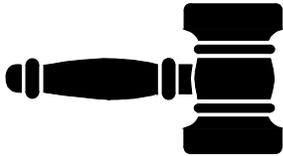

SCT Newsletter

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SCT President's Corner

by Janet Wittes

As I write this message today, September 18, I cannot predict how it will sound in October as you the members of SCT read it. I hope and trust that by then wise heads will have brought the world closer to peace, that those who stand against terror will be unambiguous in their condemnation of these dastardly acts and vigorous in their efforts at preventing future terror throughout the world.

September 11, 2001 has altered all our lives here. The big changes are obvious to everyone, but even the little changes run deep. Every morning, I walk to work along Connecticut Avenue in Washington DC. The stores have newly draped American flags over their awnings. Our local gay bookstore, whose window on September 10 displayed neatly arranged books with Beanie Baby teddy bears sitting jauntily among them, has tossed the books haphazardly in the window and knocked the bears onto their backs and tummies. We pedestrians peer into the window torn by the symbols of lost innocence.

Perhaps the most startling change has been our modified perceptions. Urbanites normally barely register sirens in the streets and planes in the sky; we perceive the sounds as mere white noise. Now, every shriek of a siren stops pedestrians in our tracks. We find ourselves hoping that the cause is only a "small" emergency. We hear each airplane and crane our necks to determine whether it is a commercial flight, the vice-president's helicopter which we often see, a fighter plane, or something even more ominous.

And this is DC where the devastation occurred to only one part of one building. We weep for New York.

To our friends from abroad, thank you for your kind words. We know that you are with us, and that in the years to come we will all work together to root out the evil that has spread out silently among us.

In spite of the chasm that has rent our lives into a "before" and an "after", we must all proceed with our work. Otherwise, as so many have pointed out, the terrorists will have won. And so, I shall review last year's activities of the Society for Clinical Trials (SCT) and give you a foretaste of our future plans.

We all have appreciated how strong and effective a president George Williams has been last year. He worked productively with each committee and with the SCT as a whole to keep us focused on our central mission, that is, to discuss "conceptual, ethical, procedural and scientific issues involved in the design, organization and analysis of clinical trials". Thank you George for your efforts for the Society in the past. I know you will continue to play a valuable role in the future. Thanks also to the members of the Board of Directors, especially those who have completed their term: Brent Blumenstein, Kay Dickerson, and Jennifer Gassman. Again, we know that you will continue to serve the Society over the coming years.

Chris Donhauser, our Treasurer, and Joel Verter, our Secretary, continued to provide invaluable leadership to the Society. I am delighted that they have agreed to serve another term. Congratulations to John Lachin, our President-Elect and to our newly elected Board members, Anne Lindblad, Peter Peduzzi, and Jay Siegel.

A special thanks to Mary Karpers-Burke for her unstinting efforts on SCT's behalf. We are grateful to Moscoe Johnson for his cheery support. Moscoe has left SCT for a new position at MMRI; we all wish him success in his new job.

Our annual meeting was a resounding success. Rick Mowery, the Chair of the Program Committee, and Bob Byington, the Chair of the Education Committee, along with their respective committees, constructed a program that addressed topics of current interest in novel ways.

They worked together to integrate the program with the short courses so that attendees could learn the basic **President's Column (continued)** principles relevant to specific topics during the short courses and then engage intellectually in the discussions and presentations of the program itself.

The current Program Committee, chaired by Anne Lindblad, is busy planning our 2002 meeting. Bob Byington has graciously agreed to chair the Education Committee again. Once more, the two committees are working closely together to forge a varied but unified set of sessions and courses. Because of the current interest within the clinical trials community of problems related

to expanding access to populations traditionally underserved by clinical trials, several of the sessions will deal with aspects of this topic. Dr. Steven Hyman, the Director of the National Institute of Mental Health, will present the Curtis Meinert Honorary Keynote Address. So, hold the dates. The Society will meet on May 12-15, 2002, in Arlington, Virginia.

Under the enthusiastic leadership of Mary Foulkes, Program Chair for SCT for our joint meeting with the International Society for Clinical Biostatistics (ISCB), we have already made excellent progress in planning that meeting. Please reserve July 20-24, 2003, in London.

