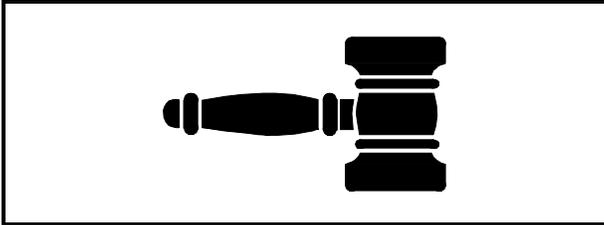

SCT Newsletter

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SCT President's Corner

by *Barry R. Davis*

As incoming president of the Society for Clinical Trials, I look forward to an interesting and busy year. My major concerns for the Society as we approach Y2K are membership and meeting attendance. We need to set goals for increasing participation in SCT, perhaps something like "2000 in 2000." Our membership and meeting attendance numbers have either been static or decreasing in the last few years.

I have asked the membership committee, under the leadership of Susan Margitic, to make a special effort this year to increase membership and meeting attendance. They have made a successful start. Also, the SCT Executive Committee has already asked each SCT Board member to take a more active role in promoting these activities. I ask all members of SCT to join us in this effort. Imagine if everyone recruited a friend. We should be good at recruiting. Isn't this what we do in clinical trials?

Each of you can discuss the benefits of belonging to the SCT and provide a membership application to all personnel in your department who are involved in any and all aspects of the conduct of randomized clinical trials. Remember, the function of the Society is the promotion of good quality randomized clinical trials, our dues are quite modest, and members get a subscription to *Controlled Clinical Trials*.

Good news! We have had major contributions from two leading clinical trials centers to help support our annual meetings. The Johns Hopkins

Center for Clinical Trials will sponsor the keynote address and the George Washington University Biostatistics Center will support a plenary session at the SCT annual meetings beginning next year in Toronto. The support will be used for the cost of travel and honoraria for speakers. Both centers have pledged gifts for the next five years, renewable thereafter.

Congratulations to Barbara Hawkins for her successful year as SCT president last year. Thanks to Program Committee Chair Stephen Piantadosi for his contributions to an excellent meeting this past May in Anaheim, California. Also, thanks to the Development Committee, under the leadership of Frank Rockhold, which obtained several substantial contributions to the SCT from industry this past year.

In 2001, the SCT will meet from May 19 to 23 in Denver, Colorado. In 2002, the SCT will meet from May 11 to 15 in Arlington, Virginia. Plans are under way for a joint meeting of the SCT/ISCB in London in 2003. The exact location and times are being worked out.

Remember, our next Annual Meeting is April 16-19, 2000, in Toronto, Canada. Marian Fisher is chairing the Committee and an exciting program is being planned. Salim Yusuf of McMaster University in Hamilton, Ontario will be the keynote speaker. I look forward to hearing from any of you with suggestions regarding the Society and its activities. You can contact me via email at

davis@utsph.sph.uth.tmc.edu.

Development Committee News

by *Frank Rockhold*

As noted by Barry Davis in the President's column, the Development Committee was successful in obtaining donations to support a number of Society initiatives in years to come. I would like to thank Fran Lopresti, Brent Blumenstein, Neil Bressler, and Linda Roach for their efforts over the last year to support the long term financial viability of the Society.

SCT 2000: April 16-19 Toronto

by Marian Fisher, Program Committee Chair

Yes, you still have plenty of time to prepare your abstract for submission by November 15, 1999! For more details, please go to:

www.sctweb.org/sctcall2000.cfm

The poster and contributed paper sessions are integral components of our meetings and we encourage your participation.

The Program Committee has reviewed suggestions recorded on the poster at the May 1999 meeting and on the May 1999 meeting evaluation forms, as well as ideas submitted by Program Committee members and others. During the summer, we have worked via email and on one-to-one telephone calls.

