



Medicines & Healthcare products
Regulatory Agency



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Miss E Laing
NHS BLOOD AND TRANSPLANT
CLINICAL TRIALS UNIT,
LONG ROAD
CAMBRIDGE
CB2 0PT
UNITED KINGDOM

15/10/2024

Dear Miss E Laing,

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

Our Reference:	CTA 25224/0007/001-0003
Eudract Number:	2021-006876-18
Product:	LyoPlas N-w
Protocol number:	v1.0
Substantial Amendment Code Number:	Amendment 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 01/10/2024.

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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:

- 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.

Yours sincerely,

Clinical Trials Unit



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