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Registration of clinical trials: a step forward but still a long path ahead

We often invite our potential authors to visit the website of the International Committee of Medical Journal Editors (ICMJE) (<http://www.icmje.org/>) before preparing a manuscript. In fact, we would like that they learn more about the following items:

- authorship and contributorship
- editorship
- peer review

- conflicts of interest
- privacy and confidentiality
- protection of human subjects and animal in research
- obligation to publish negative studies
- overlapping publications

which are of fundamental importance in scientific publishing.

In the last few years the ICMJE has also promoted the registration of all clinical trials: this issue reports the latest ICMJE editorial on this topic.

Although registration of clinical trials represents a step forward, there is still a long path ahead in order to teach the real objectives of the ICMJE initiative. In a recent study, Zarin *et al.*¹ reviewed ClinicalTrials.gov records to determine patterns of completion of the *Intervention Name* and *Primary Outcome Measure* data fields for trials registered between May 20 and October 11, 2005. This period includes time both before and after September 13, 2005, the date of implementation of the ICMJE policy. Zarin *et al.*¹ found that ICMJE policy has had a dramatic effect on trial-registration practices: in fact, the number of records in *ClinicalTrials.gov* increased from 13,153 on May 20 to 22,714 on October 11, 2005. However, the quality of the data registered varied considerably and, overall, was better for trials sponsored by academic institutions or the National Institutes of Health than for those sponsored by companies. This issue was analyzed in detail by Drazen *et al.*² in an accompanying editorial. In a companion paper, Haug *et al.*³ examined the situation in Europe.

Starting on March 1st, 2006, *Haematologica/The Hematology Journal* will adopt the ICMJE policy on clinical trial registration. In detail, trials that began before July 1, 2005, will only be considered by *Haematologica/The Hematology Journal* if they were adequately registered before journal submission. With respect to manuscripts under evaluation, the journal will accept a retrospective registration before the peer-review process has been completed. As regards trials that began after July 1, 2005, *Haematologica/The Hematology Journal* will consider such trials only if reg-

istration occurred before the first patient was enrolled.

Readers will find additional information on the registration of clinical trials at the ICMJE website: <http://www.icmje.org/faq.pdf>. The following frequently asked questions are examined by the ICMJE:

- What is the ICMJE definition of a clinical trial?
- What is the relationship between the ICMJE trials registration policy and the ongoing WHO trials registry effort?
- Which trials registries are acceptable to the ICMJE?
- How can trials registries submit requests for the ICMJE to determine whether they meet the ICMJE criteria for acceptable registries?
- Where can I get information about how to register a trial?
- I'm having trouble registering my trial in ClinicalTrials.gov or believe that my trial is not eligible for registration in that registry... What now?

The relevance of this topic is also underscored by the decision of the European Hematology Association (EHA) to organize an *ad hoc* Symposium during the 11th Congress in Amsterdam, June 15-18, 2006.

References

1. Zarin DA, Tse T, Ide NC. Trial Registration at ClinicalTrials.gov between May and October 2005. *N Engl J Med* 2005;353:2779-87.
2. Drazen JM, Wood AJ. Trial registration report card. *N Engl J Med* 2005;353:2809-11.
3. Haug C, Gotzsche PC, Schroeder TV. Registries and registration of clinical trials. *N Engl J Med* 2005;353:2811-2.