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# WELCOME

Welcome to the 40th Annual Meeting of the Society for Clinical Trials in the beautiful city of New Orleans. The theme of our meeting is Clinical Trials: A Catalyst for Societal Advancement through Innovation. Our Society is unique in that it brings together individuals from various disciplines who are dedicated to the design, conduct, and analysis of clinical trials.

Amidst all the different activities the meeting will offer, we will take some time at a dance reception on Monday, May 20th to celebrate our society and the many ways it has touched all of us. Please come and celebrate with everyone. We also have a special Founders session on Monday evening where a few of our past presidents will provide insights on the Founders of our Society and their motivations behind the foundation of the Society, to take stock of what the Society has accomplished since its foundation in 1978, and to envision the future of the Society beyond its first 40 years.

New this year, we put together a planning committee to think about and make suggestions for the 2019 annual meetings. One of the first tasks of this committee was to discuss a possible theme for the 2019 meetings, as well as how to structure the program for the 2019 meeting so it reflects a more comprehensive meeting with wide-ranging topics on clinical trials conduct and methodology. The other main goal of this committee was to increase the communication across the program, education, and trial of the year committees, and to integrate industry speakers and topics, leadership development, and clinician-focused sessions. I sincerely hope you get an opportunity to see and experience some changes we brought about to the schedule and the program in terms of organizing thematic sessions. A direct offshoot of this planning committee endeavor are the Monday round table lunch sessions, to give our new members an opportunity to learn about our Society, and our current members a glimpse into the many opportunities for leadership and involvement with the Society.

I am excited about the scientific program and educational workshops and in-conference tutorials that have been selected by the Program and Educational Committees under the leadership of Letitia Perdue and Lynda Constable. I want to thank the committee members, as well as all of those who submitted abstracts for invited and contributed sessions, workshops, and posters. I think you will find many interesting sessions in the program and will, like me, have a difficult time deciding which ones to attend! Our mission is "to work internationally to advance human health through advocating the use of clinical trials, leading the development and dissemination of optimal methods and practices in clinical trials, and educating and developing clinical trial professionals." I believe this year's meeting fulfills that goal quite well.

As President of SCT, it was also my privilege to select the keynote speakers for the meeting. Dr. Thomas Fleming will deliver the Curtis Meinert Keynote lecture on Monday, May 20th, 2019, focusing on the topic of striving to achieve and protect the integrity of clinical trials, in alignment with the theme for the 40th year meeting. Thomas R. Fleming, Ph.D., is Professor and former Chair of the Department of Biostatistics at the University of Washington in Seattle, Member of the Fred Hutchinson Cancer Research Center, and the former Director of the Statistical Center for HIV/AIDS Prevention Trial Network, NIAID. He is a Special Government Employee for the FDA, and for more than 30 years he has served as a regular member of several

FDA Advisory Committees and as an invited voting member on more than 100 occasions. He was elected to membership in the Institute of Medicine of the National Academies in 2012 and to the National Academy of Medicine in 2015.

Dr. Monica Bertagnolli will deliver the Founder's lecture on Tuesday, May 21st, 2019, focusing on building a learning health care system, and learning from every patient. This talk fits well with the theme of societal advancement and will largely be futuristic in its perspective. Dr. Bertagnolli is the Richard E. Wilson Professor of Surgery in the Field of Surgical Oncology at Harvard Medical School, and a member of the Gastrointestinal Cancer and Sarcoma Disease Centers at Dana-Farber/Brigham & Women's Cancer Center, where she collaborates with colleagues in medical oncology, radiation oncology, and pathology to treat cancer patients in a tertiary care setting. Dr. Bertagnolli has also had numerous leadership roles in multi-institutional cancer clinical research consortia, and currently serves as the Group Chair of the Alliance for Clinical Trials in Oncology, a nationwide NCI-funded clinical trials group. She is also the Chief Executive Officer of Alliance Foundation Trials, LLC, a not-for-profit corporation that conducts international cancer clinical trials. In addition, Dr. Bertagnolli is the 2018-2019 President of the American Society of Clinical Oncology, a 45,000-member organization serving the needs of physicians and other clinicians who care for patients with cancer.

The David Sackett Trial of the Year Award Ceremony will take place on Monday afternoon. The Scleroderma: Cyclophosphamide or Transplantation (SCOT) trial is the recipient of this prestigious award. Dr. Lynette Keyes-Elstein, Principal Statistical Scientist at Rho, will accept the award on behalf of the SCOT trial team. We continue our Thomas C. Chalmers Student Scholarship and Sylvan Green Travel Award programs to attract students and medical professionals to the Society. All of these offerings, together with our invited sessions, contributed papers, round table sessions, in-conference tutorials and poster sessions, provide excellent opportunities for us to acquire new knowledge and keep abreast of the many ongoing developments in clinical trials.

Finally, I would like to acknowledge and sincerely thank the SCT management office staff at Fernley & Fernley, led until recently by Mike Canino and now by Mary Ann Emely, with support from Mary Keller, and Dena Rose. I also want to thank the members of the Executive Committee (Dean Fergusson, Ted Karrison, Domenic Reda and Joe Collins) and the volunteer efforts of all of the Society's elected officers, committee chairs, and committee members who worked hard to put this meeting together. And of course the generosity of the corporate sponsors and member donors who have provided financial support to the Society is greatly appreciated.

Participate in as many of the meeting's activities as you can! Enjoy the chance to talk with colleagues and make new acquaintances. Let's celebrate the 40th birthday of our Society together!

Sumithra J. Mandrekar
SCT President, 2018-2019

# CONFERENCE SCHEDULE AT A GLANCE

| TIME | MONDAY, MAY 20, 2019 |
|---|---|
| 7:30 - 8:00 am | Continental Breakfast with Coffee and Tea |
| 8:00 - 9:30 am | SCT President's Welcome & Curtis Meinert Keynote |
| 9:30 - 10:00 am | Poster Presentation & Exhibits - with Coffee and Tea |
| 10:00 - 11:30 am | Invited Sessions |
| 10:00 - 11:30 am | In-Conference Workshop 5 |
| 11:30 am - 12:45 pm | General Lunch |
| 11:30 am - 12:45 pm | Round Table Discussion with Lunch |
| 12:45 - 2:15 pm | Invited Sessions |
| 12:45 - 2:15 pm | Chalmers Scholarship Finalists |
| 12:45 - 2:15 pm | In-Conference Workshop 4 |
| 2:15 - 2:30 pm | Break |
| 2:30 - 3:30 pm | Contributed Sessions |
| 3:30 - 4:00 pm | Poster Presentations & Exhibits with Refreshments and Light Snacks |
| 4:00 - 5:00 pm | Trial of the Year |
| 5:30 - 6:30 pm | Program Committee Meeting |
| 5:30 - 6:30 pm | Journal Editorial Meeting |
| 9:00 pm - 12:00 am | Dessert Reception with DJ and Dancing |
| **TIME** | **TUESDAY, MAY 21, 2019** |
| 7:30 - 8:00 am | Continental Breakfast with Coffee and Tea |
| 8:00 - 9:20 am | Presentation of the 2019 Class of Fellows & Founders Lecture |
| 9:20 - 9:30 am | Break |
| 9:30 - 10:30 am | Contributed Sessions |
| 10:30 - 11:00 am | Poster Presentation & Exhibits with Refreshments |
| 11:00 am - 12:30 pm | Invited Sessions |
| 11:00 am - 12:30 pm | In-Conference Workshop 3 |
| 12:30 - 2:00 pm | SCT Business Session Lunch |
| 2:00 -3:00 pm | Contributed Sessions |
| 3:15 - 4:45 pm | Invited Sessions |
| 3:15 - 4:45 pm | In-Conference Workshop 1 |
| 4:45 - 5:00 pm | Break with Refreshments |
| 5:00 - 6:30 pm | Special Founders Session |
| **TIME** | **WEDNESDAY, MAY 22, 2019** |
| 7:30 - 8:00 am | Continental Breakfast with Coffee and Tea |
| 8:00 - 9:30 am | Invited Session |
| 9:30 - 9:45 am | Break |
| 9:45 -10:45 am | Contributed Sessions |
| 10:45 - 11:00 am | Break |
| 11:00 - 12:30 am | Invited Sessions |
| 11:00 am - 12:30 pm | In-Conference Workshop 2 |
| 12:30-12:45 pm | Break/Annual Meeting Adjourned |

