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The Society for Clinical Trials

33rd Annual Meeting

May 20-23, 2012



Hyatt Regency Miami
Miami, FL, USA

www.sctweb.org

Please Join Us

On behalf of the Program Committee, I am thrilled to invite you to attend the 33rd Annual Meeting of the Society for Clinical Trials which will be held this year in Miami, Florida. It has long been a tradition for the SCT meetings to feature prominent keynote speakers, invited sessions organized and presented by the leading researchers on cutting edge topics, and the contributed poster and podium presentations by the rising stars of the field. I am proud to announce that this meeting will be no exception.

Our Annual Meeting will start on Sunday with an outstanding range of Pre-Meeting Workshops organized this year by the Education Committee, chaired by Christopher Coffey. They will consist of interactive sessions that highlight fundamental concepts and methodologies of various aspects of clinical trial design, conduct, analysis and results interpretation and dissemination. Importantly, these workshops will also showcase the current challenges and emerging trends in clinical research encountered by trialists from a broad variety of disciplines.

Our presidential invited speakers this year are Dr. John P.A. Ioannidis, Director of the Stanford Prevention Research Center at Stanford University, and Dr. Wafaa El-Sadr, Director of the International Center for AIDS Care and Treatment Programs at Columbia University. They both will deliver plenary lectures which promise to be incisive and thought-provoking. Dr. Ioannidis will speak on the synthesis of evidence from a broad range of clinical trials and Dr. El-Sadr will describe her experiences performing AIDS clinical trials in underprivileged populations in Africa and in the United States. In addition, Trial of the Year and Project ImpACT continues to be featured as a plenary session.

Our calls for invited and contributed sessions must have hit the right targets as the Program Committee had the enviable task of choosing from many high-quality proposals for Invited Sessions. It was a difficult balancing act since the proposals covered a wide range of several prominent topics in clinical trials — ranging from adaptive designs and data safety monitoring boards to FDA guidances and pragmatic trials useful for comparative effectiveness research. The program committee decided to follow the blueprint of the 2011 meeting, offering a total of 30 Invited Sessions, six of which are dedicated to the meeting's theme, "Clinical Trials in Vulnerable Populations." The remaining Invited Sessions will cover topics such as data management and information technology as well as statistical issues in the design and analysis of clinical trials — addressing the diverse interests of our membership. Our speakers also reflect this diversity: We will have presenters from FDA, NIH, pharmaceutical and biotechnology companies, consulting and contract organizations, non-profit organizations as well as academia.

In addition to the Invited Sessions, we have more than 200 contributed abstracts that will be presented in a total of 20 podium sessions and two days of poster sessions. The Society continues to support the attendance of students at the meeting through the Thomas C. Chalmers Award program, and recognizes outstanding clinician trialists through the Sylvan Green Award. The record number of submissions and the wide range of topics covered in the contributed program highlight the traditional strengths of our annual meeting as the gathering place for those who work in any specialty of clinical trials.

A program of this caliber cannot be put together without the support of SCT leadership. On behalf of the Program Committee, I want to sincerely thank Society President Rick Chappell for his tactful, resolute and enthusiastic support of our efforts and the Executive Committee for their steady hand in steering the Society through past difficult times. The Program Committee members themselves deserve thanks for their tireless efforts and generosity with their time. Of course, none of this would have happened if it were not for the skillful coordination and support of the management team at Fernley & Fernley.

Miami, our venue this year, is known for its vibrant, multicultural atmosphere and I have every reason to believe that the 2012 meeting of the SCT will mirror that excitement and enthusiasm. We look forward to seeing you all in Miami.

Mithat Gönen, PhD
2012 Program Chair
Attending Biostatistician
Department of Epidemiology and Biostatistics
Memorial Sloan-Kettering Cancer Center

2012 Program Committee

Robert Annecharico
Rick Chappell
Li Chen
Ken Cheung
Christopher Coffey
William Elgie
Dean Fergusson
Elizabeth Garrett Meyer
Susan Halabi
Jonathan Kimmelman
Bev Koski
J. Athene Lane
Anne S. Lindblad
Wendy L. McBee
Alison McDonald
Kristine M. Nelson
Wendy Parulekar
Tim Ramsay
Dominic Reda
Yves Rosenberg
John Speakman

Chair: Mithat Gönen

2012 Education Committee

Kristel Aman
Carol Baker
Michael Benatar
Marie Benavente
Jeff Blume
Li Chen
Jodi DeStefano
Janice Flegg
Marta Gilson
Susan Halabi
Devin Hunt
Jingyee Kou
Oscar Moreno
Tom Moritz
Wendy Parulekar
Roberta Scherer
Emily VanMeter
Paul Wakim
Julie Weston
David Wright

Chair: Christopher Coffey



General Information

SCT Annual Meeting May 20-23, 2012

Miami Welcomes SCT

Miami is a diverse metropolitan area in South Florida that offers a rich selection of cultural attractions, arts centers, fine dining, beaches, parks & other natural attractions, and world-class shopping. Visitors will be excited by the wide variety of things to see and do to supplement their educational and collegial experiences at the 2012 SCT Annual Meeting.

Travel Information

Airport and Train Station

Your top choice for air travel into Miami is the Miami International Airport (MIA). Visit miami.airport.com. Transportation from the airport to the downtown Hyatt Regency Miami hotel is easy:

By taxi: The average fare from MIA to the Hyatt Regency is \$22, plus a fuel surcharge.

By rail: Miami-Dade County operates an extensive public transportation system that can get travelers from MIA to downtown Miami. Please visit miamidade.gov to map your route.

By car: The Hyatt Regency Miami is an 8-mile drive from MIA.

Parking at hotel: Parking is available at the Hyatt Regency Miami for approximately \$30 per day (valet) and \$19 (self parking).

Alternative Airport: Just over 27 miles from Miami is the Fort Lauderdale Hollywood International Airport (FLL). Visit broward.org/Airport. Fort Lauderdale may be a good option for SCT attendees who are visiting from cities serviced by air carriers that fly into FLL and are able to arrange transportation on their own to Miami.

Train travel to Miami is serviced by Amtrak, to the Miami Station (MIA), located just over 10 miles from the Hyatt Regency Miami. Visit amtrak.com.

Visas and Entry Requirements

For information regarding visas and entry requirements for the United States, visit the website of the U.S. Department of State at travel.state.gov. You may also contact the nearest U.S. Embassy in your region.

Climate and Weather

Summer comes early in South Florida, making Miami a warm weather destination in May. Daytime temperatures average between 72—85°F or 22—29°C at this time of year. Most buildings are air-conditioned, as is the Hyatt Regency, so remember to bring a sweater or light jacket for the chilly meeting rooms. Sunscreen lotion, a hat and/or sunglasses are recommended for your time outdoors.

Hotel Information

Hyatt Regency Miami
400 South East Second Avenue
Miami, Florida, USA 33131-2197
Tel: +1.305.358.1234
Fax: +1.305.358.0529
Visit miamiregency.hyatt.com

About the Hyatt Regency Miami

The SCT host hotel, the Hyatt Regency, is located in downtown Miami, Florida, close to top restaurants, shopping and entertainment.

During your stay, you also may enjoy:

- Full-service business center
- Health club access at no extra charge and outdoor heated pool

Special SCT Hotel Room Rates

For the SCT meeting, the Standard Room Rate is \$225 single/double plus tax and fees.

The special group rate will be honored through April 17, 2012, or until the block of rooms is sold out; whichever comes first. SCT strongly encourages attendees to make their reservations as soon as possible. Reservations are subject to availability at the hotel's prevailing rate after April 17 or once the block is sold out. Make sure to ask for the SCT Annual Meeting to receive the group rate.

For U.S. Government employees, the Hyatt Regency offers a limited number of rooms at a special room rate of \$125 per night plus taxes and fees. These rooms are available on a first-come, first-served basis. Proof of employment will be requested upon check-in.

Hotel Reservations

Online Reservations

Visit the SCT Annual Meeting page (sctweb.org) for details or visit the hotel reservation websites.

Reservations by Phone

Reservations may also be made by telephone at +1.800.233.1234. Be sure to mention the SCT Annual Meeting to receive the special rate.

Annual Meeting Registration

Registration Fees

Early Bird registration is available **through March 30, 2012**. Registrations received after this date will not qualify for the reduced registration fee. All fees are in U.S. Dollars.

Pre-Meeting Workshop Registration

For SCT Members

(Reminder: SCT Annual Dues for 2012 must be paid in full in order to qualify for the Member Registration Fee.)

On or Before March 30 (Early Bird Special!):

Pre-Meeting Workshop Full Day	\$350
Pre-Meeting Workshop Half Day	\$200 each
Annual Meeting	\$425

After March 30:

Pre-Meeting Workshop Full Day	\$400
Pre-Meeting Workshop Half Day	\$250 each
Annual Meeting	\$525

For Non-Members

On or Before March 30 (Early Bird Special!)

Pre-Meeting Workshop Full Day	\$350
Pre-Meeting Workshop Half Day	\$200 each
Annual Meeting	\$625

After March 30:

Pre-Meeting Workshop Full Day	\$400
Pre-Meeting Workshop Half Day	\$250 each
Annual Meeting	\$725

**Non-Member Registration at the Non-Member price includes SCT membership for June – December 31, 2012.*

For Students

(Proof of Full Time Student Status must be provided with Registration)

Pre-Meeting Workshop Full Day	\$150
Pre-Meeting Workshop Half Day	\$75 each
Annual Meeting	\$150

Accepted proof of student status: Copy of valid student ID card, letter from institution registrar, letter from department head, copy of paid tuition bill for current semester.

Return Meeting and Membership Forms **ONLY** to:

Society for Clinical Trials, Inc.
100 North 20th Street, Suite 400
Philadelphia, PA 19103
Tel: +1.215.320.3878
Fax: +1.215.564.2175
Email: sct@fernley.com
Website: sctweb.org

Payment

Payment for the 33rd Annual Meeting or the Pre-Meeting Workshop Sessions can be made by a personal or company check or credit card (Visa, Mastercard, or American Express).

Full Meeting Registration will include access to mid-morning and afternoon coffee breaks (Monday – Wednesday), luncheons (Monday and Tuesday) and receptions. Arrangements for special dietary needs (kosher, vegetarian, gluten-free) must be made in advance by contacting the SCT Business Office at sct@fernley.com or +1.215.320.3878.

Guests accompanying meeting participants to luncheons are required to pay a fee of \$40 per luncheon. Notify the SCT Business Office of any guests before the meeting. Contact sct@fernley.com or +1.215.320.3878.

Registration Cancellation

All cancellations must be written and be received at the SCT office by Friday, May 4, 2012. Annual Meeting cancellations will be refunded less a \$100 administrative fee. Pre-Meeting Workshop Sessions will be refunded less a \$50 administrative fee. After May 4, **NO REFUNDS** will be issued. Refunds will be issued 4-6 weeks post conference. Special requests should be directed to the SCT Office at sct@fernley.com or +1.215.320.3878.

Registration Transfers

Registration transfers **MUST** be in writing and received by the SCT Business Office by Friday, May 4, 2012. After this date, refunds will not be issued for unused registrations. Transfers cannot be made onsite.

Onsite Registration

After Friday, May 4, attendees must register onsite in Miami.

Onsite registration is available during the Annual Meeting; however, your choice of Pre-Meeting Workshops cannot be guaranteed.

33rd Annual Meeting Registration Desk Hours

Sunday, May 20	7:00 AM – 5:00 PM
Monday, May 21	7:00 AM – 5:00 PM
Tuesday, May 22	7:00 AM – 5:00 PM
Wednesday, May 23	7:00 AM – 11:00 AM



Schedule of Events

Sunday, May 20, 2012

7:00 AM – 5:00 PM Registration

Pre-Meeting Workshops

8:00 AM – 5:00 PM

Workshop P1 (Full day) Essentials of Randomized Clinical Trials

8:00 AM – 12:00 PM

Workshop P2 Trial and Site Management for Multi-Center Trials	Workshop P3 Practical Statistical Reasoning in Clinical Trials for Non-Statisticians	Workshop P4 Adaptive Clinical Trials	Workshop P5 Biomarkers in Clinical Trials: General Principles for Study Design and Statistical Evaluation with Case Studies
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12:00 PM – 1:00 PM Lunch on your own

1:00 PM – 5:00 PM

Workshop P6 Challenges and Strategies of Clinical Data Management	Workshop P7 CDISC: How to Adapt to the Standards and How to Handle Data that Does Not Easily Fit into the Standards	Workshop P8 Statistical Procedures for Interim Analysis in Clinical Trials	Workshop P9 The Prevention and Treatment of Missing Data in Clinical Trials
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Schedule of Events

Monday, May 21, 2012

7:00 AM – 5:00 PM

Registration

8:00 AM – 5:30 PM

Exhibits

8:30 AM – 8:45 AM

Welcome – SCT President, Rick Chappell

University of Wisconsin, Madison, WI

8:45 AM – 8:55 AM

In Memory of Paul Meier – Theodore Karrison, SCT Secretary

University of Chicago

8:55 AM – 9:10 AM

Presentation of Class of 2012 Fellows

9:15 AM – 10:15 AM

Curtis Meinert Lecture – Wafaa El-Sadr

“Global HIV Prevention Trials”

Director of the International Center for AIDS Care and Treatment Programs at Columbia University

10:15 AM – 10:45 AM

Break/Exhibits/Posters

10:45 AM – 12:15 PM

Invited Sessions I

Session 1	Session 2	Session 3	Session 4	Session 5
<i>Cancer Screening RCTs: From Start to Finish</i>	<i>Clinical Site Monitoring – “The Real World of Data Quality and Limited Resources”</i>	<i>Multiplicity Issues in Confirmatory Clinical Trials for Drug Development</i>	<i>Assessing Biosimilarity and Interchangeability of Follow-on Biologics</i>	<i>Design and Conduct of Trials in Critically ill Patients – Challenges and Solutions</i>

12:15 PM – 1:30 PM

Lunch – Included with Meeting Registration

1:30 PM – 3:00 PM

Contributed Paper Session I

CPS 1A	CPS 1B	CPS 1C	CPS 1D	CPS 1E
<i>Clinical Trials in Germany</i>	<i>Dose Finding Trials</i>	<i>Randomized Trials</i>	<i>Information Technology</i>	<i>Trial Monitoring</i>

3:00 PM – 3:30 PM

Break/Exhibits/Posters

3:30 PM – 5:00 PM

Invited Sessions II

Session 6	Session 7	Session 8	Session 9	Session 10
<i>Confusions and Controversies Around Pragmatic Trials</i>	<i>Electronic Data Capture (eDC): One Size Does Not Fit All</i>	<i>Methodological Challenges and Solutions for Late-Stage Clinical Trials</i>	<i>Phase II Oncology Trials: Recent Considerations in Trial Design and Endpoint Selection</i>	<i>Common Data Elements in Clinical Research in Neurology</i>

