Virtual Program
Guide
Welcome!

It gives me great pleasure to present the 2020 SCT Virtual Program. While we cannot meet and network in the traditional way this year, we are delighted to offer an exciting virtual program to fill the void until we can meet again in person, hopefully next May in Chicago.

The virtual program consists of a number of Invited and Contributed Sessions along with Educational Workshops built around our theme of "Enhancing and Enabling the Clinical Trials Ecosystem through Interdisciplinary Collaborations". A theme that resonates that much stronger in the face of the COVID-19 pandemic in that conceiving, executing, and disseminating rigorous trials requires the talents and inclusion of many stakeholders and decision-makers.

The first phase of our Virtual Program took place in May with the successful web presentations of our Student Scholarship Sessions along with the David S. Sackett Trial of the Year award. The next phase of our program takes place over the months of September 2020 to April 2021. Along with the webinars and Contributed Session presentations on our website, we also had a special session on July 8th to recognize our 2020 Fellows.

We are grateful to everyone that helped make the Virtual Program possible including members of the Virtual Program Task Force chaired by Susan Halabi, our webmaster John Hepler, and Kevin Bragaw and Angie Stark at EAI. Most importantly, we thank those who submitted successful sessions to the SCT Annual Meeting and agreed to present their accepted material over the coming months. Collectively, our dynamic, interdisciplinary Virtual Program will appeal to all our members.

As always, please encourage your colleagues and trainees to join the Society so they too can benefit from the value our Virtual Program has to offer.

I wish everyone well during these challenging and unprecedented times.

My best,

Dean Fergusson
2020-2021
SCT Past President
THANK YOU TO OUR CORPORATE SPONSORS!

**Platinum Sponsors**
- Janssen
- Abbvie

**Gold Sponsors**
- **ASTRAZENECA**
  - AstraZeneca is a global, science-led biopharmaceutical business and our innovative medicines are used by millions of patients worldwide.
- **GW BIOSTATISTICS CENTER**
  - The GW Biostatistics Center has a 47-year history of leadership in practice-changing clinical trials and biostatistical methodology research. Center research has been recognized in reports to the US President and Congress and resulted in over 60 NEJM publications.
- **FRONTIER SCIENCE FOUNDATION**
  - Frontier Science Foundation is a non-profit research organization dedicated to the improvement of data management and statistical quality in clinical trials and medical research.

**Silver Sponsors**
- **CYTEL**
  - We provide unrivaled biostatistics and operations research knowledge to our customers. Our knowledge is available in the form of both software and services. This knowledge, supported by our trial implementation capabilities, is what makes us different. We are leaders in the design and implementation of adaptive clinical trials.
- **JAEB CENTER FOR HEALTH RESEARCH**
  - The Jaeb Center for Health Research was established in 1993 as a freestanding, nonprofit coordinating center for multi-center clinical trials and epidemiologic research. The Jaeb Center's focus is eye disorders or type 1 diabetes.
- **EMMES**
  - EMMES collaborates with clients to produce valued, trusted scientific research. We are passionate about making a difference in the quality of human health and have supported more than a thousand studies across a diverse range of diseases since our formation in 1977.

**Bronze Sponsor**
- **JOURNAL OF CLINICAL MEDICINE**
  - JCM (IF = 5.583) is an international scientific open access journal, providing a platform for advances in clinical practices, the study of direct observation of patients and general medical research. The journal is indexed by SCIE and PubMed.
Thank you to the SCT 2019-2020 Committee Chairs and Co-Chairs
Thank you to the SCT 2019-2020 Committee Chairs and Co-Chairs

Jonathan Cook
Co-Chair
Program Committee

Sharon Yeatts
Chair
Student Scholarship Committee

Lee McDaniel
Co-Chair
Student Scholarship Committee

Scott Evans
Chair
Trial of the Year Committee
Thank you to the SCT Program Task Force

Susan Halabi  
2020-2021  
SCT President

Dean Fergusson  
2020-2021  
Past President

Domenic Reda  
SCT Secretary

Li Chen  
SCT Treasurer

Jody Ciolino  
Past Chair  
Membership Committee

Dixie Ecklund  
Past Co-Chair  
Membership Committee
Thank you to the SCT Program Task Force

Jonathan Cook
2020 Chair
Program Committee

Toshi Hamasaki
2020 Co-Chair
Program Committee

Abby Shoben
Past Chair
Program Committee

Michael Grayling
2020 Chair
Education Committee

Sin-Ho Jung
2020 Co-Chair
Education Committee

Yves Rosenberg
Past Chair
Education Committee

Liz Garrett-Mayer
Past Chair
Communications Committee
Created in 1978, the Society for Clinical Trials is a multidisciplinary society with membership spanning myriad disciplines that are all critical to the field of clinical trials: biostatistics, clinical areas, IT and systems, data management, ethics, regulatory bodies, behavioral science, research coordination, patient partners, health outcomes researchers, and many others. Our members come from academia, industry, government and non-profit research and advocacy groups.

Society for Clinical Trials (SCT) is structured so that professionals with diverse interests and backgrounds can enjoy the many and varied benefits of membership. These benefits are designed to provide the highest quality education programs and other resources that will enhance and aid in the development of careers in clinical trials.

We welcome you to join us!

SCT membership benefits include:

- Networking opportunities
- Continuing education opportunities
- Substantially discounted registration fees
- Professional development
- Societal outreach and communication

The SCT Administrative Office is located at:

85 W Algonquin Road, Suite 550
Arlington Heights, IL 6000
Phone: (847) 427-8010
Fax: (847) 427-9656
Email: info@sctweb.org
**Please note:** You must be logged into the Members area of www.sctweb.org to view all the Program content.

**How to access the Virtual Program**
- Registration is required for members, non-members and students in order to attend this event.
- All current SCT members can attend for free!
- All verified Students can purchase this Educational Content for the low price of just $50!
- Non-Members can purchase this Educational Content for the low price of $170!
- Access to the recorded sessions will be provided via this Program Guide that includes links to each recorded session that you can access through April, 2021.
- You are encouraged to check the website for the latest version Program Guide and download this document to your desktop to keep as reference for the recorded sessions.

**How to access the Webinars**
- Once you have registered for the Virtual Program, SCT will register you for each webinar that is scheduled through April 2021.
- You will receive an email confirmation on a monthly basis from SCT (via Go To Webinar) that will contain your dial-in information as well as a personalized link to access that month’s webinar.
- We will also send out notifications every month a webinar is scheduled that will contain all the information for that session, including the scheduled presenters.
- **Note:** if SCT has registered you for the webinar, you do not need to re-register.

*Please note that SCT will not send out calendar invites for the webinars that you have been registered for. We encourage you to add the webinar that you have been registered for to your own calendar via your confirmation email.*

**What this Virtual Program will contain**
The program will contain content submitted for the SCT Annual Meeting that was cancelled, including:
- Recorded Presentations from Contributed Sessions
- Webinars from Education Workshops and Tutorials
- Webinars from Invited Sessions
- Recorded content including the Annual Business Meeting, Trial of the Year Presentation, Sylvan Green, Chalmers Awards Presentations, and presentation of the 2020 Fellows of SCT.
Virtual Program Guide

Please note: You must be logged into the Members area of http://www.sctweb.org/ to view all the Program content.