## SUNDAY, MAY 19, 2019

| Begin Time | End Time | Room | Floor | Type | Speaker/Organizer | Session Title |
|---|---|---|---|---|---|---|
| 7:30am | Coffee/Tea | | | | | |
| 8:00am | 12:00pm | Nottoway | 4th Floor | Pre-Conference Workshop P1 | Susan S. Ellenberg | Clinical Trial Data Monitoring Committees and Reporting Statistical Centers: The Basics and Emerging Issues |
| 8:00am | 12:00pm | Maurepas | 3rd Floor | Pre-Conference Workshop P2 | Kelley M. Kidwell | SMART Clinical Trial Design for Large and Small Samples |
| 8:00am | 12:00pm | Borgne | 3rd Floor | Pre-Conference Workshop P3 | Yves Rosenberg | Essentials of Clinical Trials |
| 9:45am | 10:15am | Refreshment Break | | | | |
| 12:00pm | 1:00pm | Lunch Break (on your own) | | | | |
| 1:00pm | 5:00pm | Nottoway | 4th Floor | Pre-Conference Workshop P6 | Eleanor J. Murray | Methods for Causal Inference from Randomized Trials with Loss to Follow-up or Non-Adherence |
| 1:00pm | 5:00pm | Maurepas | 3rd Floor | Pre-Conference Workshop P5 | Peter G. Kaufmann | Control Groups, Clinically Important Differences and Effect Sizes in Complex Interventions |
| 1:00pm | 5:00pm | Borgne | 3rd Floor | Pre-Conference Workshop P4 | Jody D. Ciolino | Statistical Concepts in Clinical Trials for Non-Statisticians |
| 2:45pm | 3:15pm | Refreshment Break | | | | |
| 5:15pm | 7:15pm | Waterbury | 2nd Floor | EDUCATION COMMITTEE MEETING | | |
| 5:15pm | 7:15pm | Oak Alley | 4th Floor | SCT BOARD MEETING | | |
| 7:00pm | 9:00pm | Nottoway | 4th Floor | Pre-Conference Workshop P7 | Nolan A. Wages | Designs for Modern Phase I Oncology Trials |
| 7:00pm | 9:00pm | Maurepas | 3rd Floor | Pre-Conference Workshop P8 | David M. Kent | Personalized Evidence-Based Medicine: Predictive Approaches to Heterogeneous Treatment Effects in Randomized Trials |
| 7:00pm | 9:00pm | Borgne | 3rd Floor | Pre-Conference Workshop P9 | Shaun Treweek | Using Studies With in a Trial (SWATs) to Increase the Evidence Base for Trial Process Decision-Making |
| 7:30pm | 10:00pm | offsite-at Arnaud's | **Fellows Dinner** | | | |

# MONDAY, MAY 20, 2019

| Begin Time | End Time | Room | Floor | Type | Speaker/Organizer | Session Title |
|---|---|---|---|---|---|---|
| 7:30am | 8:00am | Napoleon BC | 3rd Floor | Continental Breakfast with Coffee and Tea | | |
| 8:00am | 9:30am | Napoleon BC | 3rd Floor | SCT President's Welcome & Curtis Meinert Keynote | Dr. Thomas Fleming | Striving to Achieve and Protect the Integrity of Clinical Trials |
| 9:30am | 10:00am | Napoleon D | 3rd Floor | Poster Presentation & Exhibits - with Coffee and Tea | | |
| 10:00am | 11:30am | Nottoway | 4th Floor | Invited Session | Hao Zhu *U.S. Food and Drug Administration* | Role of Model Informed Drug Development (MIDD) in Drug Development and Regulatory Evaluation |
| 10:00am | 11:30am | Oak Alley | 4th Floor | Invited Session | Maria Pufulete *University of Bristol* | Using observational healthcare data to emulate randomized trials |
| 10:00am | 11:30am | Borgne | 3rd Floor | Invited Session | Katie Gillies *University of Aberdeen* | How can behavioural science help us design better trials? |
| 10:00am | 11:30am | Waterbury | 2nd Floor | Invited Session | Kimberley Goldsmith *King's College London* | What works for whom and why: the future for trials of complex interventions |
| 10:00am | 11:30am | Rhythms 1 | 2nd Floor | Invited Session | Amy Dwy *The Emmes Corporation* | THE COLLABORATION BETWEEN DATA MANAGERS AND MONITORS IN RISK BASED MONITORING IN INTERNATIONAL STUDIES |
| 10:00am | 11:30am | Rhythms 2 & 3 | 2nd Floor | In-Conference Workshop 5 | Lehana Thabane | Beyond the CONSORT extension for pilot trials: guidelines, planning, abstracts and protocols |
| 11:30am | 12:45pm | Napoleon BC | 3rd Floor | General Lunch | | |
| 11:30am | 12:45pm | Napoleon A | 3rd Floor | Round Table Discussion with lunch | | |
| 12:45pm | 2:15pm | Nottoway | 4th Floor | Invited Session | Julie Qidwai *University of Iowa* | Switching Boats Mid-Stream: Maintaining Continuity in a Large Clinical Trials Network in the Face of Change |
| 12:45pm | 2:15pm | Oak Alley | 4th Floor | Invited Session | Colin Begg *Memorial Sloan Kettering Cancer Center* | Clinical Trials: Meet the Editors |
| 12:45pm | 2:15pm | Borgne | 3rd Floor | Invited Session | David DeMets *University of Wisconsin-Madison* | The Coronary Drug Project (CDP): Looking Back 50 Years |
| 12:45pm | 2:15pm | Waterbury | 2nd Floor | Invited Session | Mary W. Redman *Fred Hutchinson Cancer Research Center* | Clinical Trialists Can Help Make Real-World Data Analysis Better |
| 12:45pm | 1:00pm | Rhythms 1 | 2nd Floor | Chalmers Scholarship Finalists | Lee Kennedy-Shaffer *Harvard University* | Sample size estimation for stratified individual and cluster randomized trials with binary outcomes |
| 1:00pm | 1:15pm | | | | Linda J. Harrison *Harvard TH Chan School of Public Health* | Power Calculation for Cross-Sectional Stepped Wedge Cluster Randomized Trials with Variable Cluster Sizes |
| 1:15pm | 1:30pm | | | | Martin Law *Medical Research Council Biostatistics Unit* | A new class of optimally curtailed trials for phase II oncology trials. |
| 1:30pm | 2:15pm | | | Judging | | |
| 12:45pm | 2:15pm | Rhythms 2 & 3 | 2nd Floor | In-Conference Workshop 4 | Leila Rooshenas | Strategies for optimizing recruitment to randomized clinical trials |
| 2:15pm | 2:30pm | | | Break | | |
| 2:30pm | 3:30pm | Nottoway | 4th Floor | Contributed Session - Trial Management Start Up | | |
| 2:30pm | 2:45pm | | | | Lawrence Ragard *Westat, Inc.* | IMPROVING TRANSPARENCY IN CLINICAL TRIAL COSTS FOR PARTICIPANTS: NATIONAL CANCER INSTITUTE (NCI) NATIONAL COVERAGE ANALYSIS INITIATIVE SUPPORTED BY THE NCI'S CANCER TRIALS SUPPORT UNIT |
| 2:45pm | 3:00pm | | | | Diane Hartford *University of Utah* | Crowdsourcing Solutions for RCT Study Start-Up Pain Points |
| 3:00pm | 3:15pm | | | | Krista Valladares *Massachusetts General Hospital* | The NeuroNEXT Model: Efficiencies Gained by Deploying an Embedded Research Administrator |
| 3:15pm | 3:30pm | | | | Jacqueline Chen *University of Southern California* | Regulatory & Consent |
| 2:30pm | 3:30pm | Oak Alley | 4th Floor | Contributed Session - Cluster Randomization Trial Design | | |
| 2:30pm | 2:45pm | | | | Dustin Rabideau *Harvard T. H. Chan School of Public Health* | Randomization Inference for a Marginal Treatment Effect in Cluster Randomized Trials |
| 2:45pm | 3:00pm | | | | Joel Stevans *University of Pittsburgh* | Implementation of the Multi-Site Pragmatic Cluster Randomized Controlled Trial: Targeted Interventions to Prevent Chronic Low Back Pain (LBP) in High Risk Patients (TARGET) |
| 3:00pm | 3:15pm | | | | Jessica Kasza *Monash University* | Staircase cluster randomised trial designs |
| 3:15pm | 3:30pm | | | | Shun Fu Lee *Population Health Research Institute* | Sample size calculation for cluster randomized crossover trials of multiple periods. |
| 2:30pm | 3:30pm | Borgne | 3rd Floor | Contributed Session - Power Considerations | | |
| 2:30pm | 2:45pm | | | | Cindy Cooper *University of Sheffield* | Anticipated and observed effect sizes in publicly funded randomised controlled trials |
| 2:45pm | 3:00pm | | | | Nicholas Seewald *University of Michigan* | Sample size considerations for comparing dynamic treatment regimens in a sequentially-randomized trial with a continuous longitudinal outcome |
| 3:00pm | 3:15pm | | | | Lifeng Lin *Florida State University* | Borrowing of strength from indirect evidence in network meta-analyses |
| 3:15pm | 3:30pm | | | | Ayoola Ademola *University of Calgary* | A Comparison of Frequentist and Bayesian Power Analyses for Non-Inferiority Trials Designs |
| 2:30pm | 3:30pm | Waterbury | 2nd Floor | Contributed Session - Regulatory & Consent | | |
| 2:30pm | 2:45pm | | | | Julia Collins *The Emmes Corporation* | Considerations in Selection of a Single IRB of Record for Multi-Site Trials |
| 2:45pm | 3:00pm | | | | Derk Arts *Academic Medical Centre, Amsterdam* | Benefits of dynamic consent in research - now and tomorrow |

