

## **Update on Trials Registration: October 2004**

The ICMJE appreciates the attention the committee's recent statement on trials registration has received. Many have raised the concern over the committee's mention that ClinicalTrials.gov is the only existing registry that currently fulfills the ICMJE-specified criteria for acceptable registries. The committee regrets that the statement failed to note that, although ClinicalTrials.gov includes numerous trials that have sites outside the U.S. (as a result about 90 countries are represented in the registry), at the time of the statement, the registry was open only to U.S. government-sponsored trials or to multi-site studies sponsored by companies applying for FDA approval that include locations outside of the United States. Consequently, many investigators who wish to register their trials did not have an acceptable registry available to them.

Fortunately, the National Library of Medicine (NLM) agrees to accept validated descriptions of all clinical trials without charge from the international community for inclusion in ClinicalTrials.gov. The NLM and ICMJE concur that the validation of trial registry data is essential. The absence of a mechanism for this validation has previously been an obstacle to universal registration of trials in ClinicalTrials.gov. In order to ensure current and accurate information for each trial, the NLM will ask those registering trials to adhere to strict submission and update procedures. NLM will look to national and international health authorities to support the validation of the descriptions of clinical trials originating within their domains. In the initial phase of registering trials from all parts of the world, the NLM will recognize and display some trials as pending receipt of validation of the description and official local acknowledgement of the existence of the trial by the relevant national or international health authority. The NLM will keep such listings up to date as they receive notification of approvals and validation from the registrant organization.

From the committee's perspective the most critical issues regarding the acceptability of registries are that the price to register or to use the registry is not a barrier to anyone, that the registry will not simply vanish when it becomes inconvenient or financially untenable, and that the registry management is in some form accountable to the public for the conduct of the registry. The ICMJE anticipates that existing registries that currently do not meet the criteria for registries acceptable to the ICMJE may undergo changes to become acceptable. In addition, new registries may develop.

The ICMJE remains confident that the many recent forces promoting trials registration will soon result in the public having better access to information about the investigation of medical interventions than it has now.

The ICMJE