

MHRA

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Trials Manager UNIVERSITY OF WARWICK WARWICK CLINICAL TRIALS UNIT, WARWICK MEDICAL SCHOOL, GIBBET HILL ROAD COVENTRY CV4 7AL UNITED KINGDOM

01/04/2021

Dear Trials Manager

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

Our Reference: Eudract Number: Product: Protocol Number: Substantial Amendment Code Number: CTA 24637/0010/001-0004 2020-000154-10 Ketamine, Morphine sulfate SOC.12/19-20 Substantial Amendment 3, 16 March 2021

ACKNOWLEDGEMENT OF AMENDMENT

Thank you for your notice of amendment, received on 26/03/2021. The information you provided to support your request is complete and therefore your request is valid.

Your request will be assessed and you will be notified of the Licensing Authority's decision within 35 days.

Please quote the EudraCT number, CTA number and your amendment code in any further communications relating to this submission.

Yours sincerely,

Submissions MHRA