From the Newsletter Editor

Have you taken advantage of the early bird rate and registered for the 39th annual meeting of the Society for Clinical Trials?

As you know the meeting will be held in Portland, Oregon, May 20-23, 2018. We are accepting early bird registrations through April 2, 2018. The meeting hotel is the Hilton Portland & Executive Tower. We also have some great late-breaking news if you are a US government employee. We have now been able to secure a block of rooms at the meeting hotel at the government rate! Check the meeting registration website for more information.

In this issue, we feature some highlights of our upcoming meeting as well as webinars we have planned throughout 2018. A big thank you to Lynda Constable and her webinar committee for planning a superb selection of talks. We also introduce you to some of the people who work "behind the scenes" to make sure SCT keeps running smoothly. We have articles on our management company, Fernley & Fernley, as well as our Webmaster, John Hepler.
39th Annual Meeting of the Society for Clinical Trials
May 20-23, 2018

Conference Registration Fees:
Register today to take advantage of early bird rates!

Member Early Bird - $485.00 (until April 2, 2018)
Non Member Early Bird - $685.00 (until April 2, 2018)
Member Regular - $585.00
Non-member Regular - $785.00

For full list of registration fees - click here

Register here
Featured Sessions at the 39th Annual Meeting
By Kaleab Abebe, Program Chair

Once again, we have a great diversity of high interest topics that will be featured at our annual meeting. In this newsletter, we feature some invited sessions scheduled for the first day of the meeting.

TITLE: THE MICRO-RANDOMIZED TRIAL DESIGN FOR DEVELOPING ADAPTIVE MOBILE HEALTH INTERVENTIONS

Session Organizer: Ashley Walton  (ashley_walton@fas.harvard.edu)
Session Chair: Tianchen Qian  (qiantianchen@fas.harvard.edu)

ABSTRACT: Micro-randomized trials (MRTs) are a clinical trial design for use in providing data to inform the development of mobile health interventions. MRTs are a type of sequential factorial design in which multiple treatment components are randomized and in which some of the treatment components may be randomized sequentially in time. Thus an individual can be randomized between different options for the treatment component on each of many times resulting in 100’s or even 1000’s of randomizations per individual during a study. Examples of treatment components in mobile health include whether or not to provide a reminder to take medication and/or different ways to frame the reminders, whether or not to provide suggestions with directions for relaxation exercises and different ways to visualize progress towards health-related goals like daily step count. Treatments are often delivered using notifications on a smartphone or a smart wearable and are delivered in the context of an individual’s every-day life. MRTs provide data for use in assessing when and in which context it is most effective to deliver treatments as part of a mobile health intervention. For example, in a MRT used for developing a mobile health physical activity intervention, activity suggestions may be more effective than no suggestion on weekdays but be equally effective as no suggestion on weekends. Or activity suggestions may be more effective than no suggestion at times for which the individual’s calendar is not very full. Addressing these types of questions helps investigators decide when it is worthwhile to interrupt the individual to provide the suggestion. The within-person randomization in MRTs is also key to investigating how the effect of a treatment component such as whether to provide an activity suggestion or not varies over time. In general MRTs can provide data that can be used to lead to insights not only about how the effects of time-varying treatments vary over time for a single individual as s/he progresses through the mHealth intervention, but also how these vary between individuals assigned to different treatments at different times. In this session, speakers who are presently conducting MRTs or have conducted MRTs will describe the rationale behind their studies, discuss challenges and present results. The four MRTs are BariFit, Smart Weight Loss, SARA and JOOLHealth. Each presenter will describe the different scientific questions addressed by their MRT, issues and challenges in addressing those questions, and how the resulting empirical data can inform the development of their just in time adaptive mHealth intervention.

SPEAKERS:
Predrag Klasnja
Inbal Nahum-Shani
Mash Rabbi
Niranjan Bidargaddi
ABSTRACT: Introduction: Most clinical trials enroll subjects and follow them for a limited time (typically 1-5 years) and are designed to address specific questions, such as the effect of an intervention with respect to a primary outcome (e.g. cardiovascular disease incidence). Although of interest, investigating other secondary outcomes (e.g. mortality, cancer) is challenging due to the limited follow-up. A long-term follow-up study of a cohort after completion of a study allows for the investigation of such outcomes and provides a more thorough description of the effect of an intervention on the entire burden of disease.

