SCT Newsletter Vol. 9

February/March, 2017

President's Message

Welcome back! Nearly all the details for our upcoming meeting in Liverpool are complete. The conference agenda is now available online. The early registration deadline has now passed but you can still register at a discount from the final/onsite registration fee if you register by **March 10.**

If you have attended prior SCT meetings, you will notice a few differences this year. This year everything is online. So we are not mailing out a conference registration envelope with the preliminary program. Pay attention to e-mail reminders if you have not registered yet. You will be able to download the final conference program and we will have an app if you wish to access the program from your portable devices. There will also be a meeting mini-program available at the registration desk on-site. We have made arrangements with a journal to have all contributed abstracts published online so that your podium presentation or poster can be referenced.

In lieu of our traditional sit down lunches, the conference will have boxed lunches available to registrants on Monday and Tuesday to give you more flexibility on how you wish to spend your lunch time. **HOWEVER**, on Monday, May 8, we hope you pick up your boxed lunch and then join us for the SCT Fellows Presentation and Business Meeting. And finally, please register for the meeting banquet, which includes sit-down dinner and musical entertainment. It will be a great way to connect with colleagues and replaces our traditional mixer.

In this issue, the SCT Spotlight column features a story on Scott Rushing, who is a long-standing member of the Society and heads the Web Committee. We have many people in the Society, such as Scott, who have IT backgrounds that provide support to clinical trials ranging from electronic data capture to study management systems to developing applications that use mobile devices to collect data from study participants.

We also include information in this newsletter on our webinar series for 2017, highlights from the February edition of the Society's journal, ***Clinical Trials***, and several announcements from the Clinical Trials Transformation Initiative. I hope you find this issue informative and enjoyable.

Upcoming SCT Sponsored Webinars
by Emily Van Meter Dressler

The Education Committee has put together five webinars for 2017 based on feedback received from attendees in 2016. The webinars cover a wide variety of topics from strategies to increase use of adaptive designs, overviews of phase I designs and master protocols, best practices for clinical trial reporting, and integration of patient reported outcomes. The webinars are an hour long, with approximately 45 minutes for the presentation and 15 minutes for questions. The 2017 schedule include webinars in the months of March, June, August, October and December. Participation in the webinars is a benefit of SCT membership. Registration opens in the Member's Only section approximately one month in advance. Recordings of past webinars can also be found on the Member's Only section.

2017 Webinar Schedule

Date: March 2, 2017
Time: 12:00 - 1:00 pm EST

Presenter: Christopher S. Coffey, PhD, Professor, University of Iowa

Topic: *Increasing the Practicality of Innovative Adaptive Trial Designs*

Description: The traditional approach to clinical trials tends to be large, costly, and time-consuming. Correspondingly, there is a need for more efficient clinical trial design. There is a growing divide between the practicality and feasibility of conducting adaptive designs in industry compared to academia. Since acceptance of adaptive designs will depend on increasing their use across all types of clinical trials, infrastructure building efforts are needed within the academic clinical trials environment. This webinar will discuss how initiatives such as the NINDS-funded Network for Excellence in Neuroscience Clinical Trials (NeuroNEXT) can greatly increase the practicality of using adaptive designs.

Click **Here** To Register

Date: June 1, 2017
Time: 12:00 - 1:00 pm EST

Presenter: Dr. Trish Groves, Director of Academic Outreach, BMJ & Editor-In-Chief BMJ Open

Topic: *How To Reduce Research Waste Through Publishing Trials and Protocols: An Editor's Guide*

Description: Estimates suggest that 85% health research is wasted, usually because it asks the wrong questions, is badly designed, not published, or poorly reported (researchwaste.net/). Full and faithful reporting of clinical trial methods, results, and inferences is vital to tackling this research waste. This tutorial will explore best practice in developing, writing, and publishing trial protocols and clinical trial reports, and will explain what journal editors and peer reviewers look for when appraising such submissions.

