



Welcome to our New Newsletter



Domenic J. Reda, SCT President 2016-2017

Hello, our annual meeting was such a success in Montreal that I wanted to get a newsletter out as soon as possible to share with you all the latest news from SCT. First, please join me in thanking all those who worked hard to make this meeting a success, especially Wendy Parulekar (SCT President 2015-2016), Leslie Ain McClure (Program Chair 2015-2016) and Li Chen (Education Committee Chair 2015-2016). For those of you who attended the meeting, I extend my thanks to you and hope you found it as enriching as I did. For those who were not able to attend, we missed you and hope we see you soon at one of our upcoming meetings.

In this issue, we share with you a few articles about the Montreal meeting, introduce you to the new SCT leadership, give you some of the highlights in the current edition of our Society Journal *Clinical Trials*, and give you some early information about two upcoming meetings so that you can get them on your calendar. We also have increased our interactions with the Clinical Trials Transformation Initiative, of which we are a member, and asked them to tell us what is happening at CTTI.

We hope to continue this newsletter in its new format on a monthly basis. If you have an article you would like us to consider for the next edition, please send it to sct@fernley.com by July 8. You can also send suggestions to us regarding articles you would like to see. We reserve the right to choose what we will include in the newsletter. That will be based on space availability, and appropriateness of content to our membership. We are unable to accept any article that we view as directly or indirectly marketing a commercial product or service.

Learning Early About Peanut Allergy (LEAP)

Selected as the 2015 David Sackett Trial of the Year

Wedny Parulekar and Scott Evans

Learning Early About Peanut Allergy Trial (LEAP), a randomized controlled trial, is the 2015 awardee for the prestigious David Sackett Trial of the Year Award, presented annually by the Society for Clinical Trials. Gideon Lack, Senior Investigator on the LEAP Trial accepted the award on behalf of the LEAP Trial team. Gideon Lack, a Professor of Paediatric Allergy, King's College London, Head of the Clinical Academic Paediatric Allergy Service, Guy's & St Thomas' NHS Foundation Trust, presented the LEAP trial at the Society's 37th Annual Meeting in Montreal, Canada.

Peanut allergy is a major health issue. The prevalence of peanut allergy among children in Western countries has doubled in the past 10 years, and is rising in Africa and Asia. The LEAP Trial was conducted in the UK and enrolled 640 children aged 4-11 months who were considered at high risk of developing peanut allergy due to pre-existing severe eczema and/or egg allergy. To determine whether peanut consumption or avoidance is the most effective strategy to prevent peanut allergy, half of the children were asked to eat peanut-containing foods three or more times each week, and the other half to avoid eating peanut until 5 years of age. Participants were monitored throughout this period during recurring visits with healthcare professionals. Adherence to consumption or avoidance advice was assessed using a telephone food frequency questionnaire at regular intervals and by measuring peanut levels in the child's home environment.

The researchers assessed peanut allergy at 5 years of age with a supervised, oral food challenge with peanut. They found that the overall prevalence of allergy in all children asked to consume peanut was 3.2% versus 17.2% in the avoidance group. This represents an overall 81 percent reduction of peanut allergy in children who began early, continuous consumption of peanut compared to those who avoided peanut. The LEAP Trial showed that early introduction of peanut significantly decreased the frequency of the development of peanut allergy among children at high risk for this allergy, thus identifying an effective approach to managing a serious public health problem. LEAP served as the basis for new guidelines from the American Academy of Pediatrics recommending early peanut introduction in high-risk children.

Each year since 2008, the SCT has been awarded to a randomized, controlled trial published (either electronically or in print) in the previous calendar year that best fulfills the following standards:

- It improves the lot of humankind.
- 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.

Nominations came from Society members, investigators, and interested scholars from around the world.

The 2015 Trial of the Year selection committee included Kay Dickersin (Chair), Marion Campbell, Christopher Coffey, Scott Evans, Tianjing Li, Wendy Parulekar, Paula Williamson, and Janet Wittes.

The 2016 Trial of the Year Selection Committee will issue a call for nominations in fall, 2016. Visit www.sctweb.org for updates.

About the Society for Clinical Trials: The Society for Clinical Trials, created in 1978, is an international professional organization dedicated to the development and dissemination of knowledge about the design, conduct, analyses, and reporting of government and industry-sponsored clinical trials and related health care research methodologies. Visit www.sctweb.org.

