Requirements for DSMB fellows for MRCT Pilot Training program (January 11, 2013)

1. Resident of one of the following countries: Brazil, China, Russia, India, Korea, Mexico, South Africa (or other African countries)

2. Clinical expertise in one of the following therapeutic areas preferred: Vaccines, Infectious disease or Inflammation

3. Demonstrated expertise in clinical trials – must have participated at least one clinical trial as an investigator

4. Proficient in spoken and written English

5. Working knowledge of clinical trial methods preferred

6. Willing to travel to attend DSMB/DMC in-person meetings (Note: these meetings may be via teleconference or in-person 1-2 times a year in the US or another host country for the trial; cost is borne by sponsoring company)

7. Commitment to review pre-meeting materials

8. Willing to disclose any potential conflicts of interest

Benefits of Participating in the MRCT Pilot Training Program for DSMB Fellows:
Fellows who successfully complete the course will be qualified to serve on a Data and Safety Monitoring Board in 2013 for clinical trials funded by Pharmaceutical, PDP (Product Development Partnership Organizations) or Government sponsors They will also be eligible to be selected for additional DSMBs constituted for trials that involve the fellow's country of residence. Additionally, the training would provide the opportunity to serve on the fellows' institutional DSMB post-training and potentially train others in their institution.

The opportunity to serve on a DSMB provides fellows with the opportunity to represent their country and serve as a "steward" of the trial's safety. Fellows will receive a certification of completion upon completion of the two-part one-day course.

Additional Details:

- 6 fellows will be selected by February 15, 2013
- Fee for the workshop (May 19th) and attendance at the Society of Clinical Trials Meeting in Boston May 19-22, 2013 will be waived
- Travel expenses up to $3,500 will be reimbursed following attendance at the course *(note: final amount and any restrictions to be confirmed by Harvard finance)*

May 19, 2013, Boston MA: DSMB Training Course Description (held in conjunction with the Society of Clinical Trials)

Part 1

The first session of the course will discuss the role of the committee as a whole as well as how each member should parlay his or her specific expertise into the deliberations of the group. The course will describe the function of DSMBs with particular emphasis on the roles of its members and its chairperson. The course leaders will walk through a typical DSMBs charter and the responsibilities emanating from that document. They will also describe how a DSMB should act in the ideal setting (the reports are clear, the meetings well attended, no new safety issue has arisen, the data are timely, and the statistical methods for early stopping are clear) along with the special roles of the chairperson and the biostatistician. The course will then address how committee members should act when the setting is not ideal. Two important topics will be the maintenance of confidentiality and how the clinicians and biostatistician can train each other in areas necessary for the intelligent discussion of the emerging data. The differences between DSMBs in government and industry will be discussed. Examples of actual trials will be presented with the course leaders describing the meetings that occurred and the course attendees discussing how they would have responded to the emerging data.

Part 2

The second session of the course will address issues related to considerations, ethical and otherwise, for DSMBs to consider in monitoring trials conducted in the developing or developed world. Discussion will address the complexities of multiregional clinical trials with particular emphasis on how cultural and other differences between countries may affect safety, efficacy, and study conduct and, in turn, the monitoring of these by the DSMB. The course will address what DSMB members need to understand about the constraints under which the DSMB, the clinics and sponsor are operating so that they can understand the role of the DSMB and its decision-making process when protecting participant safety, study conduct and the validity of the trial itself.

Faculty

Janet Wittes, PhD, Statistics Collaborative, Washington, DC
David Gordon, MD, NIH/NHLBI, Bethesda, MD
Charles Knirsch, MD, Columbia University, New York, NY
Joseph Massaro, PhD, Boston University, Harvard Clinical Research Institute, Boston, MA
Susan Ellenberg, PhD, University of Pennsylvania, Philadelphia, PA
Steve Snapinn, PhD, Amgen, Thousand Oaks, CA