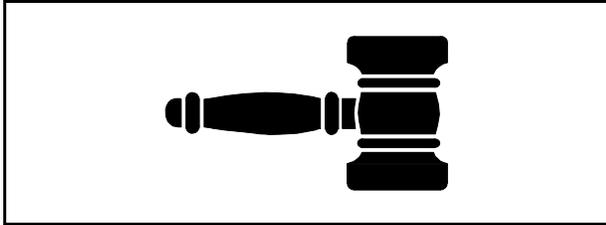

SCT Newsletter

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SCT President's Corner

by *Barbara Hawkins*

This year has been a busy one for clinical trialists. In late October of 1998, I attended the London meeting entitled "50 Years of Clinical Trials: Past, Present and Future." The meeting was organized and sponsored by the British Medical Association, the *British Medical Journal*, and the Medical Research Council (MRC) to celebrate publication in 1948 of the MRC's trial of streptomycin for pulmonary tuberculosis. The Society for Clinical Trials (SCT) was well represented at the meeting. The Program Committee included SCT members Janet Darbyshire, Taddy Dickersin, Michael Clarke, and Peter Gotzsche; SCT members Peter Armitage, Jean-Pierre Boissel, and Genell Knatterud served on the Advisory Committee. Other SCT members who participated in the meeting included Curt Meinert, Barbara Martin, John Simes, Ken Schulz, Salim Yusuf, Dianna Elbourne, and Susan Ellenberg. The highlight of the meeting for me was the opening talks by Sir Richard Doll and Philip D'Arcy Hart who were two of the investigators in the streptomycin trial. The closing speaker of the two-day meeting was Richard Peto.

Stuart Pocock attended the first Asian Clinical Trials Conference in Hong Kong, also in late October of 1998. He reported that this pioneering meeting attracted over 200 delegates and also included popular educational courses in clinical trials methods. This was an important occasion for stimulating quality trials

research in Asia, and Stuart has told us that plans are already underway for a second Asian conference in Singapore.

The SCT Program Committee was very busy in November, December, and January. Those members who could spare the time met in Baltimore on January 11 to make the final selection of abstracts for workshops, plenary sessions, and contributed papers and posters and to arrange those selected into a viable program. Thanks to the preliminary work by Mary Burke and Moscoe Johnson and the focused efforts of Steve Piantadosi and the other Program Committee members in attendance, the program was finalized by mid afternoon.

All SCT committee chairs and members have been very active this year. The Policy Committee, chaired by Sylvan Green, is currently drafting a letter to the Office of Management and Budget on behalf of the Society regarding a measure inserted into the Omnibus Appropriations Act passed by the last Congress that would provide public access to data from any federally funded research project, whether completed or not. This measure would overrule the 1980 U.S. Supreme Court decision that records held by an NIH grantee were not subject to the Freedom of Information Act. At best, this change could be nuisance to clinical trialists; at worst, it could make it impossible to complete accrual to clinical trials in which trends in the outcome data may begin to emerge before a sufficient number of patients have been enrolled to provide a valid answer to the scientific question posed by the trial.

Sylvan Green also chairs the Education Committee which has developed five pre-conference workshops for the Anaheim meeting. Frank Rockhold and the Development Committee are preparing to launch their campaign to obtain contributions from corporate sponsors for selected SCT activities. Susan Margitic and the Membership

President's Column (continued)

Committee have completed summarization of the information collected from participants in the Atlanta meeting who completed the survey questionnaire distributed at the meeting. She will share the findings with the Board and at the business meeting in Anaheim.

As usual, Rick Chappell and the Student Scholarship Committee have chosen excellent student travel award winners, whom we will meet in Anaheim. Ted Karrison has chaired the Nominating Committee. The candidates for President-Elect and members of the Board of Directors will be sent to you soon.

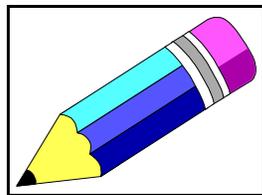
The Finance Committee, with Michael Terrin at the helm, has been relatively quiet this year but is gearing up. Michael is looking for a few "sober, banker types"; if you are one of these, I encourage you to contact Michael to volunteer for this committee.

Dennis Dixon, who took over the Publications Committee from George Williams, has had several issues to deal with during the past year. However, they are happy to report that the transition to the new editor of *Controlled Clinical Trials* has gone smoothly.