About the Trial of the Year: Find a list of past Trials of the Year on www.sctweb.org.

Save the Date!

SCT-QSPI /Regulatory Fall Innovation Workshop *New Approaches in Clinical Science for Developing Evidence*

November 14-15, 2016

Universities at Shady Grove - Conference and Events Center
Rockville, Maryland

Join colleagues with diverse interest, experience and expertise as we showcase innovations and partnerships; engage in active dialogue to advance the science and practice of clinical trials; and hear from thought leaders and dynamic speakers from regulatory, industry, academia, and patient groups.



Quantitative Sciences in the Pharmaceutical Industry

Program and registration details will be available shortly.

Our target audience includes statisticians, clinicians, epidemiologists, drug safety professionals, study management professionals, and medical scientists from the biopharmaceutical industry, government, and academia who are interested in recent developments and future directions in improving clinical trials, and patient representatives and advocates who share those interests.

The Society for Clinical Trials, created in 1978, is an international professional organization dedicated to the development and dissemination of knowledge about the design, conduct and analysis of government and industry-sponsored clinical trials and related health care research methodologies. QSPI is a standing committee of the Society for Clinical Trials, with a focus on providing an ongoing forum for timely multi-disciplinary dialog around scientific and regulatory issues related to the development and use of medicines, primarily from an informed quantitative perspective.

Society for Clinical Trials (SCT)

100 North 20th Street, Suite 400, Philadelphia, PA 19103

Email: QSPIMeeting@fernley.com

Josh Chen and Janelle Charles



Announcing our new Secretary, Board Member and Committee Chairs

Domenic Reda

Our Spring newsletter announced the election of the new officers for the Society for Clinical Trials. With the Election of Ted Karrison as President-Elect, that created a vacancy for the Secretary of the Society. I have selected Mithat Gonen, from Memorial Sloan Kettering Cancer Center as our new Secretary. The appointment of Mithat created a vacancy on our Board of Directors. The Board has approved my recommendation to name Lynda Constable, from the University of Aberdeen, to serve on the Board. Thank you, Mithat and Lynda, for agreeing to serve in this capacity for the Society.

We also have several new people heading various SCT committees and Activities. Following is a list of our Committee and Group Chairs:

Scientific Program Committee Co-Chairs Liverpool Meeting 2017	Will Meurer Jon Nicoll
Program Committee Chair Portland Meeting 2018	Kaleab Abebe
Education Committee Co-Chairs Liverpool Meeting 2016	Sumithra Mandrekar Shaun Treweek
Education Committee Chair Portland Meeting 2018	Emily vanMeter Dressler
Development	Li Chen
Fellows	Susan Halabi
Membership	Paul Thompson
Nominating	KyungMann Kim
Social Media	Chris Coffey
Student Scholarship	Jim Dignam
Web Oversight	Scott Rushing



News from the Society Journal, *Clinical Trials*

Colin Begg

As all SCT members are aware, the Society journal *Clinical Trials* is published bi-monthly. In the recently distributed June issue Constanze Schulz and colleagues from several institutions in Germany describe a new kind of randomized trial design that permits doctors and patients a degree of choice in selecting the treatment options, facilitating physicians' preferences for specific drugs, and Graham Dunn from the University of Manchester provides a commentary.

In another article Gerd Rosenkrantz, from Novartis in Switzerland, examines the theoretical implications of the common practice of discontinuing placebo responders during a placebo run-in period in randomized trials.

Ethan Basch from the University of North Carolina and colleagues reported on the extent to which physicians took action on the basis of patient-reported outcomes during a phase II cancer trial. These articles highlight the breadth of topics we cover, reflecting the broad range of interests of the Society membership. Finally, our team of Deputy Editors was expanded recently to include Jonathan Kimmelman, whose prominence as a medical ethicist will enhance our expertise in evaluating articles on this topic. Jonathan will replace Barbara Hawkins on the team. In addition to her role as Deputy Editor, Barbara has served the journal and the Society for decades in many roles, including, notably, her regular column "Perusing the Literature" that was featured for many years in the 1980s when the Society journal was called *Controlled Clinical Trials*.

Thank you Barbara!



