



# SCT

## SOCIETY FOR CLINICAL TRIALS

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Newsletter

### SCT President's Corner

By Dan Sargent, 2014-2015 President



As the saying goes (at least approximately) – ‘Time flies when you are having fun (and/or working hard).’ This certainly applies to the last year for me in my role as SCT president. As you read this, my term will be nearing an end. A few years back, when I chaired a committee to refresh the SCT Constitution and Bylaws, we had a large debate about the optimal term

for the president. Many board members (none of whom had been president) felt that a 2 year term would be preferable to the current 1 year term. However, several past presidents (wisely, in retrospect) felt that the one year term was best, citing primarily the need to constantly infuse an organization with new energy and ideas. We thus stuck with the one year term, and I think this was the right thing for the SCT.

Having said that, leadership continuity is critical to any organization, and the SCT is in very good standing in this regard, with Professor KyungMann Kim ready to assume the role of SCT president at the upcoming SCT Annual Meeting. I am also very pleased to announce that Wendy Parulekar has been selected by the membership as President-elect, to serve as president for the 2015/2016 term of office. Incoming board members for the new year, elected by the SCT membership, are Scott Evans, Michele Melia and Paul A. Thompson. Please see the next page for full details on these new officers, who we thank in advance for their service.

The last year has indeed been a busy one. We kicked off the year with the refreshing of the SCT strategic plan, which you can find on our website ([www.scteb.org/docs/2013-2016\\_SCT\\_Strategic\\_Plan.pdf](http://www.scteb.org/docs/2013-2016_SCT_Strategic_Plan.pdf)). Most of our activity this year has focused on the strategic plan initiatives. A key initiative, which has already been launched, is the introduction of SCT Webinars. These webinars are intended to provide an introduction to key subjects of interest to the SCT membership, and are available free to SCT members. For additional details see the list of upcoming presentations on page 7. Other key completed actions include acquiring a mobile app for the upcoming SCT meeting, adding a student as a non-voting

member to the SCT board, and formalizing an official SCT policy for the review and potential endorsement of position, policy, or comment statements.

Our focus now turns to the SCT 35<sup>th</sup> Annual Meeting. Much additional detail can be found later in the newsletter, but I am so excited about the very strong program organized by our program committee, with Chair Chris Coffey and Co-Chair Domenic Reda. Equally strong are the pre-conference workshops, with a huge thanks to the Education Committee, in particular Chair Stan Shapiro and Co-Chair Paul Wakim. In another new effort to ensure leadership and SCT continuity, this year we have initiated a process where each of the Education and Program Committees will have a Co-Chair, who will step into the chair role the following year. So, thanks to Chris and Stan for great service, and to Domenic and Paul for agreeing to step into the committee chair positions next year. This also means we will need new Co-Chairs for the Education and Program committees – please let myself, KyungMann, Domenic or Paul know if you are interested.

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## SCT President's Corner *(continued)*

I also want to highlight our two external plenary session speakers. Dr. Ezekiel J. Emanuel, a widely published and cited scholar and ethicist, will present on the topic '**Health Care Reform and the Impact on Clinical Research**'. Dr. Emanuel was chief of the Department of Bioethics at the NIH Clinical Center, and acted as a special advisor to the Obama Administration of Health policy. Our closing plenary session on Wednesday will feature Dr. Christopher Austin, Director of the National Center for Advancing Translational Science (NCATS), the NIH program that funds the Clinical and Translational Science Awards. Dr. Austin will be speaking on '**The National Center for Advancing Translational Sciences: Catalyzing Translational Innovation**'. Both talks should be of great interest to our membership.

Finally, I must thank all of the other committee chairs, board, members, and executive committee members – it truly takes a huge team of unpaid volunteers to move the society forward. Special thanks go to Joe Collins and Ted Karrison for continued strong work as SCT Treasurer and Secretary, respectively, and the committee chairs including Peter Peduzzi (Fellows Committee), Ivan Chan (Development Committee), Jim Dignam (Student Scholarship Committee), Wendy McBee (Membership Committee), Simon Day (Nominating Committee), Jim Neaton (Publications Committee), Scott Rushing (Web Oversight Committee), and Larry Friedman (Trial of the Year Committee).

I look forward to seeing you all in Philadelphia – please come, the venue is very nice!

