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08 September 2011

Professor Philip M. W. Bath
Professor of Stroke Medicine
University of Nottingham
Division of Stroke Medicine - Research Dept
Clinical Sciences Building
City Hospital Campus
Hucknall Road
Nottingham NG5 1PB

Dear Professor Bath

Study Title:	**Safety and tolerability of clopidogrel when added to aspirin and dipyridamole in high risk patients with recent ischaemic stroke: a randomised controlled trial**
REC reference number:	**08/H1102/112**
Protocol number:	**31350**
EudraCT number:	**2007-006749-42**
Amendment number:	**SA02/11**
Amendment date:	**22 August 2011**

Thank you for submitting the above amendment, which was received on 27 August 2011.

Research Site	Principal Investigator / Local Collaborator
Royal Victoria Infirmary, Clinical Research Facility, Level 4, Leazes Wing, Queen Victoria Road, Newcastle Upon Tyne NE1 4LP	Anand Dixit
James Paget University Hospitals NHS Foundation Trust, Lowestoft Road, Gorleston, Nr Great Yarmouth, NR31 6LA	Syed Muhammad Mazhar
Queen Elizabeth Hospital (Gateshead Health NHS Foundation Trust), Sheriff Hill, Gateshead, NE9 6SX	Timothy Cassidy

The amendment relates solely to the addition of new site(s) and/or investigator(s) within the National Health Service (NHS) or Health and Social Care (HSC) in Northern Ireland. The site-specific assessment for the site(s) will therefore form part of the research governance review. The Site-Specific Information (SSI) Form for the site should be included with the application for R&D approval.

On behalf of the Committee, I am pleased to confirm the extension of the favourable opinion to the new site(s) and/or investigator(s), subject to management permission being given by the relevant NHS/HSC R&D office(s) prior to the study starting at the site.

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/H1102/112	**Please quote this number on all correspondence**

Yours sincerely

Mr Dean Beattie
Committee Co-ordinator

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Copy to: *Margaret Adrian – TARDIS Trial Coordinator*
Mr Paul Cartledge
Clinical Trials Unit, MHRA