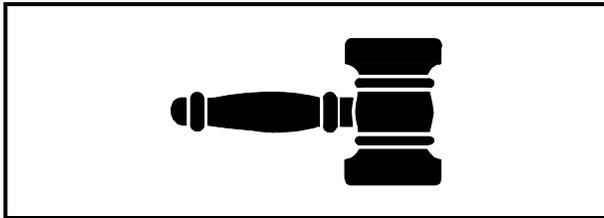

SCT Newsletter

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SCT President's Corner

by George Williams

As incoming President of the Society for Clinical Trials, I look forward to a very exciting year. I want to congratulate Barry Davis on his excellent leadership of the Society as President this last year. I also want to compliment Marian Fisher as the Program Committee Chair and Sylvan Green as the Education Committee Chair for the very successful meeting this past April in Toronto. We had a total attendance of 819. Congratulations to Janet Wittes on her election as President-Elect and to Roy Beck, Janet Darbyshire, and Steven Goodman for their election as new members of the Board of Directors. I look forward to working with Janet, the Board of Directors, and all others active in the Society for Clinical Trials.

Rick Mowery as Chair of the Program Committee and Bob Byington as Chair of the Education Committee are working with their committees to develop an outstanding program for the 2001 meeting which will be held at the Adams Mark Hotel in Denver, Colorado, from May 19 to 23. The Curtis Meinert Honorary Keynote Address will be given by Richard Horton, editor of *The Lancet*.

In 2002, the SCT will meet from May 11 to 14 at the Hyatt Regency Crystal City in Arlington, Virginia.

Plans are under way for the joint meeting of the SCT/ISCB in London in 2003 from July 20 - 24 to be held at the Hilton London Metropole. Simon Day, Diane Elbourne, and Mary Burke have made outstanding progress in the arrangements for this meeting.

Susan Margitic and the Membership Committee continue their efforts in promoting the Society to prospective new members. I also encourage each of you to spread the word about our activities to your colleagues whose work involves clinical trials and related fields of research. Brochures are available from Mary Burke in the Society office, and I would encourage you to give them to your colleagues and especially to distribute them at scientific meetings at which clinical trials are of interest.

Frank Rockhold and the Development Committee continue in their efforts to develop additional funding for Society activities. We are extremely grateful to EMMES, George Washington University, Johns Hopkins University, Merck, Monsanto-Searle, Parexel, Quintiles, and SmithKline Beecham, who have contributed support to the Society activities.

Jim Neaton continues his excellent work as editor of our journal, *Controlled Clinical Trials*. He would welcome suggestions for its future contents. I would encourage Society members to submit manuscripts to the journal; this is an excellent way to reach the variety of constituencies that are involved in trial management, design, implementation, and analysis.

Each of the SCT committees have made a conscious effort to include new members on their committees. If you are interested in serving on any of the SCT committees, please contact either the committee chairperson, Mary Burke at the Society office, or me. We want to encourage new members to become active in the Society. The chairs of the committees are listed in this *SCT Newsletter*. Do not hesitate to contact them, as we want the Society to be as open and receptive to general participation as possible.

I look forward to hearing from any of you with suggestions regarding the Society and its activities. You can contact me via email at george_williams@merck.com. Please also note that the Society's email address is sctbalt@aol.com and that its Web page location is www.sctweb.org

SCT Program Committee Update

by Richard L. Mowery

The Program Committee for the Society for Clinical Trials 2001 meeting in Denver has been hard at work reviewing and selecting potential topics for the plenary sessions and for the workshops. The Committee actually began its work during the meeting in Toronto. We have reviewed the evaluation forms from the Toronto meeting and the suggestions on the poster boards, and we have talked with Society members to develop interesting topics and issues that will form an exciting and informative program for the Denver meeting.

Richard Horton, editor of *The Lancet*, will deliver the Curtis Meinert Honorary Keynote Address on Monday, May 21, to start the 2001 meeting. The program will consist of three plenary sessions and at least sixteen workshops to be offered in four simultaneous sessions. A sampling of topics being developed by the Committee organizers that we think will present a variety of topics to appeal to the broad membership of the Society include: the decision process of a Data and Safety Monitoring Board in stopping a trial, the role of advocacy groups in clinical trials, regular and early closing of a trial, genetic testing in clinical trials, analytic issues related to quality-of-life data, and matching technology to trial needs. The organizers are currently preparing abstracts and identifying speakers for each session.

One of the goals the Program Committee has adopted is to try to ensure that each plenary session and workshop is organized to provide sufficient time for audience discussion and interaction with the speakers. This will also be emphasized for the contributed paper sessions.

The Program Committee has decided, based on feedback from the Toronto meeting, to keep the format for the 2001 meeting similar to that of the Toronto meeting. The only change will be moving the contributed paper sessions to the end of the day on Monday and Tuesday with each session running approximately two hours. This will allow for the presentation of six papers in each of the topic areas for a total of 48 contributed paper presentations.