Many scientific and management challenges are associated with conducting long-term follow-up studies. This session will present how three different impactful studies with varying study designs and populations and long-term follow-up have dealt with changes over time. Specifically, changes in primary and secondary aims, study design, outcomes and exposures of interest, data management and collection, electronic records and registries, study organization, and funding mechanisms over time. The statistical methods to account for these long-term changes will be described. Each presenter will also discuss issues related to patient retention and investigator/staff turnover in studies that span decades. The challenges and approaches experienced in these three studies are relevant to many longitudinal studies.

SPEAKERS:
Barbara H. Braffett
Ian Ford
Janet Tate
Ionut Bebu
John M. Lachin

ABSTRACT: Session Type: This session will be structured as a panel consisting of three presentations by academic clinical investigators followed by three discussants who will comment on the challenges of coordinating clinical trials and solutions for success. The speakers’ experience will represent a new investigator (early career), a mid-career investigator (serving as PI of one multicenter clinical trial) and a senior investigator (PI or multiple PI of several multi-center clinical trials). Each speaker will share their career path along with their research challenges and successes, particularly in the current practice environment. These presentations will be followed by three discussants who are well-seasoned in conducting/coordinating multicenter clinical trials. They will
comment on the speakers’ presentations as well as offer key advice for successful trial coordination from a variety of perspectives.

Description: The academic clinical investigator who leads a multicenter clinical trial has a daunting task. Balancing clinical research and clinical duties can be challenging particularly in the current environment of fee-for-service models and relative value units (RVUs). This session will highlight the realities of being an academic clinical investigator and leading a multicenter clinical trial, and the importance of collaboration. Following the presentation from three academic clinical investigators, three discussants representing clinical, biostatistics and project management will comment on the challenges and propose best practices. This will be followed by a panel discussion with a question answer session.

Audience: Although this session highlights the clinical principal investigator, I feel it does have important value to several members of SCT as collaborating colleagues. As a biostatistician, I have noticed a repeating discussion with my clinical collaborators – not enough protected research time to commit to the details of developing and running a multicenter trial. Because the collaboration between the clinical investigator and biostatistician is critical to the success of any trial, I believe biostatisticians (as well as research team members such as project and data managers) would be interested in attending this session to bring information back to clinical colleagues in their research settings.

SPEAKERS:
Holly Hinson
Will Meurer
Pooja Khatri
Ed Jauch
Irene Ewing
Valerie Durkalski-Mauldin

DAY/TIME: Monday, May 21 @ 4-5:30

TITLE: COVARIATE CONSTRAINED RANDOMISATION FOR THE DESIGN OF PARALLEL AND STEPPED WEDGE CLUSTER TRIALS

Session Organizer: Elizabeth L Turner   (liz.turner@duke.edu)
Session Chair: Andrew Forbes   (andrew.forbes@monash.edu)

ABSTRACT: It is common for parallel-arm cluster randomised trials (CRTs) and stepped-wedge (SW) CRTs to enroll a small number of clusters (e.g. < 20 clusters). In this case, the chance of imbalance of baseline covariates for intervention and control conditions is non-negligible. This threatens the internal validity of the trial and reduces power and precision when such covariates are predictive of the outcome. To address the problem of baseline imbalance of covariates in the design phase of parallel-arm and SW-CRTs, a restricted randomisation procedure could be used. Examples include matching and stratification, which are commonly used for the design of parallel-arm CRTs (Ivers 2005). Yet, these techniques have several limitations (e.g. difficulty handling continuous covariates and accommodating multiple covariates) and there is little literature on their application to SW-CRTs.
An alternative restricted randomisation approach that has been proposed for two-arm parallel CRTs is covariate constrained randomisation (CCR; Raab 2001, Moulton 2004). Despite its existence for more than a decade, CCR has been rarely used in practice, possibly because of lack of an easy way to implement the procedure. Yet it offers many benefits thanks to its flexibility to accommodate multiple covariates, both categorical and continuous. These benefits extend to the SW-CRT design but present a range of additional complexities compared to implementation for the two-arm parallel CRT. These complexities arise from the fact that in SW-CRTs the contribution of each cluster-period to the treatment effect estimate differs depending on the location of the cluster-period in the design (Matthews 2017; Girling 2016). Cluster-periods which are closer to the time at which the cluster transitions from the control to intervention condition, for example, carry greater weight than other cluster-periods. Covariate balance criteria used to perform CCR must therefore consider not simply the average of important predictor covariates (such as cluster size) across control and intervention conditions but rather the weighted average of important predictor covariates where the weights are proportional to the weight that the cluster-period provides to the treatment effect.

