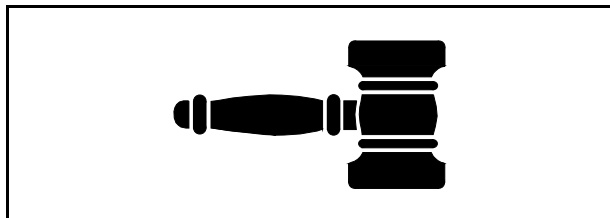

SCT Newsletter

Volume 13, Number 2

October 2003



SCT President's Corner

by Steve George

In early 2004, the Society will publish the first issue of its new journal, *Clinical Trials: The Journal of the Society for Clinical Trials*. For the first time, we will own our journal instead of simply lending our sponsorship to a journal owned by a publisher. This change in ownership is important, both symbolically and in practice, as we move to build on our success in developing the current journal, *Controlled Clinical Trials*. Many members have worked hard during the last year to bring about a successful transition, including members of the Publications Committee; Dennis Dixon, chair of the committee; past-president John Lachin; CCT editor Jim Neaton; CT editor Steve Goodman; members of the Executive Committee; Mary Burke; and others.

The most important thing that you, as individual members of the Society, can do now is to contact your institutional library to inform them of the transfer of Society sponsorship to the new journal and to request a library subscription for the new journal. Revenue from library subscriptions is a key element of support for the journal and an important element of the Society annual budget. Institutional librarians have difficulty in tracking changes in Society sponsorship without direct notification. Requests for subscriptions obviously carry more weight from faculty, staff, or employees of the institution than from those outside the

institution, such as publishers.

On a related topic, the Publications Committee has developed, and the Executive Committee has approved, a new policy on commissioned position papers for the Society. The intent is to develop position papers, endorsed by the Society, on important and timely topics in clinical trials. It is intended that these papers will be published in *Clinical Trials* and will present the consensus position of the Society. They should also help to expand the Society's role in the public discussion of important issues in the design, conduct, analysis, reporting, ethics, safety, or other areas in clinical trials of interest to the scientific community and to the public. Development of these papers will be coordinated by the Publications Committee, chaired by Dennis Dixon, to which any suggestions on topics or authors should be directed.

Another important effort is the expansion and development of the web site www.sctweb.org. During the past year, a new committee, the Web Policy Committee, has been formed to develop and monitor policy for the web site. Members are Peter Peduzzi (chair), Marie Diener-West, Roy Beck, and Mark Espeland. This committee was established to separate the function of setting policy from the technical functions of developing and maintaining the web site. The latter functions continue to be maintained, as in the past, by a hard-working Technical Working Group, chaired by Herman Mitchell. Suggestions for enhancement of the web site, especially additions or modifications of topics that would be useful to the membership, should be directed to the Web Policy Committee.

One final note: Work is well underway for the twenty-fifth annual meeting of the Society for Clinical Trials, to be held in New Orleans, May 23-26, 2004. Mark your calendars, and plan to attend!

Clinical Trials: Journal of the SCT **Submission deadline and library reminder**

Clinical Trials editor Steve Goodman reports that preparations for the first issue of our new journal, *Clinical Trials*, are going well. High quality submissions from both SCT members and others are arriving at a steady pace.

Please keep *Clinical Trials* in mind for submission of manuscripts in all areas of SCT interests, particularly statistical methods. The deadline for submission of papers presented at the SCT meeting this year is November 1; the journal will devote a special issue to these if enough are submitted.

Also, please don't forget to ask your institutional library to subscribe to *Clinical Trials*. This is extremely important for establishing the new journal and for maximizing its readership and impact.

- Journal web site: www.sctjournal.com
- E-mail address: clinicaltrials@jhmi.edu

FDA Risk Management Initiatives *by Susan Ellenberg*

The Prescription Drug User Fee Act of 2002 mandated the Food and Drug Administration to provide guidance to industry regarding risk assessment and risk management in clinical trials as well as post-market. Three documents are under development. The first, probably of greatest interest to SCT members, addresses pre-marketing risk assessment; the second addresses risk management plans that sponsors might develop to minimize specific risks that have been identified; and the third addresses principles and practices of post-marketing surveillance.

In order to promote maximal external input during every stage of guidance development, three "concept papers," representing preliminary Agency thinking in these three areas, were released last spring and discussed in a three-day conference in Washington, D.C. The concept papers, together with the transcripts of the conference, can be found at www.fda.gov/cder/meeting/riskManagement.htm.

The papers generated a substantial amount of discussion at this conference, so the transcripts are quite lively in some sections. Draft guidance documents, reflecting revisions based on discussion at the workshop together with written comments submitted to the docket, will be issued later this fall. They will be accessible via the FDA web site. Comments will

again be sought, so there will be further opportunity to contribute to the development of the final documents.

Program Committee Update

The program committee is hard at work planning the program for our May 23-26, 2004, meeting in New Orleans. The committee is chaired by Theodore Karrison and includes Dorothy Adams-Farnham, Thomas Capizzi, Rick Chappell, Emily Chew, Dorothea Collins, James Dignam, Lawrence Friedman, Jennifer Gassman, Michael Kutner, Ruth McBride, Sue Todd, and Edith Zang.

If you have suggestions for the program, contact Theodore Karrison by phone (773) 702-9326 or email: tkarrison@health.bsd.uchicago.edu

Education Committee Update

The SCT Education Committee, chaired by Bob Byington, has begun work on planning the Pre-Conference Workshops for Sunday, May 23, 2004. The committee includes Bill Blackwelder, Tim Church, Nicole Close, Rick Ferris, Virginia Howard, Angie Kimel, Wasima Rida, and Yves Rosenberg.

If you have suggestions for the Education Committee, contact Bob Byington by sending email to bbyingto@wfubmc.edu

Student Scholarship Program

Students are invited to enter the SCT Student Scholarship Competition. Three winners will be selected. Their fees, travel and living expenses will be paid for by the Society. An additional \$500, the Thomas Chalmers Scholarship Award, will be given to the student judged to have the best paper. For more information, see www.sctweb.org

Notes from the Editor

If you would like to join the SCT or learn more about the 2004 New Orleans meeting, check the SCT web site www.sctweb.org or contact Mary Burke at phone (410) 433-4722 or email sctbalt@aol.com

If you have suggestions for this newsletter, contact *SCT Newsletter* editor Jennifer Gassman in the Department of Biostatistics and Epidemiology at the Cleveland Clinic Foundation via email: jgassman@bio.ri.ccf.org