Click **HERE** To Register

Date: August 3, 2017 (TENTATIVE)
Time: 12:00 - 1:00 pm EST

Presenter: Michael Brundage, Professor, Queens University, Canada

Topic: *Integrating Patient Reported Outcomes (PROs) in Clinical Trials*

Description: Coming Soon

Click **HERE** To Register

Date: October 5, 2017
Time: 12:00 - 1:00 pm EST

Presenters: Nolan A. Wages, PhD, Assistant Professor, University of Virginia

Topic: *Designs For Phase I Oncology Trials*

Description: This talk will cover dose-finding methodology for Phase I clinical trials in oncology, with a primary focus on model-based designs. Illustrations on how to use model-based methods, such as the Continual Reassessment Method (CRM), to design, implement and carry out a Phase I trial in practice will be provided based on real oncology trials.

Click **HERE** To Register

Date: December 7, 2017
Time: 12:00 - 1:00 pm EST

Presenter: Lindsay A. Renfro, PhD, Associate Professor, Mayo Clinic

Topic: *Master Protocols: Baskets, Umbrellas, and Platform Design For Clinical Trials in Oncology*

Description: In this Webinar, I will provide an overview of the motivation for new types of trial designs that can be classified as master protocols: specifically basket trials, umbrella trials, platform trials, and other related designs. I will discuss and clarify terminology, describe the general framework of each type of design, highlight some advantages and disadvantages, and provide some examples.

Click **HERE** To Register

SCT Spotlight – Scott Rushing

Written By: Leslie McClure

Scott Rushing, Director of Research Information Systems at Wake Forest University School of Medicine, took an interesting path to get to where he is. After training as a computer engineer focused on developing and troubleshooting computer hardware, as well as software engineering, he worked as an engineer developing test controls and circuits in animal studies in a Physiology and Pharmacology lab. He completed a bachelor's degree in Computer Information Systems, but most of his training to do what he does now has been on the job. His specific research interests include the integration of cutting edge technology in clinical trials; exercise interventions using digital technology/wearable devices; and how technology can benefit research in aging populations.

Scott says that his favorite part of being involved in clinical trials is the challenge of trial coordination. He says he enjoys: "the many different facets of what it takes to get a trial initiated and sites trained and functional, and what goes into implementing custom tools for the trial and finding innovative ways of leveraging technology to solve those challenges." On the other hand, there are the limited and sometimes unrealistic timelines in which we have to accomplish those tasks. Always a tradeoff!

Scott has served the on the Board of Directors for the Society for Clinical Trials and has been the Society's webmaster for many years. He has been a member of the Society since the 1990s, and was honored to be recognized as a Fellow in 2010. His favorite SCT annual meeting so far was the meeting in Vancouver, 2010 – he loved the environment, and enjoyed learning about how trials are managed in Asia. For him, the best parts of the SCT annual meeting are meeting new people and reconnecting with member I know, and seeing the new and innovative ways others are managing their clinical research.

When he isn't solving the problems of trial coordination, Scott enjoys golf, although says he has a "love/hate" relationship with it (who doesn't?). He also enjoys photography – landscapes are his specialty – and he likes cooking meals with his family.

Thanks to Scott for his service to the Society, and for his contributions to clinical trials!

CTTI Newsletter Highlights

February 8, 2017

New Common Rule Requirements: CTTI Tools & Recommendations Can Help

Trying to get a handle on the recent changes to the Common Rule? CTTI offers a series of tools and recommendations that can help you meet new requirements affecting informed consent documents and the use of central IRBs, including:

- CTTI Recommendations for Informed Consent
- CTTI Recommendations for Use of Central IRBs for Multicenter Clinical Trials
- A Template IRB Authorization Agreement
- An Evaluation Checklist for use of Central IRBs
- A Considerations Document that clarifies central IRB and institutional responsibilities

21st Century Cures: What to Expect

As part of the NIH Collaboratory's Grand Rounds series, Gregory Daniel (Duke-Margolis Center for Health Policy) presented an overview of the 21st Century Cures Act and its implications for an emerging learning healthcare system. The presentation is available as a 1-hour video with accompanying slides from the NIH Collaboratory website, and focuses on key aspects of the Act affecting the clinical research community, including:

- Provisions affecting quality, comprehensiveness, and interoperability for data sharing
- New resources for evidence development
- Harmonization of human subjects protections and privacy measures
- Creation of a framework for patient-centered medicine

For additional information about the presentation, click here.

