



MHRA

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

02/03/2022

Dear Miss E Laing

THE MEDICINES FOR HUMAN USE (CLINICAL TRIALS) REGULATIONS 2004 S.I. 2004/1031 (as amended)(the 'Regulations')

Our Reference:	CTA 25224/0007/001-0001
EudraCT Number:	2021-006876-18
Product:	LyoPlas N-w
Protocol number:	v1.0

ACKNOWLEDGEMENT OF NOTIFICATION

I am writing to confirm receipt of your notification of a clinical trial received on 28/02/2022.

For the purposes of regulation 18(2)(c) or 20(2)(a) and (5) of the Regulations (as appropriate), this letter is notice of authorisation of the trial referenced above with effect from 14/03/2022 subject to the following condition:

- that no further correspondence is received from the Licensing Authority before the effective date requiring full assessment of your request for authorisation.

You are reminded that 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. 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**