Overview of session

Our goal is to enable attendees to gain an understanding of key features of covariate constrained randomisation and to leave with a knowledge of tools available to implement CCR for both the two-arm parallel CRT and the SW-CRT designs. To do this, we will include four talks followed by a panel discussion with the 4 presenters:

1. An introduction to covariate constrained randomisation for parallel two-arm CRTs.
2. Challenges of covariate constrained randomisation for SW-CRTs.
3. Balance metrics for covariate constrained randomisation for SW-CRTs.
4. Practical implementation of covariate constrained randomisation for SW-CRTs.

Summary

With the widespread use of CRTs (both parallel-arm and stepped-wedge) with small numbers of clusters to address questions on effectiveness of complex interventions, it is important to be able to design those trials to avoid baseline imbalance on baseline covariates. Through our proposed session in which all authors have jointly contributed to the research presented, we hope to provide an intuitive and comprehensive overview of the method and to provide attendees with practical tools to be able to go away with the knowledge of how to implement the proposed methods. We propose to use the final 20 minutes of the session for a moderated panel discussion with time for questions from the audience.

SPEAKERS:
Elizabeth L Turner
Andrew Copas
Fan Li
Karla Hemming

DAY/TIME: Monday, May 21 @ 12:45-2:15
Dr. Wenle Zhao, Professor of Biostatistics in the Department of Public Health Sciences at the Medical University of South Carolina will be presenting this exciting webinar - "Randomization Methods for Multi-center Trials"

Register here

Introduction to the March, 2018 Webinar:

In this SCT Webinar, three new randomization designs will be presented as better alternatives to the commonly used permuted block design and the minimization method, with the purpose of enhancing allocation randomness, effectively prevent serious imbalances in large number of baseline covariates, and accurately target any unequal allocations in trials with response adaptive randomization. The block urn design offers the same imbalance control as the permuted block design, but significantly reduces the proportion of deterministic assignments, and therefore reduces the risk of selection bias. The mass-weighted urn design allows any desired unequal allocations be accurately targeted. It works for trials with two or multiple arms. The minimal sufficient balance method drops the zero-imbalance tolerance attitude of the minimization method. It aims to maximize the treatment allocation randomness while prevent serious imbalances in large number of baseline covariates. All these three randomization designs are published and have been implemented in several large multicenter clinical trials. This Webinar will discuss the implementation procedures for these three randomization methods, and compare their statistical properties to those of the permuted block design and the minimization method.

About the speaker: Dr. Wenle Zhao is a professor of biostatistics in the Department of Public Health Sciences at the Medical University of South Carolina. He is the associate director of the Data Coordination Unit. Dr. Zhao obtained his PhD in biostatistics at MUSC in 1999, and has been in the clinical trial field since then. His research focus includes subject randomization designs and clinical trial management information system development. He is the primary developer of the WebDCU system which has provided full scope trial data and operation management support for more than 60 clinical trials, including all trials in three NIH funded clinical trial networks.
The Society of Clinical Trials is extremely fortunate to have John Hepler among our ranks. Not only is John a regular contributor to clinical trials through his job as a Senior Analyst/Programmer at the Wake Forest School of Medicine (Department of Public Health Sciences, Biostatistics), he also works closely with the SCT Board of Directors and staff to ensure that all of the web-based materials and applications are in good working order. John came to this role through an unorthodox path – he has a BFA in Graphic Design/Photography, and an MA in Liberal Studies (Documentary Film Focus). He has done work on research information systems for studies related to cardiovascular disease, diabetes, genetics, aging, HIV and Alzheimer’s disease. John enjoys being involved in clinical trials because of the possible discovery of medical advancements and the opportunity to develop innovative approaches to research data systems. As he says: “Creative juice can be so euphoric” (see above for his background!). As many of us might agree, John’s least favorite part of trials are meeting that are unproductive or drag on for way too long.