I would like to thank the Program Committee members for the hard work they have already devoted to preparing an exciting program for the 2001 meeting. We hope you will find many topics of interest to you. If you need to contact me, I can be reached via email at rm33a@nih.gov.

Nominating Committee News

Dr. William Henderson, Chairman of the Nominating Committee for 2001, is in the process of appointing the committee. The committee consists of the chairman, SCT President and Vice President (President-Elect), two members appointed from the SCT Board of Directors, and three members appointed from the Society at large. The Committee, once appointed, will nominate two Society members for President-Elect, and six Society members for Board of Directors.

If you would like to make suggestions for the Nominating Committee membership or suggestions for nominations for the future President-Elect or Board membership, please send these to Dr. Henderson at the addresses below:

William G. Henderson, Ph.D.
Director, Hines CSPCC
P. O. Box 5000-151K
VA Hospital
Hines, IL 60141
Phone 708-202-5853
Fax 708-202-2116
Email: henderson@research.hines.med.va.gov

Development Committee

by Frank Rockhold

The efforts of the Society for Clinical Trials Development Committee to raise funds for the Society have been reinitiated this year. I am working with the Development Committee to expand our target for donations to the Society and as always would entertain suggestions from members as to strategies for raising money and creative ideas on how to acknowledge the use of the money as part of our Society meeting or other operations. I can be reached via email:

Frank_W_Rockhold@sbphrd.com

Update on International Harmonization: Choice of Control Group

by Susan Ellenberg

A document describing the considerations for choosing control groups for clinical trials intended to establish the efficacy of pharmaceutical products has been developed by the International Conference on Harmonization (ICH). ICH is an international collaboration of the pharmaceutical industry and regulatory authorities to ensure a consistent and high quality standard for testing, review and licensure of investigational drugs and biologics. An earlier draft of this document was published in the Federal Register on September 24, 1999, with the intent of soliciting comments from the public. Several SCT members submitted comments, along with many others from the U.S., Europe and Japan. The document has now been substantially revised and should be published in final form later this year as an official FDA guidance document. A major focus of the document is the design and interpretation of active control trials performed to demonstrate efficacy of a new product by demonstrating similarity to a known effective product.

Former SCT Presidents Bob Temple and Frank Rockhold, and two other active members of the SCT, Jay Siegel and Bob O'Neill, have represented the United States in the development and revision of this important document. When the final version is published it will be available on the FDA's web site in two locations:

www.fda.gov/cber/publications.htm

www.fda.gov/cder/guidance/index.htm

Other ICH documents are also available on these web sites. Information on ICH can be found at www.ifpma.org/ich1.html.

Student Scholarship Program

Students are invited to enter the SCT 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.

For more information, contact Steve Goodman by email: sgoodman@jhmi.edu or by fax: (410) 614-2325. Information is also available on the Society's web site at www.sctweb.org

Policy Committee

by Frank Rockhold

As chair of the Policy Committee for this year, I can tell you we have already been active reviewing a policy on clinical trial principles for the American Society for Gene Therapy and a policy on access to cancer clinical trials.

One request the Policy Committee has of the Society is that Society members make us aware as soon as possible about potential issues that they feel should be addressed by the Policy Committee. Sometimes the issues reach us too late for the Policy Committee to respond in a timely fashion. Therefore, if you know of issues upon which you feel the Society should comment, please contact either George Williams or me. I can be reached via email: Frank_W_Rockhold@sbphrd.com

Pre-Conference Workshop Plans

The SCT Education Committee, chaired by Bob Byington, has begun work on planning the Pre-Conference Workshops for 2001. Topics under consideration include data acquisition technology, regulatory issues related to diagnostics and devices, statistical methods for as-treated analyses, statistical methods for genetic data, and an Essentials of Clinical Trials course. If you have any suggestions for the Education Committee, contact Bob Byington by email to bbyingto@wfubmc.edu

Notes from the Editor

If you would like to join the Society for Clinical Trials or receive information about the SCT 2001 Meeting in Denver, check the SCT web site at www.sctweb.org or contact Mary Burke at phone (410) 433-4722 or email sctbalt@aol.com. If you have suggestions for this newsletter, please contact *SCT Newsletter* editor Jennifer Gassman via email: jgassman@bio.ri.ccf.org (e-mail).

Contact information for the chairs of Society's the Development, Education, Nominating, Policy, Program and Student Scholarship Committees are included in the articles in this newsletter.

Others committees and chairs include: Finance Committee chair Michael Terrin, mterrin@mmri.org; Membership Committee chair Susan Margitic, smargiti@wfbumc.edu; and Publications Committee Chair Dennis Dixon, ddixon@niaid.nih.gov