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Ms Angela Shone UNIVERSITY OF NOTTINGHAM EAST ATRIUM, JUBILEE CONFERENCE CENTRE, TRIUMPH ROAD, NOTTINGHAM, NG8 1DH, UNITED KINGDOM

22/11/2019

Dear Ms Angela Shone,

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 03057/0070/001-0003 2018-001904-12 DDAVP INJECTION 4MCG/ML 18040 Code Number: SA/03/19 Version: Date: 2019/08/21

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 30/10/2019.

This amendment may therefore be made.

You are reminded that where it is appropriate, the Ethics Committee should also be notified of amendments.

Yours sincerely,

Clinical Trials Unit MHRA