John has been a member of the SCT for 8 years, and in addition to his work as a web designer/developer for the Society, he has been involved with many committees, including reviewing IT-focused abstracts for the annual meetings. His behind the scenes work also bring him to all the meetings as the videographer, allowing SCT to archive the annual meeting events. John’s favorite annual meetings (so far) are Liverpool in 2017 and Vancouver in 2011 – both wonderful venues with energetic attendees.

John would encourage young researchers just starting off in the field of clinical trials to consider the possibilities of novel research data systems, and to allow developers to originate innovative solutions to problems that may arise – a message consistent with the team environment many of our members have already encouraged!

While he is an active researcher and SCT member, John’s number one focus and joy is raising his two amazing sons, Jackson (10) and Austin (4), together with his lovely wife of 18 years, Sara. He also enjoys creative outlets such as carpentry, playing guitar and videography, and being outdoors golfing and doing other forms of exercise.

The SCT is very lucky to have John contribute his scientific expertise to our community, both as a researcher and as a contributor to the society. Thanks to John for all he does to help us all do better science!
11th Annual University of Pennsylvania
Conference on Statistical Issues in Clinical Trials:
*Estimands, Sensitivity Analysis and Missing Data in Clinical Trials*
Wednesday, April 18, 2018 (8:00 A.M. to 5:00 P.M.)

REGISTRATION NOW OPEN!

**Click to REGISTER**

*Or paste this URL into your browser:*
http://www.cceb.med.upenn.edu/events/annual-conference-statistical-issues-clinical-trials

Please register early. This conference has sold out repeatedly over the past decade.

### SPEAKERS AND TOPICS

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### PANELISTS

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<td>EMMES Corporation</td>
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<td>Roderick J. Little</td>
<td>University of Michigan School of Public Health</td>
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<td>Geert Molenberghs</td>
<td>Universiteit Hasselt and Katholieke Universiteit</td>
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<td>Frank Rockhold</td>
<td>Duke University, Duke Clinical Research Institute</td>
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<td>Jay Siegel</td>
<td>Retired (formerly FDA and Johnson &amp; Johnson)</td>
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<td>Eric T. Tchetgen</td>
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<td>Andrea B. Troxel</td>
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Open Mike

NIH Announces Inclusion Across the Lifespan Policy
Posted on January 24, 2018 by Mike Lauer

Last month, NIH announced a revision (NOT-OD-18-116) to a decades-old policy originally conceived in response to concerns that children were not appropriately included in clinical research. These changes broaden the policy to address inclusion of research participants of all ages, and as discussed at the last Advisory Committee to the NIH Director meeting, will apply beginning in 2019 to all NIH-supported research involving human subjects. Our goal is to ensure that the knowledge gained from NIH-funded research is applicable to all those affected by the conditions under study. Continue reading →

Continuing to Strengthen Inclusion Reporting on NIH-funded Phase III Trials
Posted on January 8, 2018 by Mike Lauer

Much has been learned about how sex and race may contribute to differences in health outcomes and physiologic conditions (Clayton, 2014). We know that, for example, a specific drug used to treat insomnia requires different dosing for women and men. African Americans with hypertension are
more susceptible to stroke than whites with the same blood pressure levels (Howard, 2013). But in many cases, findings from potentially informative stratified analyses may not be widely available. Less than a third of NIH studies required to analyze sex/gender and race/ethnicity have been found to publish sex-stratified results in peer-reviewed journals (Foulkes, 2011). Continue reading →