The Montreal Meeting by the Numbers

Elizabeth Dougherty

2016 Annual Meeting	
Number of Registrants (Full Meeting)	489
Number of Student Registrants (Full meeting)	22
Number of Attendees from outside the US	152
Number of Countries Represented	12
Number of New Members	211
Number of Invited Sessions	30
Number of Contributed Paper Presentations	110
Number of Poster Presentations	80
Number of Pre-Conference Workshops	13
Number of Pre-conference Workshop Attendees	142

Attendees: Country of Origin	
US	337
UK	79
Canada	48
France	6
Australia	4
Italy	4
Japan	4
China	2
Hungary	2
Germany	1
New Zealand	1
Taiwan	1



Highlights from the Montreal Meeting

Leslie Ain McClure

The 2016 Society for Clinical Trials annual meeting in Montreal, Quebec, was a success! The program included outstanding talks by speakers from the US, Canada, Europe and Asia, and featured some speakers new to the Society, as well as others who have been part of SCT since its inception. The diversity of topics and perspectives allowed our members to learn about new research being done in statistical methods, electronic data capture and data management, and programming, as well as in other areas such as ethical issues in clinical trials. Early morning sessions such as “Implementation of Electronic Data Capture Systems” drew large crowds, and highly topical sessions like “Courage, controversy and clinical trials: lessons from the Ebola epidemic” were standing room only! The posters were outstanding, and allowed members to learn in a less formal setting, and the society-wide luncheons were great opportunities for networking among members.

Other meeting highlights included the plenary speakers. Dr. Denis Lacombe, MD, PhD, gave the opening Curtis Meinert Lecture: “European organization for research and treatment of cancer (EORTC): vision, strategic focus and implementation strategy” and started off the meeting discussing how his organization is approaching research and treatment of cancer in Europe. The Founders Lecture was delivered by Richard Stephens, and was entitled: “Patients as cancer research – walking the walk in the UK”. Mr. Stephens spoke about how his group worked **with** cancer patients to improve their research approaches. Both talks were excellent and provided the membership with different perspectives on cancer research.

Thanks to all who helped with planning and organizing the meeting, and we look forward to a great 2017 meeting in Liverpool!



Update from the Clinical Trials Transformation Initiative (CTTI)

Leanne Madre

The clinical trials enterprise is in crisis. The growing complexity and cost of trials are creating an unsustainable system that fails to provide patients, clinicians, and regulatory agencies with the high-quality evidence needed to treat and prevent diseases. At [CTTI](#), our mission is to develop and drive adoption of practices that will increase the quality and efficiency of clinical trials. The Society for Clinical Trials (SCT) is one of CTTI's more than 70 member organizations that contribute to this mission. We recognize that achieving widespread adoption of improved practices involves the cooperation of all stakeholders in the clinical trials enterprise. CTTI engages these stakeholders in generating evidence to guide solutions, and issues [recommendations](#) and [implementation tools](#) to bring about real-world change.

Effective Use of DMCs

At the 36th Annual SCT Meeting, CTTI unveiled new recommendations intended to enhance the functioning of Data Monitoring Committees (DMCs). The safety of volunteer participants is paramount in the conduct of clinical trials, and many trials rely on DMCs to assess benefits and risks to them.

DMCs traditionally have been used to monitor masked, randomized controlled, multicenter trials; however, the criteria for when a DMC is necessary is not well defined, and their use in increasingly varied types of trials has led to diverse perspectives about how they should operate. CTTI's [DMC project](#) team conducted surveys to assess the current use and conduct of DMCs and training practices for DMC members; convened focus groups to gain an in-depth understanding of needs and best practices related to independent DMC use; and held an [expert meeting](#) with diverse stakeholders to review these results and help develop recommendations.

The newly released recommendations contain guiding principles with regard to the DMC's role, composition, communications, and training of its members. The recommendations also describe best practices for DMC meetings and provide a sample DMC charter.

- Read the [Data Monitoring Committee Recommendations](#).
- For more information, contact ctti@mc.duke.edu.

Be the Change

CTTI is not just generating new ideas—we are committed to making change happen. We hope you will join us, learn from us, and take action. To help make that happen, we look forward to providing regular updates to the SCT community so you can stay involved.

Resources:

Click for the full list of CTTI [recommendations](#) and [tools](#).

