Medicines & Healthcare products Regulatory Agency

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Alasdair Munro
UNIVERSITY HOSPITAL SOUTHAMPTON NHS FOUNDATION TRUST
TREMONA ROAD,
SOUTHAMPTON
SO16 6YD
UNITED KINGDOM

25/08/2026

Dear Alasdair Munro,

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

| | |
|---|---|
| Our Reference | CTA 11709/0290/001-0004 |
| IRAS ID | 1012411 |
| Product | Fluenz |
| Protocol number | RHM CHI 1293 |
| Substantial Modification Code Number | Substantial Modification 03 (SM03) |

**NOTICE OF ACCEPTANCE OF AMENDED SUBSTANTIAL MODIFICATION**

This letter refers to your amended modification request, received on 25/08/2026; 24/08/2026.

The licensing authority accepts the proposed amended 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**