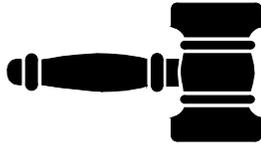

SCT Newsletter

Volume 14, Number 2

October 2004



SCT President's Corner

by *Peter Peduzzi*

In the October 2004 issue of *Clinical Trials*, the first official position paper of the Society will be published entitled "The Society for Clinical Trials Supports United States Legislation Mandating Trials Registration" by Kay Dickersin, et al. We thank Kay Dickersin and the co-authors for their hard work in preparing a position paper about this timely and important issue. Topics for position papers can be proposed by anyone in the society, and after a formal proposal is approved by the Society's Publication Committee and President with concurrence of the Executive Committee, an author or writing committee is commissioned to write a draft. The Publication Committee, chaired by Eleanor McFadden, will coordinate the preparation of commissioned papers. The final version will receive peer review by the editor of the journal and the Board of Directors and must be approved by a two-thirds majority of the Board. Several more SCT position papers are in the pipeline and should appear in the next year.

Two major initiatives for the Society over the next year are to increase both membership and institutional subscriptions to the Society's journal *Clinical Trials*. The Membership Committee, under the leadership of Barbara Hawkins, is developing strategies to increase the number of members. As part of this effort, enclosed herein is an updated membership application form that we are encouraging members to use to enroll new members into the Society. Our agreement with the publisher of the journal requires at least 1250 members to maintain the present subscription rate for the journal, and we currently have fewer than this

number. So, please make an effort to sign up a new member. Since the Society changed to the new journal early this year, institutional subscriptions to *Clinical Trials* also are lagging. The best way to increase subscriptions is for Society members to directly contact their libraries and request that they subscribe to *Clinical Trials*. Feedback from members who have done so indicates that libraries were not aware that the Society has changed journals and were receptive to subscribing to the new journal. Since both the number of members and institutional subscriptions impact on the Society's finances, whatever you can do to increase these numbers benefits all members of the Society.

Another initiative is to increase outreach efforts to other societies. We are currently discussing with several organizations about the possibility of giving pre- or post- conference workshops for the training and/or certification of clinical investigators and research coordinators at the next SCT meeting in Portland.

Committees do a great deal of the actual work of the Society. The current chairs of the standing and special SCT committees are: Tom Capizzi, Development; Ken James, Finance; Domenic Reda, Education; Barbara Hawkins, Membership; Rick Chappell, Nominating; Phil Lavori, Program; Eleanor McFadden, Publication; Sylvan Green, Student Scholarship, Mark Espeland, Web Policy; and Herman Mitchell, Web Tech. Please contact the appropriate Chair if you are interested in serving on one of these committees or have any ideas that could benefit the Society.

Finally, the Program and Education Committees are working hard to prepare the program and pre-conference workshops for the twenty-sixth annual meeting of the Society for Clinical Trials to be held in Portland, Oregon, May 22-25, 2005. Please mark your calendars and plan to attend. Note that the abstract submission deadline is December 1, 2004.

Membership Committee Announcement

by *Barbara Hawkins*

The Membership Committee is asking all current members of the Society for Clinical Trials to help the committee and the Board of Directors to increase the number of Society members during the coming months. Two groups of individuals are obvious candidates for membership:

1. Former members
2. Individuals with whom Society members collaborate in the conduct of clinical trials but who are not members of the Society.

The Secretariat can identify the first group but we need your help to contact the second group of potential members.

The Secretariat recently revised the informational brochure that describes the Society. A copy of the brochure was sent to all current members in a recent mailing from the Secretariat. Now is the time to contact your clinical trial colleagues to inform them about the Society and the new journal affiliation. The Membership Committee recommends that you send each of them a letter in which you enclose the brochure and a membership application; the Secretariat can supply you with brochures for this purpose upon request. Alternatively, you may send mailing labels to the Secretariat and the staff will mail the brochures and a membership application. Although other approaches are being explored, such as advertising the Society and the annual meeting in journals read by individuals with specific expertise who are perceived to be under represented in the Society membership, a personal contact by a member may prove to be the most effective method of identifying and attracting new members.

