Welcome and Opening Plenary Descriptions
Friday September 19, 2014

Time: 8:30 to 9:15
Track: Opening Plenary

Welcome and Introduction
The speakers will describe issues related to the practice of clinical research in the current regulatory environment and how SOCRA works to promote education and training within the clinical research community.

Presenter: Jody Green, PhD, CCRP, Research Director, Rocky Mountain Poison & Drug Center
Presenter: Wendy Lloyd, BS, CCRP, LPN, CIP, Regulatory Compliance Analyst, Vanderbilt University Medical Center

Time: 9:15 to 10:00
Track: Opening Plenary

New Challenges in Pediatric Research: Insights and Approaches
In the last decade, with the advent of new scientific technology to interrogate the human genome, there has been dramatic interest in using genomic studies to better understand the biology of chronic and life-threatening diseases and conditions in children. This has led to questions about how this type of research should be conducted in children including practical, legal, ethical, and social considerations. Likewise, through the combined efforts of governmental agencies like the FDA working with industry and pediatric researchers, there are new regulatory mechanisms directed at the inclusion of pediatric studies in drug development. We will review how both of these topics are addressed in current pediatric clinical research.

Presenter: Victor Santana, MD, Vice President of Clinical Trials Administration, St. Jude Children’s Research Hospital

Time: 10:30 to 11:15
Track: Opening Plenary

From Stem Cell Biology to Cardiac Regeneration for Pediatric Congenital Heart Disease
The past decade has witnessed a tremendous expansion of stem cell biology with a focus on clinical applications in cardiovascular diseases. The challenge remains to find the right stem cell population to treat the right individual condition at the right time of the disease progression. The scientific efforts have produced a plethora of stem cell-derived products and yet have currently only been applied to adult acquired heart disease. The field of regenerative medicine is now poised to re-purpose these technologies for pre-emptive strategies to strengthen and assist with cardiac growth required in surgical palliated congenital heart disease. Severe forms of congenital heart diseases are currently limited to surgical reconstructive surgery that commonly do not provide sustainable solutions and thus require cardiac transplantation in a high percentage of cases. Advances in ongoing clinical trials and stem cell biology offer an emerging innovation pipeline that is designed to provide adjunctive cell-based therapies to augment cardiac function with the goal of delaying or preventing cardiac transplantation for congenital heart disease.

Presenter: Timothy Nelson, MD, PhD, Assistant Professor of Medicine, Mayo Clinic

Time: 11:15 to 12:00
Track: Opening Plenary

The Cost of Ignorance: Ignorance is Expensive!
The management of diseases and conditions for which we currently lack tools to diagnosis, prevent, mitigate, treat, or cure carries a huge economic burden. Engaging in poorly conceived, poorly designed, or poorly executed clinical trials impacts future progress in healthcare management. This presentation will offer examples that highlight the impact of ignorance and mismanagement on clinical trials and clinical management.

Presenter: Richard Gorman, MD, Associate Director for Clinical Research, NIH, National Institute of Allergy & Infectious Diseases

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to the 2014 Annual Conference Program Committee

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### Track 1: Scientific

#### Time: 1:15 to 2:00

**Use of Antioxidants for Cerebral Adrenoleukodystrophy and other Neurodegenerative Diseases**

Emerging evidence implicates oxidative stress in the pathology of numerous neurodegenerative disorders. Consequently, there is growing interest in the clinical evaluation of antioxidants in the treatment of these conditions. In this presentation, Dr. Coles will discuss the role of oxidative stress and endogenous antioxidants, such as glutathione, in neurodegenerative diseases. The use of the antioxidant, N-acetylcysteine (NAC), as adjuvant therapy to hematopoietic stem cell transplantation in the treatment of cerebral adrenoleukodystrophy will be highlighted. In addition, the role of NAC and other antioxidants in Gaucher and Parkinson’s disease will be reviewed. Challenges associated with measuring oxidative stress and the application of novel neuroimaging methods to measure treatment response in clinical trials will also be discussed.

Presenter: **Jeanine Secor, BSN, CCRP, RN**

University of Washington

**Investigator-Initiated Research Trial Experience with Hyperbaric Oxygen Treatment for Traumatic Brain Injury**

This presentation will discuss how to initiate an investigator-initiated trial. In addition to pitfalls and institutional challenges, Ms. Secor will discuss successes and challenges of protocol and consent writing.