Proposed Renovation of ICH E8 and ICH E6

The International Council for Harmonisation (ICH) recently announced that it is requesting public comment on a Reflection Paper outlining a proposed approach to revising and modernizing the ICH Guidelines for clinical trial design, planning, management, and conduct. The planned modernization, which would affect the current *E8 General Considerations for Clinical Trials* and the *E6 Guideline for Good Clinical Practice*, addresses the increasing diversity of study types and data sources that are used to support regulatory and health policy decisions. FDA helped draft the Reflection Paper and supports the effort. Stakeholders are invited to **submit comments by March 11, 2017**.

February 15, 2017 - Press Release

Clinical Trials Transformation Initiative Releases New Recommendations to Improve Studies of Antibacterial Drugs for Children

Durham, NC - The Clinical Trials Transformation Initiative (CTTI) has released new recommendations to improve the quality and efficiency of research studies used to develop antibacterial drugs for children. In addition, many of the suggested strategies and practices could be applied to streamline clinical trials of other types of drugs and medical devices for children.

“Medically, children are not just little adults, and they need access to treatments that have undergone appropriate evaluation for safety and efficacy in children,” said Daniel Benjamin Jr., MD, PhD, MPH, a pediatric infectious diseases specialist at Duke University. “The CTTI recommendations address many of the common challenges of conducting this research, and if applied widely, can help deliver much-needed information and treatments to benefit our young patients.”

These recommendations resulted from a collaborative effort among research sponsors, parents, investigators, clinicians, and regulators from the US and the EMA (European Medicines Agency), who provided practical suggestions for the timing of pediatric trials, streamlining trial design, facilitating informed consent, and fostering global and community partnerships to conduct trials that can improve children’s health.

The time from approval of a new antibacterial drug for use in adults to pediatric labeling can be 5 years or longer, potentially delaying appropriate use of medicines for this vulnerable group. Antibacterial resistance is on the rise in children, and the very young can be particularly susceptible to severe illness or death from these pathogens. Despite the great need for more treatment options, many trial sponsors have challenges enrolling pediatric patients in antibacterial drug trials.

“These recommendations encourage consultation with the FDA on pediatric study plans early in drug development and emphasize the potential utility of global study networks and streamlining trials,” said Sumathi Nambiar, MD, MPH, Director of the Division of Anti-Infective Products at the U.S. Food & Drug Administration (FDA). “Our mutual goal is to provide data in the drug labeling that will better inform the safe and effective use of antibacterial drugs in children.”

The CTTI recommendations are meant to help researchers design trials that are less burdensome for families, as well as to support improved practices for approaching parents for consent during the stressful time of a child’s illness. These recommendations are based on research that showed 80% of clinicians surveyed identified parent concerns about their child participating in research to be a barrier for completing research studies with children. This emphasizes the need for better

engagement with parents throughout a clinical trial, including during the initial design stage. “This work matters to the lives of families like mine,” said Breck Gamel, a parent participant in the CTTI effort. CTTI studied other clinician concerns as well, which helped to identify educational gaps in pediatric labeling and the need for better engagement with other healthcare providers.

Established by Duke University and the FDA as a public-private partnership in 2007, CTTI comprises over 90 member organizations working to develop and drive adoption of practices that will increase the quality and efficiency of clinical trials. More information about CTTI and its projects is available at www.ctti-clinicaltrials.org.

1/24/17

FDA/CDER Announces New Division of Clinical Trial Quality (DCTQ)

The FDA’s Center for Drug Evaluation and Research has created a Division of Clinical Trial Quality (DCTQ) in the Office of Medical Policy Initiatives. The DCTQ’s mission is to develop and promote initiatives that enhance the quality and efficiency of clinical trial conduct, through internal and external collaboration and policy development. DCTQ will also spearhead initiatives to ensure data integrity and to protect human subjects, including activities that enhance science-based inspectional approaches from a clinical trial quality perspective. The new division will be led by Dr. Alyson Karesh.

