Ref: "Draft detailed guidance on the collection, verification and presentation of adverse reaction reports arising from clinical trials on medicinal products for human use (CT-3)"

We are happy for our feedback to be made public on the Clinical Trials website of the Commission.

We have found the existing guidelines extremely useful and fit for purpose. The draft revision we feel lacks the detail and clarity inherent in the existing version and would not represent a significant improvement. In particular, the reduction in the number of the examples in the section relating to "other safety information that requires expedited reporting" and the removal of the Annex 1: comments on definitions and abbreviations we would feel is not helpful.

On behalf of The Management Group
Primary Care Clinical Trials Unit
Division of Public Health and Primary Care
University of Oxford
Old Road Campus
Headington
Oxford OX3 7LF
UK

Tel: +44 (0) 1865 289313
Fax: +44 (0) 1865 289412
Email: maria.breen@dphpc.ox.ac.uk
Website: www.primarycare.ox.ac.uk/ctu