## 2014 Election Results

### *By Simon Day, Nominating Chair*

The Nominating Committee of the Society for Clinical Trials is charged with identifying candidates willing to stand for election to fill positions on the Board of Directors and as President-elect of the Society. Board members serve a four year term; the President-elect serves one year in that role before becoming President.

According to the by-laws of June 2009 (Article II, Section 4), the Nominating Committee includes the current SCT President and President-Elect, two (2) members shall be appointed from the Board of Directors; and three (3) shall be appointed from the membership of the Society at large.

This year the Committee comprised:

Simon Day, Chair  
 Dan Sargent, President  
 KyungMann Kim, President-Elect  
 Sara Pressel (Board of Directors)  
 Gabriele Dreier (Board of Directors)  
 Ivan Chan (Board of Directors)  
 Marc Buyse (Member at large)  
 Eleanor McFadden (Member at large)  
 Rick Chappell (Member at large)  
 Wendy McBee (Member at large)

The Nominating Committee began its work in September 2013 by identifying possible candidates. A call was also sent to all the membership in October 2013, inviting nominations. A list was drawn up and then prioritized by the Committee members. Six candidates for the Board and two for President-Elect were identified. After ensuring that all the members of our short list were willing to stand, we passed the list to Fernley & Fernley in November.

The online election was held after that, with all current SCT members eligible to vote. The following individuals were successful in being elected:

### President-Elect



#### **Wendy Ranjana Parulekar**

Senior Investigator NCIC Clinical Trials Group, Queen's University, Kingston, ON

Wendy Parulekar was inducted as a Fellow of the Society for Clinical Trials in 2011. She cites her goals for SCT as:

- To promote the Society as a forum to discuss and debate critical issues relating to clinical trials and other related healthcare research methodologies – are we designing the most efficient studies to answer important health care questions?
- To engage the Society in a dialogue with key stakeholders regarding the pivotal role of clinical trials in advancing the health of the population;
- To expand the global focus of the Society through engagement of international colleagues;
- To enhance the educational, networking and career building activities of the Society for its current membership.

### Board of Directors



#### **Scott Evans**

Scott Evans is a Senior Research Scientist at Harvard University. He has been involved in hundreds of clinical trials with roles ranging from design, data monitoring, analyses, reporting, evaluation, and education: "The SCT is a unique society that has been

*(Continued on next page)*

## 2014 Election Results (continued)

a great resource for many people through annual meetings, publications, and other activities. A broad goal for the SCT is to identify ways to expand, increase, and demonstrate its' value beyond the dedicated membership, to the broader clinical trials community." Scott's specific goals for SCT include:

- Attracting the next generation of clinical trialists
- Recognizing and participating in the international growth of clinical trials
- Expanding educational efforts by partnering with other societies and professional organizations for joint workshops
- Providing leadership on modern challenges and cutting-edge issues in clinical trials



### Michele Melia

Michele Melia is a Senior Statistician at Jaeb Center for Health Research in Tampa, FL. Michele has served the Society in various capacities as a member of the Program, Education and Strategic Planning committees, among other activities. She also served previously on the Board of Directors from 2005 – 07. Michele lists the following goals for SCT:

- Broad participation of all stakeholders in clinical trials
- Continuing education



### Paul A. Thompson

Paul Thompson, Director, at the Methodology and Data Analysis Center, Sanford Research, Sanford Health, in Sioux Falls, SD. Paul explains his vision for the Society: "The SCT is an organization which brings the disparate actors in clinical trials together. The SCT needs to continue the mission of education of different types of actors in the whole process. The SCT needs to stay at the forefront of the clinical trials process, as trials increasingly use cloud-based data management, direct data entry, different types of trials (including adaptive and modified participation trials), and virtual consent documents. The needs for cost containment for increasingly expensive approaches suggest that current methods are not always enough. In that regard, EMS-based historical data must be a part of the mix, and methods for this are needed. In short, we must stay on top of a continually adapting process, and the SCT needs to be a part of this adapting process."

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This year, only 172 SCT members cast votes, the lowest figure for several years. Please do take the time to vote in future elections – this really is a chance where "everyone gets their say."

## SCT Board Welcomes Student Representation

In conjunction with the SCT 2013 - 2016 Strategic Plan, developed and approved by the Board last year, the Society committed to expanding opportunities for student members to help establish some of the priorities and programs for SCT.