Presenter: **Jeanine Secor, BSN, CCRP, RN**

Director of Clinical Research, Jupiter Medical Center

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### Track 2: Project Management

#### Time: 1:15 to 2:00

**Approaches to Standardizing Processes**

Standardizing study processes is a key component to the overall project life cycle. This session will demonstrate how the project management process of initiating, planning, executing, monitoring, and closing can be standardized to many different clinical trials, including basic to complex trials. Attendees will be exposed to various tools and templates that can assist in standardizing and tracking these processes.

Presenter: **Heidi Millet, MPA, CCRP**

Project Manager, Pennington Biomedical Research Center

**Virtual Project Management**

More and more, clinical project management is done globally across multiple time zones and cultures. In order to be successful, certain adaptations have to be made to routine practices. This session will discuss some of the challenges related to virtual project management and solutions for the same. Situational examples will be provided where applicable.

Presenter: **Radhika Sivaramakrishna, PhD, PMP, CSSBB, CCRP**

Senior Director, Project Management, Covance

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### Time: 2:05 to 2:50

**Clinical Trials Data Management Systems - Transitioning from a Legacy to a Proprietary System**

Ms. O’Connell will discuss coordinating workflows, regulatory processes, data collection and management across all teams to centralize an integrated clinical trial management system. The session will focus on the challenges of how to transition from a home-grown system to an institution-wide assimilated clinical trial management system (CTMS).

Presenter: **Maureen O’Connell, BSN, RN**

Associate Director of Clinical Affairs, Thomas Jefferson University

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### Time: 3:25 to 4:10

**Project Management in Clinical Research: How It Informs Financial Decisions**

Managing clinical research studies is a complex effort compounded by the current budget climate. Applying a project management framework that enables tracking major milestones to better understand the unique characteristics of clinical studies and how these characteristics influence resource utilization is essential to program sustainability, operational effectiveness, and capacity building. Using the integrated strategic project management framework (ISPMF), budget and labor resources are analyzed to develop managerial and operational insight into the complexities of each protocol service-offering model: natural history, interventional, and screening. This presentation will provide an overview of the successful launch and implementation of the ISPMF, standard project management practices used for increasing visibility into resource utilization, and examples of how applying project management standards informs financial decisions regarding resource utilization; clinical research operations; and protocols with different degrees of difficulty, uncertainty, and complexity.

Presenter: **Laurie Lambert, BS**

Clinical Program Manager III, Leidos Biomedical Research, Inc.
**Data Management / EDC**

**Time:** 1:15 to 2:00  
**Track:** Data Management / EDC

**Event Driven Data Structure: One of the Informatics Components in Disease Oriented Infrastructure for Multi-Center Clinical Research Studies**

In multicenter clinical research studies, electronic data management is the key to success. Event driven data structure (EDDS) provides a fundamental pathway in handling volumes of clinical research data. Transforming data elements from CRF to EDDS by using common data elements (CDE) establishes a new infrastructure that has consistent data across studies on a per disease level. EDDS is able to give the end-to-end clinical research study services including data entry, data reporting, and data analysis. Our team at MD Anderson Cancer Center has achieved success in multicenter consortia for brain tumor and leukemia.

Presenter: Robert Liu, MS, Manager, System Analyst Services, MD Anderson Cancer Center

**Time:** 2:05 to 2:50  
**Track:** Data Management / EDC

**eSolutions Best Practices: Lessons Learned from FDA Warning Letters**

Failure to maintain accurate, complete, and current records is one of the top 5 most commonly cited investigator deficiencies noted during an FDA bioresearch monitoring (BIMO) visit. While electronic data capture solutions are intended to improve quality and efficiency for clinical trials, a review of FDA warning letters suggests potential pitfalls of eSource documentation. Best practices in eSolution selection, vetting, development, implementation, data management and support are important to manage risk and ensure quality of eSolutions such as eDiary, ePRO and direct clinical data capture (DCDC).

Presenter: Evonne Roberts, BSEE, Senior Director of Business Development and Product Management, assisTek

**Translational Research**

**Time:** 2:05 to 2:50  
**Track:** Translational Research

**The Perfect Marriage: Understanding and Implementing a Bench to Bedside Approach to Clinical Research**

Translational research - often referred to as translational science - provides the opportunity to take bench discoveries to the patient care area. Recognizing the need to advance this area of research, centers for excellence have been established through NIH. Known as Clinical and Translational Science Award (CTSA), these centers were implemented in 2006 and projects have continued to expand since. How can translational research impact your program?

