Safeguarding public health

MHRA

Mr S Purnell
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27/09/2012

Dear Mr S Purnell

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

Our Reference:	20363/0273/001-0011
Eudract Number:	2009-012717-22
Product:	rituximab
Protocol number:	UCL/08/0167
Substantial Amendment Code Number:	Substantial Amendment 03.08.2012 (Protocol v 5.0, change of MA holder for Oncaspar, updated Oncaspar SPC) Changes of PIs and Addition of sites)

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 24/08/2012.

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