To this end, the SCT Nominations Committee sent out a call for volunteers from the current student membership to contribute to the Board of Directors as a non-voting "guest" at Board meetings. As this new position will not be an official elected Board position, it will not include a "vote" on SCT Board issues. It will, however, provide a voice for the student membership, and ensure that the Board considers a broad set of opinions in all discussion and decisions.

The Nominations Committee is pleased to report that student member Emilia Javorsky has volunteered and been approved as the SCT student representative to the Board of Directors.

Ms. Javorsky is currently pursuing her MD (anticipated 2014) from the University of Massachusetts, where she is involved in the Clinical and Translational Research Pathway (created as part of the institutions CTSA grant).

Prior to medical school, Emilia completed a MPH concentrating in Health Policy & Management with a specific focus on health care management. Throughout medical school she assisted

research at the Clinical Unit for Research Trials in Skin at MGH, and will be doing a research rotation in device development at the Wellman Center for Photomedicine (MGH).

Most recently she spent several months in Europe on a Fulbright-Schuman grant conducting a project on enhancing transatlantic collaboration in clinical trials in the setting of proposed policy changes to the EU CTD and device regulations. In the wake of the innovation crisis and decreased public funding, at present, Emilia's primary interest is in drug and device development within the changing landscape of academia-industry relations.

As Student Guest on the SCT Board, Emilia will be invited to participate in all Board of Directors meetings, and is welcome and encouraged to participate in all Board discussions by asking questions, clarifying issues, voicing opinions and offering suggestions.

The term for this position is one year, commencing at the Board meeting on Sunday May 18, 2014.

SCT is pleased to offer a student member this opportunity to network, learn from SCT volunteer leaders, and provide input on programs that help ensure the Society is meeting the needs of all categories of current and future members.

# SCT Offers Dynamic Workshop Line Up at the SCT 35<sup>th</sup> Annual Meeting

**By Stan Shapiro, Education Chair**

The members of the Education Committee have had an active fall and winter and are excited about the coming spring and the slate of offerings they have prepared for you for Philadelphia. Once again there will be six morning and six afternoon sessions supplemented by a special evening workshop by Bob Temple (FDA) on Enrichment Strategies. The daytime workshops include state of the science sessions on SMART (Sequential Multiple Assignment Randomized) Trials and the use and evaluation of biomarkers and offerings on evolving practices with regard to the monitoring of trials with adaptive designs as well as best practices and innovations in patient and community engagement.

Some of the extremely well received offerings from last year, including a workshop on working together to achieve the best clinical site performance, will be available in Philadelphia, as well as workshops on the use of cloud computing and optimizing trial design via simulation. Please consult the [listing of workshops](#) along with their descriptions and presenting faculty. It is through the voluntary efforts of these colleagues that the Society is able to continue to make offerings available to you at an extremely reasonable cost. We hope you will avail yourselves of the opportunity.

Stan Shapiro, Chair, Paul Wakim Co-chair, Members: Kousick Biswas, Li Chen, Suzanne Firrell, Virginia J Howard, Tassos Kyriakides, Oscar Moreno, Wendy Parulekar, Domenic Reda, Yves Rosenberg, Emily Van Meter

35<sup>th</sup>  
ANNUAL  
MEETING

SCT



SOCIETY FOR CLINICAL TRIALS  
May 18-21, 2014 | Philadelphia, PA

## Sunday, May 18 - Pre-Meeting Workshops

A variety of workshops (12 half day - four hour sessions and one evening two hour session) addressing state-of-the-art methods in the design, conduct, analysis and reporting of clinical trials.

Click [here](#) for descriptions of the Pre-Meeting Workshops. Advance registration and payment required.

### Half Day Workshops - Morning (8:00 AM - 12:00 PM)

- Workshop P1: Essentials of Randomized Clinical Trials
- Workshop P2: Enhancing the Design and Conduct of Phase II Studies
- Workshop P3: Optimizing Trial Design via Simulation
- Workshop P4: Working Together to Achieve the Best Clinical Site Performance
- Workshop P5: Cloud Computing and Software-as-a-Service (SaaS) - Impact on Conducting Multi-Site Clinical Trials
- Workshop P6: Clinical Trials for Adaptive Intervention Designs: Design and Conduct of Sequential Multiple Assignment Randomized Trials