6:30 PM – 8:00 PM

Reception – Included with Meeting Registration

***All information/scheduling subject to change.**



Schedule of Events

Tuesday, May 22, 2012

7:00 AM – 5:00 PM Registration

8:00 AM – 5:00 PM Exhibits

7:50 AM – 8:50 AM **Contributed Paper Session II**

CPS 2A	CPS 2B	CPS 2C	CPS 2D	CPS 2E
<i>Cancer Clinical Trials</i>	<i>Data Standards and Data Exchange</i>	<i>Ethics of Clinical Trials</i>	<i>Safety Analysis</i>	<i>Trial Conduct</i>

9:00 AM – 10:30 AM **Invited Sessions III**

Session 11	Session 12	Session 13	Session 14	Session 15
<i>Update from the Clinical Trials Transformation Initiative: Rethinking Approaches to Clinical Trial Oversight and Premarket Safety Management</i>	<i>Developing Evidence-based Multistage Treatment Policies from Clinical Trials Data</i>	<i>Open Source Statistical Software in Drug Development: Challenges and Opportunities</i>	<i>Ethical, Regulatory and Recruitment Issues in Vulnerable Populations: Substance Use Trials as a Case Study</i>	<i>Student Scholarship Presentations</i>

10:30 AM – 11:00 AM **Break/Exhibits/Posters**

11:00 AM – 12:30 PM **Invited Sessions IV**

Session 16	Session 17	Session 18	Session 19	Session 20
<i>Guidelines for the Ethical Conduct and Ethics Review of Cluster Randomized Trials: Statement from an International Consensus Meeting</i>	<i>Mastering the Challenges: Academic Infrastructures for Clinical Trials in Europe</i>	<i>Data and Safety Monitoring Board (DSMB) Roles in Adaptive Design Trials</i>	<i>A Centennial Celebration of Jerome Cornfield and His Contributions to Clinical Trials</i>	<i>Randomized Trials in Pregnant Women</i>

12:30 PM – 1:50 PM **Lunch/SCT Business Meeting** – Included with Meeting Registration

1:50 PM – 2:50 PM **Contributed Paper Session III**

CPS 3A	CPS 3B	CPS 3C	CPS 3D	CPS 3E
<i>Biomarkers</i>	<i>Patient Recruitment, Enrollment and Retention</i>	<i>Reporting of Clinical Trials</i>	<i>Statistical Methods and Trial Design</i>	<i>Vulnerable Populations</i>

2:50 PM – 3:20 PM **Break/Exhibits/Posters**

**All information/scheduling subject to change.*

Schedule of Events

3:20 PM – 4:50 PM

Invited Sessions V

Session 21	Session 22	Session 23	Session 24	Session 25
<i>Translational Behavioral Science: A Framework to Guide the Development of Health-related Behavioral Interventions</i>	<i>Registration and Reporting of Clinical Trials: Key Informatics Issues and Approaches</i>	<i>Increasing Clinical Program Success with Modeling and Simulation</i>	<i>Safety Evaluation with Clinical Trial Information</i>	<i>Coordination and Conduct of Phase III Emergency Treatment Trials</i>

5:00 PM – 6:20 PM

Plenary Session: Trial of the Year/Project ImpACT

6:30 PM – 7:30 PM

Affinity Group Receptions – Included with Meeting Registration

Wednesday, May 23, 2012

7:00 AM – 11:00 AM

Registration

8:00 AM – 9:30 AM

Invited Sessions VI

Session 26	Session 27	Session 28	Session 29	Session 30
<i>Decision Support Interventions for Trial Participation</i>	<i>A Real-time Electronic Remote Data Capture and Therapeutic Risk Group Communication System: From Central Laboratories to Individual Patient Treatment in Pediatric Cancer Clinical Trials</i>	<i>Response-Adaptive Treatment Allocation in Clinical Trials: The Costs and Benefits</i>	<i>Emerging Issues and Their Solutions in the Implementation of Adaptive Designs in Clinical Trials</i>	<i>Dealing with Treatment Compliance in Clinical Trials on Inherently Low-compliant Populations: What to do at the Design, Monitoring and Analysis Stages</i>

9:45 AM – 11:15 AM

Contributed Paper Sessions IV

CPS 4A	CPS 4B	CPS 4C	CPS 4D	CPS 4E
<i>Clinical Epidemiology</i>	<i>Data Management</i>	<i>New Opportunities in Data Capture</i>	<i>Statistical Methods</i>	<i>Recent Trends in Trial Design</i>

11:15 AM – 11:30 AM

Break

11:30 AM – 12:15 PM

Founders Lecture – John P.A. Ioannidis
“Designing and Dissecting the Geometry of Randomized Evidence”
Director of the Stanford Prevention Research Center

**All information/scheduling subject to change.*



Pre-Meeting Workshops

May 20, 2012

Full Day Workshop

Workshop P1

8:00 AM – 5:00 PM

Essentials of Randomized Clinical Trials

This full-day pre-meeting workshop is an overview of some essential concepts related to the design, conduct and analysis of clinical trials. The workshop is intended for those with little previous experience or formal training in clinical trials as well as those who have some basic clinical trial experience but desire a better fundamental understanding of the methodological principles and concepts involved in clinical trials. No prior knowledge of biostatistics is needed. The first half of the workshop will introduce participants to some key principles associated with the design and conduct of clinical trials. Topics to be covered include the rationale for randomized clinical trials, key design and methodological issues, such as choice of eligibility criteria, control group, randomization and blinding-related issues, and how to define objectives and end-points for a trial. This first part of the workshop will cover basic principles of data collection, reporting, and quality control as well as principles of project management. The second half of the workshop will provide an overview of statistical principles and methodologies commonly utilized in clinical trials. Topics to be covered include choice of endpoints, sample size computation, methods for treatment allocation and stratification, intent to treat, procedures on how to monitor a trial, and how to analyze the results from randomized clinical trials.

Attendees should be able to describe the essential elements of a clinical trial, essential principles of project management of a multicenter clinical trial, describe key statistical concepts and their application to the validity and interpretation of clinical trial results, and use this knowledge to contribute as a researcher or collaborator in the successful conduct of a clinical trial. In addition, attendees should be able to read clinical trials literature critically.

Faculty: Dixie J. Ecklund, University of Iowa
Susan Halabi, Duke University
Laura Lovato, Wake Forest University
Michele Melia, Jaeb Center for Health Research
Yves Rosenberg, National Heart, Lung, and Blood Institute/National Institutes of Health

Workshop Organizer: Yves Rosenberg, National Heart, Lung, and Blood Institute/National Institutes of Health

Half Day Workshops – Morning

Workshop P2

8:00 AM – 12:00 PM

Trial and Site Management for Multi-Center Trials

Effective trial and site management is critical to the successful and timely completion of multi-center clinical trials. This workshop will present information on how this can be achieved. Practical examples will be presented for each topic and discussion with workshop participants will be encouraged.

Our international workshop faculty members have experience in coordinating national and international publicly funded and industry trials, as well as recruiting patients and managing activities at clinical centers. They have worked in a variety of settings and will bring their varied experiences to this workshop.

Participants will leave with a practical overview of trial and site management, tools, resources and ideas for effective trial implementation.

Topics to be covered include:

- Feasibility and site selection
- Study start-up considerations, including paperwork required from sites to participate

Pre-Meeting Workshops

May 20, 2012

- Handling payments to the sites, including different types of contracts
- Establishing study procedures
- Staffing requirements at the coordinating centre
- Training and continuing education of staff at the clinical sites, including information the coordinating centre should provide
- Techniques for interacting effectively with clinical sites and study partners
- Staff motivation at clinical sites
- Patient recruitment and retention strategies
- Data collection systems and techniques to ensure timely reporting
- Quality assurance
- Tracking study metrics
- Study record keeping suggestions
- Study close down process
- Publication arrangements and policies with clinical sites

Faculty: Marie-France Benavente, University of British Columbia
Lauren McGurk, Rho, Inc.
Beverly Koski, Independent Consultant
Alison McDonald, University of Aberdeen

Workshop Organizer: Alison McDonald, University of Aberdeen

Workshop P3

8:00 AM – 12:00 PM

Practical Statistical Reasoning in Clinical Trials for Non-Statisticians

This workshop is not an introduction to clinical trials. In fact, it assumes knowledge of and experience in clinical trials. Nor is it an introduction to biostatistics. It does not teach how to perform statistical tasks; there are no formulas and no proofs. Instead, it explains why these statistical tasks are performed and what they mean once they are performed.

This workshop walks you through the clinical trial cycle from beginning to end, and addresses statistical issues discussed between the non-statistician and the biostatistician during that cycle. It starts with the research question and ends with the publication of results. Intermediate topics include:

- Trial design, e.g. basic types of design, primary outcome measure(s), sample size calculation and power analysis.
- Analysis plan, e.g. simple vs. complex statistical models, the use of covariates, longitudinal (repeated measures) models, handling missing data.
- Trial monitoring and Data and Safety Monitoring Board reports, e.g. interim analyses, sample size re-calculation.
- Final analysis, e.g. what do “reject H_0 ” and “do not reject H_0 ” mean? What does the “p-value” mean? Why “correct” for multiple tests? What does “site-by-treatment interaction” mean?
- Subgroup analyses.



Pre-Meeting Workshops

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Objectives:

- (1) To put in plain English the reasoning and intuition behind basic statistical concepts used in clinical trials.
- (2) To improve communication between non-statisticians involved in clinical trials and their biostatisticians.

Target Audience: Non-statisticians with experience in clinical trials who seek a better understanding of statistical concepts encountered throughout the cycle of a clinical trial.

Faculty: Paul Wakim, National Institute on Drug Abuse/National Institutes of Health

Workshop Organizer: Paul Wakim, National Institute on Drug Abuse/National Institutes of Health

Workshop P4 Adaptive Clinical Trials

8:00 AM – 12:00 PM

Adaptive clinical trials—trials in which key design parameters are modified according to pre-specified decision rules during the course of the trial in response to accumulating data from the trial—may be more efficient, ethically acceptable and, if properly designed and executed, accurate than traditional designs. However, the design of such trials is inherently more complex than traditional approaches and must precisely define the planned adaptations a priori. In addition, simulation has an important role in evaluating the operating characteristics of adaptive trials. The implementation of adaptive trials introduces additional complexities in logistics, data availability, randomization, drug supply, and interactions with the sponsor and independent data and safety monitoring boards (DSMBs). The rapid proliferation of adaptive designs, and inconsistent use of terminology, has created confusion about the similarities and, more importantly, the differences among the techniques. In this session, the presenters with a broad range of experience in the conduct of these trials will address conceptual, statistical, and logistical issues in the design, implementation, and analysis of adaptive clinical trials.

First Dr. Lewis will discuss logistical and practical issues in composition, function, and interactions with all participants in the trial's design and execution and provide an example from a Phase 2 drug trial. He will describe the information flow necessary for an efficient trial and rapid and timely adaptations but also to ensure blinding. Then he will describe a case where a DMC used pre-specified rules developed in conjunction with the sponsor to drop an arm during a dose-finding trial. Dr. Pinheiro will focus on adaptive dose-ranging designs and analysis methods, discussing their motivation and key elements, and describing some of the most common approaches used in practice. He will conclude by discussing the key results and recommendations from the PhRMA Adaptive Dose-Ranging Studies working group. Then Dr. Connor will describe a dual endpoint (efficacy and safety) adaptive Bayesian design of a medical device. This trial design will be used to illustrate how interim data and a Bayesian longitudinal model can be used to calculate predictive probabilities that are used to identify the optimal trial size during the course of the trial.

Attendees should be conversant in the fundamentals of clinical trial design and methodology, but no foundational knowledge of Bayesian statistics or adaptive designs is required. The expected audience is statisticians, clinicians involved in trials, and other clinical trialists interested in adaptive designs. After the course, attendees will understand the role of adaptive trials and possess the foundation for their design, implementation, and interpretation.

Faculty: Jason Connor, Berry Consultants
Roger J. Lewis, Harbor-UCLA Medical Center
José Pinheiro, Janssen R+D

Workshop Organizer: Susan Halabi, Duke University

Pre-Meeting Workshops

May 20, 2012

Workshop P5

8:00 AM – 12:00 PM

Biomarkers in Clinical Trials: General Principles for Study Design and Statistical Evaluation with Case Studies

Despite some publicized setbacks, biomarkers continue to have the potential to greatly improve healthcare, e.g., in drug development, surrogate endpoint evaluation, risk assessment, and early detection. Biomarkers come in many varieties, such as genomic, molecular, or clinical. The utility of a biomarker is context dependent. Its credibility depends on the evidential level observed for its intended use. For candidate biomarkers measured by a medical device (e.g., in vitro diagnostic assay), quality of device measurement can be crucial in assessing biomarker utility. Moreover, when a drug relies on a companion diagnostic device to classify patients for drug eligibility, regulatory acceptance of both the drug and device are needed for joint licensure. This half-day short course will provide an overview ranging from types of biomarkers as drug development tools to the need for in vitro diagnostic device development and validation. The course outline includes:

- Literature overview of biomarker research
- General principles and practical aspects for development of a biomarker as a classifier, a diagnostic, or a surrogate, etc.
- Study designs including merits and limitations
- Statistical analysis issues for drug development versus for device development and validation
- Formal assessment in clinical trials of the clinical utility of a biomarker as predictive, prognostic or adding benefit
- Prospectively planned retrospective analysis in ongoing or completed trials, including when incomplete genomic samples are collected
- Multiplicity issues
- Misclassification issues in randomized controlled trials
- Single-trial and meta-analytic validation
- Appropriate handling of confounding factors
- Handling of missing test results
- Analytical and clinical validation of the diagnostic device
- Bridging from one companion diagnostic to another for the same intended use
- Regulatory considerations for drug versus for device evaluation
- Examples from a variety of clinical areas

The short course consists of four focused presentations:

Session 1: Overview of biomarkers in drug development

Session 2: Overview of surrogate endpoint evaluation in clinical studies

Session 3: Overview of biomarkers in device development

Session 4: Biomarker Trial Designs: Lessons from real trials

Attendees should have an understanding of clinical trials.