## MONDAY, MAY 20, 2019

| Begin Time | End Time | Room | Floor | Type | Speaker/Organizer | Session Title |
|---|---|---|---|---|---|---|
| 3:00pm | 3:15pm | | | | Eric Hardter<br>*The Emmes Corporation* | Regulatory considerations for HHS-sponsored, non-drug human subjects research studies |
| 3:15pm | 3:30pm | | | | Marie Kay<br>*University of Utah Trial Innovation Center \| Data Coordinating Center* | Improving Risk, Safety, and Data Integrity Oversight through Standardized Protocol Deviation Management – A Data Coordinating Center's Approach |
| 2:30pm | 3:30pm | Rhythms 1 | 2nd Floor | Contributed Session - Retention & Adherence | | |
| 2:30pm | 2:45pm | | | | Katie Gillies<br>*University of Aberdeen* | Investigating Clinical Trial Consultations for Discussions of Retention: A Mixed Methods Study |
| 2:45pm | 3:00pm | | | | Scott Rushing<br>*Wake Forest University School of Medicine* | Intervention Adherence Tracking Through Use of an Electronic Participant Engagement Platform |
| 3:00pm | 3:15pm | | | | Manqi Cai<br>*Columbia University* | Development of Methods to handle medication non-adherence in Early Phase Dose-Finding |
| 3:15pm | 3:30pm | | | | Andrea Anderson<br>*Wake Forest School of Medicine* | Designing an Adherence Tracking System for an International Trial |
| 2:30pm | 3:30pm | Rhythms 2 & 3 | 2nd Floor | Contributed Session - Trial Design in Specialized Populations | | |
| 2:30pm | 2:45pm | | | | Sarah Gaussoin<br>*Wake Forest School of Medicine* | Cocoa Supplement and Multivitamin Outcomes Study of Cognitive Function (COSMOS-Mind): Design of a Large Randomized Clinical Trial |
| 2:45pm | 3:00pm | | | | Michael Grayling<br>*Newcastle University* | Historical and contemporary opinions on the design of phase II oncology trials |
| 3:00pm | 3:15pm | | | | Andrew Rygiel<br>*American Society of Clinical Oncology* | DEFINING EVALUABILITY IN A PHASE II, PROSPECTIVE, NON-RANDOMIZED, PRAGMATIC CANCER CLINICAL TRIAL |
| 3:15pm | 3:30pm | | | | Amanda MacPherson<br>*McGill University* | Benefit and burden in trials of novel, disease-modifying interventions in neurodegenerative disease: A systematic review and meta-analysis |
| 3:30pm | 4:00pm | Napoleon D | 3rd Floor | Poster Presentations & Exhibits with Refreshments and Light Snacks | | |
| 4:00pm | 5:00pm | Napoleon BC | 3rd Floor | Trial of the Year | | |
| 5:30pm | 6:30pm | Oak Alley | 4th Floor | Program Committee Meeting | | |
| 5:30pm | 6:30pm | Waterbury | 2nd Floor | Journal Editorial Meeting | | |
| 9:00pm | 12:00am | Armstrong | 8th Floor | Dessert Reception with DJ and Dancing | | |

## TUESDAY, MAY 21, 2019

| Begin Time | End Time | Room | Floor | Type | Speaker/Organizer | Session Title |
|---|---|---|---|---|---|---|
| 7:30am | 8:00am | Napoleon BC | 3rd Floor | Continental Breakfast with Coffee and Tea | | |
| 8:00am | 9:20am | Napoleon BC | 3rd Floor | Presentation of the 2019 Class of Fellows & Founders Lecture | Dr. Monica Bertagnolli | Building a learning health care system, and learning from every patient |
| 9:20am | 9:30am | Break | | | | |
| 9:30am | 10:30am | Napoleon A 1, 2 | 3rd Floor | Contributed Session - Electronic Data Capture | | |
| 9:30am | 9:45am | | | | Catherine Olivier<br>*University of Leeds* | The Challenge of Innovation: Considerations for implementing two-way text messaging for primary outcome data collection in clinical trials |
| 9:45am | 10:00am | | | | Simon Hatche<br>*Ottawa Hospital Research Institute* | The BEACON Study: Protocol for a cohort study as part of an evaluation of the effectiveness of smartphone-assisted problem solving therapy in men who present with intentional self-harm to Emergency Departments in Ontario. |
| 10:00am | 10:15am | | | | Katie Jentoft<br>*Massachusetts General Hospital* | CONVERTING VALIDATED SCALES INTO CONSOLIDATED ELECTRONIC CASE REPORT FORMS |
| 10:15am | 10:30am | | | | Rebecca Neiberg<br>*Wake Forest Health Sciences* | ASSESSING DATA QUALITY OF PARTICIPANT WEIGHTS UPLOADED FROM SMART SCALES: THE STUDY OF NOVEL APPROACHES TO PREVENTION CLINICAL TRIAL – EXTENSION PHASE |
| 9:30am | 10:30am | Napoleon A 3 | 3rd Floor | Contributed Session - Interim Monitoring and Statistical Inference | | |
| 9:30am | 9:45am | | | | Jemma Hudson<br>*Health Services Research Unit, University of Aberdeen* | Joint modelling of quality of life and time-to-event data in an orthopaedic trial |
| 9:45am | 10:00am | | | | RANI JAYSWAL<br>*MARKEY CANCER CENTER, UNIVERSITY OF KENTUCKY* | Interim Monitoring Reports and SAS Macros to Facilitate Reporting and Implementation of Early Phase Clinical Trials |
| 10:00am | 10:15am | | | | Lu Mao<br>*University of Wisconsin-Madison* | Statistical Inference for Complex Time to Event Outcomes under Non-Randomized Cohorts with Application to the INVESTED Trial |
| 10:15am | 10:30am | | | | Virginia Shipes<br>*Medical University of South Carolina* | Assessing the Robustness of Interim Stopping Criteria Methods in Phase III Survival Clinical Trials |
| 9:30am | 10:30am | Borgne | 3rd Floor | Contributed Session - Adaptive Design & Analysis | | |
| 9:30am | 9:45am | | | | Anne Esler<br>*Syneos Health* | Adaptive Designs - Introduction for Non-statisticians -<br>What are they? How do they impact me? What do I need to know? |
| 9:45am | 10:00am | | | | Elizabeth Ryan<br>*University of Birmingham* | Evaluation of Bayesian adaptive designs for Phase III trials |
| 10:00am | 10:15am | | | | Clement Ma<br>*Dana-Farber/Boston Children's Cancer and Blood Disorders Center* | TARGET-CRM: a novel adaptive dose-escalation design for targeted therapies with applications in pediatric oncology |
| 10:15am | 10:30am | | | | Jérôme Tanguy<br>*Nestlé Research* | Learnings from the Adaptive Design journey |

