September 30, 2005

Ida Sim, MD, PhD
Project Coordinator, International Clinical Trials Registry Platform (RPC/EIP)
World Health Organization
Avenue Appia
CH-1211 Geneva 27
Switzerland

Dear Dr. Sim:

The following comments are provided by the Biotechnology Industry Organization (BIO). BIO represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers and related organizations in all 50 U.S. states and 33 other nations. Our members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products. We appreciate the opportunity to comment on the WHO International Clinical Trials Registry Platform (ICTRP) effort to establish norms and standards upon which international trial registration can take place ethically and scientifically.

By way of background, it is necessary to understand the unique aspects of the biotech industry. BIO represents many established companies, however, over eighty-five percent of BIO members are small, emerging companies with fewer than 100 employees. In fact, more than fifty percent of BIO member companies have fewer than 50 employees. The average development cycle for biotechnology products is 15 years. Therefore, before most biotechnology products can become commercially available, years of research and often hundreds of millions of dollars of capital are required to complete testing, gain product approval, and build the necessary manufacturing infrastructure. While there are many different funding strategies, the typical form of investment in promising, early-stage biotech companies is venture capital.

In June 2004, a working group at BIO began formulating a policy to address the need for a public clinical trial registry that would serve to inform patients and health care providers of the availability of active clinical trials and separately, a public registry/database that would provide the public with results of completed clinical trials. After many months of extensive discussion, we developed a policy

which approved the expansion of ClinicalTrials.gov (established under Section 113 of the FDA Modernization Act as a registry of information on clinical trials for drugs to treat *serious or life-threatening diseases and conditions*) for the registration of *all confirmatory trials*. Clinical trial information would be provided in a summary format within 21 days after the start of patient enrollment, consistent with the requirements of Section 113. Section 113 directs that the information be provided in a form that can be readily understood by members of the public and describes the data elements to be noted.

As recognized by the ICTRP, there is disagreement between the International Committee of Medical Journal Editors (ICMJE) and industry concerning those data elements required by the journal editors that are above and beyond those elements required by Section 113: Items 10, 13, 17, 19, and 20 of the *ICTRP Registration Data Set*. One or more of these data items may be regarded as sensitive for competitive reasons in particular circumstances. BIO has great concern that the disclosure of these points of additional information could signal to competitors what research the sponsor is targeting, thereby putting an entire research program at risk of being unfairly copied by others. Certainly, this would reduce the incentive to invest in expensive new drug discovery. In addition, posting a clinical trial for a new use, new formulation or new dosing regime could arguably be considered a prior art publication and prevent obtaining later patent coverage on these potential inventions if and when positive clinical trial results are obtained at a later date.

Parallel initiatives to develop policy in this area, notably of the Institute of Medicine and Fordham University, have also identified the ICMJE demands as problematic. The ICTRP indicates that "a procedure for delaying public release of some of this information is under investigation." While the ICTRP should be commended for taking on the exceedingly complex endeavor of identifying standards for an international registry, developing standards on the scope and content of a registry without first addressing this underlying problem seems to be premature.

BIO urges the ICTRP to focus on developing a procedure that would address the need to balance the incentive to innovate with the need to provide patients and health care providers with the information they need in order to assess the availability and suitability of a clinical trial. There might well be a time when the disclosure of sensitive details is not problematic. When a trial is beginning, however, these details are surely not helpful to anyone other than a competitor. Some have proposed a blinded repository for commercially sensitive design details and this idea is certainly worthy of exploration. Any patient who would be considering participation in a clinical trial would be personally apprised of relevant details of the trial during a requisite informed consent process.

BIO appreciates this opportunity to comment on the ICTRP guidelines. We would be pleased to work with the ICTRP to provide further input or clarification of our comments, as needed.

Sincerely,

/s/

Debra Aronson
Director, Bioethics