

01 December 2011

Information Processing Unit
Area 6
Medicines & Healthcare Products Regulatory Agency
151 Buckingham Palace Road
Victoria
London
SW1W 9SZ

ASCEND

Clinical Trial Service Unit (CTSU)
Richard Doll Building
University of Oxford
Old Road Campus
Headington
Oxford
OX3 7LF

Office telephone: 01865 743888
Office fax: 01865 743981
Freefone: 0800 585323
e-mail: ascend@ctsu.ox.ac.uk
Website: www.ctsu.ox.ac.uk/ascend

Dear Sir/Madam,

Notification of Amendment for ASCEND: A Study of Cardiovascular Events iN Diabetes (Ref: MF8000/13137-8)
EudraCT number: 2004-000991-15

Please find enclosed for your information a completed Notification of Amendment Form for ASCEND and the relevant supporting documents.

As recruitment into ASCEND is now complete, we plan to start collecting blood and urine samples from a random sample of participants, as specified in the protocol. The following documents are enclosed for approval.

1. Additional Blood & Urine sampling consent form V1.0_2011-12-01
2. Additional Blood & Urine sampling Information leaflet V1.0_2011-12-01
3. Additional Blood & Urine sampling Instruction V1.0_2011-12-01
4. GP letter for additional blood and urine results V1.0_2011-12-01

We look forward to hearing from you about these changes. Many thanks for your help.

Yours sincerely



Professor Jane Armitage
Chief Investigator

Enc: Enc: Completed Amendment Form
 Summary and rationale of proposed amendment
 Attachments 1 – 4