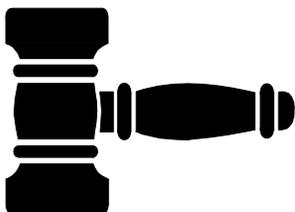

SCT Newsletter

Volume 16, Number 2

October 2006



SCT President's Corner

by Jim Neaton

It seems like such a short time since our annual meeting last May. I thought it was a great meeting. I hope you enjoyed it too. For a few months now, Bruce Pihlstrom and his Program Committee and Domenic Reda and the Education Committee have been working on planning next year's meeting in Montreal on May 20-23. I hope to see you there along with several new Society members.

We want the Society to grow and become more visible and for that we need your help. Talk to your colleagues. Tell them that there is an exciting meeting being planned in a wonderful city. Tell them to submit an abstract about novel approaches or insights they have about the planning and conduct of trials, or about the translation of trial results into practice. This is the meeting to come to if you want to share and debate methods for carrying out trials more efficiently (e.g., new ideas for training, for data collection and management, and for site monitoring).

This is the meeting to come to if you want to network with others concerning special issues in the conduct of international trials – we are an international group.

This year we are also devoting part of the program to the discussion of training programs for clinical investigators. The pre-conference workshops being discussed are very exciting and are real

bargains. In order to become the premier group in the world for individuals working on clinical trials, we need to expand our membership. Bring a friend to Montreal -- I am confident the experience will be rewarding and they will say "sign me up"!

Many individuals on several committees are working hard to make us the premier group in the world for clinical trialists so that we can more effectively carry out the objective stated for the Society many years ago: "to promote the development and exchange of information for design and conduct of clinical trials". I'd like to take this opportunity to express my thanks and appreciation to the chairs of these committee and their members. Thanks also to my fellow officers and to Jennifer Gassman for her work on this newsletter. Your collective efforts are what will strengthen and grow our Society.

In order to facilitate the work of the committees and the many new efforts the Board of Directors recommended last May based on the Futures Committee Report (see www.sctweb.org and click on SCT New Developments), we realized that we had to expand the secretariat and upgrade some of our computing capabilities there. To that end, several of us visited Mary Burke and Chris Donhauser at the Society office in Baltimore last June. It is truly amazing what Mary and Chris do for the Society. Chris has graciously agreed to continue as treasurer, accountant and tax preparer for the Society for the time being. Mary now has a part-time assistant, Sue Frock, and work has already begun on enhancements to the web site and Mary's office capabilities. These are investments that will pay off.

President's Corner (*continued*)

Also, recognizing the importance of improving our marketing and public outreach efforts and of beginning a process of planning for the day when Mary retires, we have begun visiting companies that specialize in the management of professional societies and we plan to prepare a request for proposals for a group that the Society could engage on a part-time basis now, and if satisfied with their work, on an expanded basis later.

While the results of our election have already been communicated to you, I also want to take this opportunity to welcome Eleanor McFadden as President-Elect. Eleanor began work immediately and participates on weekly calls with Dennis Dixon (Past President) and me. She is also leading the effort to prepare a request for proposal along the lines mentioned above. In addition, welcome to three new Board members: Gregory Campbell, KyungMann Kim, and K.K. Gordon Lan. They also quickly went to work for the Society.

In closing, I would like to ask each of you to:

- Encourage a colleague to join the Society and invite them to Montreal.
- Submit an abstract on your work to our meeting in Montreal.
- Consider other ways you can help the Society grow and become more visible.

Publications Committee Activities

by Colin Begg

Recent activities of the Publications Committee have focussed on drawing attention to important contemporary issues in clinical trials. A Position Paper was developed by an ad hoc committee to respond to the Brownback-Inhofe Senate Bill, which would change the law to permit marketing of new agents for seriously ill patients after only phase I clinical trials. The Position Paper articulated a strong opposition to this proposed legislation, and is posted on the SCT web site:

<http://www.sctweb.org/positionpapers/S.1956-clinical-trials.pdf>

This Position Paper drew the attention of editorialists in several prominent publications, including the New England Journal of Medicine (August 3), Lancet (May 20), Nature News Drug Discovery (May 2006), Journal of the National Cancer Institute (Sept 20), The Cancer Letter (May 26) and the London Times (August 21).

Another project was the development of a Commissioned Paper, prepared by another ad hoc committee. This paper addresses the issue of data monitoring guidelines for phase I and phase II clinical trials, and recommendations are provided for appropriate elements of such plans, decision criteria for institution of a data monitoring plan, and critical elements for a data monitoring committee to consider in exploratory trials. This is also posted on the SCT web site:

<http://www.sctweb.org/positionpapers/s6.pdf>.

