



Medicines & Healthcare products
Regulatory Agency

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Ms Ruth Nicholson
IMPERIAL COLLEGE LONDON
5TH FLOOR, SHERFIELD BUILDING,
SOUTH KENSINGTON CAMPUS
LONDON
SW7 2BB
UNITED KINGDOM

11/09/2026

Dear Ms Ruth Nicholson,

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

Our Reference	CTA 19174/0458/001-0003
IRAS ID	1008743
Product	Simvastatin, Baricitnib
Protocol number	175151
Substantial Modification Code Number	Substantial Modification 2 (SM02)

NOTICE OF ACCEPTANCE OF SUBSTANTIAL MODIFICATION

This letter refers to your modification request received on 06/08/2026.

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

COMBINED REVIEW MEDICAL
PHARMACEUTICAL

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