

Multi-Regional Clinical Trials Summit Meeting

By Norman M. Goldfarb

In January, 2010, 77 clinical research stakeholders gathered for two days at the Harvard Faculty Club in Cambridge, Massachusetts, for a Multi-Regional Clinical Trials (MRCT) Summit sponsored by Pfizer and Harvard. At the first Summit last July, the group set out to explore ways to improve the conduct of global clinical trials and address the challenges of conducting research in the developing world that were discussed in a sounding board article in the *New England Journal of Medicine* last year: *Ethical and Scientific Implications of the Globalization of Clinical Research* (360:816-823).

Attendees in Cambridge gathered to review progress and organize future work. Participants represented pharmaceutical companies, clinical research sites, contract research organizations (CROs), academic bioethics departments, and related organizations, such as PRIM&R, AAHRPP and MAGI. Rob Califf, Vice-Chancellor for Clinical Research at Duke University, and Millie Solomon of the non-profit Education Development Center (EDC) and Associate Professor of Medical Ethics at Harvard chaired the meeting. Pfizer deserves kudos for initiating and sponsoring the project. The atmosphere in the meeting room can only be described as "electric."

Most attendees were from the U.S., but international attendees included Dr. Jim Lavery of the University of Toronto; Dr. Joseph-Matthews Mfusto-Bengo of the University of Malawi College of Medicine; Dr. Edson Moreira of the Oswaldo Cruz Foundation, Brazilian Ministry of Health; Dr. Vasantha Muthuswamy of the Indian Council of Medical Research (retired); and Dr. Jan Pacht of the University Hospital Kralovske Vinohrady, among others.

Pfizer chartered five working groups following the initial MRCT meeting:

- Enhancing Quality & Efficiency of Ethics Review
- Enhancing Data and Safety Monitoring
- Enhancing Site Selection and Investigator Team Expertise
- Enhancing the Professionalism of Monitors
- Transparency of Contract Provisions

Each working group presented its ideas for feedback. The following ideas garnered the most interest and support (not in priority order):

- Develop, validate and use a common site assessment tool to improve the rigor of site selection.
- Develop one or more sample or template model data monitoring committee (DMC) charters focused on multi-regional trials for studies conducted in the developing world.
- Develop an apprenticeship or fellows program for new DMC members to participate on DMCs and gain experience.
- Encourage accreditation of research ethics committees (RECs).
- Develop a standardized ethics section for protocols (or some other study document).
- Develop new approaches for REC capacity-building.
- Encourage investigator certification, including giving certified investigators priority in study placement.
- Establish core competencies for monitors.

- Establish preferential use of CROs that offer certified monitors.
- Develop clauses for clinical trial agreements of special interest to low-resource countries in the areas of publication rights, subject injury, privacy and data use, and fair benefits.

The MRCT initiative is off to a great start in developing feasible, high-impact ideas. However, at some point, words will have to translate into action, which will require broad support. The question is: How long will we be satisfied with muddling along before we collectively agree that it is time for concerted action to address the challenges faced by the clinical research enterprise? Justin McCarthy, Pfizer Chief Counsel for R&D, noted in closing that some of the ideas could be implemented by individual companies on their own and some would need to be developed in partnership with multiple stakeholders.

More information about the initiative will be available later this year when the MRCT Project Report is published.

Author

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