MHRA
Regulating Medicines and Medical Devices

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15/06/2016

Dear Mrs E Lawrie

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

Our Reference:	20363/0273/001-0017
Eudract Number:	2009-012717-22
Product:	rituximab
Protocol number:	UCL/08/0167
Substantial Amendment Code Number:	Code

Number:
Substantial Amendment 18.05.2016 MHRA (Protocol v8.0, change of reference safety information, changes of PI)
Version: 8.0
Date: 2016/05/18

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 19/05/2016.

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

RECEIVED 16 JUN 2016

Medicines and Healthcare Products Regulatory Agency