Presenter: Francine Parfitt, MSH, CCRC, Director of Research Operations, Mayo Clinic

**Time:** 3:25 to 4:10  
**Track:** Translational Research

**The Role of Post Market Clinical Follow-Up in the Medical Device Product Life Cycle**

The product life cycle of a medical device begins long before it reaches the market and continues after surgical implantation. Global regulations inform manufacturers on clinical follow-up and post market surveillance requirements of their products. Overview of MEDDEV 2.12/2 and 21 CFR §822 will be provided.

Presenter: Leann M. Speering, MS, CCRP, Clinical Study Manager, MicroPort Orthopedics

**Time:** 4:15 to 5:00  
**Track:** Device Research

**Medical Device Case Study: Lessons Learned**

This interactive session will discuss aspects of medical device investigational studies and lessons learned through the use of a case study. Topics will include IDE, PMAs, GCP, and compliance strategies.

Presenter: Donna Headlee, RN, BSN, CCRP
### TRACK 5
#### Canadian Regulatory

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<tr>
<th>Time: 1:15 to 2:00</th>
<th>Track: Canadian Regulatory</th>
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<tr>
<td><strong>Clinical Trial Agreements: What You Need to Know When Negotiating a Clinical Trial Agreement Involving a Canadian Site</strong></td>
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<tr>
<td>This session will address key elements to consider when reviewing and negotiating a clinical trial agreement (CTA) involving a Canadian site. Among the items covered by the presentation are how to ensure all applicable parties are properly bound, how CMPA’s policies affect what you should and should not agree to in the CTA, and why it is necessary to understand local laws. 509</td>
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<tr>
<td>Presenter: Marlon Rajakaruna, BA, MBA, LLB, CRCP, Partner, Global Co-Leader of Life Sciences &amp; HC, Dentons Canada LLP</td>
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<th>Time: 2:05 to 2:50</th>
<th>Track: Canadian Regulatory</th>
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<tr>
<td><strong>Site Budgeting for Clinical Trials</strong></td>
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<tr>
<td>Ms. Appelman-Eszczuk will identify the tools required to plan a site budget. This session will offer tips to negotiate a successful site budget and effectively implement the contracted budget once a site has been initiated. In addition, this session will review how Canadian site budgets may differ from other centres. 511</td>
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<tr>
<td>Presenter: Sharon Appelman-Eszczuk, BScN, RN, CCRA, Director of Operations - GILDR Group, University of Alberta</td>
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<th>Time: 3:25 to 4:10</th>
<th>Track: Canadian Regulatory</th>
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<tr>
<td><strong>Growing Pains: Tracking the Maturation of a Research Monitoring Program within an Academic Research Centre</strong></td>
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<td>Investigators interested in participating in such an initiative recommended members of their staff to be trained as clinical research monitors. After appropriate staff training, investigators were encouraged to create cooperative agreements regarding the use of trained staff external to their research team to monitor studies. After initial implementation, the substantial time commitments of study staff required for such an undertaking prevented the full implementation of such a program. This development prompted CAMH, under the direction of the Quality Assurance program, to institute a centralized monitoring program in January 2013. This service is now provided as a core function of the Research Service office to investigators conducting regulated clinical research trials. This presentation will discuss the benefits and challenges observed in the transformation of the CAMH monitoring program and the initial findings observed during the implementation of centralized monitoring. 513</td>
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<tr>
<td>Presenter: Gregory Staios, HBSc, MSc, Research Monitor, Centre for Addiction and Mental Health</td>
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<tr>
<th>Time: 4:15 to 5:00</th>
<th>Track: Canadian Regulatory</th>
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<tr>
<td><strong>Regulatory Requirements for NHP (Natural Health Product) Clinical Trials in Canada</strong></td>
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<td>Ms. Cockerline will provide an overview of the regulatory framework, unique to Canada, for clinical trials involving natural health products in Canada that are regulated under the Natural Health Products Directorate of Health Canada. The presentation will also highlight the unique challenges facing natural health product research, including therapeutic indications, endpoints and biomarkers, product formulations, intellectual property and patents, study designs, and return on investment. 515</td>
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<tr>
<td>Presenter: Carla Cockerline, BSc, MSc, CCRA, Associate Director, Clinical Trials Division, Nutrasource Diagonostics, Inc.</td>
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### TRACK 6
#### Enrollment / Retention