Finally, plans are underway for the publication of a debate on the likely impact of biomarker developments and genomics on the way in which new agents will be evaluated in the future. Several prominent clinical trialists will articulate their views in published commentaries (in Clinical Trials) on this topic.

Nominating Committee Update

The Nominating Committee, chaired by Stan Shapiro, is responsible for designating a slate of nominees for positions of President and members of the Board of Directors. The Chairperson is responsible for ensuring that the Nominating Committee develops a list of two nominees for President and two for each position to be selected for the Board of Directors. In selecting the nominees, particular attention is paid to obtaining balance among disciplines, geography, and source of employment, in order to encourage broad representation from the Society membership. If you have suggestions for the nominating committee, contact Stan Shapiro by sending an email to stan.shapiro@mcgill.ca



Bonjour from Montreal! **SCT 2007 Meeting Update**

By Bruce Pihlstrom
Program Committee Chair

As of this writing, the SCT Program Committee is busy finalizing the program for the 28th Annual Meeting of the Society to be held at the Hyatt Regency Hotel in Montreal Canada on May 20-23, 2007. There will definitely be an international flavor to the meeting beginning with the Keynote Speaker Sir Richard Peto, Professor and Co-Director of the Clinical Trials Service Unit, University of Oxford.

As in the past, the program will consist of three plenary sessions, twelve invited sessions, and the always popular contributed sessions. Abstracts for contributed sessions are due on December 1, 2006 and may be submitted electronically by visiting the SCT Website (www.sctweb.org) or by mail to the central office. Abstracts submitted for the contributed sessions should be of interest to the diverse membership of the Society and be relevant to the design, conduct and analysis of clinical trials. In addition to statistical issues, topics on the use and evaluation of technology for data collection and data management are encouraged as well as those related to study coordination, site selection, and procedures for ensuring protocol adherence and recruitment of clinical trial participants.

The program committee is planning plenary and invited sessions that will be of wide interest to the international clinical trials community of investigators, research coordinators, and biostat-

isticians. It is clear that the Society is not just for biostatisticians – we are much more than that and the program committee is making every effort to develop a program that will reflect the diverse interests of our membership. The Education Committee is also making plans to continue the popular and successful pre-conference educational workshops at the Montreal meeting. There should be something for everyone who is interested in clinical trials at the Montreal meeting so please make sure to reserve the date on your calendar.

Merci beaucoup... and we are looking forward to seeing you next spring in lovely Montreal!

Student Scholarship Competition ***by Sylvan Green***

The SCT Student Scholarship Committee is chaired by Sylvan Green. All students enrolled in a degree program of an accredited college or university, post-doctoral fellows, or physicians enrolled in an accredited residency program are eligible and are invited to enter the competition.

Acceptable topics are 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 of clinical trials. Results of particular clinical trials are of interest only if they illustrate a methodological advance in design or analysis, or if their results have methodological implications. Important applied papers are particularly encouraged.

Three winners will be selected to present their papers at the Annual Meeting in Montreal. Their fees will be waived and their travel and living expenses for the meeting will be paid by the Society. The Thomas C. Chalmers Student Scholarship Award and a \$500 cash prize will be given to the student judged to have the best paper. The deadline for submission of abstracts (with three-page short manuscript) is December 1, 2006. For details, see www.sctweb.org (in the section on the Annual Meeting).

Education Committee News

by Domenic Reda

The SCT Education Committee for 2006-2007 is being chaired by Domenic Reda and co-chaired by Virginia Howard and Nicole Close. Committee members include Michael DiMarino, Carol Fye, Kwan Hur, Richard Kotz, Michele Melia, Pamela Moke, Claudia Moy, Kristine Nelson, Wendy Parulekar, Yves Rosenberg, Julie Weston and Ken Wilson.

The primary function of the committee is to plan the pre-conference workshop program. These workshops are selected to appeal to the diverse backgrounds of SCT membership and include offerings in advanced statistical methods, information technology, and the design, management, conduct and analysis of clinical trials. We hope to offer Continuing Medical Education credits for the first time for certain workshops. We are especially interested in your ideas for workshops for the 2007 meeting and if you are interested in speaking at a workshop. Please e-mail Domenic Reda: Domenic.Red@va.gov, Virginia Howard: vjhoward@uab.edu or Nicole Close: ncclose@yahoo.com.

Website Oversight Committee

by Mark Espeland

The Website Oversight Committee has expanded its mission. It will continue to provide recommendations on policy issues related to the SCT website. It will now also take a more active role in reviewing the management of the site, as subcontracted by the SCT Board of Directors, and provide recommendations on future directions for the website.

