

>>> A report on the ECSP2

Ed Penz questioned whether journals and articles will continue to retain the significance and brand importance that they presently enjoy. The rise of informal 'Web 2.0' tools for communication and the linking to new kinds of content are changing the paradigm. So are new kinds of 'publication', such as databases (e.g. protein sequence databanks) that are already assigning DOIs to items and wikis as a platform for (almost-formal) publishing. The latter are not yet assigning DOIs, but the indications are that they are moving in this direction. Blogs are citing DOIs, even if they are not assigning any, and we are now seeing aggrega-

tions of blogs (e.g. Science Blogs), and scientists looking to such developments to give recognition to their work outside of the traditional mechanism of citing journal articles.

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The above text has been prepared with reference to the following websites:
<http://ecsp2.blogspot.com/>
<http://konferanser.blogspot.com/2008/09/ecsp2-dag-2.html> (Norwegian)

Basic Results Reporting at ClinicalTrials.gov and 'Prior Publication'

We have received questions concerning the posting of results at ClinicalTrials.gov (<http://clinicaltrials.gov>) in compliance with US Federal law and 'prior publication' decisions by journal editors.

As you may know, US Public Law 110-85, Title VIII, mandates the submission of 'basic results' data for certain clinical trials of drugs, biologics, and devices, effective September 27, 2008. The law applies to trials that are not Phase 1 or small device feasibility studies, and that have at least one site in the US or, if conducted completely outside the US, involve interventions manufactured in the US and regulated by the FDA, regardless of who sponsors, finances, or conducts the trial. Certain other trials may also be covered by the law. In general, these summary results data must be submitted within 12 months of the completion of data collection for the primary outcome measure. The law also requires submission of results for pre-specified secondary outcome measures registered at ClinicalTrials.gov. Delays in submitting results may be granted for certain reasons, but not generally for journal submission. There could be significant penalties for failure to comply with this law.

These 'basic results' include summary data tables of baseline characteristics, participant flow, outcomes, and adverse events. With the exception of several brief free-text fields for providing descriptions of the data, no narrative information is included (e.g., there is no discussion or conclusion section). There will be no patient level data.

The June 2007 ICMJE Update on Trial Registration [1] states that "the ICMJE will not consider results posted in the same primary clinical trials register in which the initial registration resides as previous publication if the results are presented in the form of a brief, structured (<500 words) abstract or table (p. 2)." The ICMJE recently reaffirmed this position at its 2008 annual meeting in Philadelphia.

Further, a January *BMJ* editorial [2] urges other journals to consider publication of results reported under the law to ClinicalTrials.gov for the following reasons:

'Firstly, disclosure will be a legal requirement, so there is nothing editors can do about it if they still want to publish important trials of drugs and devices. Moreover, journals will continue to add value by publishing useful and readable trial reports that clinicians, the media, and patients can interpret and use. And, most importantly, the results disclosed for the FDA will not have been externally peer reviewed and will be preliminary. Peer review not only provides a stamp of quality assurance, it often leads to reanalysis of results (p.170).'

In July 2008, a *PLoS Medicine* editorial endorsed "timely and accessible reporting at all stages of clinical drug and device development." [3] In particular, the following statement has been added to its Author Guidelines:

'PLoS supports the public disclosure of all clinical trial results, as mandated for example by the FDA Amendments Act, 2007. Prior disclosure of results on a public website such as clinicaltrials.gov will not affect the decision to peer review or acceptance of papers in PLoS journals.[4]'

More information on the 'basic results' database can be found at <http://prsinfo.clinicaltrials.gov/fdaaa.html>.

Please also feel free to contact me if you have any questions about this new feature of ClinicalTrials.gov.

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References:

1. ICMJE. Clinical trial registration: looking back and moving forward. Jun 2007. Available at http://www.icmje.org/clin_trial07.pdf. Accessed on September 22, 2008.
2. Groves T. Mandatory disclosure of trial results for drugs and devices. *BMJ*. Jan 2008 ;336:170.
3. The PLoS Medicine Editors (2008) Next Stop, Don't Block the Doors: Opening Up Access to Clinical Trials Results. *PLoS Med* 5(7): e160 doi:10.1371/journal.pmed.0050160. Available at http://medicine.plosjournals.org/archive/1549-1676/5/7/pdf/10.1371_journal.pmed.0050160-L.pdf. Accessed on October 17, 2008.
4. PLoS Medicine (2007) Author guidelines: Reporting guidelines for specific study designs. Available: <http://journals.plos.org/plosmedicine/policies.php#reporting>. Accessed November 11, 2008.