The Executive Committee deserves special credit for keeping SCT activities and priorities on track between annual meetings of the Board. I have very much appreciated advice from Barry Davis, Stuart Pocock, Joel Verter, Chris Donnhauser, and Mary Burke. When you see any of the Board and committee members in Anaheim, I hope you will thank them for helping to conduct the business of the Society. I look forward to seeing all SCT members in Anaheim and to turning the gavel over to Barry Davis.

Future SCT Meeting Dates

In 2000, the SCT will meet from April 16 to 19 at the Royal York Hotel in Toronto, Ontario. In 2001, the SCT will meet from May 19 to 23 at the Adams Mark Hotel in Denver, Colorado. In 2002, the SCT will meet from May 11 to 14 at the Hyatt Regency Arlington in Arlington, Virginia. In 2003, the SCT plans to meet jointly with the International Society for Clinical Biostatistics in Europe.



Anaheim Pre-Conference Workshops

The SCT Education Committee has planned five Pre-Conference Workshops for Sunday, May 2, just prior to the Annual Meeting.

Workshop I, The Practicalities of Data Monitoring for Major Clinical Trials: Some Do's and Don'ts, will be held from 8 a.m. to 12 noon. Organizational and operational issues related to data monitoring will be addressed, and examples will be provided.

Workshop II, Multiplicities in Clinical Trials, will be held from 1 p.m. to 5 p.m. In a clinical trial setting, multiplicity refers to issues surrounding multiple treatments, subgroup analyses, covariate adjustments, sequential analyses, multiple endpoints, and multiple lifetime events. Note the new afternoon time for Workshop II.

Workshop III, Essentials of Clinical Trials, will be held from 8 a.m. to 12 noon. Clinic coordinators and clinical research associates will find this course especially useful.

Workshop IV, Montage of Computing Issues in Clinical Trials, will be held from 1 to 5 p.m., and will address topics including structured document creation, handheld data entry devices, and Y2K issues for clinical trials.

Workshop V, Special Topics in Participant Recruitment, will be held from 1 to 5 p.m. This workshop will include an overview of recruitment problems and will review four examples of recruitment in special populations.

Each workshop costs \$75. For more information about registering for a morning or afternoon short course (or both), contact Mary Burke at (410) 435-8631 (FAX), (410) 433-4722 (phone), or sctbalt@aol.com (e-mail).

The SCT Education Committee is chaired by Sylvan Green, and includes Brent Blumenstein, Julie Buring, Bob Byington, Jennifer Gassman, Stephen George, Barbara Hawkins, and Stuart Pocock.

SCT Web Site Update

by Herman Mitchell

The SCT Web Site Committee (a subcommittee of the SCT Publications Policy Committee) is working to enhance the Society's official web site, which is under construction. The web site currently resides at the following new address:

<http://www.sctweb.org>

When this phase of development is complete, the web page will feature

- A downloadable membership application
- A downloadable abstract form
- SCT Committee membership and activity information
- Current and past SCT Newsletters
- An on-line directory of member's names, phone numbers and email addresses.

To develop the structure for a Web accessible membership list, each SCT member was asked at the time of membership renewal for approval to include their name, telephone number and e-mail address for this on-line directory.

We thank Sharon Bak, Scott Rushing, and Ellen Temprosa for their work on the new SCT web site. A current version of the SCT web page functions will be available on a PC at the May meeting in Anaheim. If you have suggestions for the web site, send email to Herman Mitchell (hmitchell@rhoworld.com).

Site of the Annual Meeting

The Anaheim Marriott is the site of the 20th Annual Meeting of the Society for Clinical Trials, in Anaheim, California. Guest rooms have coffee makers. There is an indoor pool, an outdoor pool, a whirlpool, a sauna, and a health club.

This hotel is 15 miles from the Orange County/John Wayne airport (SNA), 20 miles from the Long Beach Airport (LGB), 35 miles from the Los Angeles Airport (LAX), and 2 blocks from the entrance to Disneyland.



A Note from the Editor of our Society's Journal, *Controlled Clinical Trials*

by Jim Neaton

My first two months as Editor in Chief of *Controlled Clinical Trials* have been exciting and educational. The transition has been very smooth largely because of the help we have received from the past Editor, Janet Wittes, and her assistants: Rob Hydon, Heather Garfield, and Brooke Wuthnow. I thank them for their efforts. I would also like to thank Stephanie Diment and Louise Whelan from Elsevier Science for their help. I hope these efforts are evident and that the transition will be easy for you, both as readers and authors.