Faculty: Sumithra Mandrekar, Mayo Clinic
Geert Molenberghs, University of Hasselt and Katholieke Universiteit Leuven
Gene Pennello, U.S. Food and Drug Administration
Sue-Jane Wang, U.S. Food and Drug Administration

Workshop Organizers: Li Chen, Amgen
Christopher S. Coffey, University of Iowa



Pre-Meeting Workshops

May 20, 2012

Half Day Workshops – Afternoon

Workshop P6

1:00 PM – 5:00 PM

Challenges and Strategies of Clinical Trial Data Management

This workshop will discuss real-world strategies learned from both industry and academic sectors to solve common and unique challenges related to collecting and managing clinical trial data. Participants are encouraged to bring their own experiences to include in the discussion. Taught from the perspective of experienced data managers and database developers, participants will learn about and discuss problematic areas such as:

- Communication with study team members
- Working with vendors and laboratories
- Choosing the right Data Management System
- Optimizing Case Report Form (CRF) design
- Enhancing clinical trial data quality
- Sharing and submitting information to sponsors, partners, and the FDA
- Data Sharing and access for NIH funded studies
- Regulations surrounding Data Management

This course applies to anyone working in the clinical data management field in pharmaceutical industries, research institutions as well as universities. This course would also benefit anyone who is involved in the planning and preparing of a clinical trial, conducting a clinical trial, or has management responsibility (direct or indirect) for clinical trials.

Faculty: Kristine Nelson, The EMMES Corporation
Wenle Zhao, Medical University of South Carolina

Workshop Organizer: Devin J. Hunt

Pre-Meeting Workshops

May 20, 2012

Workshop P7

1:00 PM – 5:00 PM

CDISC: What are the Standards, How Will They Help, and How to Adapt?

Although the FDA does not mandate submissions follow Clinical Data Interchange Standards Consortium (CDISC) guidelines and standards, it strongly encourages their use. This workshop begins with an overview of CDISC and the various standards it promotes. It then takes an in-depth look at some of the more difficult aspects of mapping clinical data to the Study Data Tabulation Model (SDTM) standard. We will also look at some of the challenges of doing legacy conversions (putting older studies in a more “up-with-times” model).

We will also discuss some of the challenges in creating the Analysis Data Model (ADaM) datasets, especially the all-important subject-level analysis dataset (ADSL). We will also discuss CDISC implementation strategies in your organization. Finally, we end the workshop with a panel discussion, focusing on daily “real world” issues that arise while implementing the CDISC guidelines.

The goal of this workshop is to educate attendees about the ever-evolving CDISC guidelines. Among the groups that stand to benefit from an understanding of the standards are: study coordinators and PI’s responsible for collection of the data at the research site; data managers, programmers, and statisticians who standardize, tabulate, and analyze the data; PI’s and statisticians responsible for traceability between the clinical and analysis datasets; and, of course, the FDA reviewer. Effective standards implementation by these groups reduces delivery time and increases product quality throughout the study life cycle.

Faculty: Jeff Abolafia, Rho, Inc.
Carol Baker, Rho, Inc.
Karen Wade, Rho, Inc.
Rob Woolson, Rho, Inc.

Workshop Organizer: Carol Baker, Rho, Inc.

Workshop P8

1:00 PM – 5:00 PM

Statistical Procedures for Interim Analysis in Clinical Trials

There are two basic statistical procedures in monitoring clinical trials: conditional power and group sequential methods. For conditional power evaluation, we will cover the case when the underlying stochastic process follows a discrete Brownian motion process with a linear drift. Predictive power, the Bayesian version of conditional power, will also be presented with discussion. For the topic of group sequential methods, we will start with the classical “constant boundary” approach (Pocock 1977, O’Brien-Fleming 1979 and Wang-Tsiatis 1987) where, for a given alpha value, number of looks and the shape of the boundary, there is a unique corresponding constant determining the desired group sequential boundary. We will continue to introduce a more flexible alpha-spending approach to group sequential methods. Examples will be demonstrated by the use of free software created at University of Wisconsin-Madison.

Design of survival trials will also be covered. We will present a heuristic introduction to the logrank test which is locally most powerful under the proportional hazards assumption. The most popular methods for the comparisons of two survival distributions are of the Kaplan-Meier curve at a given point in time and the logrank test. When the proportional hazards assumption is violated, we will demonstrate that these two methods might deliver quite different messages and lead to misleading interpretations.

This workshop provides a primer with the following book: Proschan MA, Lan KKG and Wittes JT. (2006) *Statistical Monitoring of Clinical Trials – A Unified Approach*, Springer.

Faculty: K. K. Gordon Lan, Janssen R+D
José Pinheiro, Janssen R+D
Michael Proschan, National Institute of Allergy and Infectious Diseases/National Institutes of Health

Workshop Organizer: Susan Halabi, Duke University



Pre-Meeting Workshops

May 20, 2012

Workshop P9

1:00 PM – 5:00 PM

The Prevention and Treatment of Missing Data in Clinical Trials

At the request of the U.S. Food and Drug Administration, the National Academy of Sciences convened the Panel on the Handling of Missing Data in Clinical Trials to prepare a report that would make recommendations that could be used to aid in the FDA's eventual development of a Guidance for Industry on that topic. This half-day workshop presents an overview of the findings and recommendations of the resultant report from the perspective of two clinical trialist members of the NAS panel. The workshop will follow the basic organization of the NAS report, though it will place greatest emphasis on aspects of trial design and trial conduct that can be used to minimize issues arising from missing data. However, because trial protocols must also describe how any missing data will be handled at the end of the study, methods for analysis of clinical trial results will be discussed at a conceptual level. We will focus more on the common features of such analyses than on the technical details of particular analytic methods. To that end, the target audience for this workshop includes biostatisticians and epidemiologists involved in the design of clinical trials, as well as study coordinators and CRAs involved in the conduct of the studies.

We first review settings in which missing data commonly arise and pose difficult problems in the analysis and interpretation of clinical trial results, as a basis for discussing aspects of clinical trial design that could minimize or even eliminate the most troublesome missing data. In particular we focus on aspects of clinical trial design that relate to appropriate definition of primary endpoints, anticipating problems that might arise when patients drop off study drug due to adverse events, lack of efficacy, or competing risks such as newly developed contraindications to therapy or deaths from other causes. We further consider alternative trial designs that would facilitate randomized comparisons among patients who can adhere to protocol defined treatment strategies.

We then consider aspects of trial conduct that will promote the collection and analysis of complete data on all randomized subjects. Proper attention should be paid to informing both investigators and participants of the scientific importance of complete data collection. We describe ways in which the Study Protocol, the Manual of Operations, and the Case Report Forms can facilitate the investigators' understanding of and adherence to the actions that must be taken to minimize missing data, as well as discussing the impact that careful subject education (including the Informed Consent documents) can have on preserving the scientific and statistical relevance of clinical trial results.

Major recommendations of the Panel also included the need for lead investigators to anticipate missing data and to plan for appropriate methods for the statistical analysis of the clinical trial results. We briefly discuss the need for easily understood and clearly described methods based on reasonable assumptions about the mechanisms giving rise to missing data and assumptions about the likely impact that missingness would have on conclusions drawn from the RCT. We give a broad, non-technical overview of some of the approaches that might be used for the primary analysis of the trial results. Then, owing to the impossibility of ever knowing that assumptions about missing data mechanisms are valid, we conclude with an overview of general criteria that should be met by sensitivity analyses that explore the potential impact of the assumptions about missing data.

Faculty: Scott S. Emerson, University of Washington
James D. Neaton, University of Minnesota

Workshop Organizer: Rick Chappell, University of Wisconsin

All information subject to change.

7:00 AM – 5:00 PM Registration

8:00 AM – 5:30 PM Exhibits

8:30 AM – 8:45 AM **Welcome – SCT President, Rick Chappell**
University of Wisconsin, Madison, WI

8:45 AM – 8:55 AM **In Memory of Paul Meier – Theodore Karrison, SCT Secretary**
University of Chicago

8:55 AM – 9:10 AM **Presentation of Class of 2012 Fellows**

9:15 AM – 10:15 AM **Curtis Meinert Lecture – Wafaa El-Sadr**
“Global HIV Prevention Trials”
Director of the International Center for AIDS Care and Treatment Programs at Columbia University

10:15 AM – 10:45 AM **Break/Exhibits/Poster Prime Time**

10:45 AM – 12:15 PM **Invited Session 1:**
Cancer Screening RCTs: From Start to Finish

RCTs of cancer screening modalities face challenges not common in treatment trials, including the need to recruit large numbers of healthy participants and monitor them for many years. Nevertheless, a number of cancer screening RCTs have been successfully completed and have been instrumental in shaping public health policy. Our session will highlight the cancer screening lifecycle. The experiences of three pivotal trials will be presented, with speakers focusing on challenges and successes in the areas of trial design, operations, and monitoring. The session will begin with a brief introduction of aspects of cancer screening RCTs that make them unique. Three trials then will be presented: the Canadian National Breast Cancer Screening Study (I and II), the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, and the National Lung Screening Trial (NLST). A discussant will then summarize the presentations and provide his own reflections on cancer screening RCTs in general. There will be an opportunity for comments and questions from the audience.

Organizer: Pamela Marcus, National Cancer Institute, National Institutes of Health

Chairs: Pamela Marcus, National Cancer Institute, National Institutes of Health
Phil Prorok, National Cancer Institute, National Institutes of Health

Speakers: Tony Miller, University of Toronto
Phil Prorok, National Cancer Institute, National Institutes of Health
Pamela Marcus, National Cancer Institute, National Institutes of Health

Discussant: Barry Kramer, National Cancer Institute, National Institutes of Health

10:45 AM – 12:15 PM **Invited Session 2:**
Clinical Site Monitoring – The Real World of Data Quality and Limited Resources

There has been a recent focus on clinical site monitoring and how much is enough. “Industry Standard” of 100% source to data system monitoring is one way to interpret the sponsor’s obligation to ensure accurate and complete records. Clinical site monitoring programs can absorb 30% to 50% of the overall trial budget. In a time where resources are limited, can we afford this investment? If we fail to make the investment will it impact data quality and integrity and thus confidence in clinical trial outcomes? This session will describe approaches



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to creating comprehensive monitoring plans that may improve the efficiency of monitoring programs. We will present two large multi-site NIH-sponsored clinical trial networks and monitoring strategies including both remote and random sampling monitoring to address these issues. We will also present an approach to Centralized data monitoring to query data bases for inconsistencies in patterns of reported data to help detect fraud or anomalous data trends that warrant further assessment or inquiry. These examples and tools will offer alternatives to 100% data auditing while maintaining data and ultimately study integrity.

Chair: Robert Lindblad, The EMMES Corporation

Speakers: Anne Zajicek, National Institute of Child Health and Human Development, National Institutes of Health – Pediatric clinical trial network under the Best Pharmaceutical Children’s Act
Maria Campanella, The EMMES Corporation – Multi-site, multi-protocol National Institute on Drug Abuse network with limited resources and increased number of clinical trials and sites actively enrolling
John Marler, U.S. Food and Drug Administration – An FDA initiative reviewing completed data sets through programmatic algorithms to detect fraud and anomalies.

10:45 AM – 12:15 PM **Invited Session 3:
Multiplicity Issues in Confirmatory Clinical Trials for Drug Development**

In drug development, confirmatory Phase III clinical trials are conducted to provide the necessary evidence to support regulatory decision-making for drug approval. Multiplicity then becomes an important problem with various unintended consequences. The most widely recognized result is the lack of reproducibility and that the findings of a trial can be misleading: seemingly significant effects occur more often than expected by chance alone and not compensating for multiplicity can have important consequences. For instance, when the multiple comparisons involve drug efficacy, they may result in approval of a drug as an improvement over existing drugs, when there is in fact no beneficial effect. On the other hand, when drug safety is involved, it could happen by chance that the new drug appears to be worse for some side effect, when it is actually not worse at all. Because of the strong level of evidence required for Phase III trials, it is mandatory to adjust statistical inferences appropriately for multiplicity in order to enable better decision making.

The U.S. Food and Drug Administration draft guidance on multiple endpoints in clinical trials is expected to be released soon. The guidance addresses a wide range of multiplicity issues primarily for confirmatory trials. This panel session is organized to comment on these issues. We bring together an expert panel of seven clinicians and statisticians, consisting of distinguished international representatives from industry, academia and regulatory agencies. The session will have three parts. In Part I, Sue-Jane Wang (FDA) will present a case study to illustrate key multiplicity issues arising in Phase III trials and to motivate the subsequent panel discussion in Part II. Based on this case study, several questions will be formulated and sent in advance to the panelists. For each question panelists will be identified to provide their perspectives at the session. Finally, in Part III the discussion will be open for questions from the audience to the expert panel.

Chair: Sue-Jane Wang, U.S. Food and Drug Administration

Speakers: Frank Bretz, Novartis
Walter Offen, Eli Lilly
H.M. James Hung, U.S. Food and Drug Administration
Mohammad Huque, U.S. Food and Drug Administration
Gary Koch, University of North Carolina
Norman Stockbridge, U.S. Food and Drug Administration
Robert Temple, U.S. Food and Drug Administration

10:45 AM – 12:15 PM **Invited Session 4:
Assessing Biosimilarity and Interchangeability of Follow-on Biologics**

As more and more biological products are going off patent, it is a concern whether the generic versions (biosimilars or follow-on biologics) of the innovative biologic products are therapeutically equivalent to the innovative biologic products and whether they can be used interchangeably. Unlike small molecule drug products, biological products are derived from living cells, which are fundamentally different from the small molecule drug products. Thus, standard methods for assessment of bioequivalence and drug interchangeability for small molecule drug products are not applicable to the biologic products.

Currently there is no established regulatory pathway for approval of follow-on biologics. Woodcock et al. (2007) pointed out that for assessment of biosimilarity of follow-on biologics, the FDA would consider the following factors regarding (1) the robustness of the manufacturing process, (2) the degree to which structural similarity could be assessed, (3) the extent to which mechanism of action was understood, (4) the existence of valid, mechanistically related pharmacodynamic assays, (5) comparative pharmacokinetics, (6) comparative immunogenicity, (7) the amount of clinical data available, and (8) the extent of experience with the original product.

In this session we will focus on the scientific/statistical issues surrounding the assessment of biosimilarity and interchangeability of follow-on biologics including quality, pharmacokinetics and pharmacodynamics, clinical efficacy and safety, and how regulatory agencies and industry are evolving to deal with these issues.

Organizer: Shein-Chung Chow, Duke University School of Medicine

Chair: Eric Chi, Amgen, Inc.

