Virtual Program Guide

Updated November 10, 2020

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

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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.

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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.

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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

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Lehana Thabane
Chair
Nominating Committee

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Chair
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Thank you to the SCT 2019-2020 Committee Chairs and Co-Chairs

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Lee McDaniel
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Student Scholarship Committee

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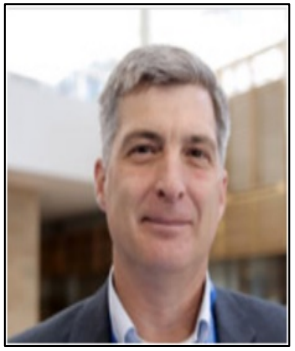
Thank you to the SCT Program Task Force

Susan Halabi
2020-2021
SCT President

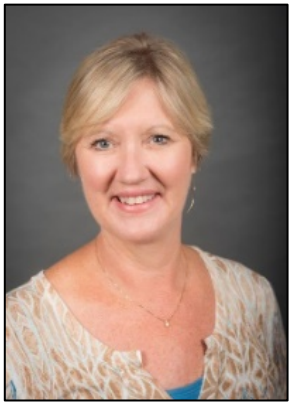


Dean Fergusson
2020-2021
Past President

Domenic Reda
SCT Secretary

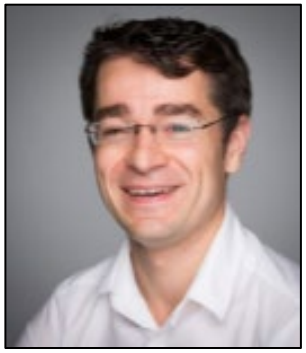
Li Chen
SCT Treasurer

Jody Ciolino
Past Chair
Membership Committee



Dixie Ecklund
Past Co-Chair
Membership Committee

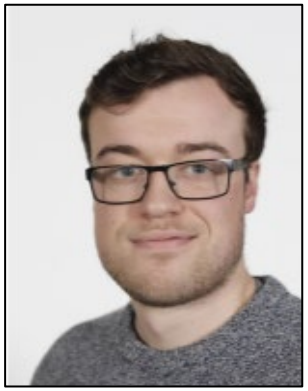
Thank you to the SCT Program Task Force



Jonathan Cook
2020 Chair
Program Committee

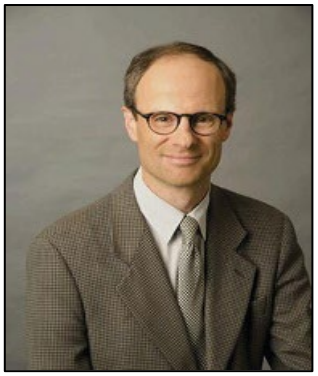
Toshi Hamasaki
2020 Co-Chair
Program Committee

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 http://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 program.
- 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

<u>Please note:</u> 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

Virtual Educational Workshop Sessions

Category: Data Management

Category: Information Systems & Technology

Category: Involving Research Partners

Category: Personalize Medicine

Category: Recruitment & Retention

Category: Statistical Analysis

Category: Systematic Reviews & Evidence Synthesis

Category: Translational Medicine

Category: Trial Design

Category: Trial Management & Research Coordination

Virtual Invited Sessions

Previous recorded Sessions are available on the 2020 Virtual Meetings Page on sctweb.org

Title	Presenter(s)	Date Scheduled
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

Title	Presenter(s)	Date Scheduled
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

Title	Presenter(s)	Date Scheduled
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

Previous recorded Sessions are available on the 2020 Virtual Meetings Page on sctweb.org

How to design and run an adaptive clinical trial: new resources and easy-to-use software	**Presenters:** 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*	**CANCELLED** **Will be rescheduled to a later date**
Improving Quality and Controlling Costs in Clinical Trials Using Responsive Survey Design	**Presenters:** 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

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.