Please contact info@sctweb.org if you encounter issues logging in.

Virtual Invited Sessions

Adjusting for prognostic baseline variables to improve precision and power in randomized trials ............................................................. 16
The win ratio approach to composite endpoints ............................................................................................................................................. 17
Methodological advances in the conduct of behavioral clinical trials: an international behavioural trials network (IBTN) update .......................................................................................................................... 18
The design and implementation of master protocols using examples from oncology clinical trials ............................................................................................................. 19
Strategies to collaboratively manage protocol deviations in multi-site clinical trials ................................................................................................................................... 20

Virtual Educational Workshop Sessions

Web-based applications for early-phase trials designs ................................................................................................................................................................................. 21
Using meta-analysis to combine results from clinical trials. ................................................................................................................................................................. 22
From Ideas to Efficacy: Designing & Optimizing Behavioral Treatments for Chronic Diseases .......................................................................................................................................................................................... 22
How to design and run an adaptive clinical trial: new resources and easy-to-use software ........................................................................................................................ 23
Improving Quality and Controlling Costs in Clinical Trials Using Responsive Survey Design .......................................................................................................................................................................................... 23

Category: Data Management

Automation of clinical trial statistical monitoring ................................................................................................................................................................................. 24
Primary Author: Chris Rogers ........................................................................................................................................................................................................................ 24
Buy or Build: Considerations for a robust data management system used in Phase 3 Clinical Studies .......................................................................................................................................................................................... 24
Primary Author: Lan Zhang ............................................................................................................................................................................................................................ 24
Central Statistical Data Quality Monitoring in Clinical Studies: an application to the ROLEX registry .......................................................................................................................................................................................... 25
Category: Information Systems & Technology

Comparing a Multimedia Interactive Virtual Informed Consent (VIC) to Traditional Paper-based Method: A randomized Clinical Trial
Primary author: Fuad Abujarad

Do study participants complete electronic questionnaires?
Primary author: Lucy Culliford

Extracting Unique Insights by Mining Single Nucleotide Polymorphisms (SNPs) from ClinicalTrials.gov and Applying the Human Phenotype Ontology
Primary author: Shray Alag

Using an Interdisciplinary Approach to Develop a Medical Record Abstraction and Quality Assurance Process for Generating the Primary Outcome in a Multi-Site Implementation Study
Primary author: Phoebe R. Gauthier

Real-Time Risk-Based Monitoring in Clinical Trials Using Business Intelligence Tools (Unlikely Companions)
Primary author: Levent Bayman

Management and sharing of individual participant deidentified data (IPD)
Primary author: Elizabeth Wright

Category: Involving Research Partners

Data from Expanded Access: Opportunity for Real World Evidence Collection and Insights?
Primary author: Kelly M. Folkers

IMPAACT 2016: Interdisciplinary Collaboration at Multiple Levels
Primary author: Meredith G. Warshaw

Category: Personalize Medicine

The Association between Genotypes and Post Cardiac Surgery Bleedings: A substudy of the Steroids in Cardiac Surgery Trial (SIRS)
Primary author: Fei Yuan

Category: Recruitment & Retention

Clinical Trial Design, Protocol Implementation, and Secular Treatment Trends for Persons Living with HIV and Opioid Use Disorder: Lessons Learned from a National Institute on Drug Abuse Clinical Trials Network
Primary author: Jessica Guyer

Interdisciplinary collaboration in review of national coverage analysis (NCA) documents to enhance clinical trial site activation and recruitment of participants
Primary author: Lawrence R. Ragard
<table>
<thead>
<tr>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implementation, recruitment, and retention for an emergency department initiated buprenorphine intervention for opioid use disorder</td>
<td>28</td>
</tr>
<tr>
<td>Primary author: Elias M. Klemperer</td>
<td></td>
</tr>
<tr>
<td>Potential participants’ views on the factors that impact on their decision to take part in a randomised trial: A qualitative evidence synthesis</td>
<td>28</td>
</tr>
<tr>
<td>Primary author: Catherine Houghton</td>
<td></td>
</tr>
<tr>
<td>Vital Status Ascertainment in a Long-Term Clinical Study of Type 1 Diabetes</td>
<td>29</td>
</tr>
<tr>
<td>Primary author: Victoria R. Trapani</td>
<td></td>
</tr>
<tr>
<td>Category: Statistical Analysis</td>
<td></td>
</tr>
<tr>
<td>A novel method of reporting adverse effects in cancer clinical trials</td>
<td>29</td>
</tr>
<tr>
<td>Primary author: Guilherme S. Lopes</td>
<td></td>
</tr>
<tr>
<td>Analysis of multicenter clinical trials with very low event rates</td>
<td>29</td>
</tr>
<tr>
<td>Primary author: Jiyu Kim</td>
<td></td>
</tr>
<tr>
<td>Addressing changes to a closeout data set</td>
<td>29</td>
</tr>
<tr>
<td>Primary author: Gary R. Gensler</td>
<td></td>
</tr>
<tr>
<td>Comparing ANCOVA and Constrained Longitudinal Data Analysis for Examining Moderators in Randomized Clinical Trials</td>
<td>29</td>
</tr>
<tr>
<td>Primary author: Joseph Rausch</td>
<td></td>
</tr>
<tr>
<td>Counterfactual mediation analysis with multistate models for surrogate and clinical time-to-event outcomes</td>
<td>30</td>
</tr>
<tr>
<td>Primary author: Isabelle R. Weir</td>
<td></td>
</tr>
<tr>
<td>Determining mental health condition patterns in Veterans with a lifetime PTSD diagnosis</td>
<td>30</td>
</tr>
<tr>
<td>Primary author: Ilaria Domenicano</td>
<td></td>
</tr>
<tr>
<td>Generalization of Randomized Trial Results with Latent Motivation – A Propensity Score Approach</td>
<td>30</td>
</tr>
<tr>
<td>Primary author: Chenxiang Li</td>
<td></td>
</tr>
<tr>
<td>How Big is a Big Hazard Ratio in Clinical Trials?</td>
<td>30</td>
</tr>
<tr>
<td>Primary author: Yuanyuan Lu</td>
<td></td>
</tr>
<tr>
<td>Improving Clinical Trial Efficiency Using Machine Learning Models of Disease Progression</td>
<td>30</td>
</tr>
<tr>
<td>Primary author: Jonathan Walsh</td>
<td></td>
</tr>
<tr>
<td>Instrumental variable methods for assessing the causal effect of an intervention in the presence of differential non-adherence; application to the AIRWAYS-2 trial</td>
<td>31</td>
</tr>
<tr>
<td>Primary author: Chris Rogers</td>
<td></td>
</tr>
<tr>
<td>Integrating expert opinions with clinical trial data to increase power to detect a treatment effect in subgroups: example of a Bayesian analysis of the VeRDICT trial</td>
<td>31</td>
</tr>
<tr>
<td>Primary author: Russell Thirard</td>
<td></td>
</tr>
<tr>
<td>The Impact of Different Missing Data Imputation Methods: a case study using the Veterans Affairs Nephropathy in Diabetes (VA NEPHRON-D) Study</td>
<td>31</td>
</tr>
<tr>
<td>Primary author: Russell Thirard</td>
<td></td>
</tr>
</tbody>
</table>
Primary author: Arsenio Paez