Speakers: Stella Grosser, U.S. Food and Drug Administration – Current regulatory experiences in the assessment of biosimilarity of follow-on biologics
Shein-Chung Chow, Duke University School of Medicine – On Scientific Factors for Assessing Biosimilarity of Follow-on Biologics
Laszlo Endrenyi, University of Toronto – On the interchangeability of Follow-on Biologics
Nan Zhang or Jun Yang, Amgen, Inc. – Scaled Margins in Assessing Follow-on Biologics

Discussant: Peter Lachenbruch, Oregon State University

10:45 AM – 12:15 PM **Invited Session 5:
Design and Conduct of Trials in Critically Ill Patients – Challenges and Solutions**

The design and conduct of trials in critically ill patients has a number of challenges. At a design level, for example, there is high heterogeneity in the patient population and analysis strategies need to accommodate for complex (and often composite) outcomes, e.g. reductions in death rates but increases in length of stay and severity of disease. At a conduct level, there are also the ethical complexities raised by informed consent in this vulnerable population, where assent (rather than consent) is the norm. In addition, there is often uncertainty about which intervention to take to trial. In this session, these challenges will be discussed with a panel of researchers experienced in designing and conducting trials in critically ill populations. Speakers will provide examples of critical care trials in action; discuss the methodological issues commonly encountered in these trials (and provide potential solutions); provide an example of how psychological and ethical theory can aid the identification of which trial to adopt and whether a trial is feasible; and discuss the importance of networks and professional buy-in to promote and aid the conduct of trials in this field.

Organizer and Chair: Marion Campbell, University of Aberdeen

Speakers: Graeme MacLennan, University of Aberdeen
Jill Francis, University of Aberdeen
Ryan Zarychanski, University of Manitoba
Brian Cuthbertson, Sunnybrook Health Sciences Centre, Toronto



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12:15 PM – 1:30 PM

Lunch – *Included with Meeting Registration*

1:30 PM – 3:00 PM

Contributed Paper Sessions I

Session 1A: Clinical Trials in Germany

- 1:30 PM 01 The German National Surgical Network (CHIR-Net); Edmund Neugebauer, Witten/Herdecke University
- 1:45 PM 02 What Influences Patient Participation in Randomized Controlled Trials of Surgical Interventions?; Katrien Oude Rengerink, Academic Medical Center
- 2:00 PM 03 Funding Strategies for Establishing Surgical Trial Centers – Experience and Strategies; Gregor Stein, Cologne University Hospital
- 2:15 PM 04 Challenges of Developing Procedures for Serious Adverse Event Management and Reporting According to Regulatory Requirements in Clinical Trials with Medical Devices in Germany
- 2:30 PM 05 Knowledge Transfer in Clinical Research: Do We Know What is Going On, Do We Know the Results and Are They Transferred into Practice?; Gabriele Dreier, University Medical Center Freiburg
- 2:45 PM 06 Clinical Trial Auditing in an Electronic World: Do Not Risk Your Data - Validate Sufficiently; Jochen Dress, Clinical Trial Center Cologne

Session 1B: Dose Finding Trials

- 1:30 PM 07 A Simple Bayesian Decision Theoretic Design for Dose Finding Trials; Ying Lu, Palo Alto VA and Stanford University
- 1:45 PM 08 Interactive Software “Isotonic Design using Normalized Equivalent Toxicity Score (ID-NETS)” for Cancer Phase I Clinical Trials; Zhengjia Chen, Emory University
- 2:00 PM 09 The Modified Toxicity Probability Interval (mTPI) Method for Phase I Dose-Finding Trials; Yuan Ji, M. D. Anderson Cancer Center
- 2:15 PM 10 Incorporating Patient’s Characteristics in Cancer Phase I Clinical Trials Using Time to DLT: Escalation with Overdose Control; Yuan Liu, Emory University
- 2:30 PM 11 A Novel Statistical Software EWOC-NETS[™] for Extending Dose Escalation With Overdose Control (EWOC) to Fully Utilize All Toxicities in Cancer Phase I Clinical Trial; Zhibo Wang, Emory University
- 2:45 PM 12 A Cox Regression Model with Isotonic Regressors with Change-Point Problems: Addressing a Clinical Question; Das Purkayastha, Novartis Pharmaceuticals

Session 1C: Randomized Trials

- 1:30 PM 13 The Long Road to Start Up RCTs within the Social Services Interventions in Denmark; Maiken W. Pontoppidan, SFI - The Danish National Center for Social Research
- 1:45 PM 14 Elements of a Phase 3 IND Study Protocol – An FDA Statistical Perspective; Renee C. Rees, FDA/CBER
- 2:00 PM 15 Must a Randomized Trial Focus on Hypothesis Testing? – Assessing Risks and Benefits of Withdrawal From Therapy When The Acceptable Risk Margin is Unclear; Lisa M. Wruck, Collaborative Studies Coordinating Center, University of North Carolina at Chapel Hill

- 2:15 PM 16 Methods of Analyses for a Complex Intervention Cluster Randomised Stroke Trial – Looking for the Goose that Lays The Golden Egg; Ivana Holloway, Medical Statistician
- 2:30 PM 17 Does Using Minimisation Make A Difference?: Empirical Evidence From Three Multi-Centre Studies; Gladys C. McPherson, University of Aberdeen
- 2:45 PM 18 The Power of Covariate-Adaptive Randomization Schemes in Clinical Trials; Wai Yin Yeung, Queen Mary, University of London

Session 1D: Information Technology

- 1:30 PM 19 Online Study Monitoring for Large Multi-center Trials Via a Data Dashboard; Ryan T. Bailey, Rho, Inc.
- 1:45 PM 20 Technologies Supporting Clinical Research in Resource Poor Settings; Marisa De Rosa, Cineca
- 2:00 PM 21 Developing and Implementing a Laboratory Information System (LIMS) to Support Trials in the United Kingdom; Jonathan Gibb, University of Glasgow
- 2:15 PM 22 The Development of a Safe Haven to Allow Access to Routinely Collected Healthcare Datasets for Use in Clinical Trials; Sharon M. Kean, University of Glasgow
- 2:30 PM 23 Developing and Implementing Generic Components to Improve Efficiency When Building Electronic Data Capture Systems for Clinical Trials; Mary MacDonald, University of Glasgow
- 2:45 PM 24 Collaborative Peer-reviewing and Data Aggregation in Site Management With Clinicalsite.org; Gustav Vella, University of Cologne, Clinical Trials Center (ZKS Köln)

Session 1E: Trial Monitoring

- 1:30 PM 25 Cross Training Within a Clinical Research Organization: Does it Work or Does it Muddy the Waters?; Nicole Close, EmpiriStat, Inc.
- 1:45 PM 26 Is an Evolving Chart Audit Plan Necessary in a Long-Term Multi-Center Trial?; Brenda K. Brewer, Westat
- 2:00 PM 27 Central Statistical Monitoring in Clinical Trials; Erik Doffagne, International Drug Development Institute (IDDI)
- 2:15 PM 28 Risk-Based Approach to Monitoring: The Way of the Future; Selma C. Kunitz, KAI Research, Inc
- 2:30 PM 29 Effective Monitoring Strategies in a Long-term Clinical Trial with Varying Levels of Clinic Staff Knowledge: The AREDS2 Experience; Wendy L. McBee, The EMMES Corporation
- 2:45 PM 30 Central Statistical Monitoring: A Model to Predict Fraud in Clinical Trials; Janice M. Pogue, McMaster University

3:00 PM – 3:30 PM

Break/Exhibits/Poster Prime Time



Monday, May 21, 2012

3:30 PM – 5:00 PM

Invited Session 6

Confusions and Controversies Around Pragmatic Trials

The term “pragmatic trial,” introduced by Daniel Schwartz and Joseph Lellouch [J Chron Dis 1967;20:637-48] to designate a trial architecture designed to answer the practical question of whether offering an intervention in the hurly-burly of routine health care does more good than harm, is receiving increasing attention as patients, clinicians, organizers and payers for health services are increasingly clamoring for reliable and relevant answers (e.g., the burgeoning programs of “Comparative Effectiveness” research). However, this increasing attention has exposed considerable confusion and disagreement about whether pragmatic trials are “less perfect experiments” than efficacy [explanatory] trials, whether permitting non-compliance and cross-overs is a “problem,” whether knowing one’s treatment and telling examiners how one feels creates “bias,” and whether other departures from the explanatory architecture achieve or undermine the stated goals of PCTs - to improve the value of clinical research for clinical and health policy decision making. This 90-minute session will briefly refresh memories about explanatory and pragmatic trial architectures and then present the views of those who are advocating more pragmatic trials, those who carry them out, and those who criticize them.

Chair: David L. Sackett, Trout Research Centre

Speakers: Sean Tunis, Center for Medical Technology Policy
Lehana Thabane, McMaster University
James H. Ware, Harvard School of Public Health

3:30 PM – 5:00 PM

Invited Session 7

Electronic Data Capture (eDC): One Size Does Not Fit All

This session will discuss the challenges in identifying appropriate eDC solutions when working across a range of different projects, particularly in the academic research organization (ARO) context where one needs to cater for both academic and commercial projects with very different needs, designs and budgets. We will also discuss the challenges of conducting studies in vulnerable populations such as remote communities and emergency care patients where additional logistic constraints are present (e.g. inappropriate internet access). This session will bring together speakers from research organizations based in Australia, China, Europe and America. Each speaker will talk about their local experience, the challenges faced and the eDC solutions they have adopted.

Organizers: Laurent Billot and Li Wei

Chair: Laurent Billot

Speakers: Laurent Billot – Statistics and Data Management at the George Institute for Global Health (Australia)
Li Wei - Division of Biometrics at the National Center for Cardiovascular Diseases (China)

3:30 PM – 5:00 PM

Invited Session 8

Methodological Challenges and Solutions for Late-Stage Clinical Trials

Many late-stage clinical trials frequently face methodological challenges in design, monitoring and analysis. Key challenges, for example, may include the lack of a reliable surrogate marker for the primary clinical endpoint, the need to provide risk-reduction counseling of uncertain benefit, and the difficulty of measuring and maintaining adequate levels of product adherence and inadequate participant retention. This session intends to invite three leading academic researchers to discuss these challenges and provide their guidance for possible solutions.

Organizer and Chair: Ying Qing Chen, Fred Hutchinson Cancer Research Center

Speakers: Victor De Gruttola, Harvard University
Jeffery Blume, Vanderbilt University
James Dai, Fred Hutchinson Cancer Research Center

3:30 PM – 5:00 PM

Invited Session 9

Phase II Oncology Trials: Recent Considerations in Trial Design and Endpoint Selection

Recently there has been a lot of discussion about what are the appropriate designs and endpoints in Phase II cancer clinical trials. Single arm designs, including the long-term staple, Simon's two-stage design, have become less popular because of concerns about the adequacy of historical controls, bias due to population selection, and recent availability of a new class of molecularly targeted agents which do not necessarily shrink tumors, but rather have different mechanisms leading to clinical benefit. The Clinical Trial Design Task Force of CTEP's Investigational Drug Steering Committee has encouraged greater use of randomization in monotherapy trials "to optimize dose and schedule or to benchmark activity against known active therapies" and adopted the position that "randomization is usually required for trials testing combinations of agents to establish efficacy" (Public Summary, July 24, 2009). The editors of JCO have echoed these recommendations (Cannistra, JCO, 2009). Many now agree that randomized Phase II designs are preferable, although they come with a host of problems of their own, the most obvious one being prohibitively large sample size requirements. So, what is a biostatistician to do? In this session, we will discuss the issues surrounding the design and endpoint selection in randomized Phase II cancer trials; present feasibly-sized randomized designs which use continuous tumor size change and progression-free survival endpoints, and hear the opinion of the JCO Statistical editors on the appropriateness of these and other designs.

Organizer: Masha Kocherginsky, University of Chicago

Chair: Theodore Karrison, University of Chicago

Speakers: Daniel Sargent, Mayo Clinic
Karla Ballman, Mayo Clinic
Masha Kocherginsky, University of Chicago
James Dignam, University of Chicago

3:30 PM – 5:00 PM

Invited Session 10

Common Data Elements in Clinical Research in Neurology

Many clinical trial datasets never materialize their full value because multiple data standards create barriers to data sharing for meta-analysis and trial planning. However, the use of shared data standards can accelerate clinical research. The NINDS Common Data Elements (CDE) Project has developed uniform standards by which clinical research data can be systematically collected and shared across the research community.

The goals of this session are to disseminate the NINDS CDE Project and to introduce the general concept of data sharing to the broad clinical trial community. Specifically, two speakers from the NINDS will introduce the CDE Project and discuss its backdrop and implications; two investigators who have used the CDEs will share their experience.

Organizer and Chair: Ken Cheung, Columbia University

Speakers: Petra Kaufmann, Office of Clinical Research, National Institute of Neurological Disorders and Stroke, National Institutes of Health
Joanne Odenkirchen, National Institute of Neurological Disorders and Stroke, National Institutes of Health
Geoff Manley, University of California, San Francisco and the Brain and Spinal Injury Center (BASIC)
Catherine Dillon, Medical University of South Carolina

6:30 PM – 8:00 PM

Reception – *Included with Meeting Registration*



Tuesday, May 22, 2012

7:00 AM – 5:00 PM

Registration

8:00 AM – 5:00 PM

Exhibits

7:50 AM – 8:50 AM

Contributed Paper Sessions II

Session 2A: Cancer Clinical Trials

- 7:50 AM 31 Identifying Optimal Outcome Measures for Phase II Trials in Cancer; Sarah R. Brown, University of Leeds
- 8:05 AM 32 Experiences in Design and Implementation of Phase II Trials in Chronic Lymphocytic Leukaemia; Dena R. Cohen, University of Leeds
- 8:20 AM 33 Lasso Tree for Cancer Stage Grouping; Yunzhi Lin, University of Wisconsin - Madison
- 8:35 AM 34 Did Death Certificates and a Mortality Review Committee Agree on Lung Cancer Cause of Death in the National Lung Screening Trial?; Pamela M. Marcus, National Cancer Institute

Session 2B: Data Standards and Data Exchange

- 7:50 AM 35 Challenges of Creating and Managing Standards (Common Data Elements) for Use in Clinical Trials; Patti A. Shugarts, KAI Research, Inc., an Altarum Company
- 8:05 AM 36 Future of Data Exchange and Data Mining: Posting Data on the Grid by a Dental Practice-based Research Network; Sherita Alai, The EMMES Corporation
- 8:20 AM 37 The Future of the caBIG® Clinical Trials Software Development Mission: Engaging the Open Source Community; Robert P. Annechiarico, Duke University
- 8:35 AM 38 CDISC Data Standards Can Facilitate Composition of Adverse Event Narratives; Anisa Scott, SAS Institute

Session 2C: Ethics of Clinical Trials

- 7:50 AM 39 Actual Versus Reported Participant Consent Practices in Cluster Randomized Trials: An International Survey of Trialists; Shazia H. Chaudhry, Ottawa Hospital Research Institute
- 8:05 AM 40 Post Trial Access to Successful Products: Ethical and Practical Dilemmas; Liza Dawson, NIH/NIAID
- 8:20 AM 41 Ethical Issues in Cluster Randomized Trials: International Survey of Research Ethics Chairs; Monica Taljaard, Ottawa Hospital Research Institute
- 8:35 AM 42 Exception From Informed Consent (EFIC): Experiences from a Randomized Trial in Pediatric Emergency Patients; Denise F. King, EMMES Corporation

Session 2D: Safety Analysis

- 7:50 AM 43 Streamlined Drug Induced Liver Injury Detection with Hy's Law and Temporal Visualization; Kelci J. Miclaus, SAS Institute
- 8:05 AM 44 Summarizing the Incidence of Adverse Events Using Volcano Plots and Time Windows; Richard C. Zink, SAS Institute, Inc.

