SCT Newsletter Vol. 4

September 2016

A Message from SCT President

Domenic J. Reda
SCT President 2016-2017

Thanks for opening the SCT newsletter for September and spending a few minutes with us. Let me start with two big reminders. We are now accepting registrations for the SCT/QSPI Regulatory Fall Innovation Workshop, to be held November 14-15 at the Universities at Shady Grove Conference Center in Rockville, Maryland (Washington DC area). More great speakers have been added since our last newsletter. See the flyer in this newsletter for some additional information about this meeting. To register, go to ***www.sctweb.org***

We are also quickly approaching the deadline for abstract and workshop proposal submission for the SCT/ICTMC Joint 2017 meeting in Liverpool UK. **THE DEADLINE FOR ALL SUBMISSIONS IS OCTOBER 10, 2017.** ***To submit an abstract, click here:*** http://www.ictmc2017.com/

In this issue, we provide you some information on lodging options in Liverpool. We also share with you some news from the Clinical Trials Transformation Initiative and the National Institutes of Health. Finally, as we go to press, the October issue of the Society's Journal, ***Clinical Trials***, is in press. The journal's editor and Past SCT President, Colin Begg, shares with us some of the highlights of the October Issue.

If you have an article you would like us to consider for the next edition, please send it to sct@fernley.com by October 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.

Time for me to get back to writing my abstract submission. And you?

Domenic J. Reda
SCT President

A Message from SCT President-Elect

Ted Karrison
SCT President-Elect

Dear SCT Members,

As a statistician engaged in the design and analysis of clinical trials, I very much appreciate the interdisciplinary nature of the enterprise. A clinical trial requires close collaboration between the principal and participating investigators, statistician(s), IT personnel, clinical research associates, and others in order to be successful in providing reliable and informative results.

There are many statistical organizations, medical societies, and professional organizations that advance the science of clinical trials, but ours is the only truly interdisciplinary one to my knowledge. As our membership has declined recently, I would encourage you to encourage your colleagues, particularly non-statistician colleagues, to consider joining the Society. We remain a vibrant, international organization dedicated to improving the conduct and value of clinical trials. We have a highly recognized journal that publishes articles on all aspects of clinical trials—ethics, regulatory issues, history, design considerations, data capture and management, clinical and policy impact—in addition to statistical methodology.

Our annual meeting brings together individuals with expertise in each of these areas and provides an opportunity for interaction and dialogue that is not offered by other organizations. We provide educational workshops at these meetings and have an ongoing, informative series of webinars given by distinguished trialists covering a variety of topics.

Clinical trials continue to bring us new challenges requiring innovative methods and approaches to meet those challenges, but they remain the preferred means for evaluating new therapies and for promoting evidence-based medicine. Now more than ever, this is the time to reach out to those with whom you interact and invite them to join our Society. I'm confident it will help make them better trialists and be well worth the investment.

Ted Karrison, PhD
SCT President-elect

Abstract Submission Portals Now Open!

4TH International Clinical Trials Methodology Conference (ICTMC) and the 38th Annual Meeting of the Society for Clinical Trials (SCT)

May 7-10 2017

Arena and Convention Centre (ACC)

Liverpool, United Kingdom

The abstract submission portal for SCT's 38th Annual meeting opened **August 22, 2016**.

Because of the earlier deadline for submitting abstracts this year, the Scientific Program Committee will give consideration to abstracts for contributed sessions which have pending final results. All submissions should still have rigorous, well described methodologies, interim results if available, and address the potential impact of the ultimate findings.

All professionals interested in the design, conduct, and the analysis of clinical trials are cordially invited to submit abstracts for:

- Invited Sessions
- Contributed Sessions
- In-conference Tutorials
- Pre-conference Workshops
- Sylvan Green Award
- Thomas C. Chalmers Student Scholarship

The deadline for submission for all categories is **October 10, 2016**
Click here to submit an abstract. http://www.ictmc2017.com/

You are receiving this e-mail because you are a member of or have expressed interest in:

Society for Clinical Trials
100 North 20th Street, Suite 400
Philadelphia, PA 19103 215-320-3878
sct@fernley.com | www.sctweb.org

If you no longer wish to receive e-mails from SCT, please contact sct@fernley.com

REGISTRATION OPEN!

SCT-QSPI* /Regulatory Fall Innovation Workshop

New Approaches in Clinical Science for Developing Evidence

November 14-15, 2016

Universities at Shady Grove Conference Center Rockville, Maryland

This multi-disciplinary workshop brings together thought leaders and dynamic speakers from regulatory, industry, academia, and patient groups for direct and open discussions on recent innovations in the science and practice of clinical trials.