Primary author: Nora Hutchinson

Primary author: Anna Heath

An introduction to ideal

How Many Patients Does It Take to Develop a New Cancer Drug? A Cohort Study of Pre-license Oncology Drugs

Primary author: Alicia M. Williams

Wearable Devices: Technology, Time Issues and Statistical Resolutions

Primary author: James Moore

An evaluation of the use of covariate constrained randomisation for stepped-wedge cluster randomised trial

Primary author: Caroline A. Kristunas

Category: Systematic Reviews & Evidence Synthesis

Race and ethnicity reporting for clinical trials in ClinicalTrials.gov and publications

Primary author: Kevin M. Fain

Analysis of Intent to Share Individual Participant Data (IPD) for Clinical Trials Registered on ClinicalTrials.gov

Primary author: Tolulope M. Abidogun

Bias In Meta-Analyses of Clinical Research Due To Poor Quality Patient-Reported Outcome Measures

Primary author: Joel J. Gagnier

An examination of treatment interventions for glioblastoma multiforme and its affect on patient withdrawals

Primary author: Emily C. Hite

Analysis and reporting of data from stratified cluster randomized trials – a systematic survey

Primary author: Sayem Borhan

Public availability of clinical trial results from a random sample of systematic reviews

Primary author: Kristina B. Lindsley

Random-effects meta-analysis of combined outcomes based on reconstructions of individual patient data

Primary author: Yue Song

Where have all the trials gone? Academic trialists do not report clinical trial results

Primary author: Penny S. Reynolds

Category: Translational Medicine

How Many Patients Does It Take to Develop a New Cancer Drug? A Cohort Study of Pre-license Oncology Drugs

Primary author: Nora Hutchinson

Category: Trial Design

An introduction to ideal

Primary author: Arsenio Paez

Adaptive Seamless Phase II/III Design for the Ketodex trial

Primary author: Anna Heath

A Bayesian Continual Reassessment Design for a Dose Ranging Study of Intranasal Dexmedetomidine for Pediatric Laceration Repair
Bayesian HPD-based sample size determination using semi-parametric prior elicitation
Primary author: Danila Azzolina

Addressing Challenges in Registering and Reporting Results for Master Protocol Studies
Primary author: Deborah Zarin

Bayesian methods to cope with poor accrual in pediatric trials
Primary author: Danila Azzolina

Beyond the RCT: When are randomised trials unnecessary for new therapeutic devices, and what should we do instead?
Primary author: Arsenio Paez

Blurring the Boundaries Between Clinical Trials and Healthcare Ecosystems
Primary author: Christina Clise

Cost-Efficient Clinical Studies with Continuous Time-to-Event Outcomes
Primary author: Grecio J. Sandoval

Data Sharing Plans in Manuscripts Reporting Results of Randomized Clinical Trials Published in International Committee of Medical Journal Editors Member Journals during 2019
Primary author: Elizabeth C. Wright

Determining a Bayesian Predictive Power Stopping Rule for Futility in a Non-Inferiority Trial with Binary Outcomes: The INK trial
Primary author: Anna Heath

Multi-arm multi-stage designs with fixed stage-wise sample sizes
Primary author: Michael J. Grayling

National Institute of Neurological Disorders and Stroke (NINDS) Common Data Element (CDE) Recommendations: Project Overview and Recent Updates
Primary author: Muniza Sheikh

Optimal incomplete designs for stepped wedge trials in continuous time
Primary author: Richard Hooper

Patient-Focused Research on Metachromatic Leukodystrophy
Primary author: Patricia Vanderwolf

Sample Size Estimates for Optical Coherence Tomography Outcome Measures Based on Trends Observed in the SPRINT-MS Trial
Primary author: Janel K. Fedler

Sequential, Multiple-Assignment, Randomized Trials for COMparing Personalized Antibiotic StrategieS (SMART-COMPASS): Design Considerations for Selecting the Optimal Treatment
Primary author: Xiaoyan Yin
Successful implementation of a novel trial design in a palliative care population
Primary author: Kathryn B. Arnold

The KidsCAN-PERC Innovative Paediatric Clinical Trials Network (iPCT): An Interdisciplinary Approach to Clinical Trials Methodology
Primary author: Anna Heath

The Value Proposition of eConsent in Clinical Trials
Primary author: Hannah F. Glenny

Sample Size Methods for Two-Stage Randomized Trials with Time to Event Data
Primary author: Rouba A. Chahine

Understanding the Length of Consent Forms for Cancer Clinical Trials
Primary author: Quyen Duong

Using Results from a Natural History Study to Reduce Patient Burden in Later Clinical Trials
Primary author: Wendi Liang

Where is the good? The bad and the ugly of single-arm trial reporting.
Primary author: Michael J. Grayling

Efficient Bayesian Adaptive Design for Oncology Clinical Trials with Multiple Biomarker Subgroups
Primary author: Daniel HJ. Kang

Contrasting case-studies of non-commercial trials being used as a pivotal evidence in licencing submissions to the European Medicines Agency
Primary author: Andrew C. Embleton-Thirsk

Efficient Bayesian Adaptive Design for Oncology Clinical Trials with Multiple Biomarker Subgroups
Primary author: Daniel HJ. Kang

The CONSIDER framework: Guiding intervention fidelity and study design in clinical trials of surgery
Primary author: Arsenio Paez

The IDEAL Reporting Guidelines for Reporting the Evaluation of Surgical Innovation
Primary author: Arsenio Paez

Category: Trial Management & Research Coordination

A digital story of strategies for surgical trainees working together to achieve success in conducting surgical clinical trials
Primary author: Janet Athene Lane

Assessing the Competency of the Clinical Research Workforce: Formal Education; Role in the Research Enterprise; Research Setting; and Years of Experience
Primary author: Carlton A. Hornung
Building a Comprehensive Clinical Site Performance Portal in Support of Risk-Based Monitoring .......................................................... 42
Primary author: James S. Wise ..................................................................................................................................................................................................................... 42

Closing Out a Long-Term Longitudinal Study: Lessons from the TODAY Study ........................................................................................................ 42
Primary author: Brian K. Burke ..................................................................................................................................................................................................................... 42

The Impact of Interdisciplinary Relationships on Single IRB Selection in a National Clinical Trial Network ........................................................................ 42
Primary author: Kari Williams ....................................................................................................................................................................................................................... 42

The Impact of Site Initiation Visits on Non-Compliance in Neurology Research ........................................................................................................ 43
Primary author: Matthew J. Gooden ........................................................................................................................................................................................................................ 43

Transition From Two Phase 3 Clinical Trials To A Reduced Follow-Up Only Trial ........................................................................................................ 43
Primary author: Levent Bayman ................................................................................................................................................................................................................... 43

