



SCT

SOCIETY FOR CLINICAL TRIALS

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Newsletter

SCT President's Corner



by Kay Dickersin, SCT President

The times they are a changin'...

In 2009, we will celebrate the 30th meeting of the Society for Clinical Trials in Atlanta, Georgia May 3-6. Looking through old issues of the Society's Journal (*Controlled Clinical Trials*, now simply *Clinical Trials*), I can see how much has changed in three decades, yet it is interesting to see how much is the same.

While our methods of data collection may have moved from paper to the web, ensuring data integrity is still as important today as it was 30 years ago. Where the ethics of randomization was once hotly debated, we have moved on to arguments of how to ensure that patients are randomized in an ethical context, that is, ensuring that all trials undertaken will contribute to knowledge and that the contributions of randomized patients are made meaningful by dissemination of a study's findings.

What about changes in the Society? Thirty years is about one generation, and we are seeing changes in leadership and outlook that reflect new blood and new ideas. For the Society and its journal to remain vibrant and a source of fresh ideas and solutions, we must continue to identify and attract the best and the brightest. We were ahead of our time in aiming for a diverse membership comprising epidemiologists, statisticians, data coordinators and managers, and clinicians, representing academia, industry, government, private organizations, and others, from many countries. These kinds of interdisciplinary alliances are what the National Institutes of Health's new Clinical and Translational Science Awards (CTSAs) are intended to foster, yet we have been doing it all along. Our membership must work hard to make sure that the forum we have built and our annual meeting are attractive to emerging efforts such as this, and that we have an international reach.

Changes in the outside world have had an impact on SCT and membership. These changes include increased engagement of the clinical research community in trials; increased industry funding of trials; the moving of a major proportion of trial coordination from academic centers to contract research organizations; the globalization of trials and increasing numbers being done in "emerging regions" such as Eastern Europe, Asia, and Latin America; the large number of overlapping and professional societies and conferences competing for our time; the presence of several journals devoted to trials; and the changing fabric of how clinical research is funded by national governments.

Other changes have led to increased public interest in trials. Selective publication of trial results, access to and coverage of off label therapies, the current processes for determining the long term safety of interventions, and the potential for conflicts of interest in research, are all topics we see daily in the news. Individual members of the Society are involved in responding to these issues, but where is the Society as an organization? We have the mechanisms in place to debate these issues publicly, through *Clinical Trials*, and to comment more formally through our Policy Committee, but we have only rarely used these outlets. The Board is working to give the Society a more prominent public face, one that that elected officials, the public, and the media will increasingly turn to when issues about clinical trials enter the public discourse. We have the expertise, let's make it count!

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Rest assured that the Society is not sitting still in the face of changes in the internal and external landscape. Last year, the SCT Board of Directors approved a Strategic Plan and is working expeditiously to get us to where we want to be. As part of that Plan we will be:

1. Embarking on an aggressive membership campaign;
2. Increasing the use of modern information technology, including launch of a new website;
3. Laying the foundation for the Society to take a more active public role in policy debates relating to trials;
4. Increasing educational opportunities; and
5. Examining our mission and operations to ensure our stability, growth and impact.

Also important is the SCT's current transition from a dedicated Baltimore-based secretariat, coordinated by Mary

Burke, to Fernley and Fernley, an association management company.

Perhaps it is because of my new vantage point, but I have never seen a Board or set of Committees working harder to meet our goals than the groups currently in action. All who are serving the Society deserve a huge thanks.

We are at an exciting juncture in the SCT's history, and I have no doubt we will emerge from this transition a stronger and an even more compelling organization. It is incumbent on each of us to help to build enthusiasm amongst our colleagues about membership in our Society, contributions to the Journal, and participation in the Society's leadership and annual meeting. If you have ideas or offers to make about specific projects, please be in touch.

With best wishes for the coming year. See you in Atlanta!
Kay Dickersin

SCT Transition Committee Update

Eleanor McFadden, SCT Transition Committee Chair

The Transition Committee continues to work with Kay Dickersin, Mary Burke and Elizabeth Franks (Fernley & Fernley) in transitioning the administrative office of the Society from Baltimore to Philadelphia. The committee met in St Louis and approved an outline plan which will see all activities moved to Philadelphia by the time of the SCT meeting in Atlanta in May, 2009.