- 8:20 AM 45 Reducing Surveillance Bias in Adverse Events Reporting in an Unmasked Treatment Trial; Mae O. Gordon, Washington University School of Medicine
- 8:35 AM 46 Assessments for Safety and Efficacy in Cardiovascular Cell Therapy Clinical Trials; Adam M. Mendizabal, The EMMES Corporation

Session 2E: Trial Conduct

- 7:50 AM 47 Shrinking the Global Village: The Challenges of Trial Management in an International Multi-Centre Trial; Claire Cochran, University of Aberdeen
- 8:05 AM 48 The Use of Central IRBs for Multicenter Clinical Trials; Devon K. Check, Duke University
- 8:20 AM 49 Tracking of Regulatory Documents in a Large Clinical Trial, The Age-Related Eye Disease Study 2 (AREDS2); Sherrie M. Schenning, The EMMES Corporation
- 8:35 AM 50 Electronic Health Record Systems for Medical Research Project Stakeholder Management; Derek C. Warren, University of Glasgow

9:00 AM – 10:30 AM

Invited Session 11

Update from the Clinical Trials Transformation Initiative: Rethinking Approaches to Clinical Trial Oversight and Premarket Safety Management

The Clinical Trials Transformation Initiative continues to engage multiple sectors in projects seeking to improve the quality and efficiency of clinical trials. This session will provide updates on projects that have been rethinking approaches to clinical trial oversight and premarket safety management. Building on recommendations presented at the 2011 SCT Annual Meeting on “Monitoring as a component of quality assurance in the conduct of clinical trials,” one project has explored approaches to building quality into the scientific and operational design and conduct of clinical trials by applying principles used in the manufacturing sector termed “quality by design” and by developing risk-based “quality management plans.” These approaches are quite consistent with recommendations in a new FDA draft guidance for industry issued in August 2011 titled “Oversight of Clinical Investigations—A Risk-based Approach to Monitoring.” A speaker from the FDA will describe the risk-based approaches proposed in that guidance and how monitoring might fit within a larger quality-by-design framework. Another project has explored the management of premarket safety with the goal of promoting responsible oversight of safety consistent with the intent of the FDA’s new premarket safety rule, effective March 28, 2011. The project is reviewing current practices for assessing safety of a premarket product across all trials of that product and for managing potential safety signals. A group of experts from multiple sectors will be convened to discuss current practices and consider future approaches consistent with the FDA’s new rule, and a biostatistical workgroup will consider methodological issues concerning the analysis of accruing safety information. During this session, there will be time to interact with the panel regarding these 2 projects and CTTI’s approach to influencing change.

Organizer and Chair: Judith M. Kramer, Duke University Medical Center

Speakers: Robert Temple, Center for Drug Evaluation and Research, U.S. Food and Drug Administration
Jose Vega, Amgen, Inc.
Leslie Ball, Center for Drug Evaluation and Research, U.S. Food and Drug Administration



Tuesday, May 22, 2012

9:00 AM – 10:30 AM

Invited Session 12

Developing Evidence-based Multistage Treatment Policies from Clinical Trials Data

Multistage treatment policies (also called dynamic treatment regimes) are time-varying, personalized decision rules that allow individualizing the treatment to the patient. They offer a framework for operationalizing, and thereby potentially improving, the adaptive clinical practice for many chronic disorders. In recent years, there has been a surge of interest in this promising research area of tremendous methodological and practical appeal. These treatment policies have found application in many health domains including oncology, HIV infection, mental illnesses, substance abuse, and stroke prevention. This session presents four talks on design and analysis of clinical trials data to develop evidence-based treatment policies.

Chair: Bibhas Chakraborty, Columbia University

Speakers: Philip Lavori, Stanford University
Eric Laber, North Carolina State University
Ying-Kuen (Ken) Cheung, Columbia University
Susan M. Shortreed, Group Health Research Institute

9:00 AM – 10:30 AM

Invited Session 13

Open Source Statistical Software in Drug Development: Challenges and Opportunities

Utilization of open source software, such as R and OpenBUGS, in clinical drug development conducted by the biopharmaceutical industry is, by and large, limited to simulations for trial/program design and exploratory analyses not included in regulatory submissions. A number of factors account for that, but chief among them is the (incorrect) perception that open source software cannot be validated and, therefore, is not accepted by regulatory agencies for analyses included in submission packages. Because research in statistical methodology increasingly makes its way into software via the open source route, this perception creates further hurdles for the utilization of novel statistical methods in an industry badly in need of innovative designs and analysis methods. This session will discuss the challenges, perceived and real, to the broader utilization of open source software in clinical drug development (not just in the biopharma industry, but also in NIH-sponsored trials), and opportunities for addressing those challenges. It will feature speakers from the FDA, academia, and the biopharma industry with practical experience with the use of open source software in drug development.

Organizer and Chair: José Pinheiro, Janssen R+D

Speakers: Mat Soukup, Center for Drug Evaluation and Research, U.S. Food and Drug Administration
Frank Harrell, Vanderbilt University
Keaven Anderson, Merck
Seth Berry, Quintiles

9:00 AM – 10:30 AM

Invited Session 14

Ethical, Regulatory and Recruitment Issues in Vulnerable Populations: Substance Use Trials as a Case Study

Individuals with substance use disorders are considered vulnerable due to many factors, such as presenting with co-occurring mental health disorders affecting cognitive functioning, being involved in the criminal justice system, and suffering economic disadvantages and social stigma, among others. This session will describe ethical, regulatory and recruitment issues when conducting clinical trials with individuals with substance use disorders. Dr. Anderson will present evidence-based strategies for providing appropriate, effective research protections to individuals and will also review evidence that suggests substance use populations may not be vulnerable in many of the ways that researchers and IRBs often assume. Dr. Campbell will discuss challenges when individuals are involved in the criminal justice system and present strategies currently used to address these challenges. Dr.

Miele will present innovative approaches to increase recruitment/retention as well as discuss regulatory and human subject challenges when using current technologies for recruitment and retention purposes.

Chair: Carmen L. Rosa, National Institute on Drug Abuse

Speakers: Emily E. Anderson, Loyola University Chicago
Aimee N. C. Campbell, Columbia University
Gloria Miele, Columbia University College of Physicians and Surgeons

9:00 AM – 10:30 AM **Invited Session 15**
Student Scholarship Presentations

In this session, students will present the papers selected as finalists in the Thomas Chalmers Scholarship Program.

10:30 AM – 11:00 AM **Break/Exhibits/Poster Prime Time**

11:00 AM – 12:30 PM **Invited Session 16**
**Guidelines for the Ethical Conduct and Ethics Review of Cluster Randomized Trials:
Statement from an International Consensus Meeting**

The cluster randomized trial (CRT) is used increasingly in knowledge translation research, quality improvement research, community based intervention studies, public health research, and research in developing countries. However, CRTs raise difficult ethical issues that challenge researchers, research ethics committees, regulators, and sponsors as they seek to fulfill responsibly their respective roles. Funded by the Canadian Institutes of Health Research, our multidisciplinary group conducted a four-year research project to study the ethical challenges in CRTs. An international consensus meeting was held in Ottawa, Ontario from 28-30 November 2011, with the view to generate consensus ethics guidelines for CRTs. In this session, we will present the Consensus Statement for the Ethical Conduct and Ethics Review of CRTs coming out of the meeting, and invite comment and discussion from the audience.

Organizer and Chair: Monica Taljaard, Ottawa Hospital

Speakers: Monica Taljaard, Ottawa Hospital
Jeremy Grimshaw, Ottawa Hospital Research Institute
Charles Weijer, University of Western Ontario
Angela White, University of Western Ontario

11:00 AM – 12:30 PM **Invited Session 17**
Mastering the Challenges: Academic Infrastructures for Clinical Trials in Europe

The clinical trials system needs to improve. Otherwise ‘the introduction of new treatments (...) will be delayed and patient lives will be lost unnecessarily’.^[1]

It typically requires years to design, review, and initiate Cooperative Group clinical trials. ‘In attempting to optimize the effectiveness and safety of trials, proposals often are redrafted and recycled by multiple stakeholders from academic institutions, federal agencies, institutional review boards, and industry. This results in frustration and a perception that stakeholders are working at crosspurposes.’^[1]

An adequate process for prioritizing trials and selecting those most likely to be successful is lacking. Slow accrual of patients is often the result. A large number of trials is not completed and published, ‘which is a terrible waste of human and financial resources.’^[1]



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Funding for Cooperative Group clinical trials is often inadequate. 'As much as half of the cost of clinical trials today are borne by the clinical investigators and clinical care providers who design and carry out these important studies. Almost universally, investigators are compelled to seek supplemental support from outside sources, such as pharmaceutical companies.'^[1] In addition the cost increases because biomarkers are more often used to predict and monitor appropriate therapy.^[1]

In Europe the Fragmentation of the health and legislative systems and funding sources represent other bottlenecks to multinational collaboration^[2]. To take advantage of its population size, and to unlock the full scientific potential the European Union has funded an increasing number of multinational clinical trials. In addition, the Union and its Member States invest significant resources to create and maintain the European Clinical Research Infrastructures Network (www.ecrin.org)^[2].

In this session we will look at the challenges we all face and present and discuss European concepts to master them in a world where 'research infrastructures are becoming increasingly diverse and distributed over various sites and are increasingly interconnected and supported by e-Infrastructures.'^[3]

[1] National Academy of Sciences: IOM: A National Cancer Clinical Trials System for the 21st Century: Reinvigorating the NCI Cooperative Group Program

[2] A European perspective – the European clinical research infrastructures network, J. Demotes-Mainard & C. Kubiak, *Annals of Oncology* 22 (Supplement 7): vii44–vii49, 2011

[3] ESFRI: Strategy Report on Research Infrastructures - Roadmap 2010

Chair: Jochen Dress, University of Cologne

Speakers: Jacques Demotes, European Clinical Research Infrastructures Network, INSERM, Institut Thématique Santé Publique
Jochen Dress, University of Cologne
Cornelius Schmaltz, Directorate General for Research and Innovation, European Commission

11:00 AM – 12:30 PM **Invited Session 18** **Data and Safety Monitoring Board (DSMB) Roles in Adaptive Design Trials**

Adaptive designs have been commonly used in modern clinical trials. Many of them have a DSMB to review certain unblinded data before making modifications to the ongoing trial. Typically the interim decision/recommendation will follow a pre-determined decision rule in the protocol or DSMB charter. However, the DSMB often has liberty to deviate from the decision rule if the committee thinks that is in the best interest of patients/subjects. Sometimes the decision rules can be more subjective for non-pivotal trials. DSMBs will always face the question regarding how the decision/recommendation will affect the rest of trial conduct and interpretation of the trial results. This session will discuss practical and logistical issues of DSMB operations in adaptive design trials such as (but not limited to) whether and how the DSMB should be formed; what information and restrictions should the DSMB have before and during a trial; how the DSMB reviews and makes recommendations; how to deal with unanticipated interim outcomes, and what the potential regulatory implications may be, etc.

Organizers: Xiaoyin Frank Fan, Vertex Pharmaceuticals
Dave DeMets, University of Wisconsin-Madison

Speakers: Sue-Jane Wang, U.S. Food and Drug Administration
Jerry Schindler, Merck & Co.
Bruce Turnbull, Cornell University (invited)

Discussant: Dave DeMets, University of Wisconsin-Madison

11:00 AM – 12:30 PM **Invited Session 19**
A Centennial Celebration of Jerome Cornfield and His Contributions to Clinical Trials

Jerome Cornfield was born in New York City in 1912. With no further academic degree than a B.A. in history, he became a leading figure in the statistics of medical research, with a substantial focus on the methodology of clinical trials. Jerry spent many years at the National Institutes of Health, first in the National Cancer Institute and later at the then-National Heart Institute. He was an early proponent of the use of Bayesian and likelihood-based methods in clinical trials, and recognized the need for statistical tools to facilitate interim decision-making when monitoring accumulating data. He was among the first to discuss randomization by group rather than by individual for certain types of applications. Jerry's knowledge, wisdom and humor were widely appreciated and he served the worlds of clinical trials, medical research, and statistics in many ways. He was elected Vice President of the American Heart Association, and President of the American Statistical Association. He chaired an FDA statistical committee to advise the FDA on difficult statistical issues during an era when statisticians did not serve on individual FDA advisory committees. He was an active participant in the yearly meetings of researchers discussing clinical trials methods, held in the mid-1970s, that led to the formation of the Society for Clinical Trials the year following his death in 1979 from pancreatic cancer. Throughout his professional lifetime and for many years thereafter, his perspective was routinely noted ("Jerry always says...") to provide incontrovertible support of a methodological position.

Each speaker will comment on Cornfield's contributions in a specific area in addition to describing developments in this area to the present day.

- Organizer and Chair:** Susan S. Ellenberg
- Speakers:** John Lachin, The George Washington University
Joel Greenhouse, Carnegie Mellon University
Janet Wittes, Statistics Collaborative
Robert O'Neill, U.S. Food and Drug Administration

11:00 AM – 12:30 PM **Invited Session 20**
Randomized Trials in Pregnant Women

Randomized trials in pregnancy are unique in that each subject comprises two individuals: the pregnant woman and her fetus. Both individuals are considered to be "vulnerable" according to regulatory guidance. Though pregnancy does not in itself diminish decision-making capacity, special consideration is often warranted. The woman is being asked to make a decision in the context of great physiological complexity concern about the outcome of the pregnancy, and usually a paucity of data regarding safety and efficacy of interventions. The fetus lacks autonomy, yet its experience before birth can have lasting consequences for its future. Risks and benefits are not equivalent for mom and baby – treatments tested can range from those with potential benefit only for the mother to those with potential benefit only to the fetus. The speakers will discuss the importance and challenges of trials in pregnant women, including informed consent issues, balancing risk, and other trial design and analysis issues applicable to this group.