Building a Drug Management System ............................................................................................................................................................................................. 43
Primary author: Jason Kojtek ........................................................................................................................................................................................................................ 43

Regulatory considerations for a multi-site clinical trial treating opioid use disorder (OUD) with vulnerable populations: pregnant women, infants, and potential prisoners .................................................................................................................................................................................. 43
Primary author: Dikla Blumberg ................................................................................................................................................................................................................... 43
## Virtual Invited Sessions

<table>
<thead>
<tr>
<th>Title</th>
<th>Presenter(s)</th>
<th>Date Scheduled</th>
</tr>
</thead>
</table>
| Adjusting for prognostic baseline variables to improve precision and  | **Presenters**  
| power in randomized trials                                            | Michael Rosenblum  
|                                                                  | Associate Professor of Biostatistics  
|                                                                  | Johns Hopkins Bloomberg School of Public Health  
|                                                                  | Min Zhang  
|                                                                  | Professor of Biostatistics  
|                                                                  | University of Michigan  
|                                                                  | School of Public Health  
|                                                                  | Michael Proschan  
|                                                                  | Mathematical Statistician, Biostatistics Research Branch  
|                                                                  | National Institute of Allergy and Infection Diseases  
|                                                                  | Daniel Rubin  
|                                                                  | Mathematical Statistician.  
|                                                                  | US Food and Drug Administration.                                           | September 30, 2020  
<p>|                                                                  | 10:00am -11:00am ET                                                      |</p>
<table>
<thead>
<tr>
<th>Title</th>
<th>Presenter(s)</th>
<th>Date Scheduled</th>
</tr>
</thead>
</table>
| The win ratio approach to composite endpoints          | **Presenters**  
|                                                       | Jong H Jeong  
|                                                       | *Professor of Biostatistics*  
|                                                       | *University of Pittsburgh*  
|                                                       | KyungMann Kim  
|                                                       | *Professor Biostatistics*  
|                                                       | *University of Wisconsin-Madison*  
|                                                       | Lu Mao  
|                                                       | *Assistant Professor of Biostatistics*  
|                                                       | *University of Wisconsin-Madison*  
|                                                       | David Oakes  
|                                                       | *Professor of Biostatistics*  
|                                                       | *University of Rochester Medical Center*  
|                                                       | Song Yang  
|                                                       | *National Heart, Lung, and Blood Institute (NHLBI)*  |
|                                                       | **November 6, 2020**  
|                                                       | **12:00 pm – 1:00 pm ET**  |
## Virtual Invited Sessions continued

<table>
<thead>
<tr>
<th>Title</th>
<th>Presenter(s)</th>
<th>Date Scheduled</th>
</tr>
</thead>
</table>
| Methodological advances in the conduct of behavioral clinical trials: an international behavioural trials network (IBTN) update | **Presenters:**
Simon Bacon  
*Professor, Department of Health, Kinesiology, and Applied Physiology (HKAP), Concordia University*

Susan Czajkowski  
*Chief of the Health Behaviors Research Branch in the Division of Cancer Control and Population Sciences of the National Cancer Institute*

Kenneth Freedland  
*Professor of Psychiatry and Psychology*  
*Washington University School of Medicine St. Louis*

Kim Lavoie  
*Full Professor*  
*Canada Research Chair in Behavioral Medicine and FRQS Chercheur-Boursier* | December 14, 2020  
*10:00am-11:30am ET* |
# Virtual Invited Sessions continued

<table>
<thead>
<tr>
<th>Title</th>
<th>Presenter(s)</th>
<th>Date Scheduled</th>
</tr>
</thead>
</table>
| The design and implementation of master protocols using examples from oncology clinical trials | **Presenters:** Timothy Chen  
Graduate Research Associate  
Ohio State University College of Medicine  
Shauna Hillman  
Statistician III-Biostat  
Mayo Clinic  
Sumithra Mandrekar  
Lead faculty Statistician for lung cancer research  
Mayo Clinic and the Alliance for Clinical Trials in Oncology  
Amy Stark  
Assistant Professor  
Ohio State University  
Pamela Tenaerts  
Executive Director at the Clinical Trials Transformation Initiative (CTTI) | January 12, 2021  
12:00pm-1:00pm ET |
## Virtual Invited Sessions continued

<table>
<thead>
<tr>
<th>Title</th>
<th>Presenter(s)</th>
<th>Date Scheduled</th>
</tr>
</thead>
</table>
| Strategies to collaboratively manage protocol deviations in multi-site clinical trials | **Presenters:**  
Dikla Blumberg  
*Project Director NIDA Clinical Trials Network*  
*The EMMES Corporation*  
Ashley Case  
*Data Manager*  
*The EMMES Corporation*  
Phoebe Gauthier  
*Research Scientist*  
*Northeast Node of the National Drug Abuse Clinical Trials Network*  
*Center for Technology and Behavioral Health, Geisel School of Medicine at Dartmouth College*  
Mitra Lewis  
*Clinical Study Manager*  
*The Emmes Company*  
Carmen Rosa  
*Regulatory Affairs Specialist*  
*National Institutes of Health*  
*Center for Clinical Trials Network*  
Dagmar Salazar  
*Protocol Specialist*  
*The Emmes Corporation* | January 27, 2021  
12:00pm-1:30p ET |
## Virtual Educational Workshop Sessions

<table>
<thead>
<tr>
<th>Title</th>
<th>Presenter(s)</th>
<th>Date Scheduled</th>
</tr>
</thead>
<tbody>
<tr>
<td>Web-based applications for early-phase trials designs</td>
<td><strong>Presenters:</strong>&lt;br&gt; Cody Chiuzan&lt;br&gt; <em>Assistant Professor, Department of Biostatistics</em>&lt;br&gt; <em>Columbia University</em>&lt;br&gt; Yuan Ji&lt;br&gt; <em>Professor, Department of Public Health Sciences</em>&lt;br&gt; <em>University of Chicago</em>&lt;br&gt; Nolan Wages&lt;br&gt; <em>Associate Professor</em>&lt;br&gt; <em>Division of Translational Research &amp; Applied Statistics,</em>&lt;br&gt; <em>Department of Public Health Sciences</em>&lt;br&gt; <em>University of Virginia</em>&lt;br&gt; Ying Yuan&lt;br&gt; <em>Professor, Department of Biostatistics</em>&lt;br&gt; <em>University of Texas MD Anderson Cancer Center</em></td>
<td>October 2, 2020 11:00am-12:30pm ET</td>
</tr>
</tbody>
</table>
## Virtual Education Workshop Sessions continued