Submissions should now be sent to me at the new editorial office at 2221 University Ave SE, Room 200, Minneapolis, MN 55414. I am being assisted in the editorial office by Marc Kjelsberg, Merrie Harrison, and Sue Meger, by an advisory board, and by a strong group of associate editors. You will become familiar with the staff in Minneapolis as we receive your submissions and call upon you to referee articles.

We are anxious to see your papers. This is the forum to discuss design issues, problems you have faced in carrying out trials, and interesting monitoring and data analysis issues. Please keep those submissions coming. If you have any questions, just e-mail us at cct@ccbr.umn.edu.

Anaheim Program

The 20th Annual Meeting of the Society for Clinical Trials will be held at the Anaheim Marriott on May 2 to 5, 1999. The keynote speaker will be Curt Meinert, discussing the Society's role in clinical trials.

The meeting will begin on Sunday with five Preconference Workshops during the day and a welcome reception from 7 to 10 in the evening. The Society's business meeting will be held during lunch on Tuesday.

Anaheim Program (continued)

Plenary Sessions will include:

- I Quality of Life Analyses in Clinical Trials
- II Use of Sham Treatments in Clinical Trials: Ethics, Design and Examples
- III Issues in Design and Conduct of Clinical Trials in Complementary and Alternative Medicine
- IV "Paperless" Remote Data Entry: Its Regulatory, Data Analysis, and Reporting Implications
- V Contrasting Characteristics of Clinical Trials Sponsored by Government vs. Clinical Trials Sponsored by Industry

Steven Piantadosi of Johns Hopkins University is the Program Committee Chair. Program Committee members include Dorothy Adams-Farnham, William Blackwelder, Jean Pierre Boissel, Joseph Collins, Gerrit DeBoer, Lloyd Fisher, Young Jack Lee, Joseph Pater, W. Joseph Shih, Steve Singer, Peter Thall, and Alicia Toledano, as well as president Barbara Hawkins and president-elect Barry Davis.

For more information about the Anaheim meeting, contact Mary Burke at (410) 435-8631 (FAX), (410) 433-4722 (phone), or sctbalt@aol.com (e-mail).

Student Scholarship Program

by Rick Chappell, Chairman

The three 1999 Student Scholarship Program student travel award winners are

- Brian Wiens, formerly of Temple University and now of Quintiles, Inc.
- Debashis Ghosh of the University of Washington
- Ying Chen of Johns Hopkins University

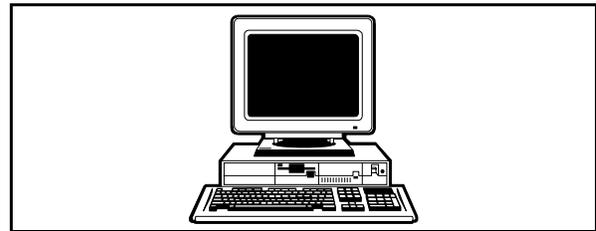
These three students were selected from among 15 applicants, from the U.S., U.K., Belgium, and Zimbabwe. The Student Scholarship session will be held from 11:40 to 12:40 on Monday, May 3.

A Student Scholarship competition will be held again for the 2000 annual meeting in Toronto. Students enrolled in a degree program of an accredited college or university, post-doctoral fellows, and physicians enrolled in an accredited residency program are eligible to apply. The

deadline will most likely be December 1, 1999.

Students are invited to submit abstracts and short manuscripts (no more than three pages) on topics related to the design and analysis of trials; data entry, management, and computing as applied to clinical trials; review of the results or methods of a class of trials; or medical, legal, or ethical issues related to clinical trials. The three students with the best abstracts are asked to submit full manuscripts for review and to present their papers at the annual meeting, with all registration fees waived and travel and living expenses paid for by the Society (up to a \$1750 limit).

The student judged to have the best manuscript and presentation receives the Thomas C. Chalmers prize, a \$500.00 cash award. In addition, all three winners receive written comments from the review committee. Questions or comments can be addressed to Rick Chappell by e-mail to chappell@stat.wisc.edu or by phone at (608) 263-5572.



Notes from the Editor

If you would like to join the Society for Clinical Trials or receive information about the 20th Annual Meeting in Anaheim in 1999, check our web page at www.sctweb.org or contact Mary Burke at (410) 435-8631 (FAX), (410) 433-4722 (phone), or sctbalt@aol.com (e-mail).

If you have suggestions for this newsletter, please send them to *SCT Newsletter* editor Jennifer Gassman in the Department of Biostatistics at the Cleveland Clinic Foundation, (216) 444-8023 (FAX) or jgassman@bio.ri.ccf.org (e-mail). The *SCT Newsletter* is published twice yearly, generally in March and October.