# TUESDAY, MAY 21, 2019

| Begin Time | End Time | Room | Floor | Type | Speaker/Organizer | Session Title |
|---|---|---|---|---|---|---|
| 9:30am | 10:30am | Waterbury | 2nd Floor | Contributed Session - Recruitment through Referrals and Electronic Methods | | |
| 9:30am | 9:45am | | | | J. Athene Lane *University of Bristol* | Optimising recruitment in clinical trials in surgery including strategies for surgical trainees working together to achieve success |
| 9:45am | 10:00am | | | | Samiha Islam *American Society of Clinical Oncology* | Experience in Implementing a Genomic Test Screening Tool as a Patient Identification Aid in a Precision Medicine Oncology Study |
| 10:00am | 10:15am | | | | Andrew Pilecki *Branding Science* | Clinical trials and healthcare professionals: An analysis of primary factors driving referral behaviors |
| 10:15am | 10:30am | | | | Jenny Donovan *University of Bristol* | Exploring the translation of the UK QRI (QuinteT Recruitment Intervention) to improve and optimise recruitment to clinical trials in the US |
| 9:30am | 10:30am | Rhythms 1 | 2nd Floor | Contributed Session - Outcomes | | |
| 9:30am | 9:45am | | | | Tolu Sajobi *University of Calgary* | A Differential Item Functioning Analysis of the DASH Outcome Measure in a Randomized Controlled Trial of Patients with Elbow Fractures |
| 9:45am | 10:00am | | | | Joel Gagnier *University of Michigan* | Bias Associated With Patient Reported Outcome Measures in Clinical Trials |
| 10:00am | 10:15am | | | | Gillian Lancaster *Keele University* | Creation of the WHO indicators of Infant and Young Child Development (IYCD) as an outcome measure for assessing pre-primary interventions in low and middle income countries: meta data synthesis and field testing methodology |
| 10:15am | 10:30am | | | | Kerry Avery *University of Bristol* | Outcome selection and reporting for innovative surgical procedures and devices: a review of current practice in IDEAL/IDEAL-D studies to inform the development of a core outcome set |
| 9:30am | 10:30am | Rhythms 2 & 3 | 2nd Floor | Contributed Session - Trial Management & Design: Innovation and Real World Dilemmas | | |
| 9:30am | 9:45am | | | | Edward Mayerson *SWOG Statistics and Data Management Center* | Trials, Tribulations, and Triumphs in Coordinating a "Not Otherwise Categorized" Cohort in an Umbrella Trial for Rare Cancers |
| 9:45am | 10:00am | | | | Melissa Plets *SWOG Statistics and Data Management Center* | Rethinking the Traditions of Trial Design: A Rare Cancer Basket Trial as a Motivating Example |
| 10:00am | 10:15am | | | | Logan Sirline *Medical University of South Carolina* | Implementation of an Innovative Lab Kit and Bio-Sample Specimen Tracking Module within a Clinical Trial Management System |
| 10:15am | 10:30am | | | | Eve Jelstrom *The Emmes Corporation* | Premature Site Closure during a Multi-site Clinical Trial |
| 10:30am | 11:00am | Napoleon D | 3rd Floor | Poster Presentation & Exhibits with Refreshments | | |
| 11:00am | 12:30pm | Napoleon A 1, 2 | 3rd Floor | Invited Session | Spencer Hey *Harvard Medical School* | Unintended consequences of participant engagement in clinical trials involving behavioral interventions. |
| 11:00am | 12:30pm | Napoleon A 3 | 3rd Floor | Invited Session | Jamie Brehaut *Ottawa Hospital Research Institute* | Safeguarding Public and Patient Trust in Pragmatic Trials Without Written Informed Consent |
| 11:00am | 12:30pm | Borgne | 3rd Floor | Invited Session | Brett Thombs *Jewish General Hospital and McGill University* | Development of reporting guidelines for randomized controlled trials using cohorts and routinely collected health data |
| 11:00am | 12:30pm | Waterbury | 2nd Floor | Invited Session | Yves Rosenberg *National Institutes of Health* | Planning and Implementing Key Design Changes in Multicenter Clinical Trials: Lessons Learned from the ISCHEMIA trial experience |
| 11:00am | 12:30pm | Rhythms 1 | 2nd Floor | Invited Session | Carmen Rosa *NIH/NIDA* | Perspectives on Data Sharing: Preparing, Analyzing, and Conducting Secondary Data Analyses using Publicly Available Clinical Trial Data |
| 11:00am | 12:30pm | Rhythms 2 & 3 | 2nd Floor | In-Conference Workshop 3 | Alison McDonald | Trial Close Out and Archiving |
| 12:30pm | 2:00pm | Napoleon BC | 3rd Floor | SCT Business Session Lunch | | |
| 2:00pm | 3:00pm | Napoleon A 1, 2 | 3rd Floor | Contributed Session - Electronic Health Records and Data Capture | | |
| 2:00pm | 2:15pm | | | | Jeremy Wolff *The Emmes Corporation* | Electronic Healthcare Record Extraction, Transfer, and Use in Clinical Trials: Lessons Learned |
| 2:15pm | 2:30pm | | | | Kerry Avery *University of Bristol* | Developing a hospital-integrated system for electronic patient-reporting, detection and management of symptoms and complications after surgery |
| 2:30pm | 2:45pm | | | | Charity Patterson *University of Pittsburgh* | MULTIPLE, INNOVATIVE, REDCAP PROJECTS FOR TWO SIMULTANEOUS MULTICENTER TRIALS. |
| 2:45pm | 3:00pm | | | | Phyllis Goodman *Cardiff University* | Extending Randomized Clinical Trial Results through Database Linkages |
| 2:00pm | 3:00pm | Napoleon A 3 | 3rd Floor | Contributed Session - Ethics | | |
| 2:00pm | 2:15pm | | | | Adelaide Doussau *McGill University* | The Ethics of Placebo Sequential Parallel Comparison Design |
| 2:15pm | 2:30pm | | | | Victoria Shepherd *Cardiff University* | Ethical aspects of surrogate decision-making for clinical trials: a systematic review of empirical research |
| 2:30pm | 2:45pm | | | | David Kerr *Axio Research* | Points of Consideration for the Independence of DMCs and SDACs |
| 2:45pm | 3:00pm | | | | Nigel Kirby *Cardiff University* | 'First do no harm' – exploring the potential impact of placebo treatments on adverse effects |
| 2:00pm | 3:00pm | Borgne | 3rd Floor | Contributed Session - Cluster Randomization Statistical Analysis | | |
| 2:00pm | 2:15pm | | | | Elizabeth Louise Turner *Duke University* | Evaluation of weighting and imputation methods to deal with missing outcomes in cluster randomized trials |
| 2:15pm | 2:30pm | | | | Madeleine Organ *Northwestern University* | Evaluating performance of covariate-constrained randomization (CCR) techniques under misspecification of cluster-level variables |
| 2:30pm | 2:45pm | | | | Melanie Bell *University of Arizona* | The mixed model for repeated measures for cluster randomized trials (MMRM-CRT): a simulation study investigating bias and type I error with missing continuous data |
| 2:45pm | 3:00pm | | | | Brittney Bailey *Amherst College* | A new predictive mean matching imputation method for data from cluster randomized trials |

## TUESDAY, MAY 21, 2019

| Begin Time | End Time | Room | Floor | Type | Speaker/Organizer | Session Title |
|---|---|---|---|---|---|---|
| 2:00pm | 3:00pm | Waterbury | 2nd Floor | Contributed Session - Trial Design: Statistical Considerations | | |
| 2:00pm | 2:15pm | | | | Jessica Overbey *Icahn School of Medicine at Mount Sinai* | IS CORRECTING FOR MULTIPLE TESTING NECESSARY IN A PLATFORM TRIAL? |
| 2:15pm | 2:30pm | | | | Fang-Shu Ou *Mayo Clinic* | Alternative test statistics and their power under non-proportional hazard assumptions |
| 2:30pm | 2:45pm | | | | Richard Emsley *King's College London* | Mediation analysis of complex interventions should reflect the trial design |
| 2:45pm | 3:00pm | | | | Andrew Chapple *LSU Health Science Center - School of Public Health* | A Hybrid Phase I-II/III Clinical Trial Design Allowing Dose Re-Optimization in Phase III |
| 2:00pm | 3:00pm | Rhythms 1 | 2nd Floor | Contributed Session - Oncology: Treatment Effects & Outcomes | | |
| 2:00pm | 2:15pm | | | | Cole Wayant *Oklahoma State University Center for Health Sciences* | Clinical trial endpoints in oncology drug advertisements: a potential mechanism for hype? |
| 2:15pm | 2:30pm | | | | Jianrong Zhang *Washington University at St. Louis* | Clinical Benefits on Progression-free Survival between Blinded Independent Central Review and Local Assessment in Phase III Randomized Controlled Trials on Solid Tumors: An Analysis of the Results from a Systematic Review |
| 2:30pm | 2:45pm | | | | Matthew Schipper *University of Michigan* | Comparing treatments effect estimates in oncology using randomized clinical trials and observational registries |
| 2:45pm | 3:00pm | | | | Loïc Lebellec *Centre Oscar Lambret* | How to quantify the treatment effect in oncology randomized clinical trials with interval-censored data? Restricted Mean Survival Time Difference versus Hazard Ratio and point estimates: results from a simulation study. |
| 2:00pm | 3:00pm | Rhythms 2 & 3 | 2nd Floor | Contributed Session - Reporting to the Public | | |
| 2:00pm | 2:15pm | | | | Kevin Fain *National Center for Biotechnology Information* | All-cause mortality reporting in ClinicalTrials.gov compared to publications. |
| 2:15pm | 2:30pm | | | | Wentao Li *Monash University* | Problematic registration, randomization, and analysis in randomized controlled trials: systematic review of Obstetrics and Gynaecology studies from an African country (2013-2018) |
| 2:30pm | 2:45pm | | | | Michael Flanagin *Axio Research LLC* | Evolving Practices of Results Reporting in ClinicalTrials.gov |
| 2:45pm | 3:00pm | | | | Yuanxi Jia *Bloomberg School of Public Health, Johns Hopkins University* | Duplicate Patterns and Duplicate Publication Bias among Chinese-sponsored Drug-related Randomized Controlled Trials |
| 3:15pm | 4:45pm | Napoleon A 1, 2 | 3rd Floor | Invited Session | Cathy Critchlow, PhD *Amgen* | Synthesize Real-World Data with Randomized Clinical Trial Data for Efficient Drug Development |
| 3:15pm | 4:45pm | Napoleon A 3 | 3rd Floor | Invited Session | Marion Campbell *University of Aberdeen* | ROLE OF THE EXPERTISE-BASED DESIGN IN TRIALS OF NON-PHARMACOLOGICAL INTERVENTIONS |
| 3:15pm | 4:45pm | Borgne | 3rd Floor | Invited Session | Pralay Mukhopadhyay *AstraZeneca* | Challenges in Design, Analysis and Selection of Endpoints in Immuno-Oncology Trials |
| 3:15pm | 4:45pm | Waterbury | 2nd Floor | Invited Session | CANCELLED | n in Clinical Trials |
| 3:15pm | 4:45pm | Rhythms 1 | 2nd Floor | Invited Session | Shaunagh Browning, MS, RN, FNP-BC *Georgetown Medical Center* | "The Clinical Research Nurse in Clinical Trials: Value Added?" A Panel Discussion on the Nurses' Role on the Clinical Trials Team |
| 3:15pm | 4:45pm | Rhythms 2 & 3 | 2nd Floor | In-Conference Workshop 1 | Laura Lovato | It Takes a Village: Multi-Disciplinary Approach to Designing Stellar Data Collection Forms |
| 4:45pm | 5:00pm | Break with Refreshments | | | | |
| 5:00pm | 6:30pm | Napoleon BC | 3rd Floor | Special Founders Session | | |

