



SCT

SOCIETY FOR CLINICAL TRIALS

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Newsletter

SCT President's Corner



by Kay Dickersin, SCT President

On May 3-6, 2009 the Society for Clinical Trials will host its 30th Annual Meeting in Atlanta, Georgia. Plans are well underway for a celebration, starting first with a special conference program.

My hat is off to Wendy Parulaker and Dominic Reda and their teams for developing an outstanding program and workshop series, respectively. Both committees worked long hours to assure that we

include presenters from all over the world, representing the diverse interests (e.g., trial coordination, data management and IT, epidemiology, statistics), and organizational homes (e.g., academic health centers, government, industry) of the Society. All this on a shoestring budget!

Features of this year's meeting include:

- SCT-Project ImpACT 2008 Trial of the Year Award
- Announcement of the Class of 2009 Fellows
- A new invited session "Current Controversies in Clinical Trials: Perspectives from SCT Fellows"
- The Thomas C. Chalmers Student Scholarship competition, and presentation of the Sylvan B. Green Finalists
- Dr. Tikki Pang, World Health Organization, who will give the Curtis L. Meinert Keynote address
- Dr. Fiona Godlee, Editor in Chief, BMJ, who will present the Founders' Lecture
- Celebration of the 30th anniversary of the SCT Annual Meeting
- 11 workshops
- 3 plenary sessions
- 14 invited sessions
- 19 contributed paper sessions
- 73 poster presentations
- Welcome reception Monday night; lunch provided Monday, May 4 and Tuesday, May 5
- New Members' Breakfast with the SCT Board on Monday, May 4
- A fond farewell to Mary Burke, the Executive Director of the Secretariat, Society for Clinical Trials for 22 years
- Loads of opportunities for networking and getting together with old friends and colleagues

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SCT President's Corner *(continued)*

As many of you know, good attendance at the Annual Meeting is of utmost importance to the Society. It is how we attract new and maintain existing members, and, along with the *Journal*, it is the foundation for the professional education and networking opportunities that we offer. All of us, our membership included, are being pulled in many directions, with numerous conferences we either want to or need to attend. For this reason, we put a good deal of emphasis on producing a stimulating program and educational offerings with both broad and specific audience appeal. We are counting on you to attend!

You, the membership, can help to ensure that the Society's conference is a great success. Please register now (and get the Early Bird rate) and make a point of distributing information about the meeting either via email or by distributing flyers to people in your organization (see <http://www.sctweb.org>). It isn't so hard and can be quite gratifying. I recently sent out an announcement to email contacts and received notes of thanks and interest in the return mail. That felt good!

I look forward to seeing you in Atlanta and to celebrating the Society's past and future!

Message from the 2009 Program Chair

By Wendy Parulekar

On behalf of the Program Committee for the 30th Annual Meeting of the Society for Clinical Trials, I would like to invite you to join us in Atlanta, Georgia during May 3-6, 2009. The planned Program topics are highly informative, thought provoking and relevant to all clinical trialists.

The outstanding Pre-Conference Workshop Program organized by Domenic Reda and the Education Committee will consist of interactive sessions that highlight fundamental concepts and methodologies of various aspects of clinical trial design, conduct, analysis and results dissemination. Importantly, these workshops will also showcase the current challenges and emerging trends in clinical research encountered by trialists from a broad variety of disciplines.

The commitment of the Society for Clinical Trials to engage the international research community is reflected in the choice of speakers for the Curtis Meinert Honorary Keynote Address and Founder's Lecture. We are delighted Dr. Tikki Pang, Director, Research Policy & Cooperation Department, World Health Organization, Geneva, Switzerland and Dr. Fiona Godlee, Editor in Chief of the BMJ, will join us in Atlanta.