Top Stories

New to eRA Commons?
Sometimes when you are trying something for the first time, it can appear to be somewhat confusing, intimidating, and possibly overwhelming. eRA is continuously developing new resources for our applicants and grantees to eliminate that perception. Recently eRA has focused on ways to help people new to navigating eRA Commons for the NIH grant application, award, and reporting processes. Because these processes require attention to detail and patience, it can often be overwhelming for those who have never done it before. .... Continue reading →

You Ask, We Answer

How do you define a “study” for the purposes of providing information on the PHS Human Subject and Clinical Trial form and registering in ClinicalTrials.gov?
Our application instructions provide guidance to submit a study record for each protocol. When in doubt, NIH supports lumping several aims or hypotheses into a single study record, to the extent that makes sense for your research. Have other questions related to the new PHS Human Subject and Clinical Trial form or NIH clinical trial policies? Find more FAQs and their answers at grants.nih.gov. Continue reading →

Where Can I Find the New PHS Human Subjects and Clinical Trials Information Form?
Like all NIH application forms, the new PHS Human Subjects and Clinical trials Information form is accessed through the submission method you are using. ASSIST, Workspace and all system-to-system solutions provide a way to access and complete the forms. .... Continue reading →
CTTI Celebrates a Decade of Impact

We enjoyed seeing so many of you at the CTTI celebration dinner and public symposium last week. The symposium featured a lineup of distinguished guest speakers, case studies, and a vibrant exchange of ideas around the future of clinical trials. Slides presented at the symposium are now available on the CTTI website. Thank you to everyone who participated in these events, especially speakers. We welcome your feedback via a survey, which you should have received earlier today, as well as directly to Pam or any CTTI staff member.

PROJECT UPDATES

New CTTI Publications

We are pleased to share that the results and recommendations from several CTTI projects have been recently published.

*The recommendations from the Recruitment Project were recently published in Contemporary Clinical Trials.* Recommendations focus on three essential areas: trial design and protocol development, trial feasibility and site selection, and communication planning. CTTI also developed resources to help facilitate adoption of the recommendations, including methods for identifying stakeholders and considerations for patient-reported outcomes. Together, the recommendations and tools are designed to guide efforts in clinical trial recruitment planning and identify areas for continual improvement.

*Results from the MCT Novel Endpoints Project were recently published in Digital Biomarkers.* The article provides a detailed accounting of where the field is currently, allowing researchers to see what measures exist for using or developing technology-derived endpoints, how they are being used, and how to access relevant literature. The article offers suggestions for incorporating mobile technology into interventional research—such as consolidating evidence supporting the clinical meaningfulness of specific technology-derived endpoints, and standardizing the use of mobile devices in clinical research to measure these endpoints.

*Recommendations from the ABDD Peds Trials Project were recently published in Contemporary Clinical Trials.* Through extensive discussions and investigations by stakeholders representing the FDA, drug developers, academia, clinical research networks,
parents, and care providers, barriers to pediatric antibacterial drug trials were identified, and suggestions for addressing these barriers were developed [6]. The key consensus elements that resulted from this effort belong to 5 major areas: early planning, protocol development and trial design, informed consent, healthcare provider engagement, and reporting and labeling.

NEWS & ANNOUNCEMENTS

CTTI Welcomes New Communications Specialist

Kristi Geercken has joined CTTI as a communications specialist. Kristi has many years of online communications experience and will maintain our website, member site, social media, and email channels—playing a valuable role in supporting CTTI’s overall communications strategy and driving adoption efforts. Please join us in welcoming Kristi!

FDA Commissioner Shares New Steps Taken to Enhance Transparency

As part of its efforts to enhance transparency, the FDA is exploring new ways to build on its obligation to share information about product approval decisions. Clinical study reports (CSRs) are one area the FDA is evaluating as a way to release information that may better inform scientists, providers, and patients. On Tues., Jan. 16, the FDA launched a pilot program to evaluate whether disclosing certain information included within CSRs following approval of an NDA improves public access to drug approval information. Read the announcement by FDA Commissioner Scott Gottlieb.