For more information, visit the [CTTI website](#) or sign up for [email updates](#).



Get Ready for Liverpool May 7-10, 2017! Yeah, Yeah, Yeah!

Emma Tomlinson

We are pleased to announce that the Society for Clinical Trials 2017 Annual Meeting will be jointly held with the 4th International Clinical Trials Methodology Conference (ICTMC) from 7-10 May 2017 in Liverpool, UK.

ICTMC
2017

**4th
International
Clinical Trials
Methodology
Conference**

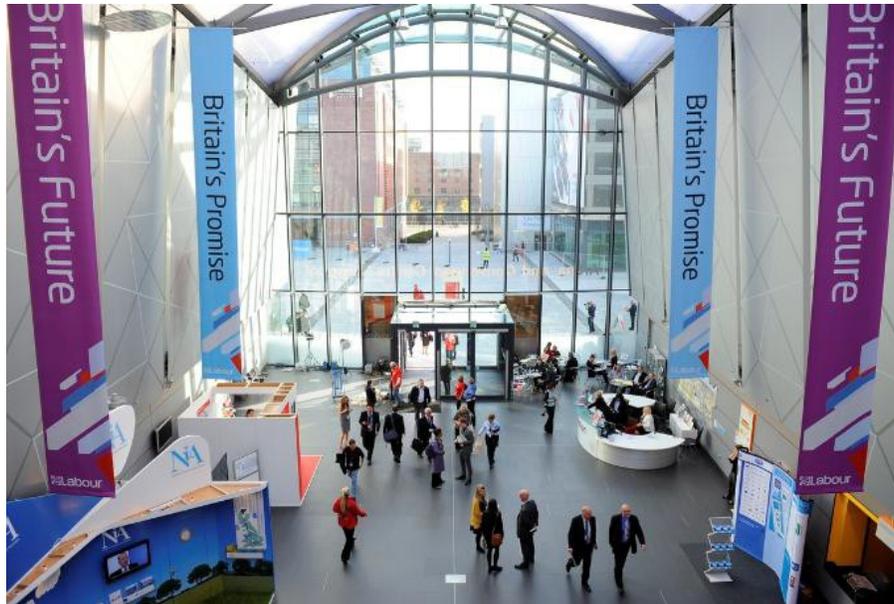


The ICTMC is a biennial conference coordinated by the MRC Network of Hubs for Trials Methodology Research. Dedicated to 'Improving Health by Improving Trials', the Network engages with stakeholders in the UK, and internationally, to improve the quality of trials and, ultimately patient care (<http://methodologyhubs.mrc.ac.uk/>). By supporting activities as diverse as research projects, Working Groups, PhD students, meetings and events, the Network provides a unique platform highlighting the importance of clinical trials methodology in the community.

Since the first International Clinical Trials Methodology Conference in 2011, delegate attendance and programme content has increased. The ICTMC is recognised as a unique opportunity for those working in clinical trials to network, engage and discuss challenges and innovations in trials. The most recent ICTMC in 2015 featured ideas and evidence on how to

improve recruitment and retention, how to streamline the trial process, make better use of information technology and embed methodology research into trials, such as through SWAT (Studies Within A Trial) methods, and much more besides. The conference showed how, by working together, we can improve the quality of research, minimise waste and provide the knowledge that patients, practitioners, policy makers and the public need to make well-informed decisions about health and social care.

The ICTMC regularly attracts over 600 delegates and we will be working together to bring the best from the ICTMC and SCT meetings to Liverpool 2017, as well as some new innovative sessions.



The 2017 event will be hosted at the ACC Liverpool, voted best UK Conference Centre for the fourth time in 2016. Liverpool is a modern, vibrant city, proud of its rich heritage and world trade roots, famous for its friendly people, and known worldwide for football and a particular pop foursome. <http://www.accliverpool.com/>

The 2017 meeting is being jointly organised by international representatives on the Scientific Programme and Education Committees, together with the Local Organising Committee, who are based in Liverpool.

With a unique venue, internationally recognised Committee support, and enthusiastic delegates, we expect this to be a valuable opportunity to celebrate the developments in clinical trials methodology to date and to explore the future of our research.

Join us in Liverpool- May 7-10, 2017.

<http://ictmc-sct2017.com/>