The Invited Session Program is built on the proposals submitted by the general membership in an overwhelming response to a call for abstracts. The Program Committee selected 17 topics for presentation of which three were given a plenary designation: Trial of the Year and Project ImpACT, Conflicts Around Conflict of Interest and Public



Reporting of Trial Results on ClinicalTrials.gov. The 14 Invited Sessions are distributed throughout the conference with the goal of providing material of interest for everyone on each meeting day. The diversity of our program is reflected by topics ranging from current controversies in clinical trials, Data Safety Monitoring Board function, risk management based adaptive monitoring, clinical trials in obesity, adaptive designs and interpretation of null results—with many topics in between.

The Contributed Paper and Poster Sessions will feature the research interests and activities of attendees. 62 abstracts were selected for oral presentation, 70+ for poster presentation and three for the Student Scholarship Session. In addition, an entire session will be devoted to a presentation and discussion of the Atlanta Clinical & Translational Science Institute plans to develop multi-center clinical trial capability as part of the NIH Clinical and Translational Science Award (CTSA) mechanism. We urge everyone to take full advantage of the opportunity to meet new people and interact with one another during these sessions.

(Continued on next page)

Registration through the SCT website is now OPEN!

www.sctweb.org

Message from the 2009 Program Chair *(continued)*

On behalf of the Program Committee, I wish to thank Society President Kay Dickersin for her leadership and enthusiasm as well as Mary Burke, who is due to retire from her role as Executive Director of the Society. Mary's work has been instrumental in the organization of the Annual Meetings over the years. Scott Rushing deserves special mention for his computer programming and web expertise as does Elizabeth Franks, our representative at

the Society's Management Company, Fernley and Fernley. Every meeting represents a successful collaborative effort involving many dedicated Society members. We welcome your contribution as an attendee and active participant in the Meeting.

The Program Committee looks forward to seeing you in Atlanta!

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



the CNN Center

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!

Registration now online!

Visit www.sctweb.org by April 10th to receive the Early Bird Registration discount! Secure hotel reservations by April 10th and mention the SCT Annual Meeting to receive the special room rate!



www.sctweb.org

Development Committee Report

By KyungMann Kim

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.

The Development Committee is currently soliciting support for its Annual Meeting programs. Specifically, we are inviting individuals and corporations to become Sponsors of the Society. SCT members and their employers who have been involved in clinical trials know that the health of the Society has direct relevance to your professional activities.

We are seeking financial support in several major areas:

Student Scholarship Fund: Each year, applicants from all over the world submit research papers to us. We invite the students with the three strongest papers to attend our Annual Meeting and to present their papers. We then select the best of the three and grant the winning student the annual Thomas C. Chalmers Student Scholarship Award, which currently includes a \$500 stipend. We pay travel costs for all three students.

Pre-Conference Workshop Fund: Each year, the Society sponsors several pre-conference workshops on topics such as the essentials of clinical trials, adaptive designs, data monitoring considerations, and data standards. This fund supports travel for faculty, supplies, and audiovisual equipment.

Travel Fund: We support the expenses of bringing world-renowned speakers to speak at plenary sessions at our Annual Meeting.

Technology Fund: This fund supports the information technology needs of our Annual Meeting, including audio/visual equipment and LCD projectors for scientific presentation.

SCT General Fund: This fund provides sustainable support for general operational activities of the Society.

We are also asking for Sponsors for our reception and coffee breaks, which are major expenses at our Annual Meeting.

We have developed the following guideline for sponsorship, but it is only a guideline:

Sponsorship Level	Minimum Contribution	Acknowledgement
Platinum	\$10,000 USD\$	Prominent acknowledgement at the meeting Four complimentary memberships Four registrations for the Annual Meeting
Gold	\$5,000 USD\$	Prominent acknowledgement at the meeting Two complimentary memberships Two registrations for the Annual Meeting
Silver	\$2,000 USD\$	Prominent acknowledgement at the meeting One complimentary membership One complimentary registration for the Annual Meeting
Bronze	\$1,000 USD\$	Prominent acknowledgement at the meeting

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

Please contact KyungMann Kim at kmkim@biostat.wisc.edu or (608) 265-6380 for further information.