### Half Day Workshops - Afternoon (1:00 PM - 5:00 PM)

- Workshop P7: Best Practices and Innovations in Patient and Community Engagement in Clinical Trials
- Workshop P8: Treatment of Non-Ignorable Missing Data - Concepts and Practice
- Workshop P9: Independent Data Monitoring Committees Recommendations for Trials with an Adaptive Design: What, How, and To Whom?
- Workshop P10: Incorporating New Media Tools in the Design and Conduct of Clinical Trials
- Workshop P11: Strengthening the Links of the Chain - Network Meta-Analysis: Applications and Interpretations
- Workshop P12: Evaluation of the Performance of Diagnostic Tests and Biomarkers Using ROC Analysis

### 2-Hour Workshop - Evening (7:00 PM - 9:00 PM)

- Workshop P13: Enrichment Strategies for Clinical Trials

## “On the Streets of Philadelphia” – Don’t Miss an Exciting Meeting in Philadelphia

**By Christopher S. Coffey & Domenic Reda, 2014 Annual Meeting Program Co-Chairs**

On behalf of the 2014 Program Committee, I am pleased and excited to announce the wonderful program for the 35<sup>th</sup> Annual Meeting of the Society for Clinical Trials. This year’s meeting will take place in Philadelphia from May 18-21. It has long been a tradition for the SCT meetings to feature prominent keynote speakers, workshops and invited sessions organized and presented by the leading researchers on cutting edge topics, and the contributed poster and podium presentations by the rising stars of the field. This year should be no exception. The vast array of topics combined with exceptional speakers makes for an Annual Meeting not to be missed.

In the fall newsletter, we invoked Rocky Balboa and predicted that this year’s meeting was “Gonna Fly Now.” Our membership clearly heard these calls and responded with a number of high quality submissions for both invited sessions and contributed abstracts. The program committee has been working very hard to achieve the very difficult task of choosing from these high-quality proposals. This was a very difficult act since the proposals covered a wide range of several prominent topics in clinical trials. A total of 24 invited sessions will be offered. A number of these invited sessions revolve around topics of current interest, such as data sharing:

- Opening the Window on Data Transparency in Clinical Research
- Data Sharing: Open Access to Clinical Trial Data: Time to Move?
- Models for Data Sharing

Other invited sessions address current thinking on issues of interest to many working in the area of clinical trials:

- STAR Child Health: Developing Evidence-Based Standards for Pediatric Research
- Design and Analytical Considerations in Biomarker Based Clinical Trials in Oncology
- Using a Centralized IRB Review Process in the Conduct of Multicenter Trials

- Heterogeneity of Treatment Effect in Randomized Clinical Trials
- Recent Design Issues for Non-Inferiority Trials

The remaining Invited Sessions will cover topics such as data management, information systems, medical issues in the oversight of clinical trials, regulatory issues, study coordination, and statistical issues in the design and analysis of clinical trials – addressing the diverse interests of our membership. Our speakers also reflect this diversity. We have presenters from the U.S. FDA, NIH, pharmaceutical and biotechnology companies, consulting and contract organizations, non profit organizations, and academia.

In addition to the Invited Sessions, we have more than 200 contributed abstracts that will be presented in a total of 25 podium sessions and two days of poster sessions. These sessions involve speakers on a range of topics that will appeal to all those involved in clinical trials including data managers, IT professionals, research coordinators and managers, investigators, and statisticians.

*“We must all hang together, or assuredly we shall all hang separately” ~ Benjamin Franklin*

A program of this caliber cannot be put together without a team effort. The members of the Program Committee each deserve many thanks for their tireless efforts and generosity with their time. Finally, none of this would have happened without the support of Society President Dan Sargent and Elizabeth Franks and the management team at Fernley & Fernley.

SCT has secured discounted rates at the headquarters hotel, the Philadelphia Sheraton Downtown. The SCT rates are available through April 20, 2014 or until the hotel block is full. After that, rooms and rate are subject to availability. Rooms in the SCT block include complimentary Internet access in the sleeping rooms. For standard block, [click here](#). For rooms at the government rate (ID required upon check in) [click here](#).

## SCT Job Board: Opportunities for Employers, Job Seekers

Remember that one of the benefits of the SCT website is the SCT Job Board. This board, on the public section of the SCT website, provides employers an opportunity to reach potential candidates by posting a detailed job description. In addition, there is also a section for job seekers to post their resume on the site.

As an added benefit, all jobs posted on the SCT Job Board will be distributed via e-mail blast to SCT members.

Employers – for more information on posting a position on the SCT website (which will also be e-mailed to all SCT members),

click [here](#) for cost and details. Remember that job seekers can also post their resumes on the SCT Job Board, so be sure to check that for potential candidates.

