London - South East Research Ethics Committee
Barlow House
3rd Floor
4 Minshull Street
Manchester
M1 3DZ

11 February 2016

Michael Stringer
Via Email

Dear Michael Stringer

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:	**08/H1102/112**
Protocol number:	**31350**
EudraCT number:	**2007-006749-42**
Amendment number:	**SA01/16**
Amendment date:	**09 February 2016**
IRAS project ID:	

The Substantial Amendment proposes to update centres, principal Investigators and closures of sites.
Remove sites;
- Princess Royal Hospital, PI Ali Khalid
- Queen Alexandra Hospital, PI Peter Howard
- Sandwell General Hospital, PI Sissi Ispoglou

Change of PI;
- Rotherham Hospital NHS FT, PI Sunil Punnoose, replacing Dr James Okwera
- Bedford Hospital NHS FT, PI Mohammed Siddiqui, replacing Dr Hlaing Ni
- Barts Health NHS FT, PI Roser Icart-Palau, replacing Dr Rajendra Yadava
- Stockport NHS Foundation Trust, PI Joseph Vassalo, replacing Dr Kamiran Dizayee
- Great Western Hospital NHS FT, PI Milda Bajoriene, replacing Dr Gopinath Ramadurai
- Torbay and South Devon NHS FT, PI Biju Bhaskaran, replacing Dr Isam Salih

Thank you for submitting the above amendment, which was received on 09 February 2016.

Research site - Remove Sites	*Principal Investigator / Local Collaborator*
Princess Royal Hospital	Ali Khalid
Queen Alexandra Hospital	Peter Howard
Sandwell General Hospital	Sissi Ispoglou
Research site - Change of PI	*Principal Investigator / Local Collaborator*
Rotherham Hospital NHS FT	Sunil Punnoose
Bedford Hospital NHS FT	Mohammed Siddiqui
Barts Health NHS FT,	Roser Icart-Palau
Stockport NHS Foundation Trust	Joseph Vassalo
Great Western Hospital NHS FT	Milda Bajoriene

Torbay and South Devon NHS FT	Biju Bhaskaran

The amendment relates solely to the new sites and investigators within the National Health Service (NHS) or Health and Social Care (HSC) in Northern Ireland. The site-specific assessment for the sites 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 sites and investigator, 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

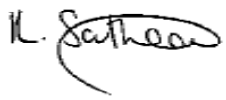
This Committee is recognised by the United Kingdom Ethics Committee Authority under the Medicines for Human Use (Clinical Trials) Regulations 2004, and is authorised to carry out the ethical review of clinical trials of investigational medicinal products.

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 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



Katie Southeard
REC Assistant

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