Medicines & Healthcare products Regulatory Agency

MHRA

MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

gov.uk/mhra

Dr Mays Jawad
QUEEN MARY, UNIVERSITY OF LONDON
DEPARTMENT W RESEARCH SERVICES,
69-89 MILE END ROAD
LONDON
E1 4UJ
UNITED KINGDOM

15/09/2025

Dear Dr Mays Jawad

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

Our Reference:	CTA 21313/0081/001-0002
IRAS ID:	1011239
Product:	Ibuprofen
Protocol number:	1.0
Substantial Amendment Code Number:	Substantial amendment 1

NOTICE OF ACCEPTANCE OF AMENDMENT

I am writing to inform you that the Licensing Authority, having reviewed your application in collaboration with the Research Ethics Committee (where applicable), accepts the proposed amendment to your clinical trial authorisation (CTA), received on 27/08/2025.

COMBINED REVIEW SCIENTIFIC

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 where it is appropriate, the Ethics Committee should also be notified of amendments.

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

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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