To whom it may concern

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

We are happy for our feedback to be made public on the 'Clinical Trials' website of the Commission. The feedback is in the name of 'Oncology Clinical Trials Office', University of Oxford

We have noted with concern that the draft guidelines are much reduced and on the whole the revised guidelines are in some areas more vague. The current guidelines have been extremely useful in terms of the detailed notes it provided and has been very useful as a source for Units such as ours upon which to base are written SOPs. The proposed revision seems to refer one to other documents such as ICH E2A, it would make more sense to have all this information contained in one place.

As our CTIMPs are mainly academic trials and tend to use marketed products, we have encountered a number of issues where investigators would look at the literature to assess the 'expectedness' of a drug reaction in the indication being studied (not necessary the indication for which the trial drug has been marketed for) and would refer to the information in the literature as 'reference document for the trial drug'. If there is solid evidence for a drug reaction in the literature but this is not stated in the IB or SmPC, would it be possible for the revised guidelines to take this into account. (Section 4.3.3 in the revised document).

The current guidelines has a comprehensive list of examples of what would constitute 'other safety information that requires expedited reporting' which is now much shortened in this revised document. In addition, the current guideline provides extremely useful information as to how to structure an Annual Safety Report which is now missing in the new proposed guidelines. The current document has been really useful in the comments section following the definitions of an AE, AR, SAR etc etc. The revised guideline has lost this comments section.

I think the revised guideline has defined the clock start for reporting much better, but does not define clearly what constitutes 'awareness' of a SUSAR by the sponsor, this information would be really useful.

We would welcome a revised guideline if the detail is adequate enough for the stakeholders not to be trying to interpret the guidelines further and all the information is contained within one place.

Joanna Black PhD MRQA
OCTO QA Manager
Email: joanna.black@clinpharm.ox.ac.uk

Office Phone: 01865-617009
General Enquiries: 01865 617000
GeneralFax:01865617010

www.octo-oxford.org.uk

Oncology Clinical Trials Office (OCTO)
Department of Clinical Pharmacology
Old Road Campus Research Building
University of Oxford
Old Road Campus, off Roosevelt Drive
Headington
Oxford OX3 7DQ