## WEDNESDAY, MAY 22, 2019

| Begin Time | End Time | Room | Floor | Type | Speaker/Organizer | Session Title |
|---|---|---|---|---|---|---|
| 7:30am | 8:00am | Napoleon BC | 3rd Floor | Continental Breakfast with Coffee and Tea | | |
| 8:00am | 9:30am | Napoleon A 1, 2 | 3rd Floor | Invited Session | Jonathan Kimmelman *McGill University* | The United States' Right-To-Try Legislation: Implications for Clinical Trials |
| 8:00am | 9:30am | Napoleon A 3 | 3rd Floor | Invited Session | Juliana Tolles *Harbor UCLA Medical Center* | Challenges and Best Practices for Data Monitoring Committees (DMCs) Overseeing Adaptive Clinical Trials |
| 8:00am | 9:30am | Borgne | 3rd Floor | Invited Session | Larisa Tereshchenko *Oregon Health and Science University* | Clinician-reported outcomes: can we do better? |
| 8:00am | 9:30am | Waterbury | 2nd Floor | Invited Session | Denise Esserman *Yale University* | Clinical, Practical and Methodological Considerations for Patient Preference Clinical Trials Designs |
| 8:00am | 9:30am | Rhythms 1 | 2nd Floor | Invited Session | Greg Ball *Merck* | The Global Regulatory Landscape and a Safety Mindset: Medical Judgment and Decision-Making within a Quantitative Framework |
| 8:00am | 9:30am | Rhythms 2 & 3 | 2nd Floor | Invited Session | Chenguang Wang *Johns Hopkins University* | Innovative Early Phase Clinical Trial Designs for Cancer Immunotherapy |
| 9:30am | 9:45am | Break | | | | |
| 9:45am | 10:45am | Napoleon A 1, 2 | 3rd Floor | Contributed Session - Web Systems | | |

## WEDNESDAY, MAY 22, 2019

| Begin Time | End Time | Room | Floor | Type | Speaker/Organizer | Session Title |
|---|---|---|---|---|---|---|
| 9:45am | 10:00am | | | | Wenle Zhao<br>*Medical University of South Carolina* | Automated Site-Subject Payment Management System for Multi-center Clinical Trials |
| 10:00am | 10:15am | | | | Chris Cook<br>*SWOG Statistics and Data Management Center* | Improving Online Tools for Clinical Trial Design |
| 10:15am | 10:30am | | | | John Nichols<br>*Wake Forest University Health Sciences* | SITE TRACKING SYSTEM FOR ADMINISTRATION AND ORGANIZATION OF CLINICAL SITE-SPECIFIC INFORMATION |
| 10:30am | 10:45am | | | | Lauren Bradley<br>*RTI International* | Innovative Application of the Jira Software Technology in the Clinical Trial Case Report Form Development Process |
| 9:45am | 10:45am | Napoleon A 3 | 3rd Floor | Contributed Session - Trial Management: Design & Adaptions | | |
| 9:45am | 10:00am | | | | Shaun Treweek<br>*University of Aberdeen* | Increasing the trial process evidence base without increasing research waste |
| 10:00am | 10:15am | | | | Marion K. Campbell<br>*University of Aberdeen* | Traumatic Decisions; Research Recruitment and Randomisation in an Acute Emergency Setting |
| 10:15am | 10:30am | | | | Gareth Davies<br>*University of Wisconsin* | *Sylvan Green Winner:* Surgeons' lack of understanding of levels of evidence and trial methodology is a major barrier to randomized trial in surgery |
| 10:30am | 10:45am | | | | Naveen Pereira<br>*Mayo Clinic* | TAILOR PCI: Transitioning a Genotype Based Randomized Clinical Trial to a Registry Using Digital Solutions |
| 9:45am | 10:45am | Borgne | 3rd Floor | Contributed Session -Data Quality & Reports | | |
| 9:45am | 10:00am | | | | Nancy Dianis<br>*Westat* | Incremental implementation of risk-based monitoring in a resource-constrained environment |
| 10:00am | 10:15am | | | | Cathryn Rankin<br>*SWOG Statistics and Data Management Center* | Maintaining a Vigilance for Quality Data |
| 10:15am | 10:30am | | | | Jeffery Oliver<br>*Abbott Nutrition, Abbott Laboratories* | APPLICATION OF KEY RISK INDICATORS TO IMPROVE DATA QUALITY: A NUTRITION COMPANY'S PERSPECTIVE |
| 10:30am | 10:45am | | | | Angela Smith<br>*SWOG Statistics and Data Management Center* | Achieving balance between standardization and customization with the Statisticians' Report Worksheet |
| 9:45am | 10:45am | Waterbury | 2nd Floor | Contributed Session - Survival Summary Measures | | |
| 9:45am | 10:00am | | | | Mark Walton<br>*Jannsen* | Testing of Multiple Survival Endpoints in a Group Sequential Design – Control of Familywise Error in CREDENCE |
| 10:00am | 10:15am | | | | Isabelle Weir<br>*Boston University School of Public Health* | Multivariate meta-analysis model for the difference in restricted mean survival times |
| 10:15am | 10:30am | | | | Jennifer Le-Rademacher<br>*Mayo Clinic* | Practical Considerations for Trial Design using the Mean Survival Time Endpoint |
| 10:30am | 10:45am | | | | Lauren Balmert<br>*Northwestern University, Feinberg School of Medicine* | Quantile Lost Lifespan: A summary measure for time-to-event data |
| 9:45am | 10:45am | Rhythms 1 | 2nd Floor | Contributed Session - Misc: Stats | | |
| 9:45am | 10:00am | | | | Hayley Belli<br>*New York University Langone School of Medicine* | An algorithmic approach for determining individualized stage duration in a Sequential Multiple Assignment Randomized Trial (SMART) |
| 10:00am | 10:15am | | | | Matthew Parkes<br>*The University of Manchester* | Futility of the Treatment, Rather than Futility of the Trial, as the Primary Focus of Interim Analyses in Clinical Trials |
| 10:15am | 10:30am | | | | Anne Welhaven<br>*University of Iowa* | Evaluation of Continual Reassessment Method with Lagged Cohort |
| 10:30am | 10:45am | | | | Rick Chappell<br>*University of Wisconsin* | Just-in-Time Consent: Efficiency vs. Ethics |
| 9:45am | 10:45am | Rhythms 2 & 3 | 2nd Floor | Contributed Session - Ensuring Trials Answer Key Questions | | |
| 9:45am | 10:00am | | | | Kimberley Goldsmith<br>*King's College London* | Independent treatment mechanisms of cognitive behavioural treatments for Irritable Bowel Syndrome |
| 10:00am | 10:15am | | | | Fatima Alvi<br>*Washington University, St. Louis* | Reducing Adenoviral Patient Infected Days (RAPID) Study: Success in Masking Subjects and Clinicians to Treatment with Ophthalmic 5% Povidone-Iodine |
| 10:15am | 10:30am | | | | Kate Harvey<br>*University of Bristol, UK* | 'Exploring the feasibility of using mixed methods within an IDEAL 2a/2b study to facilitate the safe, transparent and efficient early-phase evaluation of a novel surgical technique: The Pre-BRA study.' |
| 10:30am | 10:45am | | | | Andrew Cook<br>*University of Southampton* | Is there an inverse relationship between the importance of a research question and the scientific quality of a proposal to answer it? A reassurance for the UK's Public Health Research programme. |
| 10:45am | 11:00am | Break | | | | |
| 11:00am | 12:30pm | Napoleon A 1, 2 | 3rd Floor | Invited Session | Karla Hemming<br>*University of Birmingham* | The multiple-period cluster randomised cross-over design for comparative effectiveness research: statistical and ethical issues |
| 11:00am | 12:30pm | Napoleon A 3 | 3rd Floor | Invited Session | Jerry Barnes<br>*University of Iowa* | Preparing and Submitting Data to Open and Limited-Access Repositories |
| 11:00am | 12:30pm | Borgne | 3rd Floor | Invited Session | Catherine Meyers, MD<br>*National Institutes of Health, National Center for Complementary and Integrative Health* | The Landscape of Embedded Pragmatic Clinical Trials in the US: Focus on Opioid Use and Pain Management |
| 11:00am | 12:30pm | Waterbury | 2nd Floor | Invited Session | Sally Jo Zuspan, RN, MSN<br>*University of Utah* | Introduction to Quality by Design and Risk Management: Can you get your staff and study teams to bite? |
| 11:00am | 12:30pm | Rhythms 1 | 2nd Floor | Invited Session | Claire Cochran<br>*University of Aberdeen* | From Grant to GANNT, the challenges of setting up a trial in 2018 – lessons learnt for the international stage |
| 11:00am | 12:30pm | Rhythms 2 & 3 | 2nd Floor | In-Conference Workshop 2 | Julia Collins | Site Selection for Clinical Trials: Tips, Tricks and Process Considerations |
| 12:45pm | 2:00pm | Maurepas | 3rd Floor | Board Meeting | | |