Target dates for some key activities are:

- New web site – October 2008
- Web site enhancements to allow submission and review of abstracts – December 2008
- New Membership database – October 2008
- Transfer of all old membership records to the new database – late 2008

- Transfer of responsibility for the financial aspects of SCT – December 2008
- Transfer and Archiving of SCT files – May, 2009

Throughout this year, Fernley & Fernley will work closely with Mary Burke on all the SCT activities so that they have a full understanding of what is involved in running the Society and preparing for an SCT annual meeting.

Fernley & Fernley is already involved with the production of the newsletter, post-meeting surveys, selecting sites for future SCT meetings and detailed planning for the Atlanta meeting in 2009.

This transition requires a substantial commitment from many people, and I would like to thank the members of the committee, SCT members who are involved in transition activities and especially the staff in the Fernley & Fernley and current SCT offices. Thanks to their efforts, by the time of the next newsletter, the transition should be almost complete.

SCT Upcoming Dates to Remember:

October – Dues invoices will be mailed.

November – Ballots for 2009 elections will be mailed

December 1 – SCT Student Scholarship submission deadline

December 1 – SCT Conference abstract submission deadline

January 15 – SCT Fellows Nomination deadline

January 31 – Trial of the Year submission deadline

May 3 – 6 – SCT Annual Conference, Atlanta, GA

Education Committee Update

By Domenic Reda and Christopher Coffey, SCT Education Committee Chairs

The SCT Education Committee for 2008-2009 is being chaired by Domenic Reda and co-chaired by Chris Coffey. Last year we expanded the size of the committee and increased the number and diversity of workshops offered. Your response was quite positive as evidenced by the increase in workshop registration and the positive feedback we received. The Committee is already hard at work planning pre-conference workshops and short courses for the 2009 meeting in Atlanta. We are eager to hear from you regarding any suggestions you have for workshops, especially if you or someone you know is interested in presenting a workshop. Broad topic areas may include general workshops that appeal to the diverse membership as well as those targeted to specific interest groups in the Society, such as clinical investigators, site coordinators, trial monitors, information technology specialists, biostatisticians and clinical

trialists. Four and eight-hour workshops will be considered. If you have a suggestion for a workshop, please contact Domenic Reda at Domenic.Red@va.gov or Christopher Coffey at CCoffey@uab.edu.

Committee members for this year include:

Domenic Reda	Liz Murphy
Christopher Coffey	Kristine Nelson
Denise Bonds	Wendy Parulekar
Li Chen	Yves Rosenberg
Marta Gilson	Roberta Scherer
Susan Halabi	Elsayed Soliman
Keri Hammel	Cindy Stowe
John Lum	Julie Weston
Tom Moritz	Carole White

Publications Committee Update

By Colin Begg, SCT Publications Committee Chair

A one-day meeting was held in New York on June 4th, sponsored by the Publications Committee, to take stock of our Society journal, *Clinical Trials*, and to brainstorm initiatives for the future of the journal. It was attended by Colin Begg, Kay Dickersin, Susan Ellenberg, Steve Goodman, Barry Kramer (Editor JNCI), Alfredo Morabia (Editor, Preventive Oncology), Jim Neaton, Wendy Parulekar, Roberta Scherer and Janet Wittes (Dave Sackett and Rick Chappell participated in absentia).

The consensus is that the journal is in good shape, and ably led by Steve Goodman, who has agreed to another 5-year term as Editor. It just received its first impact factor of 1.9, putting it firmly in the middle of pack (39 of 81) of the journal category "Medicine, Research & Experimental," excellent placement for a four year old journal. However, there were many ideas to streamline the editorial process and to solicit topics for publication that would raise the profile of the journal and be of interest to the Membership. This year a fair number of Associate Editors will be rotating off the board, and emphasis will be put on finding replacements that can help improve the turn around time for reviewing submitted articles. There was also a consensus that the journal should focus on publishing only the highest quality submissions, even if this was at the expense of shorter issues.