Last year, the various committees accomplished several goals. The Membership Committee, chaired by Susan Margitic, worked diligently to propose a new membership form and to think of new ways to expand our membership. Thank you Susan, for your many contributions over the years. Our new membership chair, Heidi Krause-Steinruff, will continue in Susan's footsteps.



The Website Working Group, led by Herman Mitchell, continues to upgrade and develop our website (www.sctweb.org). Please visit it to find up-to-date information on SCT and its activities. The website is very well designed and easy to

navigate. Many thanks to Herman and the rest of his team for their past service and for their willingness to continue.

Michael Terrin, who has ably chaired the Finance Committee over the past several years, has agreed to serve another two-year term. The committee is responsible for establishing financial policy for the society. Thanks to Mike and his committee (which includes Chris, our Treasurer), we are on sound financial footing.

The Development Committee is undergoing a change in orientation. Under the able and enthusiastic leadership of Frank Rockhold, the committee has forged a path toward finding financial "angels" for SCT. The task is daunting because many other societies and non-profit organizations appeal to the same set of donors. Our new chair, Frances LoPresti, aims to work with Frank and the Executive Committee to formulate an approach to expanding our list of supporters while reducing the burden of fundraising on the members of the Development Committee.

The Nominating Committee, chaired by Joerg Hasford, is already at work thinking about the nominees for President and Board of Directors for 2003.

Dennis Dixon and Steven Goodman, who have chaired the Publication and Scholarship Committees, respectively, for the last several years, have generously agreed to serve for another term. Both have been effective leaders of their committees and I am grateful

that they are willing to continue.

The Policy Committee, currently chaired by Barbara Hawkins, deals with the internal policies of the society. The committee, composed of past presidents of the society, springs to life if issues arise.

Thanks are also due to Jim Neaton for his leadership as editor of *Controlled Clinical Trials*, our official journal. The papers the journal publishes continue to engage the readership. Members of SCT should submit papers to the journal. It reaches many professionals involved in clinical trials.

All of us at SCT are grateful to Jennifer Gassman for preparing the *SCT Newsletter*. Jennifer has been producing these newsletters for over a decade! Many thanks.

We do have some unfinished business. We have procedures in place to deal with internal policies; however, as a society, we have been struggling with how to deal with events outside ourselves. The issue came to the fore in 2000 with the revised Helsinki Declaration. Many of us in SCT emphatically disagreed with several aspects of the revised statements, especially those pertaining to control groups. Last year's Policy Committee, chaired by Frank Rockhold, prepared a strong draft statement from the SCT pointing out the serious deficiencies in the new Declaration.

Unfortunately, we as a society have no mechanism to speak to the outside world so that the statement had no forum. I believe SCT needs the ability to take public positions on topics of professional interest to us. I hope that we will be able to develop procedures to allow us a such a public voice.

Finally, SCT's strength resides in you, the members. The more we are active as individuals, the more the Society will grow in importance to ourselves and to others. If you have ideas to strengthen the society or if you want to participate more actively in its committees, please contact me (janet@statcollab.com) or Mary Karpers-Burke (sctbalt@aol.com). I look forward to a peaceful and productive year.

News from the Program Committee

by *Anne Lindblad*

The 2002 Program Committee is working hard to prepare for the meeting in Arlington Virginia in May. It is an exciting challenge to create a program that will appeal to the diverse membership of the Society for Clinical Trials. We would like to thank the many SCT members who have contributed their thoughts and ideas to us. We found we had more topics than time slots to present. I have forwarded those topics we will be unable to address this year to next year's Program Chair, Mary Foulkes.

By a unanimous decision, Program Committee members voted to maintain last year's format and schedule of sessions. During the plenary sessions and the workshops, we hope to cover a variety of topics that will be both educational and thought provoking. Topics under development include multinational clinical trial

experience, ethical considerations, trials conducted in special populations, insurance and regulatory issues, and considerations in the use of information technology.