- Organizers:** Elizabeth Thom, The George Washington University Biostatistics Center
Mary Foulkes, The George Washington University Biostatistics Center
- Speakers:** George Saade, University of Texas Medical Branch, Galveston
Ben Willem Mol, University of Amsterdam
Anne Drapkin Lyerly, University of North Carolina, Chapel Hill
- Discussant:** Catherine Spong, National Institute of Child Health and Human Development

12:30 PM – 1:50 PM **Lunch/SCT Business Meeting** – *Included with Meeting Registration*



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1:50 PM – 2:50 PM

Contributed Paper Sessions III

Session 3A: Biomarkers

- 1:50 PM 51 Exploratory Biomarker Analysis for Randomized Phase 2 Oncology Trials; Hongjie Deng, Amgen Inc.
- 2:05 PM 52 Leveraging Enrichment Design Methods to Improve the Likelihood of Success of Clinical Trials; Imogene M. Grimes, Otsuka Pharmaceutical Development & Commercialization, Inc.
- 2:20 PM 53 Survey of Commonly Used Analytical Methods for Analyzing Biomarkers with Limit of Detection; Tulay Koru-Sengul, University of Miami Miller School for Medicine
- 2:35 PM 54 A Phase II Design with Direct Assignment Option for Initial Marker Validation; Ming-Wen An, Vassar College

Session 3B: Patient Recruitment, Enrollment and Retention

- 1:50 PM 55 Use of a Formal Study Run-in Phase to Reduce Recruitment Errors in a Multi-centre Randomized Controlled Trial: Is Quality Better Than Quantity?; Gordon S. Doig, Royal North Shore Hospital, University of Sydney
- 2:05 PM 56 How Effective are Patient Information Leaflets? A Framework and Methods for Evaluation; Mark W. Garner, University of Aberdeen
- 2:20 PM 57 Recruiting Patients for an Interdisciplinary, Multi-center International Randomized Clinical Trial: Barriers and Strategies, Bypass Angiographic Revascularization Investigation 2 Diabetes Trial (BARI 2D); Lisa D. Mighton, University Health Network/Toronto General Hospital
- 2:35 PM 58 Patients and Clinical Trials: How to Improve Their Participation?; Carlo Tomino, Italian Medicines Agency

Session 3C: Reporting of Clinical Trials

- 1:50 PM 59 Development of a Taxonomy to Facilitate Reporting of Behavior Change Techniques, The Active Ingredients' of Behavior Change Interventions; Jill J. Francis, University of Aberdeen
- 2:05 PM 60 Which Components of Interventions are Reported in Titles and Abstracts? A Systematic Review to Compare Reporting Practices for Pharmacologic and Non-pharmacologic Interventions; Nicola McCleary, University of Aberdeen
- 2:20 PM 61 Failure to Report Protocol Violations in Clinical Trials: A Threat to Internal Validity?; Elizabeth A. Sweetman, Royal North Shore Hospital, University of Sydney
- 2:35 PM 62 The COMET (Core Outcome Measures in Effectiveness Trials) Initiative; Paula R. Williamson, University of Liverpool

Session 3D: Statistical Methods and Trial Design

- 1:50 PM 63 Standard Deviation Choice and Sample Size Calculation in Clinical Trials; Henian Chen, University of South Florida
- 2:05 PM 64 Formal Methods for Determining Sample Size- Survey of SCT Membership; Jonathan A. Cook, University of Aberdeen
- 2:20 PM 65 Adaptive Designs for Clinical Comparative Effectiveness Research: Are We Ready?; John A. Kairalla, University of Florida
- 2:35 PM 66 Perception and Use of Adaptive Designs in the Industry and Academia: Persistent Barriers and Recommendations to Overcome Challenges; Caroline C. Morgan, Cardinal Systems

Session 3E: Vulnerable Populations

- 1:50 PM 67 Challenges of Collecting Health Data and Maintaining Contact with an Aging Study Population; Jo Ann L. Hartline, Cancer Research And Biostatistics
- 2:05 PM 68 Extended Follow-up in Multi-phase Clinical Trials; Katherine Trigiani, Sunnybrook Research Institute
- 2:20 PM 69 Issues to Consider in the Set-up of Complex Intervention Trials in Vulnerable Populations; Shamaila Anwar, University of Leeds
- 2:35 PM 70 Designing Clinical Trials for Testing Disease-modifying Agents on Alzheimer’s Disease; Chengjie Xiong, Washington University

2:50 PM – 3:20 PM **Break/Exhibits/Poster Prime Time**

3:20 PM – 4:50 PM **Invited Session 21
Translational Behavioral Science: A Framework to Guide the Development of Health-related Behavioral Interventions**

Our ability to improve health-related behaviors, such as physical activity and dietary patterns, is enhanced by our understanding of the fundamental bases of human behavior and the translation of that knowledge into effective interventions. In drug development, research concerned with the development and testing of interventions is labeled “bench to bedside” or Translational research. Translational research begins with basic research to identify mechanisms and intervention targets, proceeds to the conduct of small-scale human trials to assess safety and optimal dosing, and includes pilot studies to assess feasibility and provide estimates of yield and effect. These early phases of therapy development are followed by large-scale, Phase III clinical trials that test the effects of the treatment on the health outcomes of interest. This paradigm is well-accepted in the biomedical arena; however, no such widely accepted paradigm exists for guiding the development of health-related behavioral interventions. In this symposium, members of the NIH-sponsored ORBIT (Obesity Related Behavioral Intervention Trials) consortium, which aims to develop new approaches to reducing obesity based on basic behavioral science research, will first present a framework that can be used to guide the development of health-related behavioral interventions, followed by a description of the aims, study designs and methodological approaches of two ORBIT projects that are using this framework to develop innovative obesity-related interventions. One project uses a series of qualitative, epidemiologic and proof-of-concept studies to develop a multi-level intervention to reduce the progression of visceral fat in women undergoing menopause. The other utilizes a sequential randomized assignment trial and qualitative analysis to design and test an intervention to promote weight loss in obese African American adolescents. The discussant will comment on needs and opportunities in basic and translational behavioral science research and highlight NIH’s role in supporting Translational behavioral science.

- Organizers & Chairs:** Susan Czajkowski, National Heart, Lung, & Blood Institute, National Institutes of Health
Lynda Powell, Rush University Medical Center
- Speakers:** Susan Czajkowski, National Heart, Lung, & Blood Institute, National Institutes of Health – Overview of a Framework to Guide Health-related Behavioral Intervention Development
Lynda Powell, Rush University Medical Center – WISHFIT: Women In the Southside Health Project - FITness Studies
Sylvie Naar-King, Wayne State University – Interventionist Procedures for Adherence to Weight Loss Recommendations in Black Adolescents
- Discussant:** Robert Kaplan, Office of Behavioral & Social Sciences Research, National Institutes of Health



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3:20 PM – 4:50 PM

Invited Session 22

Registration and Reporting of Clinical Trials: Key Informatics Issues and Trends

Following the invited session “Reporting of Clinical Trial Results at Clinicaltrials.gov: Key Scientific Issues” at SCT 2011, this session is intended to highlight informatics approaches to the reporting of clinical trial results, not just at clinicaltrials.gov but also in two key reporting initiatives within the National Cancer Institute.

The Food and Drug Administration Amendments Act of 2007 (FDAAA) expanded clinical trial registration and results reporting requirements in clinicaltrials.gov and made them mandatory for the first time. These requirements have increased in parallel with requirements of public sector study sponsors, such as the National Cancer Institute, both of which are occurring at a time when the budgets of academic medical centers are under considerable pressure.

This session will examine the current and potential future registration and reporting requirements both of clinicaltrials.gov and of the National Cancer Institute’s Clinical Trials Reporting Program. Emphasis will be placed on opportunities that have been taken, and future opportunities that could be taken, to streamline the reporting process and to minimize duplicative reporting requirements.

Another aspect of clinical trials reporting is NCI’s longstanding expedited reporting requirements for serious adverse events in clinical trials. Recent developments to automate this process will be discussed. Representatives both of government sponsors and academic sites will present their experience in managing and responding to these requirements and challenges.

Organizer and Chair: John Speakman, National Cancer Institute, National Institutes of Health

Speakers and Jose Galvez, National Cancer Institute, National Institutes of Health

Discussants: Charles Hurmiz, St. Jude Children’s Research Hospital

Nicholas Ide, ClinicalTrials.gov

David Patton, National Cancer Institute, National Institutes of Health

Ken Quinn, Roswell Park Cancer Institute

3:20 PM – 4:50 PM

Invited Session 23

Increasing Clinical Program Success with Modeling and Simulation

The fact that regulators have been leading the effort to modernize clinical trial design has spurred interest in industry and academia. Improving the development strategy by taking into account data from early development and applying innovative statistical methods is one of the major objectives for biostatisticians designing and supporting clinical programs. Modeling and simulation approaches can help to optimize an individual trial, to see the benefit of novel designs, and to increase success of a clinical program by making better decisions while developing a drug. In this session, presenters from academia, the pharmaceutical industry, and CROs will share their experience and ideas on how modeling and simulation can increase clinical program success and enable study and program teams to make better decisions through the process. Simulated case studies and examples from real trials will be used to motivate and illustrate the key ideas.

Organizer & chair: Olga Marchenko, Quintiles

Speakers: Don Berry, MD Anderson Cancer Center

José Pinheiro, Janssen R+D

Russell Reeve, Quintiles

Discussant: Tom Parke, Tessella Technology & Consulting

3:20 PM – 4:50 PM

Invited Session 24
Safety Evaluation with Clinical Trial Information

The lack of understanding of drug safety profiles may result in serious public health consequences. Proactive planning of safety evaluations is an essential part of clinical drug development.

Drug safety evaluation, however, can be very different from efficacy evaluation, primarily due to small treatment differences as well as varying risk over time. Such differences pose new challenges using clinical trial information for drug safety evaluation. Handling the challenges requires the understanding of possible behavior of drug safety characteristics and limitations of clinical trials, careful strategies in handling data, and innovative statistical methods. In this session, clinicians and statisticians will jointly discuss the principles for safety data collection and analyses, the potential issues related to the drug safety evaluation and present statistical methodologies addressing the issues.

- Organizers:** Li Chen, Amgen
Qian Li, U.S. Food and Drug Administration
- Speakers:** James Kaiser, U.S. Food and Drug Administration
Seta Shahin, Amgen
Qian Li, U.S. Food and Drug Administration
- Discussant:** Joan Hu, Simon Fraser University

3:20 PM – 4:50 PM

Invited Session 25
Coordination and Conduct of Phase III Emergency Treatment Trials

This session will examine the coordination and conduct of large multicenter emergency care trials using a recently completed Phase 3 trial as a case study. The Rapid Anticonvulsant Medication Prior to Arrival Trial (RAMPART) was a double-blind, randomized, controlled, non-inferiority clinical trial designed to compare the efficacy of intramuscular midazolam versus intravenous lorazepam in the pre-hospital treatment of status epilepticus. The emergent nature of the disease inherently created special requirements for the coordination and conduct of the trial including: exception from informed consent, randomization in the ambulance, training of paramedics, tracking of study drug packages, and data management, project management, and regulatory management issues.

- Organizer:** Wenle Zhao, Medical University of South Carolina
- Speakers:** Valerie Durkalski, Medical University of South Carolina or Robert Silbergleit,
University of Michigan
Deneil Harney, University of Michigan
Catherine Dillon, Medical University of South Carolina

5:00 PM – 6:20 PM

Plenary Session I: Trial of the Year/Project ImpACT

6:30 PM – 7:30 PM

Affinity Group Receptions – Included with Meeting Registration

- Information Technology
- Clinical Research Associates
- MD Clinical Trialists
- Members of Industry or FDA
- Trialists Practicing in Europe



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7:00 AM – 11:00 AM Registration

8:00 AM – 9:30 AM **Invited Session 26**
Decision Support Interventions for Trial Participation

Ethical guidelines suggest that in order to provide valid informed consent, clinical trial participants should understand key information about the trial in which they are being invited to participate. However, poor participant understanding of the research processes, a lack of knowledge about the expectations and demands of the trials, and insufficient support when faced with the decision have been demonstrated across a range of clinical areas (Prescott 1999; Jenkins 2000; Flory 2004). As such, the existing approach to obtaining informed consent is inadequate and needs to be re-examined.

Decision support interventions may improve the informed consent process by improving subjects' knowledge and understanding of the decision to participate, and allowing them to reflect on what matters most to them. Preliminary exploratory studies provide some evidence that decision support tools could be useful in this context. Better informed participants may be more likely to make improved decisions (whether consent or refusal) about RCT participation (Juraskova 2008, Abhyankar 2011), and be more aware of the expectations on them as a trial participant throughout the study.

This session will describe the burgeoning literature on decision support interventions for informed consent, and discuss implications for recruitment, retention, and other aspects of trial design.

Organizers: Jamie Brehaut, Ottawa Hospital Research Institute
Katie Gillies, University of Aberdeen

Chair: Marion Campbell, University of Aberdeen

Speakers: Jamie Brehaut, Ottawa Hospital Research Institute
Katie Gillies, University of Aberdeen
Vikki Entwistle, University of Dundee
Stan Shapiro, McGill University

8:00 AM – 9:30 AM **Invited Session 27**
**A Real-time Electronic Remote Data Capture and Therapeutic Risk Group
Communication System: From Central Laboratories to Individual Patient Treatment
in Pediatric Cancer Clinical Trials**

The Children's Oncology Group (COG) has complex classification systems in place for pediatric clinical trials, including those for acute lymphoblastic leukemia and neuroblastoma. Classification of patients is based on biological, clinical, and genomic data obtained at initial diagnosis/during therapy. The COG web-based remote data entry (RDE) system enables submission of data in real time from central laboratories and treating institutions. The use of RDE technology, including an automated risk-assignment algorithm that triggers an email to the patient's treating institution, permits much more rapid determination and delivery of the appropriate level of therapeutic intensity to an individual patient enrolled in a clinical trial than ever before. This approach is applicable to any disease where therapy varies on the basis of factors identified at baseline or early therapy, and will be useful in adult cancer in the near future with the advent of prognostic and targeted genomic factors.

Organizers: Meenakshi Devidas, University of Florida
Wendy B. London, Harvard Medical School
James R. Anderson, University of Nebraska College of Public Health

Chair: Meenakshi Devidas, University of Florida

Speakers: James R. Anderson, University of Nebraska College of Public Health
Wendy B. London, Harvard Medical School
Meenakshi Devidas, University of Florida

Discussants: Sally Hunsberger, National Cancer Institute, National Institutes of Health
Meredith Regan, Harvard University

8:00 AM – 9:30 AM

Invited Session 28

Response-Adaptive Treatment Allocation in Clinical Trials: The Costs and Benefits

Response adaptive randomization (RAR) was originally proposed based on study subject ethical considerations. Early implementation of RAR using the Play the Winner (PW) or Random Play the Winner (RPW) algorithm resulted in allocation ratios with wide variations. Optimal target allocation ratios aim to minimize the total number of failures or to maximize the statistical power, but often end with an allocation ratio close to the equal allocation. The implementation of RAR requires a procedure to ensure that the target allocation ratio is achieved with a small variation and the treatment groups are compatible with regards to baseline characteristics. This needs to be balanced with joint considerations of study subject ethics and trial operation. In this session, the speakers will share their opinions and experiences in the design and implementation of RAR in large multicenter clinical trials, with the goal of providing suggestions on the selection and implementation of RAR based on operation issues in clinical trial practice.