We also agreed on a general goal to stimulate more opinion articles or editorials on topics of considerable contemporary interest or controversy. If you have ideas for controversial issues relevant to clinical trials that might be suitable, you are encouraged to drop a note to Steve (sgoodman@jhmi.edu) with a brief suggestion of the topic, and the rationale for expressing an opinion or stimulating a debate. Please do not submit completed editorials. The goal is to have Steve and his team review the idea before much work is committed to the project. Another initiative will be for the journal to pay more attention to prominent contemporary clinical trials, both for the journal and as part of the Trial of the Year nomination process. This could involve journal articles that would "tell the story" of a trial, especially if the trial was controversial, or if its execution met unusual obstacles. We may also provide commentaries on very prominent completed trials, perhaps with the participation of the trial PI. In order to succeed in these initiatives, we need notification from our members of suitably prominent trials. If you would like to participate in this initiative as part of a "watchdog group", please contact Colin Begg at beggc@mshcc.org.

SCT Student Scholarship Committee Update

By Sylvan Green, SCT Student Scholarship Committee Chair

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 SCT Student Scholarship 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 inter-

est 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 Atlanta. 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, 2008.** For details, see www.sctweb.org (in the section on the Annual Meeting).

Congratulations to the 2008 Student Scholarship Award Winners

(presented at the SCT 2008 Conference held in St. Louis in May):

Peng Zhang, Harvard University School of Public Health, "Analyzing Time to a Composite Endpoint with a Silent Component Whose Occurrence is Monitored Periodically with Error while Adjusting for Informative Dropouts".

Yiyi Chen, University of Iowa College of Public Health, "Optimal Adaptive Group Sequential Design for Phase II Clinical Trials: A Bayesian Decision Theoretic Approach".

Lisa Hampson, University of Bath, "Group Sequential Tests when the Primary Endpoint is a Delayed Response".

The overall winner of the Thomas Chalmers Scholarship Award was Lisa Hampson.

Are you getting all of your Society for Clinical Trials messages?

With today's spam filters, your email system may be blocking emails from SCT. To ensure that you receive the SCT Newsletter and other SCT communications, you should add or ask your IT person to add the following email address and domain name to your safe sender list or whitelist: sctbalt@aol.com and @fernley.com.

To do this in Outlook, click on the Tools menu, slide down to Options, and click.

Click on the Junk E-mail button. Click on the Safe Senders tab.

Click on the Add button. Type in the e-mail address or domain (e.g. sctbalt@aol.com or @fernley.com), and click on OK. Click OK, then Click OK again.

Also, if your email address has changed since you last renewed your membership, the SCT office may not have your current email address. You can email your address corrections to Mary Burke at sctbalt@aol.com. If you are unsure what email address is on file with SCT, you can check this by doing a member search on the SCT website www.sctweb.org.



Fellows Committee Update

Committee Seeking Nominations for the Honorary Title "Fellow of the SCT"

By Barry R. Davis, SCT 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 2008 Fellows class (inducted in May in St. Louis) were Jean-Pierre Boissel, Marc Buyse, Paul L. Canner, J. Richard Crout, Marian R. Fisher, Joerg Hasford, William G. Henderson, Frances F. LoPresti, Ruth McBride, Frank W. Rockhold, Joel I. Verter, O. Dale Williams, and Salim Yusuf. A complete list of all the Fellows can be found at www.sctweb.org/fellows.cfm. We are now seeking nominations for the Class of 2009.

Candidates for this honor must have been an SCT member for at least five of the last 10 years or for a total of at least 10 years. Each nominee will be evaluated by the Committee on the basis of contributions to the advancement of clinical trials in one or more of the following areas:

- Methodologic development
- Coordination, conduct, or leadership of individual clinical trials
- Education
- Ethics
- Promotion of a better understanding by the general public or the importance of randomized clinical trials

- Service to the Society

The 2009 Committee on Fellows is currently being established and will be announced in the next newsletter. Any member of the Society may nominate a candidate. To do so, please assemble the following materials:

- Candidate's current curriculum vitae
- Three or more letters of support of the nomination from individuals qualified to describe the candidate's contributions to the Society. At least two of the letters should be from individuals at an institution, agency, or organization other than the candidate's.

Nomination packages may be submitted by email, fax, courier, or post to:

Barry R. Davis, MD, PhD
SCT Committee on Fellows
Coordinating Center for Clinical Trials
University of Texas School of Public Health
1200 Herman Pressler St. E-809
Houston, TX 77030-3900 USA
1-713-500-9530 (fax)
barry.r.davis@uth.tmc.edu

All nominations should be received no later than January 15, 2009, for candidates to be considered for induction in 2009. Please send an email message of the nominee's name before preparing the package (to prevent dual work) and whenever materials are being sent via courier, fax or post.

