scientific integrity of the proposed changes (change to primary objective and sample size) must be taken into consideration during the statistical analysis. This is something that should be addressed in the SAP. The sponsor should be prepared to justify trial integrity at the analysis stage. It will be expected thorough insurance that any changes to this ongoing study have exclusively been based on external information, and this should be adequately documented.

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