# POSTER PRESENTATIONS

| Poster Number | Day and Time | Title | Last Name | First Name | Affiliation |
|---|---|---|---|---|---|
| 1 | Monday 9:30 - 10:00 AM | Consistent Data Collection Across Multiple Countries | Adkisson | Meaghan | WFUBMC |
| 4 | Monday 9:30 - 10:00 AM | GCP Compliance Challenges in Complementary and Alternative Medicine Trials | Arevalo | Bert | Westat |
| 7 | Monday 9:30 - 10:00 AM | Procedural Considerations for the Secure Remote Review of Executed Informed Consent Forms | Collins | Julia | The Emmes Corporation |
| 10 | Monday 9:30 - 10:00 AM | Statistical Approaches for Summarizing the Clinical Event Reporting and Adjudication Process. | Cook | Thomas | University of Wisconsin-Madison |
| 13 | Monday 9:30 - 10:00 AM | Surmounting Barriers with Targeted Solutions: Launching the Pharmacotherapies for Alcohol and Substance Abuse Consortium | Crawford | Margaret | RTI International |
| 16 | Monday 9:30 - 10:00 AM | Scaling the communication management hurdle: Communications Manager | Forrest | Mark | University of Aberdeen |
| 19 | Monday 9:30 - 10:00 AM | Automated Assignment of Congenital Heart Surgery Procedure Types for Accurate Prediction of ICU Length-of-Stay | Ge | Shirley | Boston Children's Hospital |
| 22 | Monday 9:30 - 10:00 AM | A review of software availability for adaptive clinical trials | Grayling | Michael | Newcastle University |
| 25 | Monday 9:30 - 10:00 AM | Innovative digital recruitment and retention tools for more efficient conduct of randomised trials | Griffiths | Gareth | University of Southampton |
| 28 | Monday 9:30 - 10:00 AM | A two-stage selection designs for basket clinical trials | Hsiao | Chin-Fu | National Health Research Institutes |
| 31 | Monday 9:30 - 10:00 AM | Language Bias among Chinese-sponsored Drug-related Randomized Controlled Trials | Jia | Yuanxi | Bloomberg School of Public Health, Johns Hopkins University |
| 34 | Monday 9:30 - 10:00 AM | Increasing Access to Clinical Research Using an Innovative Mobile Recruitment Approach: The (MoRe) Concept | Johnson | Marcus | Durham VA Health Care System |
| 37 | Monday 9:30 - 10:00 AM | Utilizing cloud-based software to increase efficiency and reduce errors and increase efficiency in communication during the conduct of multi-site clinical trials | Klements | David | Massachusetts General Hospital |
| 40 | Monday 9:30 - 10:00 AM | Assessing Clinical Trial Self-Perceived Competence Among International Sites Participating in the AIDS Malignancy Consortium | Lee | Jeannette | University of Arkansas for Medical Sciences |
| 43 | Monday 9:30 - 10:00 AM | Trial salvage: Pragmatic design adaptation in response to recruitment challenges | Lewis | Rebecca | The Institute of Cancer Research |
| 46 | Monday 9:30 - 10:00 AM | Digital images of surgical wounds taken by patient themselves after leaving hospital: exploring the feasibility of a method for remote and blinded outcome assessment of surgical site infection. | Macefield | Rhiannon | University of Bristol |
| 49 | Monday 9:30 - 10:00 AM | The Influence of Institution Accrual on Patient Survival in Canadian Cancer Clinical Trials | Maracle | Brooke | Queen's University |
| 52 | Monday 9:30 - 10:00 AM | Using AI and Natural Language Generation to Automate Pharmaceutical Clinical Study Reports | McCrindle | Jeffrey | Yseop, Inc. |
| 55 | Monday 9:30 - 10:00 AM | Minimization as a Randomization Method | Morrison | Laura | Emmes Canada |
| 58 | Monday 9:30 - 10:00 AM | Change in Pain and Physical Activity in the InRespond Trial: Can Composite Outcomes Improve Responsiveness? | Parkes | Matthew | The University of Manchester |
| 61 | Monday 9:30 - 10:00 AM | Surrogate decision-making for clinical trials: a qualitative exploration of surrogate decision-makers' experiences | Shepherd | Victoria | Cardiff University |
| 64 | Monday 9:30 - 10:00 AM | On Covariate Adaptive Randomization Methods in Acute Stroke Trials | Singh | Gurbakhshash | Central Connecticut State University |
| 67 | Monday 9:30 - 10:00 AM | Creating Dynamic SAS Reports Across Multiple REDCap Projects | Talton | Jennifer | Wake Forest School of Medicine |
| 70 | Monday 9:30 - 10:00 AM | Inclusion of Limited English Proficient Individuals in Clinical Research | Tran | Jessica | Icahn School of Medicine at Mount Sinai |
| 73 | Monday 9:30 - 10:00 AM | A Bold Collaboration Between the Recruitment Innovation Center (RIC) and the Department of Veterans Affairs (VA) to Develop a Case-Based Framework for Sharing Algorithmic Approaches to Facilitate Clinical Research Planning and Recruitment | Velarde | Kandi | US Department of Veterans Affairs |
| 76 | Monday 9:30 - 10:00 AM | Endpoint Surrogacy in Oncological Randomized Controlled Trials with Immunotherapies:<br>A Systematic Review of Meta-analyses | Zhang | Jianrong | Washington University in St. Louis |
| 3 | Monday 3:30 - 4:00 PM | Challenges to Preventing Pregnancy During Ebola Vaccine Clinical Trials in Liberia | Barber | Susanna | National Institutes of Health -- National Institute of Allergy and Infectious Diseases |
| 6 | Monday 3:30 - 4:00 PM | UGT2B17, exemestane metabolism, and their association with physical health-related quality of life in postmenopausal women participating in the Mammary Prevention 3 Trial | Basmadjian | Rob | Queen's University |
| 9 | Monday 3:30 - 4:00 PM | Missing Data and Sensitivity Analysis with Implications for Sample Size and Power of Randomized Clinical Trials. | Cook | Thomas | University of Wisconsin-Madison |
| 12 | Monday 3:30 - 4:00 PM | Development of a resource to guide set-up and conduct of international surgical clinical trials | Croft | Julie | Clinical Trials Research Unit, Leeds Institute of Clinical Trials Research, University of Leeds |
| 15 | Monday 3:30 - 4:00 PM | PARTICIPANT-DIRECTED DATA ENTRY VIA iPad IN SINGLE AND MULTI-SITE CLINICAL TRIALS | Davis | Patty | Wake Forest School of Medicine |
| 18 | Monday 3:30 - 4:00 PM | Prognosticating Outcomes and Nudging Decisions with Electronic Records in the ICU (PONDER-ICU) Trial: Implementation in a learning health system | Dress | Erich | University of Pennsylvania |
| 21 | Monday 3:30 - 4:00 PM | Relative sample size reduction of three standard statistical methods in the analysis of randomized controlled trials: a simulation study | Egbewale | Bolaji | Ladoke Akintola University of Technology |
| 24 | Monday 3:30 - 4:00 PM | Optimizing data capture and management for tolerability outcomes: The BASE Study | Gassman | Jennifer | Cleveland Clinic |
| 27 | Monday 3:30 - 4:00 PM | A Comparison of Industry and NIH-funded Clinical Trials Registered in ClinicalTrials.gov | Gresham | Gillian | Cedars-Sinai Medical Center |
| 30 | Monday 3:30 - 4:00 PM | Evaluation of new methods for valid inference in the presence of selection bias | Halani | Khalif | Emmes Canada |
| 33 | Monday 3:30 - 4:00 PM | A novel method for PFS ratio endpoint in a Phase II genomic-driven clinical trial | JAYSWAL | RANI | MARKEY CANCER CENTER, UNIVERSITY OF KENTUCKY |
| 36 | Monday 3:30 - 4:00 PM | All New Zealand Acute Coronary Syndrome - Quality Improvement (ANZACS-QI) Programme: Using Routinely Collected National Patient Database for Clinical Trials | Jiang | Yannan | University of Auckland |
| 39 | Monday 3:30 - 4:00 PM | Sample sizes Group Clinical Trials with a Survival Endpoint - It's Accrual World | Julious | Steven | The University of Sheffield |
| 42 | Monday 3:30 - 4:00 PM | Process Mapping RCT Study Start-Up | Kay | Marie | University of Utah Trial Innovation Center \| Data Coordinating Center |