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:
http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Central%20Statistical%20Data%20Quality%20Monitoring%20in%20Clinical%20Studies:%20an%20application%20to%20the%20ROLEX%20registry
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:
http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Ensuring%20Consistency%20Across%20CDISC%20Dataset%20Programming%20Processeshttp://www.sctweb.org/members/virtualmeeting.cfm?keyword=Ensuring%20Consistency%20Across%20CDISC%20Dataset%20Programming%20Processes
Keyword: Data Management

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
Email: fuad.abujarad@yale.edu
Recording link:
http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Comparing%20a%20Multimedia%20Interactive%20Virtual%20Informed%20Consent%20(VIC)%20to%20Traditional%20Paper-based%20Method:%20A%20randomized%20Clinical%20Trial
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
Recording link:
http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Extracting%20Unique%20Insights%20by%20Mining%20Single%20Nucleotide%20Polymorphisms%20(SNPs)%20from%20ClinicalTrials.gov%20and%20Applying%20the%20Human%20Phenotype%20Ontology
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
Recording link:
http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Using%20an%20Interdisciplinary%20Approach%20to%20Develop%20a%20Medical%20Record%20Abstraction%20and%20Quality%20Assurance%20Process%20for%20Generating%20the%20Primary%20Outcome%20in%20a%20Multi-Site%20Implementation%20Study
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
Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Real-Time%20Risk Based%20Monitoring%20in%20Clinical%20Trials%20Using%20Business%20Intelligence%20Tools%20(Unlikely%20Companions)
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:
http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Data%20from%20Expanded%20Access:%20Opportunity%20for%20Real%20World%20Evidence%20Collection%20and%20Insights?
Keywords: Other

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
Keywords: Involving Research Partners, Trial Management & Research Coordination

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:
http://www.sctweb.org/members/virtualmeeting.cfm?keyword=The%20Association%20between%20Genotypes%20and%20Post%20Cardiac%20Surgery%20Bleedings:%20A%20substudy%20of%20the%20Steroids%20in%20Cardiac%20Surgery%20Trial%20(SIRS)
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
Recording link:
http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Clinical%20Trial%20Design,%20Protocol%20Implementation,%20and%20Secular%20Treatment%20Trends
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
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
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
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%20a%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%20a%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
E-mail: ilaria.domenicano@yale.edu
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
Recording link:
http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Improving%20Clinical%20Trial%20Efficiency%20Using%20Machine%20Learning%20Models%20of%20Disease%20Progression
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;%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
E-mail: russell.thirard@bristol.ac.uk

Recording link:
http://www.sctweb.org/members/virtualmeeting.cfm?keyword=ntegrating%20expert%20opinions%20with%20clinical%20trial%20data%20to%20increase%20power%20to%20detect%20a%20treatment%20effect%20in%20subgroups:%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
E-mail: amw346@cornell.edu

Recording link:
http://www.sctweb.org/members/virtualmeeting.cfm?keyword=The%20Impact%20of%20Different%20Missing%20Data%20Imputation%20Methods:%20a%20case%20study%20using%20the%20Veterans%20Affairs%20Nephropathy%20in%20Diabetes%20(VA%20NEPHRON-D)%20Study

Keywords: Statistical Analysis

Wearable Devices: Technology, Time Issues and Statistical Resolutions

Primary author: James Moore
E-mail: jmoore@xerispharma.com

Recording link:
http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Wearable%20Devices:%20Technology,%20Time%20Issues%20and%20Statistical%20Resolutions

