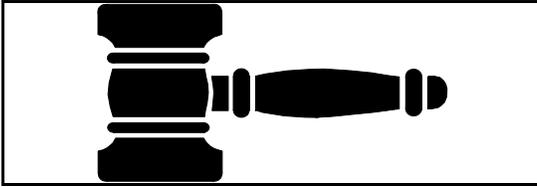

SCT Newsletter

Volume 14, Number 1

April 2004



SCT President's Corner

by Steve George

The twenty-fifth annual meeting of the Society for Clinical Trials, to be held in New Orleans, May 23-26, 2004, is just around the corner. The Program Committee, chaired by Ted Karrison, and the Education Committee, chaired by Bob Byington, have put together an excellent program with something for those interested in any aspect of the design, conduct, and analysis of clinical trials. This also will be a great time to get together with fellow members as we celebrate an important milestone in the Society's history. I hope you are planning to attend!

Another important event has just occurred: the publication of the first issue of our new journal, *Clinical Trials: The Journal of the Society for Clinical Trials*. As a reminder, as of December 31, 2003, the Society withdrew its sponsorship of our previous journal, *Controlled Clinical Trials*. Please remember that institutional librarians have difficulty in tracking changes in Society sponsorship without direct notification. We need your help 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. Requests for subscriptions obviously carry more weight from faculty, staff, or employees of the institution than from those outside the institution, such as publishers. For your convenience, there is a form at the journal web site (<http://www.sctjournal.com/>) which can be used to request a library subscription.

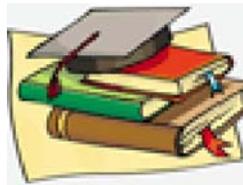
I look forward to seeing you in New Orleans.

Student Scholarship Program

by Sylvan Green

Student Scholarship Committee Chair

The mission of the Student Scholarship Committee is to enhance the participation of students in order to broaden the Society's membership base. The Committee reviews abstracts, manuscripts, and presentations submitted by students to the Annual Meeting.



The members of the Committee this year are: Sylvan Green (Chair), Marie Diener-West, Mary Foulkes, Michael Hughes, and Eleanor Schron. In the first part of 2004, the Committee reviewed abstracts (accompanied by short manuscripts) submitted by students for the 2004 Annual Meeting in New Orleans. The Committee selected three students to present at the Student Scholarship session. This session is scheduled for Monday, May 24, 2004, at 3:30 PM; all meeting attendees are encouraged to attend.

The student presenters chosen for 2004 are Jiameng Zhang (University of Pennsylvania), Yanli Zhao (University of Minnesota), and Sally Hopewell (U.K. Cochrane Centre). The Committee has requested a full manuscript from these students; after their presentations at the Student Scholarship session, Committee members will meet and determine the winner of the Thomas C. Chalmers award.



Education Committee Workshops

The SCT Education Committee, chaired by Bob Byington, has planned the Pre-Conference Workshops for Sunday, May 23, 2004.

The workshops include:

Morning Sessions (8:00 a.m.-12:00 p.m.)

- (1) Essentials of Clinical Trials
- (2) Regression Modeling Strategies I
- (3) Independence in Data Monitoring of Clinical Trials: Does one size fit all?

Afternoon Sessions (1:00-5:00 p.m.)

- (4) Current Perspectives on the Design, Conduct and Analysis of Clinical Trials Assessing Health-Related Quality of Life
- (5) Regression Modeling Strategies II
- (6) Group-Sequential Methods

The cost of each workshop is \$125, and you can register for the workshops when you register for the meeting. Registration forms are on line at www.sctweb.org

Program Committee Update

by *Ted Karrison*

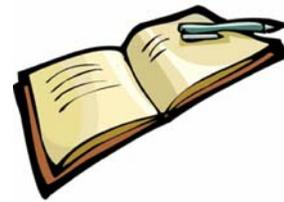
Program Committee Chair

The 25th anniversary meeting of the Society is drawing nearer! The final program is now in place and I hope you will find it to be of interest. Each day there will be a plenary session and four simultaneous invited workshops, followed by contributed papers. Steven Piantadosi will deliver the keynote address and the program will include our annual Student Scholarship competition for the Thomas C. Chalmers prize. The Education Committee, under the leadership of Bob Byington, has also put together an excellent set of pre-conference workshops for those wishing to expand or refresh their knowledge about clinical trials methodology.

If you have been looking at the preliminary

program that was mailed with the registration packet, please note that a fourth invited workshop has been added for Monday afternoon, entitled "Last Observation Carried Forward (LOCF): Is This Ever the Preferred Analysis?" organized by Susan Ellenberg. The final 2004 program can be viewed on the SCT website at www.sctweb.org.

I would like to thank the members of the 2004 Education and Program Committees for their hard work in putting together this year's program. I hope that it has broad appeal to all of those involved in the conduct of clinical trials, and I look forward to seeing you in New Orleans.



