



Medicines & Healthcare products
Regulatory Agency

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Dr Mays Jawad
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JOINT RESEARCH MANAGEMENT OFFICE, DEPT W,
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UNITED KINGDOM

18/08/2026

Dear Dr Mays Jawad,

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

Our Reference	CTA 21313/0082/001-0002
IRAS ID	1008285
Product	Omegaven
Protocol number	1.0
Substantial Modification Code Number	Substantial modification 1 Route A

NOTICE OF ACCEPTANCE OF SUBSTANTIAL MODIFICATION

This letter refers to your modification request received on 16/07/2026.

The licensing authority accepts the proposed substantial modification to your clinical trial authorisation (CTA), including the labelling, subject to any conditions.

COMBINED REVIEW MEDICAL

You are reminded that, where appropriate, a favourable opinion from the ethics committee is also required before this modification can be made (please refer to the Modification Tool outcome).

Please ensure that the public registry where you have registered your trial has been updated to reflect any relevant changes.

Yours sincerely,

Clinical Investigations & Trials
MHRA