

The Australian Clinical Trial Registry

Not so long ago, the International Committee of Medical Journal Editors (ICMJE) — represented by 11 general medical journals including *The Medical Journal of Australia* — took a fairly passive and advisory role in medical publishing. The major outcome of its efforts was the *Uniform requirements for manuscripts submitted to biomedical journals*, which is an internationally accepted reference for biomedical publishing. It gives recommendations for preparing manuscripts for submission, and includes statements on editorial roles and responsibilities, authorship, and ethical issues governing biomedical publication.¹

Recently, the ICMJE has adopted a more aggressive, interventionist role. This new function first surfaced with the ICMJE's 2001 statement *Sponsorship, authorship and accountability*, which conveyed the requirements for publishing clinical trials conducted with corporate sponsorship.² The statement's bottom line was that publication of such trials depended on compliance with transparent processes regarding responsibility for the trial, access to and control of data, and control of publication by researchers. In short, transparency and independence were stressed.

The next ICMJE foray came with its 2004 statement on *Clinical trial registration*,³ which, despite being cautiously welcomed by research and media commentators,^{4,5} has reverberated in the research community, and in particular in the pharmaceutical industry, ever since.⁶ This statement was a response to the pharmaceutical industry's longstanding unethical practice of "silent" clinical trials. It decreed that ICMJE journals would only consider publishing reports of trials that had been registered before enrolling the first participant. This policy came into operation on or after 1 July 2005 for new trials, and any ongoing trials are to be registered before 13 September 2005.

The need for prospective registration of clinical trials is not a new idea.^{7,8} Almost a decade ago, for example, the Australian Health Ethics Committee first acknowledged the need to establish a clinical trials register in Australia.⁹ Now, in one swoop, the ICMJE has provided the impetus to move trial registration from the realm of theoretical nicety to its rightful place on various ethical and political agendas.

In a follow-up statement in May this year, *Is this clinical trial fully registered?*,¹⁰ the ICMJE reaffirmed its clinical trial registration policy and endorsed the World Health Organization's minimal registration data set of 20 fields. It also reaffirmed its requirements for an acceptable clinical trial registry:

- it must be electronically searchable, with free access;
- it must be open to all registrants;
- the trial data must be validated; and
- it must be a not-for-profit concern.

The clinical trial registry site currently endorsed by the ICMJE is sponsored by the United States National Library of Medicine (<http://www.clinicaltrials.gov>), but the committee acknowledges that further registries will come on stream. These are under development in Japan, India and South Africa.¹¹

In May this year, the Australian Government announced a grant of \$1.5 million for the establishment of The Australian Clinical Trial Registry at the National Health and Medical Research Council Clinical Trials Centre at Sydney University.¹² The Australian Registry (<http://www.actr.org.au>) complies with ICMJE and WHO requirements and became available for registrations in late June 2005.

It is highly likely that more national trial registries will emerge. The WHO is currently developing an approval process to assess compliance of registers with ICMJE and WHO requirements.¹¹ The WHO also plans to provide a web-based portal to all registries. These developments make sense: a cluster of national and regional clinical trial registries linked by an international agency. The WHO is ideally suited to assume this role and it will free the ICMJE to do what it does best — formulate publication policy.

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