Safeguarding public health

MHRA

Ms C Roffe
NORTH STAFFORDSHIRE COMBINED HEALTHCARE NHS TRUST
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09/10/2012

Dear Ms C Roffe

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

Our Reference:	21434/0001/001-0007
Eudract Number:	2006-003479-11
Product:	OXYGEN COMPRESSED OR LIQUID GAS
Protocol number:	06/Q2604/75
Substantial Amendment Code Number:	Document Amendments July 2012

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 10/09/2012.

For information only in relation to updating patient information sheet and informed consent:
* You are referred to 'Detailed guidance on the request to the competent authorities for authorisation of a clinical trial on a medicinal product for human use, the notification of substantial amendments and the declaration of the end of the trial' (CT-1)
# 127 states that for substantial amendments to information that is assessed, according to Directive 2001/20/EC, only by the Ethics Committee of the Member State concerned, the sponsor should only notify the amendment to the Ethics Committee.>

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