<table>
<thead>
<tr>
<th>Title</th>
<th>Presenter(s)</th>
<th>Date Scheduled</th>
</tr>
</thead>
</table>
| Using meta-analysis to combine results from clinical trials.         | **Presenters:** Yulia Marchenko  
                      Executive Director of Statistics  
                      STATA  
                      Kristin MacDonald  
                      Director of Statistical Services  
                      STATA  
                      Houssein Assaad  
                      Senior Statistician and Software Developer  
                      STATA | October 14, 2020  
                      12:30pm – 2:00pm ET |
| From Ideas to Efficacy: Designing & Optimizing Behavioral Treatments for Chronic Diseases | **Presenters:** Susan M. Czajkowski  
                      Division of Cancer Control and Population Sciences  
                      National Cancer Institute  
                      Ken Freedland  
                      Professor of Psychiatry and Psychology  
                      Associate Director, Behavioral Medicine Center  
                      Washington University School of Medicine St. Louis  
                      Lynda H. Powell  
                      Chairperson, Department of Preventive Medicine, Rush Medical College  
                      Rush University Medical Center | October 29, 2020  
                      2:00 pm– 3:30 pm ET |
## Virtual Education Workshop Sessions continued

<table>
<thead>
<tr>
<th>Session Title</th>
<th>Presenters</th>
<th>Date/Time</th>
</tr>
</thead>
</table>
| **How to design and run an adaptive clinical trial: new resources and easy-to-use software** | Munya Dimairo  
* BSc (Hons) (Statistics), MSc (Medical Statistics), PhD (Medical Statistics)  
* School of Health and Related Research  
* Research Fellow  
* The University of Sheffield  
  
Michael Grayling  
* Research Fellow  
* Population Health Sciences Institute  
* Faculty of Medical Sciences  
* Newcastle University  
  
Graham Wheeler  
* Senior Statistician  
* Cancer Research UK & UCL Cancer Trials Centre  
* University College London | November 11, 2020  
10:00am – 11:30am ET  |
| **Improving Quality and Controlling Costs in Clinical Trials Using Responsive Survey Design** | James Wagner  
* Research Associate Professor, ISR, Survey Research Center Survey Methodology and JPSM  
* University of Maryland  
  
Brady West  
* Research Associate Professor in the Survey Methodology Program  
* Survey Research Center at the Institute for Social Research  
* The University of Michigan-Ann Arbor | April 6, 2021  
11a ET – 12:30p ET |
Recorded Sessions

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Category: Data Management

Automation of clinical trial statistical monitoring
Primary Author: Chris Rogers
E-mail: chris.rogers@bristol.ac.uk
Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Automation%20of%20clinical%20trial%20statistical%20monitoring
Keywords: Data Management, Information Systems & Technology, Health Informatics

Buy or Build: Considerations for a robust data management system used in Phase 3 Clinical Studies
Primary Author: Lan Zhang
e-mail: lzhang@bsc.gwu.edu
Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Buy%20or%20Build:%20Considerations%20for%20a%20robust%20data%20management%20system%20used%20in%20Phase%203%20Clinical%20Studies
Keywords: Data Management, Trial Design, Systematic Reviews & Evidence Synthesis
Central Statistical Data Quality Monitoring in Clinical Studies: an application to the ROLEX registry
Primary Author: Daniele Bottigliengo
e-mail: daniele.bottigliengo@phd.unipd.it
Recording link:
Keywords: Data Management, Information Systems & Technology

Ensuring Consistency Across CDISC Dataset Programming Processes
Primary Author: Rick M. Mitchell
e-mail: rickmitchell@westat.com
Recording link:
Keyword: Data Management

Comparing a Multimedia Interactive Virtual Informed Consent (VIC) to Traditional Paper-based Method: A randomized Clinical Trial
Primary author: Fuad Abujarad
Email: fuad.abujarad@yale.edu
Recording link:
Keywords: Health Informatics, Information Systems & Technology, Involving Research Partners

Do study participants complete electronic questionnaires?
Primary author: Lucy Culliford
Email: lucy.culliford@bristol.ac.uk
Recording link:
http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Do%20study%20participants%20complete%20electronic%20questionnaires?
Keywords: Information Systems & Technology, Outcomes
Extracting Unique Insights by Mining Single Nucleotide Polymorphisms (SNPs) from ClinicalTrials.gov and Applying the Human Phenotype Ontology
Primary author: Shray Alag
Email: 21shraya@students.harker.org
Keywords: Information Systems & Technology, Health Informatics, Statistical Analysis

Using an Interdisciplinary Approach to Develop a Medical Record Abstraction and Quality Assurance Process for Generating the Primary Outcome in a Multi-Site Implementation Study
Primary author: Phoebe R. Gauthier
E-mail: phoebe.r.gauthier@dartmouth.edu
Keywords: Information Systems & Technology, Trial Management & Research Coordination, Health Informatics

Real-Time Risk-Based Monitoring in Clinical Trials Using Business Intelligence Tools (Unlikely Companions)
Primary author: Levent Bayman
E-mail: levent-bayman@uiowa.edu
Keywords: Health Informatics, Information Systems & Technology

Management and sharing of individual participant deidentified data (IPD)
Primary author: Elizabeth Wright
E-mail: wrightel@niddk.nih.gov
Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Management%20and%20sharing%20of%20individual%20participant%20deidentified%20data%20(IPD)
Keywords: Health Informatics, Information Systems & Technology
Category: Involving Research Partners

Data from Expanded Access: Opportunity for Real World Evidence Collection and Insights?
Primary author: Kelly M. Folkers
E-Mail: kelly.folkers@nyu.edu
Recording link:

IMPAACT 2016: Interdisciplinary Collaboration at Multiple Levels
Primary author: Meredith G. Warshaw
E-mail: mwarshaw@sdac.harvard.edu
Recording link:
http://www.sctweb.org/members/virtualmeeting.cfm?keyword=IMPAACT%202016:%20Interdisciplinary%20Collaboration%20at%20Multiple%20Levels

Category: Personalize Medicine

The Association between Genotypes and Post Cardiac Surgery Bleedings: A substudy of the Steroids in Cardiac Surgery Trial (SIRS)
Primary author: Fei Yuan
E-Mail: fei.yuan@phri.ca
Recording link:

Keywords: Other
Keywords: Involving Research Partners, Trial Management & Research Coordination
Keywords: Personalize Medicine, Outcomes, Involving Research Partners
**Category: Recruitment & Retention**

**Clinical Trial Design, Protocol Implementation, and Secular Treatment Trends for Persons Living with HIV and Opioid Use Disorder: Lessons Learned from a National Institute on Drug Abuse Clinical Trials Network**  
Primary author: Jessica Guyer  
E-mail: guyerj@ohsu.edu  
Keywords: Feasibility/Pilot Studies, Recruitment & Retention, Trial Design

**Interdisciplinary collaboration in review of national coverage analysis (NCA) documents to enhance clinical trial site activation and recruitment of participants**  
Primary author: Lawrence R. Ragard  
E-mail: LawrenceRagard@westat.com  
Recording link: [http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Interdisciplinary%20collaboration%20in%20review%20of%20national%20coverage%20analysis](http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Interdisciplinary%20collaboration%20in%20review%20of%20national%20coverage%20analysis)  
Keywords: Recruitment & Retention, Involving Research Partners, Other