The following three plenary session topics have received the highest rankings from the Program Committee and are expected to be part of the SCT 2000 meeting:

- ! The Impact of Healthcare Systems on Clinical Trials
- ! Interim Data - Who Should Be Privy to What Information When?
- ! Joint Public/Private Funding of Clinical Trials

The workshop component of the program is currently under development and will feature topics in a variety of areas:

- ! Trial Management (e.g., visiting a clinical site)
- ! Statistical Analysis (e.g., analyzing data with missing values)
- ! Information Technology (e.g., software tools for creating web data entry forms)
- ! General Interest (e.g., improving the informed consent process)

As part of the luncheon on Monday, we are suggesting that some of the tables be designated as "topic tables". This would provide you with the opportunity to network with individuals with similar interests. Please send your suggestions for these luncheon table topics to me via email:

fisher@biostat.wisc.edu

The SCT Program Committee is limited by the bylaws to 15 voting members and must include the President and President-Elect (Barry Davis and George

Williams, respectively). The remaining members (listed alphabetically) are Robin Bechhofer, Carlo Berti, myself (Marian Fisher), Bill Henderson, Fran LoPresti, Susan Margitic, Ruth McBride, Rick Mowery, Joe Pater, Frank Rockhold, Jay Siegel, Alicia Toledano, and Julie Weston. I appreciate each of their contributions of time and talent.

Our Committee is working hard to create a varied, educational and engaging program. However, what will make this meeting a success is your attendance, enthusiasm, questions, and contributions. Reserve April 16-19, 2000 in your calendar and come!

Student Scholarship Program

by Steve Goodman

Students (including post-doctoral fellows and physicians in residency programs) are invited to submit abstracts for the annual student scholarship program of the Society for Clinical Trials, which is held at the annual meeting. The deadline for submission of abstracts (with accompanying three page summary) is December 1, 1999.

Acceptable topics include clinical trial-related issues such as study design and data analysis; meta-analysis; medical, ethical or legal issues; data entry, management, and computing as it relates to clinical trials; review of the results or methods of a class of trials; or scholarship in the history or theory of clinical trials. Results of particular clinical trials are of interest if they illustrate a methodologic advance in design or analysis, or if their results have methodologic implications.

Three students will be selected to present their papers at the meeting (which must be done by the student themselves), with all fees waived and travel and living expenses paid for by the Society, subject to a negotiable \$1750 US limit. An additional \$500, the Thomas Chalmers memorial award, will be given to the student judged to have the best paper.

For further information, link to the SCT website at www.sctweb.org, or contact Steve Goodman by email to sgoodman@jhmi.edu, or via fax to 410-614-2325.

Membership Committee Update

by Susan Margitic

We need your help to increase and diversify SCT Membership. The SCT Membership Committee has formulated a number of strategies to augment and diversify the Society's membership. We need your help to implement some of these strategies.

- ! Display the new SCT posters at your institution. (These will be included in the next SCT mailing.)
- ! Forward e-mail messages about the April 2000 meeting in Toronto to e-mail listserves of interest, including your local colleagues or professional organizations with listserves. Email Susan Margitic (smargiti@wfubmc.edu) about this, and she will forward the message to you for circulation. (The message is listed to the right.)
- ! Place SCT brochures at study investigator meetings. Contingent upon receiving approval from meeting organizers, brochures could be placed at registration tables or in meeting packets. Contact the SCT office by email (sctbalt@aol.com) to order brochures.
- ! Arrange to have your next study investigator meeting held back-to-back with the annual SCT meeting. Contact Mary Burke at the office (sctbalt@aol.com) to discuss arranging such meetings.
- ! Arrange with related professional organizations (e.g., American Statistical Association, Cochrane Project) to establish links between their web sites and the SCT web site. Please contact Susan Margitic (smargiti@wfubmc.edu) about this if you have web sites to suggest.