FEATURED TOPICS

Day 1: Emerging Trends in Clinical Trial Design and Analysis

Session 1: Estimands – Clinical Objectives, Statistical Methods, and Missing Data

- Intended Measure of Treatment Effect ('Estimand')
- Relationship of Study Objectives, Design, and Estimation
- Patient, Regulator, and Practicing Clinician's Perspectives

Session 2: Basket and Platform Trials – Challenges and Opportunities

- Issues and Challenges in Basket Trials
- Implementation of Platform and Basket Trials
- Bayesian Perspectives

Day 2: Leveraging Real World Evidence in Understanding Medical Products and Interventions

Session 3: Real World Evidence – Sources and Applications

- Electronic Medical Records
- Regulatory Applications
- Registry-Based Clinical Trials

Session 4: Transforming Real World Data Into Evidence – Active and Passive Networked Patient Engagement

- Social Media Listening
- Patient Powered Research Networks
- Pragmatic Clinical Trials

CONFIRMED SPEAKERS: Estelle Russek-Cohen (FDA), Jonathan Jarow (FDA), Michael Lauer (NIH), Lisa LaVange (FDA), David Ohlssen (Novartis), Greg Powell (GSK), Sally Okun (PatientsLikeMe), Ben Saville (Berry Consultants), Richard Schilsky (ASCO), Richard Simon (NCI), and more …

Visit *http://meeting.sctweb.org/qspi* to Register and for Additional Conference Details.

PROGRAM CO-CHAIRS

Janelle K. Charles, Ph.D.
Mathematical Statistician/Senior Staff Fellow
Office of Biostatistics (OB)/OTS/CDER/FDA

Joshua Chen, Ph.D.
Global Head, Biostatistics and Programming
Sanofi Pasteur

PROGRAM COMMITTEE

Thomas Birkner, Ph.D.
Mathematical Statistician, OB/OTS/CDER/FDA

Ivan S.F. Chan, Ph.D.
Vice President, Pipeline Statistics and Programming, AbbVie

Li Chen, Ph.D., Sc.D.
Director of Biostatistics, Amgen

Susan Halabi, Ph.D.
Professor of Biostatistics and Bioinformatics, Duke University

Michael Hale, Ph.D.
Vice President, Head of Biostatistics and Programming, Shire

Theodore Karrison, Ph.D.
Research Associate & Director of Biostatistics Lab
The University of Chicago Biological Sciences

Bo Li, Ph.D.
Mathematical Statistician, OB/OTS/CDER/FDA

Olga Marchenko, Ph.D.
Vice President of Advisory Services, Quintiles

Jose Pinheiro, Ph.D.
Senior Director, Janssen R&D

Renée Rees, Ph. D.
Lead Mathematical Statistician, OBE/ CBER/FDA

Yves Rosenberg, M.D.
Branch Chief, Division of Cardiovascular Sciences, National Heart, Lung, and Blood Institute, NIH

John Scott
Deputy Director, Division of Biostatistics, OBE/CBER/FDA

David Stock, Ph.D.
Director, Global Biometric Sciences/BMS

Marc Walton, M.D., Ph.D.
Sr. Scientific Director, Quantitative Sciences, Janssen Research and Development

News from the Society Journal: Clinical Trials

By Colin Begg, Editor

The October issue of *Clinical Trials* is largely devoted to the proceedings from the University of Pennsylvania 8th annual conference on clinical trials, edited by Susan Ellenberg. This conference, held in April 2015, was devoted to statistical and related issues in pragmatic clinical trials.

Several prominent speakers gave presentations that generally highlighted the importance of these trials that occur at the boundary of clinical practice, and the fact that these types of trial are frequently quite complex, posing challenging issues relating to design, conduct, analysis and ethics. As is customary in reports from these conferences, the transcriptions of the extensive discussions, involving speakers, panelists and interested parties from the audience, provide excellent insight into the controversies and challenges of successfully conducting pragmatic trials in the evolving landscape of clinical research and clinical care.

In other news from the journal I am pleased to report that submissions of articles to date in 2016 is up by more than 10% from the previous three years. This is good news in that it would appear to show increasing interest in publishing in the journal. The bad news is that it will correspondingly lower the acceptance rate, and increase the workload for the editorial team! Joking aside, we strongly encourage Society members to regard *Clinical Trials* as your first choice journal for submitting your best work.