Job seekers – be sure to check the SCT Job Board regularly for new positions. Remember that you can also post your resume on the SCT site.

Remember to check out [www.sctweb.org](http://www.sctweb.org) for the Job Board and other information to assist your professional development, including educational opportunities at the upcoming 35<sup>th</sup> Annual Meeting in Philadelphia (registration now open).

## 35<sup>th</sup> Annual Meeting

### May 18 – 21, 2014, Philadelphia, Pennsylvania, USA

All professionals interested in the design, conduct, and analysis of clinical trials are cordially invited to attend the 2014 SCT Annual Meeting. Join us in Philadelphia to hear from:

- leading edge trialists
- epidemiologists
- ethicists
- biostatisticians
- policy experts
- regulators, and others

All presenters will share their knowledge, practice and vision with SCT Annual Meeting attendees.

#### [Schedule of Events](#)

Over three days of meetings, you will be able to hear from industry leaders through:

- [Workshops on Sunday](#): You can choose from 13 total workshops – select up to two half day plus an evening workshop).
- Renowned Keynote speakers
- Engaging Invited Sessions
  - [Click here for a schedule of Invited Sessions by day/time](#)
  - [Click here for a schedule and description for each Invited Session](#)
- Distinctive Contributed Papers & Poster Presentations
- Networking Opportunities with Others in the Clinical Trials Community
- Presentations by finalists of the Thomas Chalmers Scholarship Competition
- Presentation by recipient of the Sylvan Green MD/DO/DDS Award
- Announcement of the 2013 Trial of the Year Award
- SCT Business Session
- Exhibits featuring vendor partners serving the clinical trials community.

**Join SCT in Philadelphia for stimulating keynote addresses from:**



#### **Ezekiel J. Emanuel, MD, PhD**

Vice Provost for Global Initiatives, the Diane v.S. Levy and Robert M. Levy University Professor, and Chair of the Department of Medical Ethics and Health Policy at the University of Pennsylvania

For the past 30 years, federal regulations that arose in response to the Tuskegee scandal have governed biomedical research—largely unchanged. Two factors, however, are likely to lead to significant changes in the near future. One is the ongoing effort to revise the Common Rule, which began in 2009 under the auspices of Dr. Emanuel when he served at the Office of Management and Budget. Another is the dramatic transformation in the American health care system catalyzed by the Affordable Care Act and the need for new

kinds of research to inform clinical practices. Dr. Ezekiel Emanuel, Vice Provost for Global Initiatives and Chair of the Department of Medical Ethics and Health Policy at the University of Pennsylvania, will explore the future of clinical research in the wake of these two changes. He will discuss efforts to reform the Common Rule and where they stand. He will also project the future of clinical research in the light of health care reform and the demand for more comparative effectiveness research.



#### **Christopher P. Austin, MD**

Director, National Center for Advancing Translational Sciences

The process by which observations in the laboratory or the clinic are transformed into demonstrably useful interventions that tangibly improve human health is frequently termed “translation”. This multi-stage and multifaceted process is poorly understood

scientifically, and the current research ecosystem is operationally not well suited to the distinct needs of translation. As a result, biomedical science is in an era of unprecedented accomplishment without a concomitant improvement in meaningful health outcomes, and this is creating pressures that extend from the scientific to the societal and political. To meet the opportunities and needs in translational science, NCATS was created as NIH’s newest component in December 2011, via a concatenation of extant NIH programs previously resident in other components of NIH. NCATS is scientifically and organizationally different from other NIH Institutes and Centers. It focuses on what is common to diseases and the translational process, and acts a catalyst to bring together the collaborative teams necessary to develop new technologies and paradigms to improve the efficiency and effectiveness of the translational process, from target validation through intervention development to demonstration of public health impact. This talk will provide an overview of NCATS mission, programs, and deliverables, with a view toward future developments.

[Click here for CPS Presenter Guidelines](#)

[Click here for Tips on Poster Presentations](#)

**Register online by May 11, or onsite at the Sheraton Philadelphia Downtown Hotel.**

#### **Don’t Miss out on Philadelphia!**

After taking in some thought-provoking meeting sessions, engaging in stimulating intellectual debate with colleagues, and walking through ideas with poster presenters, make sure to enjoy the sights, restaurants and cultural offerings of Philadelphia!