**Implementation, recruitment, and retention for an emergency department initiated buprenorphine intervention for opioid use disorder**  
Primary author: Elias M. Klemperer  
E-mail: eklemper@med.uvm.edu  
Recording link: [http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Implementation,%20recruitment,%20and%20retention%20for%20an%20emergency%20department%20initiated](http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Implementation,%20recruitment,%20and%20retention%20for%20an%20emergency%20department%20initiated)  
Keywords: Recruitment & Retention, Trial Management & Research Coordination

**Potential participants’ views on the factors that impact on their decision to take part in a randomised trial: A qualitative evidence synthesis.**  
Primary author: Catherine Houghton  
E-mail: catherine.houghton@nuigalway.ie  
Recording link: [http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Potential%20participants%E2%80%99%20views%20on%20the%20factors%20that%20impact%20on%20their%20decision](http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Potential%20participants%E2%80%99%20views%20on%20the%20factors%20that%20impact%20on%20their%20decision)  
Keywords: Recruitment & Retention, Qualitative Research, Systematic Reviews & Evidence Synthesis
Vital Status Ascertainment in a Long-Term Clinical Study of Type 1 Diabetes
Primary author: Victoria R. Trapani
E-mail: vtrapani@bsc.gwu.edu
Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Vital%20Status%20Ascertainment%20in%20Long-Term%20Clinical%20Study%20of%20Type%201%20Diabetes
Keywords: Recruitment & Retention, Outcomes, Qualitative Research

Category: Statistical Analysis

A novel method of reporting adverse effects in cancer clinical trials
Primary author: Guilherme S. Lopes
E-mail: lopes.guilherme@mayo.edu
Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=A%20novel%20method%20of%20reporting%20adverse%20effects%20in%20cancer%20clinical%20trials
Keywords: Statistical Analysis, Data Management, Outcomes

Analysis of multicenter clinical trials with very low event rates
Primary author: Jiyu Kim
E-mail: jiyu.kim@nyulangone.org
Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Analysis%20of%20multicenter%20clinical%20trials%20with%20very%20low%20event%20rates
Keywords: Statistical Analysis

Addressing changes to a closeout data set
Primary author: Gary R. Gensler
E-mail: ggensler@emmes.com
Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Addressing%20changes%20to%20closeout%20data%20set
Keywords: Statistical Analysis, Data Management, Outcomes

Comparing ANCOVA and Constrained Longitudinal Data Analysis for Examining Moderators in Randomized Clinical Trials
Primary author: Joseph Rausch
Email: joseph.rausch@nationwidechildrens.org
Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Comparing%20ANCOVA%20and%20Constrained%20Longitudinal%20Data%20Analysis%20for%20Examining%20Moderators%20in%20Randomized%20Clinical%20Trials
Keywords: Statistical Analysis
Counterfactual mediation analysis with multistate models for surrogate and clinical time-to-event outcomes
Primary author: Isabelle R. Weir
E-mail: iweir@sdac.harvard.edu
Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Counterfactual%20mediation%20analysis%20with%20multistate%20models%20for%20surrogate%20and%20clinical%20time-to-event%20outcomes
Keywords: Statistical Analysis, Outcomes, Trial Design

Determining mental health condition patterns in Veterans with a lifetime PTSD diagnosis
Primary author: Ilaria Domenicano
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Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Determining%20mental%20health%20condition%20patterns%20in%20Veterans%20with%20a%20lifetime%20PTSD%20diagnosis
Keywords: Statistical Analysis, Personalize Medicine

Generalization of Randomized Trial Results with Latent Motivation – A Propensity Score Approach
Primary author: Chenxiang Li
E-mail: cl3859@nyu.edu
Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Generalization%20of%20Randomized%20Trial%20Results%20with%20Latent%20Motivation%20%E2%80%93%20A%20Propensity%20Score%20Approach
Keywords: Statistical Analysis, Recruitment & Retention

How Big is a Big Hazard Ratio in Clinical Trials?
Primary author: Yuanyuan Lu
E-mail: yuanyuanlu@usf.edu
Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=How%20Big%20is%20a%20Big%20Hazard%20Ratio%20in%20Clinical%20Trials?
Keywords: Statistical Analysis, Outcomes

Improving Clinical Trial Efficiency Using Machine Learning Models of Disease Progression
Primary author: Jonathan Walsh
E-mail: drjrw@unlearn.ai
Keywords: Statistical Analysis, Trial Design, Data Management
Instrumental variable methods for assessing the causal effect of an intervention in the presence of differential non-adherence; application to the AIRWAYS-2 trial
Primary author: Chris Rogers
E-mail: chris.rogers@bristol.ac.uk
Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Instrumental%20variable%20methods%20for%20assessing%20the%20causal%20effect%20of%20an%20intervention%20in%20the%20presence%20of%20differential%20non-adherence%3B%20application%20to%20the%20AIRWAYS-2%20trial
Keywords: Statistical Analysis

Integrating expert opinions with clinical trial data to increase power to detect a treatment effect in subgroups: example of a Bayesian analysis of the VeRDICT trial
Primary author: Russell Thirard
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Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Integrating%20expert%20opinions%20with%20clinical%20trial%20data%20to%20increase%20power%20to%20detect%20a%20treatment%20effect%20in%20subgroups%3B%20example%20of%20a%20Bayesian%20analysis%20of%20the%20VeRDICT%20trial
Keywords: Statistical Analysis, Personalize Medicine, Trial Design

The Impact of Different Missing Data Imputation Methods: a case study using the Veterans Affairs Nephropathy in Diabetes (VA NEPHRON-D) Study
Primary author: Alicia M. Williams
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Keywords: Statistical Analysis

Wearable Devices: Technology, Time Issues and Statistical Resolutions
Primary author: James Moore
E-mail: jmoore@xerispharma.com
Keywords: Statistical Analysis
An evaluation of the use of covariate constrained randomisation for stepped-wedge cluster randomised trial
Primary author: Caroline A. Kristunas
E-mail: c.kristunas@le.ac.uk
Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=An%20evaluation%20of%20the%20use%20of%20covariate%20constrained%20randomisation%20for%20stepped-wedge%20cluster%20randomised%20trial
Keywords: Statistical Analysis, Trial Design

Category: Systematic Reviews & Evidence Synthesis

Race and ethnicity reporting for clinical trials in ClinicalTrials.gov and publications
Primary author: Kevin M. Fain
E-mail: kevinfain@yahoo.com
Keywords: Health Informatics, Systematic Reviews & Evidence Synthesis, Recruitment & Retention

Analysis of Intent to Share Individual Participant Data (IPD) for Clinical Trials Registered on ClinicalTrials.gov
Primary author: Tolulope M. Abidogun
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Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Analysis%20of%20Intent%20to%20Share%20Individual%20Participant%20Data%20(IPD)%20for%20Clinical%20Trials%20Registered%20on%20ClinicalTrials.gov
Keywords: Systematic Reviews & Evidence Synthesis, Trial Design

Bias In Meta-Analyses of Clinical Research Due To Poor Quality Patient-Reported Outcome Measures
Primary author: Joel J. Gagnier
E-mail: jgagnier@umich.edu
Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=gagnier
Keywords: Outcomes, Systematic Reviews & Evidence Synthesis
An examination of treatment interventions for glioblastoma multiforme and its affect on patient withdrawals
Primary author: Emily C. Hite
E-Mail: emhi8771@colorado.edu
Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=An%20examination%20of%20treatment%20interventions%20for%20glioblastoma%20multiforme%20and%20its%20affect%20on%20patient%20withdrawals
Keywords: Systematic Reviews & Evidence Synthesis, Choosing interventions, Recruitment & Retention