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<th>Time: 1:15 to 2:00</th>
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<tr>
<td><strong>Nuts and Bolts of Human Research Regulations, the IRB Application, and the Informed Consent Form</strong></td>
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<td>Ms. Estanol will review the history and foundation of human research regulations. Additionally, this session will review the definition of research and discuss the categories of review. The key components of an IRB application, an informed consent form, the HIPAA authorization form, etc. will be discussed. 609</td>
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<tr>
<td>Presenter: Laverne Estanol, MS, CHRC, CIP, CCRP, Director, VA-HRPP, VA San Diego Healthcare System</td>
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<tr>
<td><strong>Recruitment Strategies in the Digital Age</strong></td>
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<td>This presentation will review the evolution of recruitment and identify current and effective recruitment strategies. Ms. Larrabee will discuss how to utilize your website and social media to recruit participants. 611</td>
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<tr>
<td>Presenter: Patricia Larrabee, RN, NP, CCRC, CEO, Rochester Clinical Research Inc</td>
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<tr>
<td><strong>Research for Her: A Novel Recruitment Story</strong></td>
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<td>Novel recruitment strategies require commitment and creativity. Dr. Rimel will discuss the historic under-representation of women in clinical trials and her group’s effort utilizing novel web-based strategies to enroll patients in women’s cancer research. 613</td>
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<tr>
<td>Presenter: B J Rimel, MD, Associate Director, Gynecologic Oncology Clinical Trials, Cedars-Sinai Medical Center</td>
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<tr>
<td><strong>Imaging in Clinical Trials: Maximizing Protocol Compliance and Image Standardization</strong></td>
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<td>The purpose of this presentation is to provide the study coordinator with an improved understanding of how medical imaging can be used in meeting enrollment criteria for clinical trials. Ms. Trembath will present an overview of medical imaging procedures including risks, radiation, and benefits. In addition, this presentation will review effective methods to communicate with medical imaging departments to obtain trial-required data and how to include medical imaging in study budgets. 615</td>
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<tr>
<td>Presenter: LisaAnn Trembath, MSM, CNMT, CCRA, Associate Director, Clinical Imaging Operations, Avid Radiopharmaceuticals</td>
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**Friday Afternoon - September 19, 2014**

**Breakout Session Descriptions**

**Advanced Management**

### Time: 1:15 to 2:00  
**Track: Advanced Management**

**Site Visits and Audits - The Study Coordinator’s Perspective**
Site visits and audits can be labor intensive and stressful. This session is designed to assist study coordinators, clinical research associates, and quality assurance auditors in understanding the study coordinator’s responsibilities in preparing for the different types of site visits and audits. Ms. Willbee will discuss how improving communication and interactions between study coordinators, clinical research associates, and quality assurance auditors at site visits and audits can help to ensure that completeness, compliance, and accuracy are achieved. 709

Presenter: Kathleen Mieras, BA, CCRP, CLPI, CPFT, Supervisor, Pulmonary Research, Mayo Clinic

### Time: 2:05 to 2:50  
**Track: Advanced Management**

**Tips and Tricks on How to Successfully Work with Industry Sponsors from the Site’s Perspective**
As a busy high enrolling site, we have had to streamline our approach to working with multiple sponsors and CROs, while still working together as a team. Guidelines, tips and tricks as well as tools from a major university will be shared. Ms. Willbee will discuss how to successfully balance a high volume workload while remaining productive as a site, running as efficiently as possible, and meeting the expectations of the sponsors. 711

Presenter: Tina Willbee, BS, CCRP, Administrative Manager, University of Michigan Comprehensive Cancer Center

Presenter: Nabeela Iqbal, MBBS, CCRP, Administrative Manager, Phase I and Experimental Therapies Program, University of Michigan Comprehensive Cancer Center

### Time: 2:30 to 3:15  
**Track: Advanced Management**

**Coordinating Investigator-Initiated Multicenter Trials**
This session will outline the responsibilities of the lead coordinating site in a multicenter trial. Ms. Keach will discuss various issues from regulatory requirements to training sites on the conduct of the protocol, study procedures, SAE reporting, and data collection. Strategies for maintaining communication and collaboration throughout the duration of the study and developing standard operating procedures will also be discussed. 713