Education Committee Update

By Christopher S. Coffey and Domenic J. Reda

The SCT Education Committee is completing a very productive year. The Atlanta meeting will offer 11 pre-conference workshops that have been selected to appeal to the diverse backgrounds of SCT members. The ever popular full day workshop on Fundamentals of Clinical Trials is designed to provide a comprehensive overview of clinical trials design, conduct, and analysis methods. Importantly, this course will be co-sponsored this year by the Atlanta Clinical and Translational Science Institute. This is a first attempt by the society to involve local institutions in the advertisement of this workshop. In addition, there will be ten half day workshops. Those interested in statistical methodology can choose from workshops on group randomized trials, comparison of survival distributions, adaptive clinical trials, and hot topics in clinical trials (which will cover statistical aspects associated with non-inferiority trials, subgroup analyses, benefit:risk analyses, and using prediction to make informed decisions during an interim analysis). The workshop on implementing systems for electronic data capture may be of particular interest to

information technology specialists. Workshops that may appeal to a broad spectrum of meeting attendees include those on trial and site management, dissemination of trial results, non-classical trial designs, harmonization of the clinical research ethics submission and review process, and surrogate outcomes. The all-star workshop faculty includes such noted experts as David Murray, Gordon Lan, Sara Pressel, Scott Evans, Barry Davis, L. Kay Bartholomew, Lawrence Friedman, Ralph D'Agostino, Janet Wisely, and Greg Campbell.

Committee chairmen Domenic Reda and Chris Coffey extend a sincere thank you to committee members Denise Bonds, Li Chen, Marta Gilson, Susan Halabi, Keri Hammel, John Lum, Tom Moritz, Elizabeth Murphy, Kristine Nelson, Wendy Parulekar, Yves Rosenberg, Roberta Scherer, Elsayed Soliman, Cindy Stowe, Julie Weston, and Carole White. If you are interested in becoming a member of the committee for the 2010 meeting, or have suggestions for future workshops, please leave Domenic Reda or Chris Coffey a note at the 2009 meeting or send an email to Domenic.Red@va.gov or ccoffey@uab.edu.

Nominating Committee Update

By Stan Shapiro

The 2008-2009 Nominating Committee was comprised of Judith Abrams, Colin Begg, Kay Dickersin, Dennis Dixon, Yves Rosenberg, and Stan Shapiro. In addition to a lot of hard work, it has been a privilege for us to help serve the SCT in this manner.

Congratulations to the newly elected Board members:

Bob Byington, President Elect
Nicole Close, Director
Heidi Kraus-Steinrauf, Director
Gerald Beck, Director

All of the candidates who stood for election for the Board deserve a special vote of thanks.

It is through the dedication and hard work of the members of the Society that we will continue to flourish as a strong professional society. Not too long after that the work of next year's Nominating Committee will start. On behalf of that group I would urge you to think about individuals (including yourself) whom you would like to see assume leadership positions in the Society and to submit names of potential candidates to the 2009/2010 Nominating Chair, who will be announced after the 2009 Annual Meeting.

Fellows Committee Update

By Barry R. Davis

Thank you for submitting nominations for the 2009 SCT Fellows. The SCT Committee on Fellows has completed the evaluation process and named 10 new SCT Fellows. They will be announced at the Annual Meeting in Atlanta, May 3-6.

Members of the 2008- 2009 SCT Committee on Fellows:

Barry Davis, Chair	William Henderson
Marc Buyse	Ellie Schron
Marian Fisher	Joel Verter
Larry Friedman	Dale Williams
Joerg Hasford	George Williams
Barbara Hawkins	

SCT Scholarship Committee Update

By Marie Diener-West

The world lost a clinical trials giant when Dr. Sylvan B. Green passed away on December 13, 2008 after a brave fight with pancreatic cancer. Since 2002, Dr. Green was Professor of Epidemiology and Biostatistics at the College of Public Health at the University of Arizona and the inaugural Linda McCartney Breast Cancer Chair in Biometry at the University of Arizona, Arizona Cancer Center. Before that he had a 24-year career in the Biometry Branch of the National Cancer Institute followed by 5 years as a Professor at the Case Western Reserve University School of Medicine.

