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

14/04/2021

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

NOTICE OF ACCEPTANCE OF AMENDMENT

I am writing to inform you that the Licensing Authority accepts the proposed amendment to your clinical trial authorisation (CTA), received on 26/03/2021.

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.

Yours sincerely,

Clinical Trials Unit MHRA