Effective Date for Common Rule Revisions Delayed by Six Months

The U.S. Department of Health and Human Services and 15 other federal departments and agencies have announced an Interim Final Rule (IFR) that delays by six months the effective date and general compliance date of the revisions to the “Federal Policy for the Protection of Human Subjects” (also known as the Common Rule). Most provisions in the revised Common Rule were scheduled to go into effect on Jan. 19. The IFR delays the effective date and general compliance date to July 19, providing regulated entities additional time to prepare to implement these revisions. Until that date, regulated entities will be required to comply with the pre-2018 Common Rule.

FDA Clarifies Information on Research Subject Payment and Reimbursement

The FDA published updates to the Payment for Research Subjects: Information Sheet on Mon., Jan. 29, to clarify that reimbursement for travel expenses to and from the clinical
trial site and associated costs such as airfare, parking, and lodging are acceptable under current practices. This update is in response to inquiries received from stakeholders about appropriate reimbursement practices. The title of this information sheet has been revised to “Payment and Reimbursement to Research Subjects” to reflect these changes.
Get to Know Fernley
By Tia Diggs, Executive Director

Have you ever wonder who the person is who answers the SCT phone line or who plans the conferences?

Sit back and learn more about Fernley & Fernley your association management company.

Meet the Team –

Executive Director - Tia Diggs, MBA has been a part of the Fernley family since 2013 and joined the SCT family in April 2017. During her time at Fernley, Tia has managed several trade associations and a few professional societies. She helps each client move into the next realm of success. In her spare time, Tia enjoys spending time with her husband and two daughters, Jordyn (15) and Jailyn (7) and their cat Kiara. She is also an avid Pittsburgh Steelers fan, waving her Terrible Towel every chance she gets. Additionally, she is involved in her community through her work with Alpha Kappa Alpha Sorority, Inc. Have a question for Tia or would like to get to know her more, send her an email at tdiggs@fernley.com, she is happy to know more SCT members.

Associate Director - Mary Keller joined Fernley and became part of the SCT Team in October, 2017. Mary has spent over fifteen years serving the volunteer community in Nonprofit Association management, volunteer and client engagement, team leadership and project development. Mary has significant experience travelling internationally, working with global clients and multi-national companies, government agencies, Board of Directors and Advisory Councils where successful engagement and client satisfaction is mission critical. A native New Yorker, Mary adopted Pennsylvania as her home 17 years ago, is the proud grandmother of 7 and enjoys a late fall motorcycle ride just to watch the leaves turn. Feel free to contact Mary at mkeller@fernley.com
Meeting Planner – Nicolette Pelbano is a dedicated Meeting Manager with over 3 years experience in association meeting planning and holds a Masters of Business Administration from Arcadia University. She joined the Fernley team in 2014 and has been a part of the SCT family since the start of her career at Fernley. Nicolette has strong communication skills geared towards both event leadership and providing outstanding customer service. She thrives when working in a fast-paced atmosphere, is organized, highly motivated, and detail oriented. In her spare time, Nicolette enjoys reading and spending time with her family, and is also an avid Harry Potter fan.

In addition to the core team, there are many others behind the scene that help advance for mission of SCT. They include:

The Accounting Department (From left to right)
Shawn Jackson, Accounts Receivable
Kevin Sitoski, Director of Finance
Zina Smith, Staff Accountant
Mike Betz, Accounts Payable

The Member Services Department (from left to right)
Dave Polsz, Director of IT
Mike Mirabella, Director of Member Services
Together we work as a team to help SCT member pay dues, register for the conference, post jobs and anything that brightens the day of our members.

Founded in 1886, Fernley & Fernley is one of the most distinguished association management companies in the nation. Having received charter accreditation by the Association Management Company Institute (AMCI), exemplifies our commitment to quality and dedication to our industry. At Fernley & Fernley we recognize that each of our clients is unique, with their own special needs. We work hard to understand each client's specific agenda and align our services and staff to meet those goals and objectives. With the professionals at Fernley & Fernley, you can be confident that you have partnered with an association management company that will allow you to focus on your mission, while we manage the details.
SAVE THE DATES
SCT UPCOMING MEETINGS

New Orleans May 17 - May 23, 2019

Baltimore May 15 - May 20, 2020

Chicago May 14 - May 20, 2021