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
Recording:
http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Race%20and%20ethnicity%20reporting%20for%20clinical%20trials%20in%20ClinicalTrials.gov%20and%20publications
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
E-mail: tolu.abidogun@nih.gov
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
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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
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Recording link:
http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Analysis%20and%20reporting%20of%20data%20from%20stratified%20cluster%20randomized%20trials%20%E2%80%93%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
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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%20do%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
E-mail: nora.hutchinson@mail.mcgill.ca
Recording link:
http://www.sctweb.org/members/virtualmeeting.cfm?keyword=How%20Many%20Patients%20Does%20It%20Take%20to%20Develop%20a%20New%20Cancer%20Drug?%20A%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
E-mail: arsenio.paez@kellogg.ox.ac.uk
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
E-mail: anna.heath@sickkids.ca
Recording link:
http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Adaptive%20Seamless%20Phase%20II/III%20Design%20for%20the%20Ketodex%20trial
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
E-mail: anna.heath@sickkids.ca
Recording link:
http://www.sctweb.org/members/virtualmeeting.cfm?keyword=A%20Bayesian%20Continual%20Reassessment%20Design%20for%20a%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
E-mail: danila.azzolina@uniupo.it
Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Bayesian%20HPD-based%20sample%20sizedetermination%20using%20semi-parametric%20prior%20elicitation
Keywords: Trial Design, Statistical Analysis, Trial Management & Research Coordination

Addressing Challenges in Registering and Reporting Results for Master Protocol Studies
Primary author: Deborah Zarin
E-mail: deborah.zarin@gmail.com
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
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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
Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Cost-Efficient%20Clinical%20Studies%20with%20Continuous%20Time-to-Event%20Outcomes
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
Recording link:
http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Determining%20a%20Bayesian%20Predictive%20Power%20Stopping%20Rule%20for%20Futility%20in%20a%20Non-Inferiority%20Trial%20with%20Binary%20Outcomes:%20The%20INK%20trial
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
Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Multi-arm%20multi-stage%20designs%20with%20fixed%20stage-wise%20sample%20sizes
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
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Recording link:
http://www.sctweb.org/members/virtualmeeting.cfm?keyword=National%20Institute%20of%20Neurological%20Disorders%20and%20Stroke%20(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
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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
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Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Sequential,%20Multiple-Assignment,%20Randomized%20Trials%20for%20COMparing%20Personalized%20Antibiotic%20StrategieS%20(SMART-COMPASS):%20Design%20Considerations%20for%20Selecting%20the%20Optimal%20Treatment
Keywords: Trial Design, Statistical Analysis, Personalize Medicine

Simulation-based Design of Pragmatic Trials in Psoriatic Arthritis Using Propensity Scores
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Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Simulation-based%20Design%20of%20Pragmatic%20Trials%20in%20Psoriatic%20Arthritis%20Using%20Propensity%20Scores
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%20a%20novel%20trial%20design%20in%20a%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
Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=The%20KidsCAN-PERC%20Innovative%20Paediatric%20Clinical%20Trials%20Network%20(iPCT):%20An%20Interdisciplinary%20Approach%20to%20Clinical%20Trials%20Methodology
Keywords: Trial Design, Statistical Analysis, Health Economics

The Value Proposition of eConsent in Clinical Trials
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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
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Recording link:
http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Where%20is%20the%20good?%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:
http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Efficient%20Bayesian%20Adaptive%20Design%20for%20Oncology%20Clinical%20Trials%20with%20Multiple%20Biomarker%20Subgroups
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
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Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Contrasting%20case-studies%20of%20non-commercial%20trials%20being%20used%20as%20a%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
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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
E-mail: arsenio.paez@kellogg.ox.ac.uk
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
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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

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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

Primary author: James S. Wise
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Recording link:
http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Building%20a%20Comprehensive%20Clinical%20Site%20Performance%20Portal%20in%20Support%20of%20Risk-Based%20Monitoring

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
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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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Recording link:
http://www.sctweb.org/members/virtualmeeting.cfm?keyword=The%20Impact%20of%20Interdisciplinary%20Relationships%20on%20Single%20IRB%20Selection%20in%20a%20National%20Clinical%20Trial%20Network

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
Primary author: Levent Bayman
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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
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Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Building%20a%20Drug%20Management%20System
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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Recording link: http://www.sctweb.org/members/virtualmeeting.cfm?keyword=Regulatory%20considerations%20for%20a%20multi-site%20clinical%20trial%20treating%20opioid%20use%20disorder%20(oud)%20with%20vulnerable%20populations:%20pregnant%20women,%20infants,%20and%20potential%20prisoners
Keywords: Trial Management & Research Coordination