



Research Ethics Committee (REC) for Wales
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15 November 2011

Professor Alan K Burnett
Professor of Haematology
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: Version 8

Amendment date: 24 October 2011

The above amendment was reviewed at the meeting of the Committee held on 10 November 2011.

Ethical opinion

Dr. Jenney declared an interest and left the room – she is a co-investigator for this study.

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
European Commission Notification of Substantial Amendment Form	Version 8	24 October 2011
Covering Letter	Signed by Prof. A Burnett, WCTU	24 October 2011
Participant Information Sheet: Adult Patient Information Sheet and consent form 3	6 (tracked changes version)	24 October 2011
Participant Information Sheet: Adult Patient Information Sheet and consent form 1	7 (tracked changes version)	24 October 2011
Protocol	8 (tracked changes)	24 October 2011

	version)	
GP Information Sheet 1	2	24 October 2011

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

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.

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) 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



Dr Gordon Taylor
Chairman

E-mail: corinne.scott@wales.nhs.uk

Enclosures: List of names and professions of members who took part in the review

Copy to: Dr K J Pittard Davies, Cardiff University

REC for Wales

Attendance at Committee meeting on 10 November 2011

<i>Name</i>	<i>Profession</i>	<i>Capacity</i>
Dr Gail Boniface	Occupational Therapist	Expert
Dr Paul Brown	Radiographer	Expert
Dr Maurice Buchalter	Alternate Vice Chairman / Hospital Consultant (Cardiologist)	Expert
Dr Kate Bullen	Psychologist	Expert
Mrs Monika Hare	Research Fellow	Lay
Mr HAO Hughes	Pharmacist	Expert
Dr Meriel Jenney	Hospital consultant (Paediatric oncologist)	Expert
Mr Keith Jones	Retired Probation Officer	Lay Plus
Dr Gordon Taylor	Chairman / Statistician	Expert
Mrs Wendy Turkie	Nurse	Expert
Dr Richard Walker	Deputy Director, Rowan Tree Cancer Care	Lay
Mr Stewart Williams	Management Consultant	Lay Plus

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Dr Corinne Scott	Co-ordinator
Ms Catherine Turpin	Research and Development Secretary

Written comments received from:

<i>Name</i>	<i>Position</i>
Dr Pete Wall	Vice Chairman / Clinical Physiologist