Analysis and reporting of data from stratified cluster randomized trials – a systematic survey
Primary author: Sayem Borhan
E-mail: borhana@mcmaster.ca
Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Analysis%20and%20reporting%20of%20data%20from%20stratified%20cluster%20randomized%20trials%20-%20a%20systematic%20survey
Keywords: Systematic Reviews & Evidence Synthesis, Trial Design, Statistical Analysis

Public availability of clinical trial results from a random sample of systematic reviews
Primary author: Kristina B. Lindsley
E-mail: k.b.lindsley@umcutrecht.nl
Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Public%20availability%20of%20clinical%20trial%20results%20from%20a%20random%20sample%20of%20systematic%20reviews
Keywords: Systematic Reviews & Evidence Synthesis

Random-effects meta-analysis of combined outcomes based on reconstructions of individual patient data
Primary author: Yue Song
E-mail: yus280@g.harvard.edu
Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Random-effects%20meta-analysis%20of%20combined%20outcomes%20based%20on%20reconstructions%20of%20individual%20patient%20data
Keywords: Systematic Reviews & Evidence Synthesis, Statistical Analysis, Outcomes
Where have all the trials gone? Academic trialists do not report clinical trial results
Primary author: Penny S. Reynolds
E-mail: PReynolds@anest.ufl.edu
Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Where%20have%20all%20the%20trials%20gone?%20Academic%20trialists%20not%20report%20clinical%20trial%20results
Keywords: Systematic Reviews & Evidence Synthesis, Trial Management & Research Coordination

Category: Translational Medicine

How Many Patients Does It Take to Develop a New Cancer Drug? A Cohort Study of Pre-license Oncology Drugs
Primary author: Nora Hutchinson
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Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=How%20Many%20Patients%20Does%20It%20Take%20to%20Develop%20a%20New%20Cancer%20Drug%20Cohort%20Study%20of%20Pre-license%20Oncology%20Drugs
Keywords: Translational Medicine, Health Economics, Systematic Reviews & Evidence Synthesis

Category: Trial Design

An introduction to ideal
Primary author: Arsenio Paez
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Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=An%20introduction%20to%20ideal
Keywords: Complex Interventions, Trial Design

Adaptive Seamless Phase II/III Design for the Ketodex trial
Primary author: Anna Heath
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Keywords: Trial Design, Statistical Analysis
A Bayesian Continual Reassessment Design for a Dose Ranging Study of Intranasal Dexmedetomidine for Pediatric Laceration Repair
Primary author: Anna Heath
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Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=A%20Bayesian%20Continual%20Reassessment%20Design%20for%20Dose%20Ranging%20Study%20of%20Intranasal%20Dexmedetomidine%20for%20Paediatric%20Laceration%20Repair
Keywords: Trial Design, Statistical Analysis, Feasibility/Pilot Studies

Bayesian HPD-based sample size determination using semi-parametric prior elicitation
Primary author: Danila Azzolina
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Keywords: Trial Design, Statistical Analysis, Trial Management & Research Coordination

Addressing Challenges in Registering and Reporting Results for Master Protocol Studies
Primary author: Deborah Zarin
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Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Addressing%20Challenges%20in%20Registering%20and%20Reporting%20Results%20for%20Master%20Protocol%20Studies
Keywords: Trial Design

Bayesian methods to cope with poor accrual in pediatric trials
Primary author: Danila Azzolina
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Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Bayesian%20Methods%20to%20Cope%20with%20Poor%20Accrual%20in%20Pediatric%20Trials
Keywords: Trial Design, Statistical Analysis, Recruitment & Retention
Beyond the RCT: When are randomised trials unnecessary for new therapeutic devices, and what should we do instead?
Primary author: Arsenio Paez
E-mail: arsenio.paez@kellogg.ox.ac.uk
Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Beyond%20the%20RCT:%20When%20are%20randomised%20trials%20unnecessary%20for%20new%20therapeutic%20devices,%20and%20what%20should%20we%20do%20instead?
Keywords: Trial Design, Trial Management & Research Coordination, Outcomes

Blurring the Boundaries Between Clinical Trials and Healthcare Ecosystems
Primary author: Christina Clise
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Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Blurring%20the%20Boundaries%20Between%20Clinical%20Trials%20and%20Healthcare%20Ecosystems
Keywords: Trial Design, Recruitment & Retention, Trial Management & Research Coordination

Cost-Efficient Clinical Studies with Continuous Time-to-Event Outcomes
Primary author: Grecio J. Sandoval
E-mail: sandoval@bsc.gwu.edu
Keywords: Trial Design, Statistical Analysis, Health Economics

Data Sharing Plans in Manuscripts Reporting Results of Randomized Clinical Trials Published in International Committee of Medical Journal Editors Member Journals during 2019
Primary author: Elizabeth C. Wright
E-mail: wrightel@niddk.nih.gov
Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Data%20Sharing%20Plans%20in%20Manuscripts%20Reporting%20Results%20of%20Randomized%20Clinical%20Trials%20Published%20in%20International%20Committee%20of%20Medical%20Journal%20Editors%20Member%20Journals%20during%202019
Keywords: Trial Design, Trial Management & Research Coordination, Systematic Reviews & Evidence Synthesis
Determining a Bayesian Predictive Power Stopping Rule for Futility in a Non-Inferiority Trial with Binary Outcomes: The INK trial
Primary author: Anna Heath
E-mail: anna.heath@sickkids.ca
Keywords: Trial Design, Statistical Analysis

Multi-arm multi-stage designs with fixed stage-wise sample sizes
Primary author: Michael J. Grayling
E-mail: michael.grayling@newcastle.ac.uk
Keywords: Trial Design

National Institute of Neurological Disorders and Stroke (NINDS) Common Data Element (CDE) Recommendations: Project Overview and Recent Updates
Primary author: Muniza Sheikh
E-mail: msheikh@emmes.com
Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=NINDS%20Common%20Data%20Element%20(CDE)%20Recommendations:%20Project%20Overview%20and%20Recent%20Updates
Keywords: Trial Design, Trial Management & Research Coordination

Optimal incomplete designs for stepped wedge trials in continuous time
Primary author: Richard Hooper
E-mail: r.l.hooper@qmul.ac.uk
Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Optimal%20Incomplete%20Designs%20for%20Stepped%20Wedge%20Trials%20in%20Continuous%20Time
Keywords: Trial Design
Patient-Focused Research on Metachromatic Leukodystrophy
Primary author: Patricia Vanderwolf
E-mail: arobert@rarediseases.org
Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Patient-Focused%20Research%20on%20Metachromatic%20Leukodystrophy
Keywords: Trial Design, Health Informatics, Trial Management & Research Coordination