# POSTER PRESENTATIONS

| Poster Number | Day and Time | Title | Last Name | First Name | Affiliation |
|---|---|---|---|---|---|
| 45 | Monday 3:30 - 4:00 PM | Novel Mode and Effectiveness of International Collaborative Clinical Research Training Programs among Chinese Physicians | Kong | Yuanyuan | National Clinical Research Center for Digestive Disease; Beijing Friendship Hospital, Capital Medical University |
| 48 | Monday 3:30 - 4:00 PM | A systematic literature review of site staff training methods in clinical trials | Lane | J. Athene | University of Bristol |
| 51 | Monday 3:30 - 4:00 PM | A Programmatic Approach to the Increased Data Monitoring in the Cooperative Group System Required for FDA Registration Trials | Li | Hongli | SWOG Cancer Research Center |
| 54 | Monday 3:30 - 4:00 PM | Is Pre-Screening a Good Option for Master Protocols? The Lung-MAP Story | Minichiello | Katie | SWOG Statistics and Data Management Center |
| 57 | Monday 3:30 - 4:00 PM | Re-Enrolling Older Adults Eight Years after Original Study Ended: Issues & Solutions | Morris | Patricia | Washington University School of Medicine |
| 60 | Monday 3:30 - 4:00 PM | Proposed guidelines for causal inference from pragmatic randomized trials | Murray | Eleanor | Harvard TH Chan School of Public Health |
| 63 | Monday 3:30 - 4:00 PM | Application of the NIST Randomness Beacon to randomized trials. | Peralta | Rene | National Institute of Standards and Technology |
| 66 | Monday 3:30 - 4:00 PM | A Web-Based Approach for Tracking and Management of Sleep Device Mailings for In-Home Sleep Assessments in the WHISPER Study | Robertson | Julia | Wake Forest Health Sciences |
| 69 | Monday 3:30 - 4:00 PM | "What matters to you?" Preliminary results from a randomized controlled effectiveness trial | Tollefsen | Thomas | Regional Center for Child and Adolescent Mental Health |
| 72 | Monday 3:30 - 4:00 PM | Implementation of Brain Imaging in the Epidemiology of Diabetes Interventions and Complications Study | Trapani | Victoria | George Washington University |
| 75 | Monday 3:30 - 4:00 PM | Categorization of Medical Information Databases | Wakabayashi | Yumi | Kochi University |
| 2 | Tuesday 10:30 - 11:00 AM | A modular core outcome set for seamless, standardised evaluation and reporting of outcomes throughout the surgical device innovation lifecycle: the COHESIVE study | Avery | Kerry | University of Bristol |
| 5 | Tuesday 10:30 - 11:00 AM | 'Don't Cut it Out': The Importance of Quality Control in Surgical Trials | Bailey | Lisa | The University of Sydney |
| 8 | Tuesday 10:30 - 11:00 AM | A Pilot Study to Assess Feasibility and Acceptability of At-Home Self-Collection Sampling for Urine and Saliva | Beck | Karen | Merck & Co., Inc. |
| 11 | Tuesday 10:30 - 11:00 AM | PERFORMING ELIGIBILITY CHECKS FOR COMPLICATED SCENARIOS | Bruschi | Sarah | Wake Forest School of Medicine |
| 14 | Tuesday 10:30 - 11:00 AM | Association between estrogen and prevalent health-related quality of life in postmenopausal women randomized to the MAP.3 chemoprevention trial | Cameron-Dermann | Lindsey | Queen's University |
| 17 | Tuesday 10:30 - 11:00 AM | A Tool for Design and Analysis of Adaptive Bayesian Clinical Trials | Chandereng | Thevaa | University of Wisconsin-Madison |
| 20 | Tuesday 10:30 - 11:00 AM | Establishment of Good Clinical Data Management Practices for a Randomized Clinical Trial during an Ebola Outbreak | Dodd | Lori | |
| 23 | Tuesday 10:30 - 11:00 AM | Comparison Between Protocols and Publications for Prognostic and Predictive Cancer Biomarker Studies | Doussau | Adelaide | McGill University |
| 26 | Tuesday 10:30 - 11:00 AM | Pre-implementation of a multi-center, Phase IV, Investigator initiated clinical trial: Experiences from the Canadian Research Initiative in Substance Misuse | Fikowski | Jill | Canadian Research Initiative in Substance Misuse |
| 29 | Tuesday 10:30 - 11:00 AM | Emergency research without consent: an ethical analysis of the ketamine versus haloperidol trial | Goldstein | Cory | Rotman Institute of Philosophy |
| 32 | Tuesday 10:30 - 11:00 AM | A use of adaptive design in clinical trial for evaluating safety and efficacy of the extracorporeal continuous-flow ventricular assist device in patients with severe heart failure or refractory cardiogenic shock | Hamasaki | Toshimitsu | National Cerebral and Cardiovascular Center |
| 35 | Tuesday 10:30 - 11:00 AM | A Randomized Controlled Trial with right-skewed dual endpoints in the presence of an unproven but incumbent competing intervention: Rationale and design | Henn | Lisa | Arbor Research Collaborative for Health |
| 38 | Tuesday 10:30 - 11:00 AM | Optimization of a Shared Network Drive to Increase Utilization Efficiency in a Clinical Research Setting | Johnson | Marcus | Duke University School of Medicine |
| 41 | Tuesday 10:30 - 11:00 AM | Considerations in implementing an electronic patient reported outcomes (ePRO) system | Lewis | Rebecca | The Institute of Cancer Research |
| 44 | Tuesday 10:30 - 11:00 AM | Graphical Displays of Patient-Reported Outcomes in Interim Clinical Trial Data Monitoring Committee Reports | Li | Geng | University of Wisconsin-Madison |
| 47 | Tuesday 10:30 - 11:00 AM | EXPLORING CHALLENGES ASSOCIATED WITH EARLY IMPLEMENTATION OF LOW-COST PRAGMATIC TRIALS | Lipman | Paula Darby | Westat |
| 50 | Tuesday 10:30 - 11:00 AM | Use of wearable devices to monitor physical activity in clinical studies: the CAPABILITY study protocol | Lorenzoni | Giulia | University of Padova |
| 53 | Tuesday 10:30 - 11:00 AM | A Procedure for Comparison of Matched Pairs by Ranking Method | Mei | Chaoqun | University of Wisconsin-Madison |
| 56 | Tuesday 10:30 - 11:00 AM | Building the infrastructure to support patient engagement in clinical trials within an academic hospital | Monfaredi | Zarah | Ottawa Hospital Research Institute |
| 59 | Tuesday 10:30 - 11:00 AM | Information Sharing through an Interactive Process Map | Pautler | Mary | University of Utah |
| 62 | Tuesday 10:30 - 11:00 AM | A Literature Review of Baseline Covariate Adjustment Methods in Randomized Clinical Trials | Sajobi | Tolulope | University of Calgary |
| 65 | Tuesday 10:30 - 11:00 AM | Pragmatic Clinical Trials in Headache and Migraine Research: A Scoping Review | Tanveer | Sarah | Johns Hopkins Bloomberg School of Public Health |
| 68 | Tuesday 10:30 - 11:00 AM | Legal and Ethical Considerations for the Inclusion of Limited English Proficient Individuals in Clinical Research: A Literature Review | Tran | Jessica | Icahn School of Medicine at Mount Sinai |
| 71 | Tuesday 10:30 - 11:00 AM | Data Integration in a Multi-site Intervention Through Use of Application Programming Interfaces (APIs) | White | Jack | Wake Forest Baptist Medical Center |
| 74 | Tuesday 10:30 - 11:00 AM | Expediting New HIV Therapy to the Market through Collaboration with a Contract Research Organization | Wolbach | Tracy | Westat |
| 77 | Tuesday 10:30 - 11:00 AM | Projecting post-trial life expectancy and life-gained: Using A Markov Microsimulation Model | Yuan | Fei | Population Health Research Institute, McMaster University |
| 79 | Tuesday 10:30 - 11:00 AM | Sample size planning in the design of healthcare delivery intervention trials using the symbolic data framework | Zahrieh | David | Mayo Clinic Rochester |

# SCT 2018 TRIAL OF THE YEAR AWARD

**SCT David Sackett Trial of the Year Presentation**

Monday, May 20, 2019, 4:00 pm – 5:30 pm

Napoleon BC

*The Scleroderma: Cyclophosphamide or Transplantation (SCOT) trial* is the recipient of the prestigious David Sackett Trial of the Year Award, presented annually by the Society for Clinical Trials (SCT). Dr. Lynette Keyes-Elstein, Principal Statistical Scientist at Rho, will accept the award on behalf of the SCOT trial team. She will present the SCOT trial on May 20, 2019 at the Society's 40th Annual Meeting in New Orleans, Louisiana.

