PhRMA Update Calls for Expanded Disclosure of Study Results

On April 20, 2009, the Pharmaceutical Research and Manufacturers of America (PhRMA) released a revision to its voluntary "Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results." The revised and updated PhRMA Principles expand upon the guidance provided in the 2004 version, commit PhRMA members to the public registration and disclosure of a wider range of clinical trials, tighten standards for authors and contributors to journal publications, and call for increased access by investigators to study data and results. The revised Principles, which take effect October 1, 2009, commit PhRMA's members to implement many of the disclosure and registration obligations created by the 2007 FDA Amendments Act (FDAAA) and anticipate certain expanded reporting obligations before the statutory requirements take effect.

Study Registration and Disclosure of Study Results

In an effort to increase transparency regarding clinical trials, the revised PhRMA Principles expand members' commitment to register and post information about clinical trials on publicly available databases such as www.clinicaltrials.gov. Key changes include:

Registration. The 2004 version of the Principles did not contain a requirement that a clinical trial be registered at its inception on a publicly available database. The revised Principles contain new language committing to the "timely submission and registration on a public database of summary information about all clinical trials that we conduct involving the use of our marketed or investigational products in patients." In addition to anticipating the broadening registration requirements of the FDAAA, this commitment moves the PhRMA principles closer to the September 2004 standards of the International Committee of Medical Journal Editors (ICMJE), which require, as a condition of publication in member journals, registration of the trial in a public-trials registry prior to the enrollment of the first subject.

Results. The 2004 version of the Principles committed PhRMA members to communicate study results in the form of journal publication, abstract or poster presentation at meetings, or other public means, but did not specify the posting of results on a centralized, publicly available database. The revised Principles expand the pledge that members will post summary results on a publicly available database of all clinical trials in patients involving products that are approved for marketing or that are investigational products whose development programs are discontinued, regardless of outcome. One change from the prior version is that the commitment to report results no longer excludes post-marketing trials. In addition, even in clinical trials of investigational products for which development has not been discontinued, members commit to publishing information and data of significant medical importance.

Excluded Trials and Studies. The revised Principles clarify that the commitments to register and post summary results do not apply to most Phase I trials conducted in healthy adults, rather than "patients." Nevertheless, under the Principles, results of exploratory Phase I trials in healthy adults, even those involving a novel or proprietary design, should be disclosed if the trial provides significant medical information.

Authorship Standards

Although the 2004 Principles were largely consistent with the authorship standards of the ICMJE, the revised Principles adopt ICMJE's standards in whole and commit to following those standards "in lockstep." Among other things, the ICMJE standards specify that each author should have sufficiently participated to be able to take public responsibility for the content of the published work and that the acquisition of funding, collection of data, or general supervision of research does not alone justify authorship.

The revised Principles also create guidelines for "Contributors" who do not meet the criteria for authorship. Contributors should be properly acknowledged and listed along with brief descriptions of their contribution.

Finally, the new Principles provide that authors submitting a manuscript to a medical journal should disclose the identities of all sources of authorship assistance and financial support as well as any other financial and personal relationships that may bias their work.

Investigator Access

The updated Principles expand upon the commitments set forth in the prior version, including by committing to provide all investigators with full summaries of study results and allowing investigators from multi-site trials to review data from the entire study in response to a reasonable scientific inquiry.

Implementing the Revised Principles

PhRMA's revised Principles reflect the increasing demands on the pharmaceutical industry to be transparent in conducting clinical research. Developing and implementing sensible policies and compliance practices in this area is an ongoing process that demands periodic reassessment, especially in light of the continuing implementation of the FDAAA requirements. FDAAA already requires sponsors to register and report basic results on www.clinicaltrials.gov, and sponsors should be prepared for the expansion of the registration and reporting requirements to be rolled out over the coming months.

If you have any questions about the update PhRMA Principles, its relationship to the FDAAA, or related compliance issues, please contact your regular Ropes & Gray legal advisor.