Presenter: Jill Keach, BS, Clinical Research Coordinator, Mayo Clinic

### Time: 3:25 to 4:10  
**Track: Advanced Management**

**Shades of the Informed Consent Rainbow**
This presentation will compare and contrast guidelines versus laws as they pertain to consenting research patients and how each has evolved. This session will look at how to determine when a patient has been sufficiently "informed", when a patient should not be consented for a trial, and ethical considerations of placing patients with limited understanding on a trial regardless of what the law may allow. Ms. Smith will also explore specific factors such as length, readability, and required elements of informed consent documents. 715

Presenter: Pamela Smith, CCRP, Senior Clinical Trial Coordinator, Moffitt Cancer Center

**Monitoring / Audit**

### Time: 1:15 to 2:00  
**Track: Monitoring / Audit**

**Risk Based Monitoring and Quality Management Systems**
This presentation will demonstrate how risk based monitoring (RBM) plans are developed by providing an analysis of data collected from monitoring visits (findings and observations). Ms. Adams will provide insight into the areas where higher deficiencies have been discovered during monitoring visits. The presentation will also provide attendees with recommendations to assist clinical site staff in developing corrective and preventative action plans and implementing quality management systems based on the observations noted during monitoring visits. Funded by NCI Contract No. HHSN261200800001E. 809

Presenter: Amy Adams, CCRC, RAC, Clinical Project Manager, Leidos Biomedical Research Inc

### Time: 2:05 to 2:50  
**Track: Monitoring / Audit**

**Monitoring with an Auditing Perspective - Preparing for an FDA Inspection from Day One**
This presentation will review the objectives of an FDA BIMO audit, with an emphasis placed on preparing a site for inspection. Ms. Chittester will discuss ways a monitor can use this knowledge to prepare their sites for a potential inspection – from day one – rather than when the FDA calls. 811

Presenter: Brandy Chittester, MS, CCRA, Director of Clinical Monitoring Services, IMARC Research Inc

### Time: 3:25 to 4:10  
**Track: Monitoring / Audit**

**Approaches to Risk-Based Monitoring**
Clinical site monitoring accounts for up to 30% of the total cost of a trial. Ensuring data integrity and patient safety and privacy has traditionally been interpreted by the industry as requiring 100% source document verification (SDV) and on-site monitoring. However, the FDA’s 2011 guidance suggesting alternate approaches to monitoring, combined with increasing evidence of the inefficiency and less than optimal accuracy of 100% SDV, and the extremely low rates of data correction due to monitoring, has led to renewed interest in risk-based approaches to clinical monitoring. This session will highlight case studies and regulatory, sponsor, and CRO perspectives on the successful use of risk-based monitoring strategies. 813

Presenter: Jeffrey Handen, PhD, Vice President, Professional Services, Medidata Solutions Inc

### Time: 4:15 to 5:00  
**Track: Monitoring / Audit**

**GCP Compliance Audits: What Clinical Sites Want from Auditors**
An audit can be structured so that it doesn’t cause too much disruption at the site, anxiety and confusion are minimized, and the compliance audit process overall becomes a pleasant learning experience. When working with a site, the auditor should keep in mind what the site would like to achieve from the audit, in addition to their own goals. Suggestions and advice from site personnel will be shared. There is a way to keep everyone happy. 815

Presenter: Celine Clive, BS, MBA, President, Polaris Compliance Consultants, Inc.
Breakout Session Descriptions

Saturday - September 20, 2014

Institute of Aging, Canadian Institutes of Health Research

Gerhard Fortwengel, PhD, MPH, MSc, Presenter:
Process for Nanotechnology Based Medicines

Vaidehi Limaye, PhD, Presenter:
categorization analysis.

A Scheme for Classification and Regulatory Approval Process for Nanotechnology Based Medicines

Gerhard Fortwengel, PhD, MPH, MSc, Presenter:

International Research

Time: 10:50 to 11:35

Keeping Russia and Ukraine in Your Study Plan

What are the benefits of conducting studies in Russia and Ukraine? What recent changes have made it easier than ever to conduct studies in Russia and Ukraine? What should you expect in terms of study startup time and will your efforts be worth it? After this session participants will have answers to these questions. In addition, a case study will be reviewed.

