

CSE Endorsement of Principles: ICMJE's Statement on Clinical Trial Registration

CSE supports the principles of "Clinical Trial Registration: A Statement from the International Committee of Medical Journal Editors" regarding registration of trials before patient enrollment and encourages editors of medical journals publishing trials to adopt it as part of their submission requirements.¹ This is a rapidly moving field, and refinements of procedures are in progress by ICMJE, the World Health Organization, and other groups. However, registration of trials will make comprehensive information more readily available to all interested parties.

Trials Requiring Registration

ICMJE defines a trial as "any research project that prospectively assigns human subjects to intervention and comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome. The trial must have at least one prospectively assigned concurrent control or comparison group in order to trigger the requirement for registration." Registration of phase 1 trials is not usually required, registration of phase 2 trials may be required, but all phase 3 trials whose primary purpose is to affect clinical practice should be registered.

Responsibility for Registration

Responsibility for registering trials is shared by the sponsor or organization coordinating the trial and the lead investigators. It is recommended that the lead investigator

verify in the contract that it is the sponsor's responsibility to register the trial and confirm that it is fully registered before enrolling subjects. Fully registered trials should meet the Characteristics of Approved Registries mentioned below. Furthermore, the registries should contain information that is of value to patients and health professionals (for example, the name of the intervention).

Time of Registration

Clinical trials should be registered on or before subject enrollment. ICMJE's updated statement considers trials that are going on and were registered before 13 September 2005 as meeting the trial-registration requirement.²

Approved Registries

Registries that meet the Minimum Registration Data Set and are approved by ICMJE include those listed below.

- (1) www.clinicaltrials.gov
- (2) isrctn.org
- (3) www.umin.ac.jp/ctr/index/htm
- (4) www.actr.org.au
- (5) www.trialregister.nl

Characteristics of Approved Registries

Registries should meet the following criteria:

- Be electronically searchable.
- Be accessible to the public at no charge.
- Be open to all registrants and managed

by a not-for-profit organization.

- Include a mechanism or process to ensure the validity of the registration data if the registry receives reports of concerns of accuracy or completeness.
- Contain information required according to the Minimal Registration Data Set in Table 1 of "Is this clinical trial fully registered? a statement from the International Committee of Medical Journal Editors".²

References

1. DeAngelis C, Drazen JM, Frizelle FA, Haug C, Hoey J, Horton R, et al. Clinical trial registration: a statement from the International Committee of Medical Journal Editors. *Ann Intern Med* 2004;141:477-8. Available at www.icmje.org. Accessed 21 March 2006.
2. DeAngelis C, Drazen JM, Frizelle FA, Haug C, Hoey J, Horton R, et al. Is this clinical trial fully registered? a statement from the International Committee of Medical Journal Editors. Available at www.icmje.org/clin_trialup.htm. Accessed 8 November 2005.

The CSE Editorial Policy Committee approved the statement on 21 March 2006. It was approved by the CSE Board on 3 April 2006 and published online on 14 April 2006.