Scleroderma is a devastating progressive heterogeneous autoimmune disease that is associated with considerable mortality and morbidity. No FDA-approved therapy is available for patients with scleroderma, and mortality rates have remained constant over the past forty years. In the SCOT trial, adults with severe scleroderma were randomly assigned to undergo myeloablative autologous hematopoietic stem-cell transplantation (AHCT) or to receive cyclophosphamide. AHCT resulted in improvement in the primary end point, a global rank composite score incorporating survival, event-free survival (survival without respiratory, renal, or cardiac failure), forced vital capacity, the score on the Disability Index of the Health Assessment Questionnaire, and the modified Rodnan skin score. The American Society for Blood and Marrow Transplantation Task Force now recommends AHCT as the standard of care for patients with severe disease. The SCOT trial was supported by the National Institute of Allergy and Infectious Diseases of the National Institutes of Health.

Lynette Keyes-Elstein
*Rho Federal Systems, North Carolina*

Lynette Keyes-Elstein is a Principal Statistical Scientist working at Rho Federal Systems in North Carolina. Since 2008, she has served as a principal investigator for NIAID/DAIT sponsored statistical and clinical coordinating centers overseeing clinical studies focused on autoimmune diseases. Her team has collaborated on over 70 clinical studies across 11 autoimmune diseases in support of multiple federally funded research networks and independent investigators. Lynette appreciates a good design or analysis challenge and enjoys brainstorming with her colleagues on creative solutions. She is looking forward to sharing some of the challenges encountered with the SCOT study at the SCT Annual Meeting… after doing a little exploration of New Orleans via Segway. Lynette holds degrees in biochemistry, immunology, and a doctorate in biostatistics from University of North Carolina-Chapel Hill.

## ABOUT THE SCT TRIAL OF THE YEAR

Each year since 2008, it has been awarded to a randomized, controlled trial published (either electronically or in print) in the previous calendar year that best fulfills the following standards:

- It improves the lot of humankind.
- It provides the basis for a substantial, beneficial change in health care.
- It reflects expertise in subject matter, excellence in methodology, and concern for study participants.
- It overcomes obstacles in implementation.
- The presentation of its design, execution, and results is a model of clarity and intellectual soundness.

Nominations came from Society members, investigators, and interested scholars from around the world.

The 2020 Trial of the Year Selection Committee will issue a call for nominations in fall 2019.

Visit www.sctweb.org for updates.

# SYLVAN GREEN AWARD

This award was created in 2011 to honor Sylvan Green, MD for his service to the Society. He served as President of the Society in 1994, chaired the Education and the Student Scholarship Committees and was inducted as a Fellow in 2007. This award is open to physicians and dentists involved in clinical trials or epidemiology projects.

The 2019 Sylvan Green Award winner, Dr. Gareth Davies, will present his talk **Wednesday, May 22, 2019** — Contributed Session — Trial Management: Design & Adaptions from 10:15 to 10:30. The award certificate will be presented during the Business session on **Tuesday, May 21, 2019**, from 12:30 – 2:00 in Napoleon BC (3rd floor).

Gareth Sion Davies
*University of Bristol –*
*Bristol Centre of Surgical Research*

**"Surgeons' Lack of Understanding of Levels of Evidence and Trial Methodology Is a Major Barrier to Randomized Trials in Surgery"**

# THOMAS C. CHALMERS AWARD

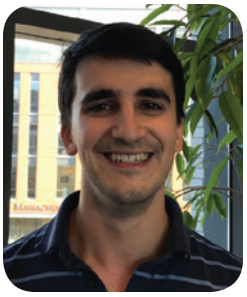
### 2019 Thomas C. Chalmers Student Scholarship Finalists

This Scholarship was named in honor of Dr. Thomas C. Chalmers, who was a founding member of the SCT, served on the Board and was President in 1984. It recognizes his lifetime of service to the Society. Please visit the SCT website at www.sctweb.org for further information.

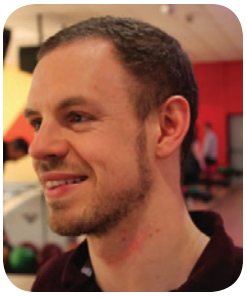
The 2019 Finalists for the Scholarship will present their abstracts on Monday, May 20 at 12:45 – 2:15. The winner will receive their award on Monday, May 20 after the presentations.

## FINALISTS

**Linda Harrison**
Department of Biostatistics at Harvard T. H. Chan School of Public Health
*Power Calculation for Cross-Sectional Stepped Wedge Cluster Randomized Trials with Variable Cluster*



**Lee Kennedy-Shaffer**
Biostatistics Department at the Harvard T.H. Chan School of Public Health
*Sample size estimation for stratified individual and cluster randomized trials with binary outcomes*



**Martin Law**
Medical Research Council's Biostatistics Unit, part of the University of Cambridge
*A new class of optimally curtailed trials for phase II oncology*

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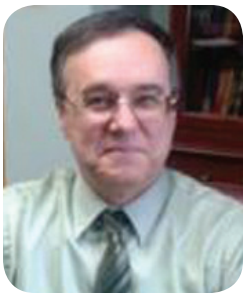

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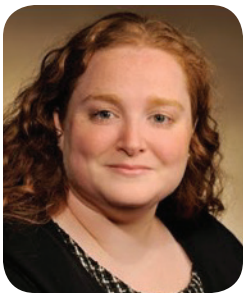

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The Board of Directors for the Society of Clinical Trials invites all meeting attendees to join in saluting the 2019 Class of Fellows during the Opening Session, Tuesday, May 21, 2019 at 8:00 am

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*Medical University of South Carolina, Charleston, SC*

Mithat Gonen, Ph.D.
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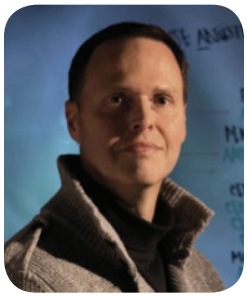

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# UPCOMING MEETINGS

## 41st ANNUAL MEETING

Baltimore Marriott Waterfront • Baltimore, MD, USA
May 17-20, 2020

## 42nd ANNUAL MEETING

Chicago Marriott Downtown Magnificent Mile
Chicago, IL, USA
May 16-21, 2021


SCT
SOCIETY FOR CLINICAL TRIALS
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www.sctweb.org

SCT
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# 40th ANNUAL MEETING

of the Society for Clinical Trials

May 19 – May 22, 2019

**Sheraton New Orleans Hotel**

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## www.sctweb.org

Remember that one of the benefits of the SCT website is the SCT Job Board. This board, on the public section of the SCT website, provides employers an opportunity to reach potential candidates by posting a detailed job description. In addition, there is also a section for job seekers to post their resume on the site.

Employers – for more information on posting a position on the SCT website (which will also be e-mailed to all SCT members), visit www.sctweb.org. Remember that job seekers can also post their resumes on the SCT Job Board, so be sure to check that for potential candidates.

Job seekers – be sure to check the SCT Job Board regularly for new positions. Remember that you can also post your resume on the SCT site.

# SCT WEBINAR SERIES

| | |
|---|---|
| **New Standard for Outcome Reporting in Clinical Trials: Instrument for Reporting Planned Endpoints in Clinical Trials Inspect 2019**<br>**Martin Offringa and Nancy Butcher** | July 2019<br>Date TBA |
| **Innovative Statistical Approaches for Utilization of External Evidence in Clinical Trials: Challenges and Opportunities**<br>**Yunling Xu, CDRH/FDA** | October 2019<br>Date TBA |
| **Understanding the Estimand Framework**<br>**Vlad Dragalin, Janssen** | December 2019<br>Date TBA |