HOTEL ACCOMMODATION

We have reserved rooms at various hotels within Liverpool which are all within 10 – 15 minute walk from the ACC, Liverpool. Please find below details on the hotels and the discounted rates we have for conference delegates.

Staybridge Suites Liverpool

21 Keel Wharf, Liverpool, L3 4FN
Staybridge Suites Liverpool is situated directly opposite the venue offering apartment-style-en-suite accommodation for the home from home feeling.
Click here for further details.
To book call: +44 (0)800 988 4663 or
email: sales@liverpool.staybridge.com quoting Group Code: ICT
Rate is £125.00 bed & breakfast per room per night and subject to availability, to benefit from this rate all bookings must be made prior to the 24th March 2017.

Jurys Inn Liverpool

31 Keel Wharf, Liverpool L3 4FN
Jurys Inn Liverpool is located opposite the ACC Liverpool and is a 2 minute walk. **Click here** for further details.
To book call: +44 (0)151 244 3805 or
email: Tayla_Dooley@jurysinns.com quoting Group Code: ICTMC
Rate is £112.00 bed & breakfast per room per night and subject to availability, to benefit from this rate all bookings must be made prior to the 10th March 2017.

Pullman Hotel Liverpool

Kings Dock, Monarchs Quay, Liverpool, L3 4FP
Pullman Hotel Liverpool is a 4star hotel and is located onsite at the ACC, Liverpool.
Click here for further details.
To book click here or call +44(0)151 945 1035
£145.00 Bed & Breakfast per room per night, based on single occupancy.

Express by Holiday Inn Liverpool

Britannia Pavilion, Albert Dock, Liverpool, L3 4AD
Express by Holiday Inn Liverpool Albert Dock is a 3star hotel and is only a 4 minute walk from the ACC, Liverpool.
Click here for further details.
To book call: +44(0)0151 702 6369 or
email: enquiries@exliverpool.com, quoting reference Group Code: CON Allocation
Rates are dependent on date requirements and start from £75.00 Bed & Breakfast per room per night

Hiton Liverpool

3 Thomas Steers Way, Liverpool, L1 8LW
Hilton Liverpool Hotel is a 4star hotel and is a short 10 minute walk from the ACC, Liverpool.
Click here for further details
To book call: +44(0)151 708 4200 or click here to book online
£130 Bed & Breakfast per room per night based on single occupancy
£140 Bed & Breakfast per room per night based on double occupancy

Hampton by Hilton

Kings Dock Mill, 7 Hurst Street, Liverpool, L1 8DA
Hampton by Hilton Liverpool City Centre is a 3star hotel and is a short 10 minute walk from the ACC, Liverpool.
Click here for further details.
To book call: +44(0)151 702 6210 or click here to book online
£109.99 Bed & Breakfast per room per night

Novotel Liverpool Centre

40 Hanover Street, Liverpool, L1 4LN
Novotel Liverpool Centre is a 4star hotel and is a short 12 minute walk from the ACC, Liverpool.
Click here for further details.
To book call: +44(0)151 702 5151 or email h6495-re1@accor.com, quoting group code: ICTMC
£139.00 Bed & Breakfast per room per night, based on single occupancy and full pre-payment required 28 days prior to arrival

Days Inn Liverpool

James Street, Liverpool, L2 7PQ
Days Inn Liverpool is a 3star hotel located a short 15 minute walk from the ACC, Liverpool.
Click here for further details.
To book call: +44(0)151 203 1910 and quote ICTMC17
£70.00 Bed & Breakfast per room per night, based on single occupancy

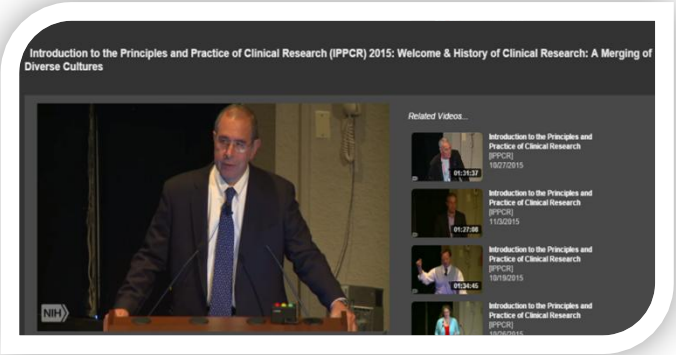
Additional Accommodation Options

There are additional hotels and accommodation options available within the Liverpool area which is within close proximity of the ACC, Liverpool. **Click here** for further details, please note that we only have conference rates arranged at the above hotels.