Sample Size Estimates for Optical Coherence Tomography Outcome Measures Based on Trends Observed in the SPRINT-MS Trial
Primary author: Janel K. Fedler
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Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Sample%20Size%20Estimates%20for%20Optical%20Coherence%20Tomography%20Outcome%20Measures%20Based%20on%20Trends%20Observed%20in%20the%20SPRINT-MS%20Trial
Keywords: Trial Design, Outcomes, Statistical Analysis

Sequential, Multiple-Assignment, Randomized Trials for COMparing Personalized Antibiotic Strategies (SMART-COMPASS): Design Considerations for Selecting the Optimal Treatment
Primary author: Xiaoyan Yin
E-mail: xyin@bsc.gwu.edu
Keywords: Trial Design, Statistical Analysis, Personalized Medicine

Simulation-based Design of Pragmatic Trials in Psoriatic Arthritis Using Propensity Scores
Primary author: Alisa J. Stephens-Shields
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Keywords: Trial Design, Statistical Analysis, Outcomes
Successful implementation of a novel trial design in a palliative care population
Primary author: Kathryn B. Arnold
E-mail: karnold@fredhutch.org
Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Successful%20implementation%20of%20novel%20trial%20design%20in%20palliative%20care%20population
Keywords: Trial Design, Recruitment & Retention, Choosing interventions

The KidsCAN-PERC Innovative Paediatric Clinical Trials Network (iPCT): An Interdisciplinary Approach to Clinical Trials Methodology
Primary author: Anna Heath
E-mail: anna.heath@sickkids.ca
Keywords: Trial Design, Statistical Analysis, Health Economics

The Value Proposition of eConsent in Clinical Trials
Primary author: Hannah F. Glenny
E-mail: Debbie.Profit@otsuka-us.com
Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=The%20Value%20Proposition%20of%20eConsent%20in%20Clinical%20Trials
Keywords: Trial Design, Recruitment & Retention, Information Systems & Technology

Sample Size Methods for Two-Stage Randomized Trials with Time to Event Data
Primary author: Rouba A. Chahine
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Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Sample%20Size%20Methods%20for%20Two-Stage%20Randomized%20Trials%20with%20Time%20to%20Event%20Data
Keywords: Trial Design, Recruitment & Retention, Statistical Analysis

Understanding the Length of Consent Forms for Cancer Clinical Trials
Primary author: Quyen Duong
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Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=duong
Keywords: Trial Design, Statistical Analysis, Trial Management & Research Coordination
Using Results from a Natural History Study to Reduce Patient Burden in Later Clinical Trials
Primary author: Wendi Liang
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Recording link:
http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Using%20Results%20from%20a%20Natural%20History%20Study%20to%20Reduce%20Patient%20Burden%20in%20Later%20Clinical%20Trials
Keywords: Trial Design, Trial Management & Research Coordination, Statistical Analysis

Where is the good? The bad and the ugly of single-arm trial reporting
Primary author: Michael J. Grayling
E-mail: michael.grayling@newcastle.ac.uk
Recording link:
http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Where%20is%20the%20good%3F%20The%20bad%20and%20the%20ugly%20of%20single-arm%20trial%20reporting
Keywords: Trial Design, Statistical Analysis, Systematic Reviews & Evidence Synthesis

Efficient Bayesian Adaptive Design for Oncology Clinical Trials with Multiple Biomarker Subgroups
Primary author: Daniel HJ. Kang
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Recording link:
Keywords: Trial Design

Contrasting case-studies of non-commercial trials being used as a pivotal evidence in licencing submissions to the European Medicines Agency
Primary author: Andrew C. Embleton-Thirsk
E-mail: a.embleton@ucl.ac.uk
Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Contrasting%20case-studies%20of%20non-commercial%20trials%20being%20used%20as%20pivotal%20evidence%20in%20licencing%20submissions%20to%20the%20European%20Medicines%20Agency
Keywords: Trial Design
Efficient Bayesian Adaptive Design for Oncology Clinical Trials with Multiple Biomarker Subgroups

Primary author: Daniel HJ. Kang
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Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Efficient%20Bayesian%20Adaptive%20Design%20for%20Oncology%20Clinical%20Trials%20with%20Multiple%20Biomarker%20Subgroups

Keywords: Trial Design

The CONSIDER framework: Guiding intervention fidelity and study design in clinical trials of surgery

Primary author: Arsenio Paez
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Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=The%20CONSIDER%20framework

Keywords: Trial Design

The IDEAL Reporting Guidelines for Reporting the Evaluation of Surgical Innovation

Primary author: Arsenio Paez
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Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=The%20IDEAL%20Reporting%20Guidelines%20for%20Reporting%20the%20Evaluation%20of%20Surgical%20Innovation

Keywords: Trial Design

Category: Trial Management & Research Coordination

A digital story of strategies for surgical trainees working together to achieve success in conducting surgical clinical trials

Primary author: Janet Athene Lane
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Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=A%20digital%20story%20of%20strategies%20for%20surgical%20trainees%20working%20together%20to%20achieve%20success%20in%20conducting%20surgical%20clinical%20trials

Keywords: Trial Management & Research Coordination, Recruitment & Retention
Assessing the Competency of the Clinical Research Workforce: Formal Education; Role in the Research Enterprise; Research Setting; and Years of Experience
Primary author: Carlton A. Hornung
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Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Assessing%20the%20Competency%20of%20the%20Clinical%20Research%20Workforce:%20Formal%20Education;%20Role%20in%20the%20Research%20Enterprise;%20Research%20Setting;%20and%20Years%20of%20Experience
Keywords: Trial Management & Research Coordination, Involving Research Partners

Building a Comprehensive Clinical Site Performance Portal in Support of Risk-Based Monitoring
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Keywords: Trial Management & Research Coordination, Data Management, Information Systems & Technology

Closing Out a Long-Term Longitudinal Study: Lessons from the TODAY Study
Primary author: Brian K. Burke
E-mail: bburke@bsc.gwu.edu
Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=burke
Keywords: Trial Management & Research Coordination, Data Management

The Impact of Interdisciplinary Relationships on Single IRB Selection in a National Clinical Trial Network
Primary author: Kari Williams
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Keywords: Trial Management & Research Coordination
The Impact of Site Initiation Visits on Non-Compliance in Neurology Research
Primary author: Matthew J. Gooden
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Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=The%20Impact%20of%20Site%20Initiation%20Visits%20on%20Non%20Compliance%20in%20Neurology%20Research
Keywords: Trial Management & Research Coordination, Data Management, Recruitment & Retention

Transition From Two Phase 3 Clinical Trials To A Reduced Follow-Up Only Trial
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Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Transition%20From%20Two%20Phase%203%20Clinical%20Trials%20To%20A%20Reduced%20Follow-Up%20Only%20Trial
Keywords: Trial Management & Research Coordination, Statistical Analysis, Data Management

Building a Drug Management System
Primary author: Jason Kojtek
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Keywords: Trial Management & Research Coordination, Information Systems & Technology, Data Management

Regulatory considerations for a multi-site clinical trial treating opioid use disorder (OUD) with vulnerable populations: pregnant women, infants, and potential prisoners
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Keywords: Trial Management & Research Coordination