Visit the [SCT 2014 meeting page](#) for important program information and registration details. Questions? Call +1.215.599.6633 or email [sct@fernley.com](mailto:sct@fernley.com).

#### **Remember!**

Members save on Annual Meeting Registration Fees, so renew your SCT Membership today in the SCT members only section of the website - just \$170 for regular membership; \$50 for students.

Encourage your colleagues to join SCT and attend – visit [www.sctweb.org](http://www.sctweb.org) for complete information.

## 2014 Student Scholarship Presentations at the 35<sup>th</sup> Annual Meeting

The Thomas C. Chalmers Student Scholarship Program, started in 1985, is open to pre- and post-doctoral students participating in clinical research training programs. The 2014 Finalists for the Thomas C. Chalmers Student Scholarship receive funding to attend the 35<sup>th</sup> Annual Meeting and will present their abstracts during a contributed paper session taking place on Monday May 19, 2014: This year's Thomas C. Chalmers Student Scholarship finalists are:

**Laura L. Fernandes, Department of Biostatistics, University of Michigan**

*Adaptive Phase I Clinical Trial Design Using Markov Models for Conditional Probability of Toxicity in Oncology*

**Lee S. McDaniel, Department of Biostatistics, University of Wisconsin Madison**

*Sample Size Under the Additive Hazards Model*

**Yong Zang, Department of Biostatistics, MD Anderson Cancer Center, The University of Texas**

*Optimal Marker-Strategy Clinical Trial Design to Detect Predictive Markers for Targeted Therapy*

In addition, the 2014 Sylvan Green recipient will be recognized at the 35<sup>th</sup> Annual Meeting. The Sylvan Green Award is open to physicians and dentists involved in clinical trials or epidemiology projects. Eligible topics include clinical trial-related issues such as study design and data analysis methods; 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.

SCT thanks the Student Scholarship Committee, chaired by James J. Dignam, and includes Borko Jovanovic, Scott Keith, Robert Lindblad, Zhibao Mi, Stephanie L. Pugh, Joseph R. Rausch, Jeff Szychowski, Jie Yang and Sharon Yeatts.

A call for 2015 scholarship applications will go out in Fall 2014.

## SCT Introduces New Webinar Series!

SCT is excited to introduce a new benefit for Society members! The SCT-sponsored webinar series will feature presentations on cutting-edge topics by leaders of the clinical trials community. The one-hour meetings will allot time for questions & discussion among audience members and the presenter. These webinars will be available only to SCT members.

The first webinar took place on Tues. March 18, 2014. Presenter Steve Goodman, MD, MHS, PhD, Associate Dean for Clinical and Translational Research and Professor of Medicine and Health Research & Policy, Stanford University and longtime editor of *Clinical Trials*, the Society's official journal, focused this webinar on "Sharing Clinical Trial Data is So Hard, and Why the IOM Needs Your Help."

The session was very well-attended and SCT thanks Dr. Goodman for contributing his time and sharing his expertise with Society members. The webinar recording and slides are now posted on the Members Only Section.

The upcoming schedule of presenters and topics is as follows:

**June 17, 2014 (12 – 1 PM Eastern)**

Presenter: Marc Buyse, ScD

Topic: Risk Based Monitoring for Clinical Trials

**August 12, 2014 (12 – 1 PM Eastern)**

Presenter: Debra Steinberg

Topic: Web-based Event Ascertainment and Outcomes Tracking in a Multi-center Clinical Trial

**October 14, 2014 (12 – 1 PM Eastern)**

Presenter: Janet Wittes, PhD

Topic: On data for DMCs: Clean or speedy? Complete or limited?

**December 9, 2014**

Presenter: Ken Cheung, PhD

Topic: Sample Size Determination for Phase 1 Clinical Trials

TO REGISTER: These webinars are a benefit of SCT membership and registering is free to SCT members. Members will be notified when registration opens for each webinar. The registration link will be posted in the Members Only Section. If you need assistance with login credentials, e-mail us at [sct@fernley.com](mailto:sct@fernley.com)

## Upcoming News & Events

April 8, 2014

### **7<sup>th</sup> Annual Conference on Statistical Issues in Clinical Trials:**

Topic: Current Issues Regarding the use of Biomarkers and Surrogate Endpoints in Clinical Trials

Perelman School of Medicine, University of Pennsylvania  
Philadelphia, PA

The 2014 Conference will bring together leading scientists who will discuss state-of-the-art approaches for using biomarkers and surrogate endpoints in the design, analysis and interpretation of clinical trials. Participants from academic institutions, industry, and government agencies with an interest in clinical trials methodology are encouraged to register.

