

**Clinical Research Update - Issue 1
March 2005**

Dear Colleague

WELCOME to the very first edition of a regular bulletin in which we will aim to give you a headline summary of recent changes in clinical research, and useful internet links for you to access further information. We plan to issue this every 3 months or so, and in the first instance we will focus on the UK, but we hope to be able to include information on other countries as time goes on. If you have any useful information which you feel our subscribers would benefit from please contact us at info@logic2.co.uk. Also please let us know what you think of this newsletter, using the same address. All feedback and suggestions will be gratefully received.

UK Ethics Committees

COREC have issued version 2 of their Standard Operating procedures for Ethics Committees in the UK. These came into effect on 15 November 2004, and, as version 1 did, cover a wide range of information including requirements for submissions, giving an ethical opinion, Ethics Committee meetings, Site Specific Assessments, special considerations for vulnerable populations, and much, much more. You can access a copy from the COREC website, and also a summary document which lists the main changes from version 1: www.corec.org.uk/recs/index.htm#041029a

The new SOPs also introduced new requirements for quarterly safety reporting for ongoing studies and guidelines for applicants were issued on 13 December 2004 with immediate effect. These are again available from the COREC website: www.corec.org.uk/applicants/apply/safety.htm?CONTENT_ID=4088857&chk=gq2jP9 Changes to relevant SOPs and standard approval conditions will be made early this year.

MHRA

The MHRA have formed a new Enforcement and Intelligence group which will be responsible for, among other things, dealing with Clinical Trials Fraud. This new group appears to be an expansion of the remit of the Inspections and Enforcement group.

UK Clinical Research Collaboration (UKCRC)

This initiative was set up last year to bring together all the stakeholders in clinical research in the UK to maximise the potential of the NHS for research. There are various workstreams looking at different aspects and a fair sized chunk of money is also being put into improving the infrastructure for clinical research in the NHS. For more information visit the website: www.ukcrc.org

Clinical Trials Directive

One of the most useful sources I have found for information about the Directive and its implications is the MHRA website. There is a section on the Clinical Trials Directive which

appears to be updated pretty regularly, and provides loads of useful updates, documentation and links. <http://medicines.mhra.gov.uk/ourwork/licensingmeds/types/clintrialdir.htm>

The Department of Health and the Medical Research Council have collaborated to produce a Clinical Trials Toolkit, aimed at publicly funded research. It can be found at <http://www.ct-toolkit.ac.uk> and contains links to some of the critical documents and also an algorithm issued by the MHRA to help researchers establish whether their study falls under the EU Directive on Clinical Trials or not.

Actually getting hold of a copy of the Directive is not as easy as you might think! I have found that the best site for this is the EUDRACT site:

<http://eudract.emea.eu.int/document.html> which also provides you with copies of the 5 European guidelines which were finalised last April. If you haven't seen these yet, then it's time you took a look!

In January 2005 the Directorate General of the European Commission produced a question and answer document regarding the legislation governing clinical research. Click on this link to access a pdf copy.

http://pharmacos.eudra.org/F2/pharmacos/docs/Doc2005/01_05/ClinicalTrialQ&A%2024-01-05.pdf

GCP Directive

There is another directive coming on GCP. The draft version has been issued and comments were invited by the end of July 2004. As far as we are aware this directive has not yet been issued, and we do not know when it will be. We will keep looking out, and will include updates on this in future bulletins.

That's all for this time. Just an extra note that the Institute of Clinical Research issue a monthly update bulletin which is available on the website www.instituteofclinicalresearch.org and includes lots more information on all aspects of clinical research. We will continue to send you this bulletin if you wish, which will contain more of a distillation of clinical research legislation and guideline updates.

Best wishes

Jo Burmester