News from the Publication Committee

by *Dennis Dixon*

Publication Committee Chair

All Society members by now have started receiving their personal copies of our new journal, *Clinical Trials*. As in the past, appointment of a new editor presents an opportunity to make some changes, even though we were justifiably proud of what we had. In this case the changes are numerous: besides a new editor, Steve Goodman; a new publisher, Arnold; a new name; a new size; a new format; and on and on. One specific change, though, is in the wrong direction. In our last year with *Controlled Clinical Trials* over 500 libraries and other institutions subscribed. Fewer than 10% of those have subscribed to *Clinical Trials*. Although this precipitous drop-off is not entirely unexpected, given the short time between the announcement and appearance of the new journal and current pressure on library budgets, subscription numbers will not quickly rise to former levels without the assistance of all Society members. This is a serious matter, because library subscriptions account for a much larger proportion of journal revenue (> 90%) than do the individual subscriptions.

(Publication Committee, continued)

The Society needs every member to ask his or her university / company / departmental / agency library to subscribe. And then check periodically to reinforce the request. Information on subscribing can be found on the page just behind the table of contents of the print journal or on the journal's web site, www.sctjournal.com. (There's even an on-line form for you to forward to the library if you know the contact information.) This is so urgent I'm tempted to start a chain letter asking 10 colleagues around the country to submit requests to their libraries and ask 10 of their colleagues to do the same. If you do email your library, please cc the journal publisher at ejournal@hodder.co.uk so they can keep a record of such requests and follow-up if necessary.

In a break with tradition, the Publication Committee this year has news besides developments with the journal. You will know from earlier correspondence and Newsletters that the Society will begin to take public positions on matters of high interest to members. At the time of this writing work is underway to prepare two Society commissioned papers. One is to consider appropriate characteristics of data and safety monitoring plans when fully independent data monitoring committees may not be required. The other is to express Society support for the proposal for a truly comprehensive registry of clinical trials. Papers become Official Position Papers of the Society if 2/3 of the Board of Directors vote to support them, and then they get expedited editorial review for publication in *Clinical Trials*. The Publication Committee is happy to have been asked to assume responsibility for this new Society initiative.

**FDA-JHU sponsored workshop:
Bayesian Approaches to Clinical Trials**
by *Susan Ellenberg*

On May 20-21, the FDA and the Johns Hopkins University Department of Biostatistics will jointly sponsor a public workshop entitled, "Can Bayesian Approaches to Studying New Treatments Improve Regulatory Decision - Making?"



The goals of the workshop are as follows:

- Communicate the underlying concepts of Bayesian design and analysis of clinical trials in non-technical terms.
- Illustrate the use of Bayesian approaches to clinical trials with case studies.
- Demonstrate how a Bayesian approach uses evidence in the decision making process.
- Review the experience of the Center for Devices & Radiological Health using Bayesian approaches and discuss the potential for application of Bayesian approaches in clinical trials of investigational pharmaceuticals.
- Discuss how studies using a Bayesian approach can satisfy regulatory requirements

The workshop will be held on the NIH campus, in Masur Auditorium located in the NIH Clinical Center (Building 10).

The workshop agenda can be found at www.fda.gov/oc/meetings/bayesian.html, and information about registration is at www.jhu.edu/advanced/bayesian

Development Committee Update

by Tom Capizzi

Development Committee Chair



The goal of the Development Committee is to raise funds, consistent with the professional integrity of the Society, to support infrastructure needs and SCT's educational and program goals. The committee works closely with the Board of

Directors to generate a potential

sponsor list and in the development of a solicitation process.

Since October 2003 we have been soliciting funds for 2004 activities. As of March 15, 2004, we have received \$17,250 from 10 sponsors. The breakdown of funds received is as follows: Student Scholarship program-\$12,000; SCT travel fund-\$500, Annual Meeting Reception- \$3000, Technology fund-\$500, and \$1250 for the General Fund. The Society is grateful for the participation of each of our sponsors. The list of our 2004 sponsors can be found on the Society web site (www.sctweb.org).

The SCT Executive Committee has charged the Development Committee with identifying new funding mechanisms such as obtaining grants from non-profit foundations. In order to address this new objective, the committee is seeking to increase its membership. If you have suggestions for new funding sources or would like to join the committee, please contact me at tom_capizzi@merck.com

In 2003 Fran LoPresti decided to resign from the Development Committee after several years as chair. On behalf of the Society, I want to thank Fran for her outstanding service and contributions to the committee. Her willingness to share her experience with me ensured a smooth transition process for which I am thankful.

Society Web Page and Online Ballot

by Herman Mitchell

Web Site Editor

For this year's Society for Clinical Trial Officer and Board of Directors elections, we will provide for the first time an online voting system. Along with this newsletter you will receive a ballot that lists the candidates and provides a 6-digit alphanumeric code that can be used for voting on the SCT website (www.sctweb.org). You need only click on the online voting link and pick your candidate choices and enter the 6-digit code. The online system will update the code database indicating that you have voted and simultaneously register your vote in a separate database unlinked to your code in order to maintain confidentiality.

If you chose to vote via mail, just return your ballot in the envelope provided and the Society administrative office will register your vote and cancel the voting code. If you have a problem with registering your vote Mary Burke at the Society office (410-433-4722) can assist you.

Notes from the Newsletter Editor



If you would like to join the SCT or learn more about the 2004 New Orleans meeting, you can 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