Other strategies to enhance SCT membership include 1) swapping SCT mailing labels with other professional organizations. (This will be done with subscribers to *Applied Clinical Trials*, a journal that focuses on regulatory, ethical and methodological issues in industry-sponsored clinical trials) and 2) placing SCT meeting announcements as

free ad fillers or in the calendar list of events sections of journals and professional new letters. Please contact Susan if you have suggestions on where to place such ads. Below is the e-mail announcement that we hope you will share with your colleagues:

EXCHANGE IDEAS ABOUT CLINICAL TRIALS IN TORONTO! The Society for Clinical Trials

- * The Society for Clinical Trials, a professional organization dedicated to the design, conduct, management and analysis of clinical trials, will hold its annual meeting on April 16-19, 2000 at the Royal York Hotel in Toronto, Canada.
 - * Pre-conference workshop courses, plenary sessions, simultaneous workshops and contributed paper/poster sessions address topics of interest to those in academia, private industry and government, including biostatisticians, physicians, nurses, clinic coordinators, computer scientists, data managers, epidemiologists, behavioral scientists, bioethicists and pharmacologists.
 - * The student scholarship competition promotes submission of abstracts for possible presentation at the annual meeting, with paid travel expenses.
 - * The deadline for submission of abstracts for oral and poster presentations 11/15/99.
 - * The deadline for the student scholarship competition is 12/1/00.
 - * For more information about the annual meeting or about joining the Society for Clinical Trials and receiving the peer-reviewed journal *Controlled Clinical Trials*, visit the SCT WEB site at www.sctweb.org or contact the SCT office by phone (410-433-4722) or email (sctbalt@aol.com).
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SCT Web Site Update

by Herman Mitchell

The Society for Clinical Trials website (www.sctweb.org) has expanded its features to include on-line submission of abstracts for the upcoming meeting in Toronto. The abstract form can be printed for a standard mail-in submission or filled out on-line and submitted directly through the website. You will receive verification of the submission via e-mail. All instructions are found on the website, along with hotel reservation procedures and city information for the meeting.

In addition to the abstract submission on-line, the SCT website will permit you to look up an SCT member's telephone number and e-mail address via on-line search. Members' names are included in the on-line directory if the member has given permission for inclusion on the membership renewal form. Prior copies of newsletters and information regarding the Society's committees and officers can also be found on the site.

In the next few months, the SCT website will provide access to employment notices for organizations with positions available and for those looking for employment. Posting of position availability and information regarding those seeking positions can be submitted on-line.

The SCT website has been developed and is being maintained by a volunteer committee which includes Sharon Bak, Fran LoPresti, Scott Rushing, and Ella Temprosa. Please send any comments or suggestions to Herman Mitchell, the SCT web editor, at hmitchell@rhoworld.com.

Control Groups in Clinical Trials

by Susan Ellenberg

A proposed new Food and Drug Administration guidance document that should be of interest to many SCT members was published in the Federal Register on September 24, 1999. The document is entitled Choice of Control Group in Clinical Trials and was developed under the auspices of the International Conference on Harmonization, a collaboration of industry scientists and regulatory

authorities in the U.S., Europe and Japan. This document discusses in detail the considerations for utilizing different types of control groups, and gives special attention to the issues surrounding the use of active control trials to establish efficacy of new products. The document should be available on the FDA web site (see below). A draft of the document is also available on the ICH website. The document has also been issued for comment in Europe and Japan.

Comments on the document are solicited. All comments should reference Docket no. 99D-3082, and be sent to the following address: Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852.

Comments will be accepted until December 23, 1999. The comments of SCT members on this document will be particularly valuable.

For more information on the International Conference on Harmonization, please refer to the following website: www.ifpma.org/ich1.html. The document itself can be found at www.ifpma.org/pdfifpma/e10.pdf. FDA guidance documents can be retrieved from the following website: www.fda.gov/cber/guidelines.html.

Pre-Conference Workshops

Pre-Conference Workshops are being planned for Sunday, April 16, 2000, by the SCT Education Committee, which is chaired by Sylvan Green. Please contact Sylvan Green at fax (216) 368-5817 with your suggestions for the SCT 2000 Pre-Conference Workshops.

Notes from the Editor

If you would like to join the Society for Clinical Trials or receive information about the SCT 2000 Meeting in Toronto, check the SCT web site at www.sctweb.org or contact Mary Burke at phone (410) 433-4722 or email scbalt@aol.com. If you have suggestions for this newsletter, please contact *SCT Newsletter* editor Jennifer Gassman by phone (216) 444-9938 or email jgassman@bio.ri.ccf.org.