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Regulating Medicines and Medical Devices

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15/11/2015

Dear Mrs E Lawrie

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

Our Reference:	20363/0273/001-0015
Eudract Number:	2009-012717-22
Product:	rituximab
Protocol number:	UCL/08/0167
Substantial Amendment Code Number:	Code Number:Substantial Amendment 11.09.2015 MHRA (Protocol 7.0, change of reference safety information, changes of PI)
Version: 7.0	
Date: 2015/09/11	

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 28/10/2015.

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