The Conference will be held at the Smilow Center for Translational Research Auditorium on the campus of the Perelman School of Medicine at the University of Pennsylvania. Registration deadline is March 31, 2014, or when the registration limit is reached.

For information and registration visit <http://www.cceb.med.upenn.edu/biostat/conferences/ClinTrials14/>  
For questions contact Marissa Fox Phone: 215-573-7393, Email: [mfox@mail.med.upenn.edu](mailto:mfox@mail.med.upenn.edu)

Conference co-sponsors: American Statistical Association, the Society for Clinical Trials and the University of Pennsylvania Center for Clinical Epidemiology and Biometry .

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June 23 - 27, 2014

### **The Summer Institute in Statistics for Clinical Research (SISCR 2014)**

The University of Washington in Seattle

This Institute consists of a series of half day, one day and one-and-a-half day workshops conducted by experts in the field and designed to introduce participants to modern issues in the design and conduct of clinical trials and the statistical analysis of clinical trial data. Prerequisites are minimal, and the modular nature of the Institute enables participants to design a program best suited to their backgrounds and interests.

For more information, visit <http://www.biostat.washington.edu/suminst/siib/general>

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August 2-7, 2014

### **2014 Joint Statistical Meetings**

Boston Convention and Exhibition Center  
415 Summer Street, Boston, MA 02210

JSM (the Joint Statistical Meetings) is the largest gathering of statisticians held in North America. It is held jointly with the American Statistical Association, the International Biometric Society (ENAR and WNAR), the Institute of Mathematical Statistics, the Statistical Society of Canada, the International Chinese Statistical Association, the International Indian Statistical Association, the Korean International Statistical Society, and the International Society for Bayesian Analysis. Attended by more than 6,000 people, meeting activities include oral presentations, panel sessions, poster presentations, continuing education courses, an exhibit hall (with state-of-the-art statistical products and opportunities), career placement services, society and section business meetings, committee meetings, social activities and networking opportunities. For more information, visit <http://www.amstat.org/meetings/jsm/2014/index.cfm>

## Social Media & the SCT Hub on [www.sctweb.org](http://www.sctweb.org)

A new feature you may have noticed in the upper left corner of the [sctweb.org](http://www.sctweb.org) homepage is the SCT Hub, which links visitors to the various social media platforms through which SCT is expanding its web presence and increasing its dialogue in the clinical trials community. Connect with SCT online!:

SCT Facebook » <http://www.facebook.com/SCT.org>

SCT LinkedIn » <http://www.linkedin.com/groups?gid=3668632>

SCT Twitter (SCTpres) » <https://mobile.twitter.com/SCTPres?p=i>

SCT Twitter (SCTorg) » <https://mobile.twitter.com/SCTorg>



## Support the Society

An SCT member recently brought to our attention a unique and generous way to support the Society financially. Consider donating the honorarium, speaking fee or board service fee that you receive from your "outside" work to the Society. You can give the group that is cutting you a check SCT's name and tax ID number, and request that the check be sent directly to us. Or, you can accept the payment and subsequently provide a donation in your name to the SCT. You may designate to which of the special funds your gift is allocated:

- Mary Karpers-Burke Member Sponsorship
- General Fund
- Curtis Meinert Honorary Keynote Address
- Thomas Chalmers Student Scholarship Award
- Sylvan Green Scholarship Program

Remember to consult your tax advisor regarding the impact of this type of gift on your own personal tax situation.

### Your AD here

#### Advertising opportunities with SCT

SCT accepts advertising in both our newsletter and on our website. All requests to advertise and advertisement content and artwork are subject to the approval of the Executive Committee of the SCT Board of Directors.

Contact Liz Dougherty, SCT Associate Director, at [edougherty@fernley.com](mailto:edougherty@fernley.com) for more information and deadlines.

SCT Newsletter • 4-color, PDF newsletter • Emailed 2x per year to full SCT membership; archived on SCT website	Full page, run of book	\$1,000
	½ page, run of book	\$800
	¼ page, run of book	\$500
SCT website	Homepage ad, placement in right rail, 30 days; ad specs provided separately	\$2,000
	Any other page of website, placement right rail, 30 days, ad specs provided separately	\$1,250