News from the Society Journal: *Clinical Trials*

By Colin B. Begg

Among the articles featured in the next issue of *Clinical Trials* will be an article by Joshua Gagne addressing the FDA labeled dosing recommendations for renally-excreted drugs for patients with kidney impairments, showing data that the recommendations are usually based on very small numbers of patients and are typically based on pharmacokinetic studies as opposed to clinical outcomes. Vince Mor and colleagues describe the design of a creative, novel cluster randomized trial to test strategies for advanced care planning in nursing homes, laying out in detail the logistical, organizational and regulatory challenges. Finally a group of experts led by Tom Fleming examine current challenges facing data monitoring committees, outlining a number of recommendations. In a commentary Michael Terrin cautions that any policy changes should be evidence-based. As always the issue includes articles on a broad range of topics of interest to the SCT membership.

Register Now For The

38th Annual Meeting of the Society for Clinical Trials

Being Held Jointly With the International Clinical Trials Methodology Conference

ICTMC 2017 4th International Clinical Trials Methodology Conference

SCT Society for Clinical Trials

The agenda for the 38th Annual Meeting of The Society for Clinical Trials, and the 4th International Clinical Trials Methodology Conference is now complete.

The conference will cover topics of interest to all involved in Clinical Trials from Data Management to Recruitment & Retention.

Click **HERE** to View The Conference Agenda

Spotlight On This Year's Keynote Speakers:

Professor Hywel C. Williams, DSc, FMedSci, NIHR Senior Investigator

Hywel became Director of the UK NIHR Health Technology Assessment Programme in 2016, having chaired the HTA commissioning board from 2010-15. The NIHR HTA Programme is the largest UK funder of pragmatic clinical trials and other studies that can directly influence clinical practice in the UK National Health Service.

The HTA Programme is over 20 years old and manages a portfolio of over 400 active studies with an annual spend of around £76 million. About half of HTA work is commissioned following extensive topic identification and prioritisation, and half is researcher-led. Hywel cares passionately about research that is directly relevant to the NHS and has been a champion of public and patient involvement in research.

Click **HERE** to read more.

Dr. Susan Ellenberg, PhD., Professor of Biostatistics

Dr. Susan Ellenberg is Professor of Biostatistics, Department of Biostatistics and Epidemiology, Perelman School of Medicine at the University of Pennsylvania. Her research has focused on practical problems and ethical issues in designing, conducting and analyzing data from clinical trials, including surrogate endpoints, data monitoring committees, clinical trial designs, adverse event monitoring, vaccine safety and special issues in cancer and AIDS trials.

At Penn, in addition to her teaching and administrative duties she serves as senior statistician for several multicenter clinical trials and directs the Biostatistics Core of the Penn Center for AIDS Research and chairs the organizing committee for the annual Penn conference on statistical issues in clinical trials.

Click **HERE** to read more.

Dr. J. Michael Gaziano, MD, MPH

Principal Investigator, Million Veteran Program and Scientific Director of the Massachusetts Veterans Epidemiology Research and Information Center (MAVERIC), VA Boston Healthcare System; Chief, Division of Aging, Brigham and Women's Hospital, Professor of Medicine, Harvard Medical School, all in Boston, Massachusetts.

Dr. Gaziano is a preventive cardiologist and internationally recognized chronic disease edidemiology of chronic diseases using large data sources. He has a particular interest in the lifestyle, metabolic, biochemical and genetic determinants of common chronic disease such as cardiovascular disease and cancer.

Click **HERE** to read more.

Click HERE To View The Conference Agenda

Register Now!

Annual Meeting Venue & Accommodations

ACC Liverpool is a multi award-winning building located on the world-famous Liverpool waterfront. It sits alongside the Grade I listed Albert Dock complex and World Heritage Site on the eastern bank of the river Mersey, in the heart of Liverpool City Centre.

For more information about accommodations and visiting Liverpool, click here

Liverpool Trivia

“What song gave The Beatles their first US number 1 hit?”