Methods of identifying the source of new members are being considered by the Membership Committee. If you wish, you may add your name to the membership applications that you distributed, e.g., "Referred by [your name]." This notation will be used to "credit" you for the new member. We anticipate that, through the generosity of an anonymous donor, an award will be made to the Society member who is responsible for the most NEW MEMBERS at the 2005 annual meeting of the Society.



Education Committee update

by *Domenic Reda*

The SCT Education Committee has begun planning the Pre-conference Workshops, which will be held on Sunday, May 22, 2005. Back by popular demand will be the workshop on Fundamentals of Clinical Trials, which will be expanded this year, at the suggestion of past attendees, to include an afternoon session on basic statistical principles and methods. Workshops on more advanced statistical topics will include a session on Bayesian Adaptive Dose Finding, which will be given by Peter Thall. Proposals for workshops on use of the Internet in clinical trials, clinical investigator training and clinical research monitoring are also being considered.

We want to thank Bob Byington for his service the past seven years as Chair of the committee and for his valued advice as we proceed with plans for this year's offerings. The committee includes Tim Church, Nicole Close, Carol Fye, Virginia Howard, Michele Melia, Yves Rosenberg and Christian Speas. If you have suggestions for the Education Committee, e-mail committee chair Domenic Reda at Domenic.Red@med.va.gov

Student Scholarship Program

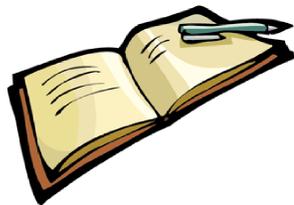
Students are invited to enter the SCT Thomas Chalmers Student Scholarship Competition. Three winners will be selected. Their fees will be waived and their travel and living expenses will be paid for by the Society. An additional \$500, the Thomas Chalmers Memorial Award, will be given to the student judged to have the best paper. Student abstracts should be submitted with a three-page summary. The deadline for submission is December 1, 2004. For more information, see www.sctweb.org

FDA Critical Path Initiative

by Susan Ellenberg

The FDA has recently issued a report announcing a Critical Path initiative, aimed at encouraging improved approaches to drug development. Appropriate methods of clinical trial design and analysis are an important component of this initiative. For example, in a section on utilizing patient-reported outcomes, the report notes, "Much work needs to be done on clinical trial design and patient-driven outcome measures to ensure that endpoints in new therapeutic areas accurately reflect patient needs and values."

Other parts of the document address evaluation of biomarkers and other surrogate markers of efficacy for use in drug development, the use of pharmacokinetic / pharmacodynamic modeling to improve trial designs, the use of enrichment designs, and the need to further explore the role of Bayesian approaches to clinical trial design and analysis. The entire report can be found at <http://www.fda.gov/oc/initiatives/criticalpath/whitepaper.html>.



Publication Committee Update

by Eleanor McFadden

As the new chair of the SCT Publications committee, I would like to extend a vote of thanks to Dennis Dixon for the excellent work he did while chair. I would also like to thank retiring members Hermann Mitchell, Jeff Sloan and Janet Wittes and welcome three new members - Colin Begg, Joan Hilton and Bev Koski. Our main focus for now is to support the authors who are writing position papers for the Society. The first of these, on Trials' Registries, will appear soon in the society journal. In relation to the journal, can I also remind you again to check with your libraries to make sure that they are subscribing to the new journal, *Clinical Trials, the Journal of the Society for Clinical Trials*, published by Hodder Arnold.



2005 Program Committee

The program committee has met by email several times and conference call once. A few topics have generated a consensus (for an invited session); they include ethics and Phase I trials, the use of previous subjects' outcomes to alter the randomization scheme (outcome adaptive randomization), as well as sample size re-estimation on the basis of current effects (another sense of adaptive design). We are discussing a session on science policy, both how it is made and what role the Society might play (how to find out what the members think on controversial issues, and how (or whether) to frame and disseminate SCT positions). Sessions on industry/government collaboration, designs for behavioral treatments, cluster randomization, harmonization of regulatory environments, biobanks, and computable trial registries are also under discussion. Good ideas continue to flow in from the membership; email to philip.lavori@med.va.gov is the best way to add your voice to the discussion.



Notes from the Editor

If you would like to join the SCT or learn more about the 2005 Portland meeting, check the SCT web site www.sctweb.org or contact Mary Burke at phone (410) 433-4722 or email scbalt@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