Registration Now Open for NIH Clinical Research Distance Learning Courses

In 1995, the National Institutes of Health (NIH) Clinical Center offered its first clinical research course to a small group of 20 students. Since then, the portfolio of courses and their scopes have expanded, and the NIH Clinical Center has trained more than 30,000 health care professionals around the world through courses in its Core Curriculum in Clinical Research that are available through distance learning.

What courses are available? Currently, the NIH Clinical Center offers two of its three courses in clinical research: the Introduction to the Principles and Practice of Clinical Research (IPPCR) and the Ethical and Regulatory Aspects of Clinical Research (Bioethics). These courses highlight the latest principles in clinical research through a series of lectures taught by NIH, FDA, and industry experts. In response to the needs of working professionals around the world, the IPPCR course will now be offered exclusively online to provide 24 hour access to course content. Additionally, the Bioethics course will include an online option. At this time, there is no formal registration for the third course of the curriculum, Principles of Clinical Pharmacology, however archived content is available online.



What makes NIH Clinical Center Core Curriculum in Clinical Research courses unique? There is no fee to register for these courses, and although the courses are offered online, the NIH Clinical Center uses a cohort model for outside institutions interested in participating in the courses known as *remote sites*. As a remote site, each partnering institution will identify its cohort and the students will be able to view the course videos, review course content, ask questions of faculty utilizing an on-line discussion board and engage in course activities with other registered participants at their institution.

Course Registration Information and Dates:

Ethical and Regulatory Aspects of Clinical Research

Dates: September 28, 2016 – November 16, 2016 (Wednesdays at 8:30AM EST)

Overview: This 7-week course covers essential topics related to the ethics of clinical research and is designed for researchers and research teams, clinical staff, IRB members, and others interested in the ethics of clinical research.

Registration: Visit http://www.bioethics.nih.gov under “Courses, Lectures, & Training.”

Introduction to the Principles and Practice of Clinical Research

Dates: September 12, 2016-April 14, 2017

Overview: IPPCR course is a maximum 30-week, self-paced course designed to educate participants on how to effectively conduct clinical research. All lectures for the 2016-2017 course have been previously recorded and will be available to all registered participants.

Registration: Visit http://cc.nih.gov/training/training/ippcr1.html and select “Registration.”

News from the Clinical Trials Transformation Initiative

Updated AACT Database Now Available for Use

CTTI's State of Clinical Trials Project updates the Aggregate Analysis of ClincalTrials.gov (AACT) database twice annually. The latest version of the AACT database is now available on the CTTI website, along with supporting documents to assist with interpretation. This latest dataset reflects data downloaded from ClinicalTrials.gov on March 27, 2016. Since its initial release, the AACT database has been used to answered many questions regarding the landscape of clinical trials.

IND Safety Reporting Webinar Recording Available

A recording of CTTI's webinar on IND safety reporting is now available. This webinar explored challenging safety reporting scenarios using case studies. We invite you to share the video with colleagues who may encounter such challenging, but common, safety reporting situations, which can create confusion about how best to comply with the FDA final rule. Thank you to our presenters, Patrick Archdeacon (FDA), Annemarie Forrest (CTTI), and Nina Stuccio (Merck)!

Recruitment Recommendations Webinar Recording Available

A recording is now available for the public webinar unveiling of CTTI's recruitment recommendations. The recommendations provide practical solutions for moving recruitment planning upstream to reduce barriers to clinical trial participation. Responses to questions from the webinar's Q&A session are also available online. We encourage you to share these resources with your colleagues in the clinical trials enterprise. Thank you to our presenters, Jonca Bull (FDA) and Elizabeth Mahon (Janssen)!

FDA Final Guidance on Patient Preference Information in Device Decision-Making

The FDA has published a final guidance document, Patient Preference Information – Voluntary Submission, Review in PMAs, HDE Applications, and *De Novo* Requests, and Inclusion in Decision Summaries and Device Labeling. The guidance encourages voluntary submission of patient preference information by sponsors and other stakeholders for consideration as part of FDA's benefit-risk assessment for medical devices. It provides recommendations for collecting and submitting this information, including what may constitute valid scientific evidence. The FDA will host a webinar on the guidance on September 27, 2016; see the CDRH webinar webpage for more information.

Liverpool Trivia Questions and Answers

Last month's Liverpool trivia question:

What mythical creatures sit on top of the Royal Liver Building clock towers near the Liverpool waterfront?

And the answer is:

The Liver Bird (displayed on the left)

The next question is:

What did Liverpudlians have to cross in order to produce superlambanana?

Check the October SCT Newsletter for the answer!