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Ethics
Service

Research Ethics Committee (REC) for Wales
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06 June 2012

Professor Alan Burnett
Cardiff University
Department of Haematology
School of Medicine
Heath Park
Cardiff
CF14 4XN

Dear Professor Burnett

Study title: AML 17: A Programme of Development for the Treatment of Younger Patients with Acute Myeloid Leukaemia and High Risk Myelodysplastic Syndrome
REC reference: 08/MRE09/29
Protocol number: 372-07
EudraCT number: 2007-003798-16
Amendment number: Non Substantial Protocol Amendment
Amendment date: June 2012

Thank you for your letter of 1 June 2012, notifying the Committee of the above amendment.

It is noted that you do not consider this to be a substantial amendment to the clinical trial authorisation, as defined in the Medicines for Human Use (Clinical Trials) Regulations 2004, and that ethical review by the Committee is therefore not required.

Documents received

The documents received were as follows:

Document	Version	Date
Protocol	7.2	June 2012
Notification of a Minor Amendment	Non Substantial Protocol Amendment	01 June 2012
Covering Letter	Signed by Alison Jenkins, AML17 Trial Manager	01 June 2012

Statement of compliance

This Committee is recognised by the United Kingdom Ethics Committee Authority under the Medicines for Human Use (Clinical Trials) Regulations 2004, and is authorised to carry out the ethical review of clinical trials of investigational medicinal products.

The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

Cynhelir Cydweithrediad Gwyddor Iechyd Academaidd y Sefydliad Cenedlaethol ar gyfer Ymchwil Gofal Cymdeithasol ac Iechyd gan Fwrdd Addysgu Iechyd Powys

The National Institute for Social Care and Health Research Academic Health Science
Collaboration is hosted by Powys Teaching Health Board

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

08/MRE09/29:

Please quote this number on all correspondence

Yours sincerely

A handwritten signature in black ink, appearing to read 'Helen Williams', with a large, stylized flourish at the end.

Helen Williams
Assistant Co-ordinator

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Copy to:

Dr K J Pittard Davies, Cardiff University