Organizer: Valerie Durkalski, Medical University of South Carolina

Speakers: Wenle Zhao, Medical University of South Carolina
Ying Yuan, University of Texas MD Anderson Cancer Center
Oleksandr Sverdlov, Bristol-Myers Squibb

Discussant: Sue-Jane Wang, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

8:00 AM – 9:30 AM

Invited Session 29

Emerging Issues and Their Solutions in the Implementation of Adaptive Designs in Clinical Trials

Adaptive designs represent a new technology in drug development. These designs have an impact on drug development strategies, clinical trial management systems and clinical data management systems. Adaptive design will also change enrollment, EDC/IV(W)RS, drug supply management, DMC operating procedures, trial protocols, informed consent forms, and data analysis plans. In this session, we will discuss the emerging issues associated with adaptive clinical trials and present the latest solutions for their successful implementation: controlling flexible randomization and optimizing the quantities of required drug supplies, expanding role and broader responsibility of DMC, and a fully integrated adaptive execution environment, with a particular focus on maintaining validity and integrity of the trial.

Chair: Vlad Dragalin, Aptiv Solutions

Presenters: Olga Kuznetsova, Merck Sharp & Dohme Corp.
Paul Gallo, Novartis Pharmaceuticals
Judith Quinlan, Aptiv Solutions



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8:00 AM – 9:30 AM

Invited Session 30

Dealing with Treatment Compliance in Clinical Trials on Inherently Low-Compliant Populations: What to do at the Design, Monitoring and Analysis Stages

Ensuring treatment compliance is difficult in general. Particular difficulties are found in vulnerable populations, such as those with substance abuse disorders. A very low treatment compliance rate, common in such populations, can render a clinical trial worthless. We've heard physicians say "if they don't take their medication, they can't get better". In a clinical trial context, one can similarly say "if they don't take their medication, we cannot find out whether it is effective". It is therefore important to design a clinical trial to maximize compliance, monitor the trial to assess the actual compliance level, and analyze its data in a way that minimizes the detrimental impact of poor treatment compliance. This session will provide some answers to the following critical questions on treatment compliance at these important stages of a clinical trial:

- (1) How best to design a study to maximize medication or psychosocial treatment compliance? What are successful (and unsuccessful) trial design strategies for improving compliance? Are clinical trials where compliance is so low worth doing? At what compliance level does a trial become useless?
- (2) What are participants telling us about the barriers that affect compliance?
- (3) What are available technologies and methods to maximize compliance? How best to monitor to ensure compliance?
- (4) How best to analyze the data in the presence of less-than-perfect treatment compliance? Which should be the primary analysis: intent-to-treat, "completers," or something else? What are the pros and cons?

Organizers: Paul Wakim, National Institute on Drug Abuse, National Institutes of Health
Michele Straus, National Institute on Drug Abuse, National Institutes of Health

Speakers: Paul Wakim, National Institute on Drug Abuse, National Institutes of Health
Lawrence M. Friedman, Consultant to National Institutes of Health
Viviana Horigian, University of Miami Miller School of Medicine
Michele Straus, National Institute on Drug Abuse, National Institutes of Health
James Rochon, Rho Inc.

9:45 AM – 11:15 AM

Contributed Paper Sessions IV

Session 4A: Clinical Epidemiology

- 9:45 AM 71 Soundness of Evidence Derived from Meta-analysis of High Quality Observational Studies: A Case in Cardiology; Catherine Klersy, IRCCS Fondazione Policlinico San Matteo
- 10:00 AM 72 Using Meta-Synthesis of Three Randomized Controlled Trials in Colorectal Cancer (CRC) Screening to Inform Assumptions on Natural History of CRC in Microsimulation Modeling; Ann G. Zauber, Memorial Sloan-Kettering Cancer Center
- 10:15 AM 73 Combining Randomized and Observational Data Using Network Meta-Analysis to Explore Drug Safety: The Case of Antifibrinolytics in Cardiac Surgery; Brian Hutton, Ottawa Hospital Research Institute
- 10:30 AM 74 The Publication of Preclinical Evidence Supporting Translation of New Drugs: An Empirical Analysis; Carole Federico, McGill University
- 10:45 AM 75 Can Exercise Enhance Smoking Cessation Outcomes? A Pragmatic Randomized Controlled Trial (Fit2Quit Study); Yannan Jiang, The University of Auckland
- 11:00 AM 76 Group-Based Trajectory Models in a Clinical Study in Nutrition; Yassin Mazroui, Université Bordeaux Segalen, INSERM U897, ISPED, Bordeaux Cedex F-33076

Session 4B: Data Management

- 9:45 AM 77 The Life Study Outcomes Management Tool; Lea N. Harvin, Wake Forest University School of Medicine
- 10:00 AM 78 Improving Data Quality Using Quality Improvement; Daniel Jeffers, Cincinnati Children's Hospital Medical Center
- 10:15 AM 79 Streamlining Data Collection and Flow for Central Units in Large Multi-Center Clinical Trials; Pam Mangat, George Washington University
- 10:30 AM 80 Design of a Comprehensive Rule-based, Real-time Data Validation Function in a Web-based Clinical Trial Management System; Keith H. Pauls, Medical University of South Carolina
- 10:45 AM 81 Survey of the Current Beliefs and Attitudes of the Canadian Critical Care Trials Group Regarding Source Data Verification; Roxanne Ward, Children's Hospital of Eastern Ontario Research Institute
- 11:00 AM 82 Reproducible Research and Clinical Trials; Paul A. Thompson, Sanford Research/USD

Session 4C: New Opportunities in Data Capture

- 9:45 AM 83 The Use of Ancillary Data Capture Systems in Clinical Trials; Colleen C. Allen, The EMMES Corporation
- 10:00 AM 84 Electronic Patient Reported Data for Risk Screening in Primary Care Clinics using OpenClinica and CDISC ODM; Cal Collins, OpenClinica
- 10:15 AM 85 Implementation of Digital Pen Technology to Capture Clinical Trial Data; Nicole Close, EmpiriStat, Inc.
- 10:30 AM 86 Responding to the Growing Need for Alternative Platforms for Collecting Clinical Research Data; Milena Silverman, Memorial Sloan-Kettering Cancer Center
- 10:45 AM 87 Challenges and Implications of Patient Reported Clinical Outcomes for Randomised Controlled Trials; Suzanne Breeman, University of Aberdeen
- 11:00 AM 88 Electronic Patient-Reported Outcome (ePRO) Assessment in Clinical Trials: Strategies for Preserving Statistical Power; Antonia Bennett, Memorial Sloan-Kettering Cancer Center

Session 4D: Statistical Methods

- 9:45 AM 89 Randomized Decision Designs when the Number of Available Subjects Precludes a More Standard Study Design; James Anderson, U Nebraska College of Public Health
- 10:00 AM 90 Bio-Creep Under Serial Use of Non-inferiority Trials Designed for Preservation of Effect; Katherine S. Odem-Davis, Fred Hutchinson Cancer Research Center
- 10:15 AM 91 The Use of Bayesian Predictive Distribution in Clinical Trials; Bo Yang, Merck Research Laboratories
- 10:30 AM 92 Measurement Issues in the Hamilton Rating Scaled for Depression May Conceal Positive Findings in Clinical Trials for Major Depression; Chengwu Yang, Pennsylvania State University College of Medicine
- 10:45 AM 93 Futility Boundary Design Based on Probability of Success; Yijie Zhou, Merck Research Laboratory



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11:00 AM 94 Some Strategies for Defining Non-Inferiority Bounds in Active-Controlled Trials with No Placebo-Controlled Data for the Active Comparator; Aditi Sapre, Merck Research Laboratories

Session 4E: Trial Design

9:45 AM 95 Use of Routinely Collected Data Within Primary Care Medical Centre-based Trials; Nicola Greenlaw, University of Glasgow

10:00 AM 96 Routine Data – Is it Good Enough for Trials?; Alex M. Wright-Hughes, Leeds University

10:15 AM 97 Contemporary Clinical Research in Adult Cardiovascular Medicine: A Perspective from ClinicalTrials.gov; David F. Kong, Duke Clinical Research Institute

10:30 AM 98 The Clinicaltrials.gov Results Database as a Resource for Designing Clinical Trials; Elizabeth C. Wright, NIDDK/NIH

10:45 AM 99 Supplementing the Design of Comparative Binary Outcome Trials with Sequential Meta-Analyses; Mireya Diaz, Henry Ford Hospital

11:00 AM 100 Developing Stop-Go criteria for Pilot / Feasibility Studies to Continue to Full Trials; John Norrie, University of Aberdeen

11:15 AM – 11:30 AM Break

11:30 AM – 12:15 PM **Founders Lecture – John P.A. Ioannidis**
“Designing and Dissecting the Geometry of Randomized Evidence”
Director of the Stanford Prevention Research Center

Poster Presentations

Order of Poster Presentations is subject to change – Please consult final program

**Poster Presentation Monday, May 21, 2012, 8:30 AM – 5:00 PM
Prime Time 10:15 – 10:45 AM and 3:00 – 3:30 PM**

- Working with At-Risk Populations; Allison Caban-Holt, University of Kentucky
- Interobserver Reliability of Tongue Diagnosis Using Traditional Korean Medicine for Stroke Patients; Mi Mi Ko, Korea Institute of Oriental Medicine
- Factors that Affect Men’s Feelings About Their Urination: Findings from a Multi-center Clinical Trial of Phytotherapy to Treat Lower Urinary Tract Symptoms; Alan B. Cantor, University of Alabama Birmingham
- Compliance Assessment for Eligibility in a 1-Year-Long Ophthalmic Clinical Trial Investigating Eye Drops; Talat Almukhtar, Jaeb Center for Health Research
- Strategies Implemented to Ensure Data Accuracy for Final Analysis; Kathryn E. Mangoff, Sunnybrook Research Institute
- Integration of Data Management Systems for Large International Randomised Controlled Trials; Michael X. Shi, Sunnybrook Research Institute
- Improving Data Management Through Data Transfer; Janice C.H. Kwok, Sunnybrook Health Sciences Centre
- Adjudicating Life Study Outcomes through the Outcome Management Tool; Lea Harvin, Wake Forest University Health Sciences
- Recording Clinical Interviews and the Revolution of Digital Technology; Melissa M.C Jovellanos, University of Toronto
- Implementation of a Drug Management Utility in a Multi-Site, Randomized, Double-Blinded Study; Jennifer McCormack, The EMMES Corporation
- Conquering the Challenges of Conducting a Trial’s Central Initial Training at an O’Hare Hotel: The Blood Pressure in HemoDialysis (BID) Pilot Study Experience; Kimberly A. Wiggins, Cleveland Clinic
- Integrating Data from Disparate Sources into a Central Database in Trial with Hybrid Funding: The Blood Pressure In HemoDialysis (BID) Pilot Study; Jennifer J. Gassman, Cleveland Clinic
- The Italian Register for Clinical Trials; The “Unique” E-access for Regulatory, Submission and Management of Clinical Trials; Carlo Tomino, Italian Medicines Agency
- An Efficient and Inexpensive System for the Distribution and Tracking of Investigational Medicinal Products in Clinical Trials; Patrick G. McDonnell, University of Dundee, Dundee, UK
- Gynecologic Oncology Group (GOG): Making A Web-Based Cardiff Teleform Generated PDF Patient Clinical Reporting Form Dynamic with the Use of Adobe FDF Files; Karen Puehn, Gynecologic Oncology Group Statistical & Data Center
- Eosinophilia as a Potential Surrogate for Definitive Diagnosis of Strongyloidiasis in an Immigrant Population at a Community Clinic; Kathryn E. Spates, SAIC-Frederick, Inc.
- Posting Study Results to Clinicaltrials.gov: Effective Tools and Lessons Learned; Elizabeth Paynter, Rho
- Changing Directions in the Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial – Involving Outside Investigators in Manuscript Preparation and Ancillary Studies; Sara L. Pressel, University of Texas School of Public Health
- The Global Obstetrics Network (GONet): An International Collaborative Group; Elizabeth A. Thom, The George Washington University
- Estimating Death Rates in Substance Use Disorder Clinical Trials; Robert W. Lindblad, The EMMES Corporation
- Statistical Considerations for Analysis of Progression-Free Survival Data; Imogene M. Grimes, Otsuka Pharmaceutical Development & Commercialization, Inc.
- A Study of Autologous Valve Replacement - CD133+ Stem Cell-Plus-Fibrin Composite Based Sprayed Cell Seeding for Intra-Operative Heart Valve Tissue Engineering; Aenne Glass, University of Rostock
- Confidence Intervals for Difference of Correlated Proportions Based on Paired and Unpaired Data; Jiajun Liu, Merck Research Laboratories



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Poster Presentation Monday, May 21, 2012, 8:30 AM – 5:00 PM Prime Time 10:15 – 10:45 AM and 3:00 – 3:30 PM