Clinical Trial of the Year

The Society for Clinical Trials welcomes nominations for the SCT/ImpACT Clinical Trial of the Year

By Steve Goodman and Dave Sackett

The award will be presented (during our 2009 annual meeting) to an outstanding trial presented/published in 2008.

Nominations are now open for any trial from any country that fulfills some or all of the following standards:

- It improves the lot of mankind.
- It provides the basis for a substantial, beneficial change in health care.

- It reflects expertise in subject matter, excellence in methodology, and concern for study participants.
- It overcomes obstacles in implementation.
- The presentation of its design, execution, and results is a model of clarity and intellectual soundness.

Deadline for submissions is January 31, 2009. Please go to the Society's web site and complete a nomination form, or (if that site is still under construction) send your nomination, literature citation, trial summary, and message of support to the selection committee c/o Dave Sackett: sackett@bmts.com

Development Committee Update

By KyungMann Kim, SCT Development Committee Chair

The purpose of the Society for Clinical Trials' Development Committee is to raise funds, consistent with the professional integrity of the Society, to support educational and program goals at its annual meetings.

This year the Committee's membership included KyungMann Kim (Chair) from the University of Wisconsin-Madison, Gordon Lan from Johnson & Johnson Pharmaceutical Research & Development, Debrorah Shapiro from Merck, and Jay Siegel from Centocor Research & Development.

I am very pleased to report that the Committee set a new fund-raising record of \$40,500, surpassing the record set in 2007. The donations were from 17 corporations, both for-profit and not-for-profit, in the amount ranging from \$500 to \$7,000. They are Amgen, Centocor R&D, Cytel, Duke University, the EMMES Corporation, Ethicon Endo-Surgery*,

Frontier Science & Technology Research Foundation, GlaxoSmithKline, Johnson & Johnson Pharmaceutical R&D, Jaeb Center for Health Research, KAI Research, Maryland Medical Research Institute, Merck, Pfizer*, PRA International*, sanofi-aventis, and Statistics Collaborative. It is of note that there were three first-time donors this year (indicated with an asterisk).

I would like to take this opportunity to thank the Committee members, Mary Burke from the Society's Office and Sue DiBlassio from Centocor R&D who tirelessly worked to make sure that a donation would be made from Ethicon Endo-Surgery. More importantly the committee expresses sincere gratitude toward the donors on behalf of the Society, whose generosity made the Society's annual meeting in St. Louis in May a success that it was.

If you'd like to join the Development Committee, please contact me at kmkim@biostat.wisc.edu

Save the Date!

SCT 30th Annual Conference

May 3 – 6, 2009

Omni Hotel at CNN Center
Atlanta, GA

Get ready to enjoy southern hospitality at the SCT Annual Conference at the Omni CNN Center!

Atlanta offers something for everyone – an outstanding selection of dining options, world class shopping, rich southern history, Olympic caliber sporting venues, and of course, one of the most famous media outlets in the world in the CNN Center Complex, located adjacent to our host hotel.



Plan for a great trip by learning more about Atlanta at www.atlanta.net.

The SCT Conference hotel – the Omni Hotel at CNN Center – is conveniently located in the heart of downtown Atlanta, offering views of the spectacular downtown skyline or picturesque Centennial Olympic Park. It is also connected to Philips Arena and the Georgia World Congress Center, and it is the nearest hotel to the Georgia Dome. For convenient arrivals or departures, Atlanta Hartsfield International Airport is a mere 15-minute commute (12 miles).



SCT will celebrate 30 years at the 2009 Meeting in Atlanta. Be sure to be there as SCT commemorates its rich history and bright future!



the CNN Center

SCT 31st Annual Conference

May 16 – 19, 2010

Marriott Baltimore
Baltimore, Maryland

Thank you to the SCT Volunteer Leadership!

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Notes from the Editor



If you would like to join the SCT or learn more about participating in upcoming meetings, visit the SCT website at www.sctweb.org or contact Mary Burke at 410/433-4722 or sctbalt@aol.com.

If you have suggestions for this newsletter, contact SCT Newsletter Editor Elizabeth Franks at Fernley & Fernley, Inc. – 215/564-3484 or efranks@fernley.com.