The membership of the committee for this year is Marie Diener-West of the Johns Hopkins Bloomberg School of Public Health, Mark Espeland of the Department of Biostatistical Sciences at Wake Forest University, Maureen G. Maguire of the Department of Ophthalmology at the University of Pennsylvania, Chad McLamb of the Cancer Center Information Systems at the Duke University Medical Center,

Pamela S. Moke of the Jaeb Center for Health Research at the University of South Florida, and Rema Raman of the Division of Biostatistics and Bioinformatics at the University of California San Diego. Scott Rushing, who serves as the webmaster for the SCT website, is also an ex officio member.

Several improvements in the website are planned for the upcoming year. These include refining the online meeting registration process, re-engineering the membership application process, re-engineering the online abstract submission process, and relocating the SCT website to a hosting company that provides more timely backups.



Committee Seeking Nominations for the Honorary Title “Fellow of the SCT”

by Bob Byington

Fellows Committee Chair

The Society established the title of “Fellow of the Society for Clinical Trials (FSCT)” in 2005 to honor past or current Society member who have made significant contributions to the advancement of clinical trials. This title is granted to a number of society members each year at the Annual Meeting.

The members of the 2006 Fellows Class (inducted in May in Orlando) were Peter Armitage, David DeMets, Katherine Detre, Fred Ederer, Susan Ellenberg, Lloyd Fisher, Bill Friedewald, Curt Furberg, Michael Gent, Mort Hawkins, Genell Knatterud, John Lachin, Paul Meier, Curt Meinert, Stuart Pocock, Bob Temple, and Janet Wittes.

We are now seeking nominations for the Class of 2007. Candidates for this title must have been a member of the SCT for at least 5 of the last 10 years or a total of at least 10 years. Each nominee will be evaluated on the basis of his or her contributions to the advancement of clinical trials in one or more of the following areas:

- Methodological development
- Trial coordination, conduct or leadership
- Education
- Ethics

Committee on Fellows (*continued*)

- Promoting a better understanding by the general public of the importance of randomized clinical trials
- Service to the Society

A Committee on Fellows has been established to evaluate each candidate on the criteria described above. This year the members of the Committee are Bob Byington (Chair), Susan Ellenberg (2006 FSCT), Lloyd Fisher (2006 FSCT), Mae Gordon, Joel Greenhouse, Ruth McBride, Stuart Pocock (2006 FSCT) and Frank Rockhold.

Any member of the Society may nominate a candidate. To do so, please collect the following:

- The candidate's CV
- At least 3 letters of support of the nomination from individuals qualified to describe the candidate's contribution to the Society. At least two of these letters should be from an institution, agency, or organization other than the candidate's.

Then submit the CV and the 3+ letters to Bob Byington by December 22, 2006. His address is:

Robert P. Byington, PhD
SCT Committee on Fellows
Department of Epidemiology and Prevention
Wake Forest University School of Medicine
Medical Center Boulevard
Winston-Salem, NC 27157-1063
USA

This class of Fellows will be awarded this title at the May 2007 Meeting of the Society in Montreal.

Janet Wittes receives Janet L. Norwood Award

by *Richard F. Sarver*

The University of Alabama at Birmingham and the School of Public Health, along with the Department of Biostatistics and the Section on Statistical Genetics, announces that Dr. Janet Turk Wittes, president of Statistics Collaborative Inc. which she founded in 1990, is the recipient of the Fifth Annual Janet L. Norwood Award for Outstanding Achievement by a Woman in the Statistical

Sciences. The award ceremony, lecture by Dr. Wittes, and reception will occur at the University of Alabama at Birmingham's Alys Stephens Center on Friday, October 13, 2006.

Dr. Wittes received her BA in Mathematics from Radcliffe College, and her MA & PhD in Statistics from Harvard University. She began her career in academe. Then, in 1983, she joined the Biostatistics Research Branch, National Heart, Lung, and Blood Institute as its Chief. Her research has focused on the design and analysis of randomized clinical trials. She is a Fellow of the American Statistical Association, the American Association for the Advancement of Science and the Society for Clinical Trials. She is a past President of The International Biometric Society – Eastern North American Region (1995) and The Society for Clinical Trials (2001). From 1990 through 1995 she served as the Editor-in-Chief of Controlled Clinical Trials. She is a member of many Data and Safety Monitoring Boards (DSMBs) for randomized clinical trials sponsored by both industry and government. Coauthored with Drs. Michael Proschan and Gordon Lan, her recently (2006) published book, entitled “Monitoring Clinical Trials: A Unified Approach”, deals with methods for interim analysis of data.

Visit this UAB web site for up-to-date details:
<http://www.soph.uab.edu/ssg/default.aspx?id=1818>

Notes from the Editor

If you would like to join the Society for Clinical Trials or attend the 2007

meeting in Montreal, Quebec, check the SCT web site at www.sctweb.org or contact Mary Burke by 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 Quantitative Health Sciences at the Cleveland Clinic via email: gassmaj@ccf.org