- Change Point Identification with Adaptive Partitioning in Isotonic Regression for Event-Time Data; Yong Ma, George Washington University
- SAS Enterprise Guide and Graphics in Clinical Trials; Levent Bayman, University of Iowa
- Methods for Calculating Variability of the Incremental Cost Effectiveness Ratio in Cost-Effectiveness Studies; Nicole C. Foster, Jaeb Center for Health Research
- Use of Historical Controls in Assessing Long-Term Zoster Vaccine Efficacy; Gary R. Johnson, VA Cooperative Studies Program Coordinating Center, VA Connecticut Healthcare System
- Sampling Considerations for Genetic Associations in the Environmental Polymorphisms Registry (EPR); Lindsey A. Ho, SRA International, Inc.
- Repeat Participants in Clinical Research: An Overlooked Sub-Population? Evidence from 20 Years of Inner City Asthma Consortium (ICAC) Studies; Miguel A. Villarreal, Rho, Inc.
- Results of Remote Monitoring Techniques for Multi-Center Ophthalmic Imaging Trials; Dana A.H. Keane, Optos, Inc.
- The Use of Adult Learning Theory in Critical Care Clinical Trials Site Initiation Meetings Improves Confidence in New Research Skills and Techniques and May Enhance Study Conduct; Elizabeth A. Sweetman, Royal North Shore Hospital, University of Sydney
- Demographic and Health Factors Associated with Enrollment in Post-Trial Studies: The Women's Health Initiative Hormone Therapy Trials; Sarah A. Gaussoin, Wake Forest School of Medicine
- Impacting a Clinical Trial's Success by Integrating Regulations, Standards and Guidelines into Organizational Culture; Jan H. Hickey, Department of Veterans Affairs Cooperative Studies Program
- Effective Processing and Monitoring of Contracts Between Sponsor and Collaborative Centres; Dalah C. Mason, Sunnybrook Research Institute
- Resolving the Conflict: Sponsor-Investigators and the Ethical Concern Behind the Consent Process; Melissa Y. Brown, Sunnybrook Research Institute
- The Quality of Medical Record Abstraction in a Multi-Center Study: The Importance of Training; Nancy Payte, Westat
- Outcomes Adjudication - The Preparation Process; Ainy Zahid, Sunnybrook Research Institute
- Transitioning an Adolescent Cohort from a Randomized Clinical Trial (TODAY) to a Post-Intervention Follow-Up Study (TODAY2); Christen J. Long, The George Washington University Biostatistics Center
- Adverse Event Reporting for Hematopoietic Stem Cell Transplant Studies; Mary E. Crann, The EMMES Corporation
- NeuroNEXT: Developing Infrastructure for Phase 2 Clinical Trials in Neurological Disorders; Dixie J. Ecklund, University of Iowa CTSDMC
- Risk Management of Non-CTIMP Trials: Focus on Complex Intervention Trials; Liz Graham, University of Leeds
- Serious Unexpected Events in an Obstetric Clinical Trial – Definitional Challenges; Laura A. Magee, The University of British Columbia
- Strategies to Maximise Response Rates to Postal Questionnaires in Pragmatic Trials Involving Elderly Stroke Patients and Their Caregivers; Shamaila Anwar, University of Leeds
- Planning for the End: The Type 1 Diabetes Genetics Consortium (T1DGC); Joan E. Hilner, University of Alabama at Birmingham, School of Public Health
- Pregnant Women's Views About Participation in Trials – A Qualitative Study; Katrien Oude Rengerink, Academic Medical Center
- Good Clinical Practice Compliance in a Surgical Trial - Results of Monitoring and Audit; Inga Rossion, Study Center of the German Surgical Society

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Poster Presentation Monday, May 21, 2012, 8:30 AM – 5:00 PM
Prime Time 10:15 – 10:45 AM and 3:00 – 3:30 PM

Recruiting and Retaining Minority Subjects for Genetic Research: Challenges and Successes; Andrea S. Zombeck, SRA International, Inc.

Parental Perception of a Contract Improves Adherence in Longitudinal Randomized Controlled Trials of Disease Prevention in Early Life; Helen R. Fisher, Kings College London

Data Collection for an Aging Cohort in Long-Term Clinical Trials; Pam Mangat, George Washington University

Participant Perception of Treatment Assignment is Related to Symptom Severity in a Clinical Trial of Phytotherapy; Jeannette Y. Lee, University of Arkansas for Medical Sciences

Dollars and Sense: Effective Fiscal Management of the Carotid Revascularization Endarterectomy Versus Stenting Trial (CREST); Alice J. Sheffet, UMDNJ-New Jersey Medical School

Adjudication of Safety Outcomes in a Web-Based Clinical Trial Management System; Aaron S. Perlmutter, MUSC

Study Design Issues in a Randomized Trial Comparing the Cost-Effectiveness of Immediate Treatment vs. Observation/Deferred Treatment Approaches; Danielle L. Chandler, Jaeb Center for Health Research

Safety in Non-Drug Randomised Complex Intervention Trials; John Norrie, University of Aberdeen

Starting a Genetic Repository; Alice K. Henning, The EMMES Corporation

Interim Analysis with Sample Size Re-estimation for Binary Outcome in a Trial of Intravitreal Ranibizumab versus Saline Injection for Prevention of Vitrectomy in Eyes with Proliferative Diabetic Retinopathy and Vitreous Hemorrhage; Michele Melia, Jaeb Center for Health Research

Sample Size for Pre-post Comparison with Intervention Delivered to Cluster; Zhiying You, School of Medicine, University of Alabama at Birmingham, Birmingham, AL

Alcoholism Treatment Studies: A Design Proposal to Improve Relevance; Robert A. Lew, VA Boston Healthcare System, Boston, MA

Randomised Controlled Trials with the Purpose to Gain Reimbursement for Medical Devices in Germany - Responsible Institutions and Trial Design Requirements for the Implementation of Study Results in the Decision-making Processes Using the Example of Negat; Doerthe Seidel, Private University of Witten/Herdecke gGmbH



Poster Presentations

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Poster Presentation Tuesday, May 22, 2012, 8:30 AM – 5:00 PM Prime Time 10:30 – 11:00 AM and 2:50 – 3:20 PM

- Aging in Numbers - National Health Care Trends and the National Institute on Aging Funded Clinical Trials; Tibor Szentendrei, KAI Research, Inc.
- Factor Analysis of the Correlates and Characteristics of Stressful Life Events in the TODAY Cohort; Laura Pyle, George Washington University
- Strategies Implemented for Successful Data Retrieval and Accuracy in a Long Term Follow-up Study; Mariam Saleem, Sunnybrook Research Institute
- An Approach to Study Drug Management in Randomised Controlled Trials; Sunny Chan, Sunnybrook Research Institute
- Using iPods® as an Intervention Delivery Method and Fidelity Monitoring Device; Tamara Olinger, Rush University Medical Center
- Establishing a Remote Data Entry System in a Rural Tribal Community; Dixie J. Ecklund, University of Iowa CTSDMC
- Clinical Data Management of HIV/AIDS-Related Illnesses in HIV Clinical Trials: Challenges and Solutions; Maija A. Anderson, Fred Hutchinson Cancer Research Center
- Coding Open-ended Responses: Identifying Problems and Solutions; Jennifer W. Talton, Wake Forest School of Medicine
- Database Structure for Multiple Protocols Within a Project; Danielle L. Smith, The EMMES Corporation
- Optimizing Optical Character Recognition Software for High Quality Data; Jennifer N. Andringa, Cincinnati Children's Hospital Medical Center
- Challenges to Transitioning from Paper-based Data Collection to Electronic Data Capture; Trinh Hoac, Sunnybrook Research Institute
- Utilizing a Web-Based Telephone Call Tracking System in the Collection of Cognitive Data; Darrin A. Harris, Wake Forest School of Medicine
- Improving the Reliability of Web-based Randomization using Encrypted Allocation Information Embedded into Data Elements; Gordon S. Doig, Royal North Shore Hospital, University of Sydney
- A Tailored Communication Platform for a Virtual Intervention Team; Elizabeth F. Avery, Rush University Medical Center
- Consort-like Flowcharts in DSMB Reports; Patricia A. Feeney, Statistics Collaborative, Inc.
- Ethical Issues in Secondary Research with Human Specimens; Liza Dawson, NIH/NIAID Division of AIDS
- Reducing Barriers to Cancer Care and Increasing Access to Clinical Research Participation at the Ralph Lauren Center for Cancer Care and Prevention; Margaret Michel, Memorial Sloan-Kettering Cancer Center
- Compensation for Bodily Damage to Participants in Un-notified Clinical Trials in Japan; Toshinori Murayama, Kyoto University Hospital
- Increasing Institutional Oversight for Multicenter Protocols: An Institutional Office at Memorial Sloan-Kettering Cancer Center (MSKCC); Supriya G. Parikh, Memorial Sloan-Kettering Cancer Center
- Use of Barnard's Test as a More Powerful Alternative to Fisher's Exact Test; Peter M. Calhoun, Jaeb Center for Health Research
- Interpretation and Results Comparing Frequentist and Bayesian Interim Monitoring: Survival and Continuous Outcomes; Alice R. Pressman, Kaiser Permanente
- Implementation and Diagnostics for Frequentist and Bayesian Interim Monitoring: Sequential Bounds and Chain Convergence in SAS; Marnie Bertolet, University of Pittsburgh, School of Public Health
- Analysis of Safety Data Using SAS; Thomas Bruckner, University Heidelberg
- Multiple Hypotheses Testing and Simultaneous Confidence Intervals for Multiple Adverse Event Assessment; Zhibao Mi, VA Cooperative Study Program

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**Poster Presentation Tuesday, May 22, 2012, 8:30 AM – 5:00 PM
Prime Time 10:30 – 11:00 AM and 2:50 – 3:20 PM**

- Enrollment Propensity Weighting to Assess the Generalizability of a Randomized Clinical Trial; Marie G. Gantz, RTI International
- Sample Size Considerations in Cluster Randomised Trials with Unequal Clusters – Experience from Two UK Stroke Rehabilitation Trials; Ivana Holloway, Medical Statistician
- Monitoring Rare Events in a Single Arm Non-inferiority Trial (111; CRUK/09/011); Eleftheria Kalaitzaki, The Institute of Cancer Research
- The VACS Index Score as an Alternative Endpoint in HIV/AIDS Studies; Katherine A. Kirkwood, VA Cooperative Studies Program Coordinating Center, VA CT Healthcare System
- The Use of a Multifaceted Clinical Trial Implementation and Education Strategy to Minimise Major Protocol Violations; Fiona Simpson, Royal North Shore Hospital, University of Sydney
- The Novel Use of Site Selection Surveys to Improve Sub-optimal Recruitment; Fiona Simpson, Royal North Shore Hospital, University of Sydney
- Responsive Recruitment Strategies to Maximise Recruitment: Experience from National UK Stroke Trials; Shamalia T. Anwar, University of Leeds
- Challenges of Recruiting Women to a Clinical Trial of Treatment for Mucopurulent Cervicitis; Jeannette Y. Lee, University of Arkansas for Medical Sciences
- Transformation of Regulatory Requirements into a Training Curriculum for Investigational Site Teams of Clinical Trials with Medical Devices in Germany** Granted by the German Federal Ministry of Research and Education, Germany, BMBF Grant O1KN1106; Heike Moenkemann, Clinical Trials Center Cologne (BMBF grant O1KN1106)
- Methodology Matters: Spotlight on the Network of Hubs for Trials Methodology Research (HTMR) in the UK; Emily Crowe, Network of Hubs for Trials Methodology Research
- Evaluation of a New Institutional Clinical Research Monitoring Program for Investigator Initiated Studies; Jami N. Jackson, Memorial Sloan-Kettering Cancer Center
- Lessons Learned: Effective Training Strategies for Electronic Data Capturing; Siobhan Tobin, Sunnybrook Research Institute
- Developing and Maintaining Standard Operating Procedures for a Multi-Trial Data Coordinating Centre; Cerisé D. Robinson, Sunnybrook Research Institute
- Role of Glucocorticoid Receptor SNPs in Receptor Function and Metabolic Disease; Lisa B. Murphy, SRA International Inc.
- Ensuring Successful Adherence to Study Requirements in a Multi-centre Study; Asma T. Qureshi, Sunnybrook Research Institute
- Developing an Effective Site Feasibility Questionnaire for the Site Selection Process; Johanna Sanchez, Sunnybrook Research Institute
- Partners in Research: Effective Collaboration between a National Clinical Trial (TODAY Study) and Oklahoma-Based Multi-Tribal Health Boards; Jennifer Q. Chadwick, University of Oklahoma Health Science Center
- Web-based Intervention for Returning Veterans with Risky Alcohol Use and Posttraumatic Stress Symptoms; John A. Hermos, VA Boston Healthcare System
- Minority Cancer Survivors' Attitudes and Experiences Related to Participation in Cancer Clinical Trials; Margaret M. Byrne, University of Miami
- Development of a Decision Aid to Improve Minority Cancer Patients' Decisions About Participating in Clinical Trials; Margaret M. Byrne, University of Miami
- Factors Influencing Recruitment in Clinical Trials; Katrien Oude Rengerink, Academic Medical Center
- WHO can RECIST?: The Evolution of Solid Tumor Response Criteria; Bingyan Wu, Rho, Inc.



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Poster Presentation Tuesday, May 22, 2012, 8:30 AM – 5:00 PM Prime Time 10:30 – 11:00 AM and 2:50 – 3:20 PM

- Recruitment and Retention of Trial Subjects in the 21st Century: Insights from Experience from Conducting Several Recent Large International Trials in Cardiology; Susan Chrolavicius, McMaster University
- Monitoring Blood Sample Collection and Shipment in a Publicly Funded Post Thrombotic Syndrome (PTS) Randomized Controlled Trial (RCT); Adrielle H. Houweling, McGill University
- Challenges and Strategies in the Start-up Phase of Large, International Clinical Trials in Cardiac Surgery; Jessica C. Vincent, Hamilton Health Sciences/McMaster University
- Transitioning Paper to Electronic Case Report Forms Mid-study from One Clinical Research Organization to Another; Caroline Kim, EMMES Corporation
- NIAID Auditing Services Program (NASP): Providing Worldwide Quality Assurance Audits of DAIDS Monitoring Functions; Jan S. Peterson, The EMMES Corporation
- Provision of Coverage Analysis in Multi-Site Clinical Trials Aids All Sites and Particularly Smaller, Community-Based Practices; Kati M. Stoermer, University of Michigan
- Implementation of Likelihood-based Continual Reassessment Method Designs in Dose Finding Trials; Emily M. Van Meter, University of Kentucky
- Application of Different Randomized Phase II Trial Designs in a Breast Cancer Trial; Heidi L. Weiss, University of Kentucky
- Ranking and Selection Design of a Phase IIa HIV Vaccine Clinical Trial in China with Three Active Arms and Multiple Endpoints of Interest; Yunda Huang, Fred Hutchinson Cancer Research Center
- US-China Collaborations on the Design of China's First Phase IIb HIV Vaccine Efficacy Trial; Yunda Huang, Fred Hutchinson Cancer Research Center
- Design of a Neonatal Intervention Based on Joint Evaluation of Efficacy and Toxicity; Dennis D. Wallace, Research Triangle Institute
- A Two Stage Phase II Design Incorporating the Possibility that the Treatment Effect May be Restricted to a Biomarker Defined Subgroup: Investigation of a PARP Inhibitor (Olaparib) in Castration Resistant Prostate Cancer (CRPC); Roger P. A'Hern, Clinical Trials and Statistics Unit
- Designing Trials for Proving Efficacy of Multifunctional Food: Some Notes on the Need for Multiplicity Adjustment; Federica obec, ZETA Research Ltd
- Could Methods be a Factor in Early Closures of HIV Pre-exposure Prophylaxis Trials?; Madzouka B. Kokolo, Ottawa Hospital Research Institute

Mark Your Calendar! Upcoming Meetings



Boston Public Gardens, Boston, MA
May 19 – 22, 2013 – Sheraton Boston



Caesars Palace lit up at night on the Vegas Strip
May 18 – 21, 2014 – Caesars Palace Las Vegas



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