Presenter: Jeffrey Blum, Director, Business Development, ClinStar LLC

Time: 11:40 to 12:25

Financial Benefits of Conducting Clinical Research in Canada

Canada is a go-to destination for clinical research from many perspectives – recruitment, quality / integrity data, and market access which are all supported with a strong business case. The purpose of this presentation will be to review the business case for conducting clinical research in Canada by addressing specifics including SRED tax credit, government/ regulatory support, foreign exchange, private sector leadership and innovation, internationally respected academic sites and many other factors that are unique to Canada that should be considered when selecting countries in which to conduct clinical studies.

Presenter: Stephen Garland, BA

Time: 1:40 to 2:25

A Scheme for Classification and Regulatory Approval Process for Nanotechnology Based Medicines

Nanomedicines play an important role in each stage of drug development; however, no specific regulatory approval norms for research involving nanomedicines currently exist. This presentation will review a strategy for regulatory approval based on risk categorization analysis.

Presenter: Vaidehi Limaye, PhD, Professor, University of Mumbai

Presenter: Gerhard Fortwengel, PhD, MPH, MSc, Professor, University of Applied Sciences and Arts, Hannover

Time: 2:30 to 3:15

Drug Trials vs Trials in Physical Interventions - What About Patient’s Informed Consent?

The protection of human subjects in medical research is a cornerstone of ethics. The elements that should be covered and the process of informed consent are well established for pharmaceutical drug trials. Ethically, a patient who is involved in medical research that involves a physical intervention must be properly informed. However, ICH GCP may also be applied to other clinical investigations that may have an impact on the safety and well-being of human subjects; for example, in physical therapy research. The presentation is based on a joint research project between Marmara University Istanbul and University of Applied Sciences and Arts Hannover comparing drug trials and physiotherapy trials, and will summarize their similarities and differences according to European legislation and other physiotherapy research directives.

Presenter: Gerhard Fortwengel, PhD, MPH, MSc, Professor, University of Applied Sciences and Arts, Hannover

Presenter: Ufuk Yurdalan, PhD, Professor, Marmara University Istanbul

Time: 3:45 to 4:30

It Takes a Village: Creating a Research Billing Infrastructure for Non-Profit Community Hospital Systems

Has your community based hospital shied away from research studies because they require specific billing requirements that are unique to research? Community based hospitals may not have the knowledge or support in which to develop their own infrastructure necessary for research billing. The presentation will identify the key functions and departments in which to enlist support and develop partnerships. This includes partnering with physicians’ office billing personnel and getting “buy-in” from hospital administration.

Presenter: Diana Louder, RN, BSN, MHA, CCRP, Program Manager, Mary Washington Hospital

Time: 4:35 to 5:20

The Financial Training a Coordinator Needs

Clinical trial coordinators should be trained to understand clinical trial finance. In addition to understanding the budget and coverage analysis, coordinators should understand back end billing and when the patient should be billed for routine costs. This session will provide examples of how to discuss the impact of clinical trial finance with physicians and subjects. Examples will be provided through the use of hands-on exercises and demonstrations.

Presenter: Kelly Willenberg, MBA, BSN, CHC, CHRC, President, Kelly Willenberg LLC

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Saturday - September 20, 2014

**TRACK 2**

**Risk Management**

**Time:** 8:30 to 9:15  
**Track:** Risk Management

**Principles of Risk Management in Clinical Research**
Managing risks in clinical research is critical to the success of the project. It is important for members of the research team to understand the principles of risk management and engage those principles when developing research proposals and when conducting research. This presentation is intended to introduce risk management principles and propose useful techniques for managing risks associated with clinical research.  

Presenter: Patricia Beers Block, BS, CCRP, Assistant Professor, Rutgers University, School of Health Professions

**Time:** 9:20 to 10:05  
**Track:** Risk Management

**Dealing with Risk from the Sponsor Side**
This session will discuss how to manage a clinical study using a risk based approach. The goal is for risk assessment, mitigation, and management to assist the study team in maintaining control. Examples will be discussed.

Presenter: Joanne Malia, BS, MS, Associate Director, Medical Research Process Management, Purdue Pharma LP

**Time:** 10:50 to 11:35  
**Track:** Risk Management

**Risk Management from the Clinical Investigator Perspective**
Managing risks in clinical research is critical to the success of the project. It is important for members of the research team to understand the principles of risk management and engage those principles when developing research proposals and when conducting research. This session, presented from the clinical investigator perspective, will focus on useful techniques for identifying and managing risks at the clinical site.