We are looking forward to a banner year in abstract submissions. The due date is December 3, 2001. We will be especially interested in abstracts that offer insights into how a topic to be presented represents an improvement over other methods or offers a unique approach. Topics on innovative uses of information technology are always of interest. We encourage audience participation and sharing of personal experiences related to presented topics during discussion periods and the Poster presentations. We hope discussions will continue through lunch and beyond. This is our opportunity to learn from each other, so please plan to come to the meeting and participate. If you need to contact me I can be reached at alindblad@emmes.com. Hope to see you in Arlington
SCTWEB:

Society for Clinical Trials Web Site

by Herman Mitchell

Use of the Society web site www.sctweb.org continues to increase and we are pleased to report on some of the new features that have been added and on some that are planned for the near future.

On-line abstract submission

The SCT 2000 meeting in Denver was the second year for which we accepted abstracts on-line.

We are pleased to report that approximately 96% of the meeting abstracts were submitted via the web for the Denver meeting. Our on-line submission process had two weaknesses that we have attempted to address this year, namely, tables in abstracts were losing their format structure when received by the SCT office, and we could not accept math and equation symbols. We have added the ability to attach a Microsoft Word file to the on-line abstract submission form. This will allow you to include tables and equations in your abstracts and have them read correctly by our Society administrative office. In fact, it greatly improves the efficiency of the preparation of the program and journal if you send your abstract via MS Word attachment, so we strongly encourage everyone to use this method if possible. We will, of course, continue to accept full abstract entry on-line, or faxed and mailed forms.

On-line Job Board

We continue to make improvements to our Society on-line job board, many of which are behind the scenes administrative features. The Society's job board is one of the real bargains on the web. We provide access to a highly focused pool of biostatisticians, epidemiologists, data managers, CRAs, systems and related technical experts in clinical trials, and all for only \$50 for a 90-day posting. Most of the process is automated and you can enter all your information regarding the posting on-line. You must, however, contact Mary Burke (410-433-4722) to make payment and activate the posting. We are currently working a means to make the entire process automated (see below).

Current and Future Developments

We are actively working on accepting payment for Society activities (meetings, membership, job postings, etc.) on-line. We will keep you posted and announce this feature. Also, we hope to permit members to update their membership and contact information on-line. We only allow access to Society members' email and telephone information on-line, and this requires that the member affirmatively acknowledge that this information can be made available. The member search feature is one of the most frequently used components of the web site.

Pre-Conference Workshop Plans

The SCT Education Committee, chaired by Bob Byington, has begun work on planning the Pre-Conference Workshops for 2002. Possible topics include medical devices, regulatory issues, and microarray analyses. It is anticipated that there will more participation than usual from federal employees, including FDA employees, since the meeting is being held in the Washington, D.C., area. If you have any suggestions for the Education Committee, contact Bob Byington by email to bbyingto@wfubmc.edu

Nominating Committee News

The SCT Nominating Committee consists of the chairman Joerg Hasford, 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 will nominate two Society members for President-Elect and six Society members for Board of Directors.

If you would like to make suggestions to the Nominating Committee, please contact Nominating Committee chair Joerg Hasford by email at has@ibe.med.uni-muenchen.de or by telephone at 49-899-2095x7481.

Development Committee

by Fran LoPresti

The Development Committee is charged with developing funding sources to support SCT activities. These include support for the Student Scholarship program, the SCT Travel fund, SCT web site development, SCT infrastructure projects, and defraying costs for SCT meeting receptions. This year, Board members will play a more pronounced role in nominating and contacting potential donors. Committee members include Brent Blumenstein, Tom Capizzi, Kathryn Durham, and Brian Wiens. If you have any suggestions for potential donors or would like to participate on the committee, please send e-mail to Fran LoPresti:

FFLoPresti@Magellanhealth.com

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:

www.sctweb.org



Thanks to our Donors

On behalf of the entire Society for Clinical Trials, we extend our sincere gratitude to the EMMES Corporation, the Department of Biostatistics and Epidemiology at the Johns Hopkins University, and the Biostatistics Center at George Washington University for their generous support of the Society last year.

Notes from the Editor

If you would like to join the Society for Clinical Trials or receive information about the SCT 2002 Meeting in Arlington, 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 in the Department of Biostatistics and Epidemiology at the Cleveland Clinic Foundation via email:

jgassman@bio.ri.ccf.org