Dr. Green was widely recognized as an international expert in the area of clinical trials and clinical trials methodology. He freely and generously benefited the broader scientific community by his outstanding dedication and service to the clinical trials profession and service on countless data and safety monitoring committees, advisory boards and review committees. And, he educated hundreds, if not thousands, of physicians and researchers through seminars, workshops, and short courses on clinical research methods and clinical trials. Dr. Green was SCT president in 1994-5 and served on the Board from 1993-1996. He served as Associate Editor of *Controlled Clinical Trials* from 1995-1998, chaired and contributed to numerous sessions at the annual SCT meetings, and served as Chair of the Education Committee from 1994-2001. A longtime member of the Student Scholarship Committee, Dr. Green served as Chair since 2003.

Dr. Green's contributions were varied and extensive in the design and analysis of clinical trials, prevention trials, community-based intervention trials, and epidemiologic studies in both medicine and public health. These include the design of early AIDS trials as well as the Community Intervention Trial for Smoking Cessation (COMMIT). His publications ranged from reports of study findings in specialty journals to contributions on innovative statistical methods for clinical trials. Dr. Green co-edited two versions of the *Textbook of Clinical Trials*. In recognition of his substantive, methodological and educational contributions and their lasting impact on the design and conduct of clinical trials, Dr. Green was elected as a Fellow of the Society in 2007. He epitomized the essence of the Society.

The SCT Student Scholarship Committee reviewed this year's scholarship submissions and three finalists were 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. To honor Dr. Green's longtime commitment to the support of students with promising careers in clinical trials, the three finalists will be named as the **Sylvan B. Green SCT Student Scholarship Finalists** on the Annual Meeting program.

The Committee will review the manuscripts and oral presentations of these finalists at the afternoon Student Scholarship Session on Monday, May 4, 2009 at the Annual Meeting in Atlanta. The winner of the Thomas Chalmers Student Scholarship Award and \$500 cash prize will be announced at the Business Meeting on May 5.

Committee members for this year include:

Chair: Sylvan Green (in memoriam)

Members:

Andrei Adin-Cristian	KyungMann Kim
Marie Diener-West	Eleanor Schron
Mary Foulkes	Janet Wittes
Michael Hughes	



Sylvan B. Green, M.D.

1946 – 2008

SCT Upcoming Events:

April 27, 2009

All-Day Symposium in Honor of Dr. Edmund Gehan

Georgetown University, New Research Building Auditorium, 3900 Reservoir Road

April 29, 2009

University of Pennsylvania Annual Conference on Statistical Issues in Clinical Trials: From Bench to Bedside to Community

University of Pennsylvania School of Medicine, Biomedical Research Building Auditorium

May 3 – 6, 2009

SCT Annual Meeting

Omni CNN Center, Atlanta, GA



August 23 – 27, 2009

ISCB 2009 – 30th Annual Conference of the International Society for Clinical Biostatistics

University of Economics, Prague, Czech Republic

For more information on these events, like how you can participate, please visit the SCT website:

<http://www.sctweb.org/links.cfm>

Future SCT Conference Dates



Vancouver Steam Clock

May 15 – 19, 2011

Hyatt Regency Vancouver



Baltimore Inner Harbor

May 16 – 19, 2010

Marriott Baltimore Waterfront



Bagg's Lighthouse, Miami

May 20 – 23, 2012

Hyatt Regency Miami

Thank you to the SCT Volunteer Leadership!

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Publications Committee

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Student Scholarship Committee

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Trial of the Year Committee

Dave Sackett

Web Oversight Committee

Mark Espeland, PhD

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.