Medicines & Healthcare products Regulatory Agency

MHRA

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Dr Mays Jawad
QUEEN MARY, UNIVERSITY OF LONDON
DEPARTMENT W RESEARCH SERVICES,
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UNITED KINGDOM

11/02/2025

Dear Dr Mays Jawad

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

Our Reference:	CTA 21313/0081/001-0001
IRAS ID:	1011239
Product:	Ibuprofen
Protocol number:	1.0

NOTICE OF ACCEPTANCE OF AMENDED REQUEST

I am writing to inform you that the Licensing Authority, having reviewed your application in collaboration with the Research Ethics Committee, accepts your amended request for a clinical trial authorisation (CTA), with effective received date of 21/11/2024.

COMBINED REVIEW MEDICAL - Remarks: *Clinical Conditions for Approval:

Authorisation of your trial is subject to compliance with the following condition(s):

1. For the conduct of this trial in the UK, the screening period is defined as 28 days before surgery (up to Day 0). Therefore, all eligibility criteria must be reassessed and confirmed by the study investigator or delegated prior to the IMP administration.

This is for immediate implementation; the study centres must be informed. In addition, this must be clarified in the protocol at the time of the next protocol amendment (section 7.2 and 11.1). Please note that compliance with these conditions is subject to specific scrutiny in any future GCP inspection.

If your trial does not meet these conditions your trial does not have authorisation and therefore you cannot proceed with the trial. You must inform the MHRA immediately if this is the case. All changes to the terms and conditions of this trial must be made as a request for a substantial amendment to this clinical trial authorisation.

If you have a query on these comments, please contact Dr Charles Garasi at Charles.Garasi@mhra.gov.uk.

*Remarks:

The following comments are for future consideration/information only and do not affect the approval status of your study. No response is required.

1. The Study schedule in Section 11.1 of the PROTECT-AEGIS protocol currently states “Prescreening (up to 365 days before surgery)”. However, no Screening period is present in the schedule. In line with the condition of approval above, Section 11.1 and Section 7.2 of the protocol should clarify that the pre-screening period is defined as up to 365 days before surgery, and the screening period is within 28 days up to Day 0 prior to surgery." The Sponsor should revise the Study Schedule in Section 11.1 and Section 7.2 to correct any discrepancy and ensure accuracy throughout the protocol.

PHARMACEUTICAL

The authorisation is effective from the date of this letter although 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, changes made as part of your amended request may need to be notified to the Ethics Committee. 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