Presenter: Nelson Kopyt, DO, FASN, FACP, CPI, Chief of Nephrology, Lehigh Valley Medical Center

**Time:** 11:40 to 12:25  
**Track:** Risk Management

**Risk Management from the Research Monitor Perspective**
This presentation will cover the obvious and subtle risks of clinical research. Assessment and ranking of the risks will be suggested so that a study sponsor or monitor may mitigate study risks. Such an approach could be considered a monitoring Risk Management Plan.

Presenter: Ina Abel, MPA, BSN, BS, RN, CCRP, Manager, Clinical Research Monitoring, St Jude Children’s Research Hospital

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**TRACK 2**

**Quality Management**

**Time:** 1:40 to 2:25  
**Track:** Quality Management

**Document Control**
Employing an organized, efficient document control system is essential to management of the quality system. Establishing, communicating and controlling changes in standardized policies, processes, procedures and other documents are keys to the overall quality management system. Determining the needs of the work unit and defining the types of documents necessary might dictate what type of document control system is required, but the basic elements of all document control are the same. No matter what method or software is used, the keys to document control are: identification, creation/authoring, approval, implementation, change control, inactivation, archiving and retention. This presentation will review the minimum basic requirements for a document control system and explore available options.

Presenter: Mark Wentworth, BS, CCRP, Senior Regulatory Specialist, Mayo Clinic

**Time:** 2:30 to 3:15  
**Track:** Quality Management

**Steps to Ensure an A+ on Your IRB Audit**
This presentation will discuss how to run an IRB seamlessly. In addition to ensuring excellent quality assurance in the regulatory area, Ms. Shoup will discuss how following best practices in IRB management can lead to good audit outcomes for organizations. This session will highlight strategies to help institutions stay prepared for FDA regulatory inspections.

Presenter: Pamela Shoup, CCRP, Executive Director, Toledo Community Oncology Program

**Time:** 3:45 to 4:30  
**Track:** Quality Management

**What Really Is the Purpose of GCP Training? A Quality Management Perspective**
Often GCP training is performed just to ‘tick a box’ in preparation for a GCP inspection. This session will present how GCP training should form the basis for future staff training and the implementation of proactive quality management during clinical trials. Attendees will learn how GCP training, together with quality by design principles, can facilitate high quality clinical trials.

Presenter: Anatoly Gorkun, MD, PhD, Assoc CIPD, Senior Manager, Training and Standards, MedImmune

**Time:** 4:35 to 5:20  
**Track:** Quality Management

**Study Coordination Quality Management System-Overview, Training, Implementation and Maintenance**
Ms. Pumper will present an overview of a study coordination quality management system (QMS). The purpose of the study coordination QMS is to establish processes, procedures and working documents required for planning and executing study coordination core business functions via a centralized “roadmap” that is easily accessible via the organization’s intranet. Documents can be referenced by the personnel performing study coordination functions. The QMS will enable research business performance to be improved while meeting or exceeding customer requirements. In addition, Ms. Pumper will review training and implementation expectations, examples of user feedback, and updates and maintenance required for the system.

Presenter: Geralyn Pumper, BA, MHA, RN, Program Manager, Mayo Clinic
**Breakout Session Descriptions**

**Track 3: Complementary and Alternative Medicine**

**Clinical Investigation of Ayurvedic Methods**
Ayurveda is a traditional and indigenous system of medicine based on natural and holistic methods, which evolved in the Indian subcontinent thousands of years ago. This session will review the fundamental concepts of Ayurveda as a holistic and integrative healing modality: the concept of five elements, three energies, body constitution, and Ayurvedic pathophysiology. Dr. Bhargava will discuss the various methods of Ayurvedic healing and challenges involved in scientific inquiry of those methods. Dr. Bhargava will discuss examples of research involving Ayurveda, available support from the NIH National Center for Complementary and Alternative Medicine (NCCAM), and practical ways of studying these holistic methods.

Presenter: **Peeyush Bhargava, MD, ABIHM**, Director, Vedic Healing

Time: **9:20 to 10:05**

**When Alternative Medicine May Be a Drug**
Substances that are not usually considered drugs, such as juice or tea, may be considered a drug when used in clinical trials. The description in the study protocol of how the substance will be used is important in determining if an IND must be filed. Examples of such instances will be discussed.

Presenter: **Harvey Arbit, PharmD, MBA, CCRP, RAC**, President, Arbit Consulting, LLC

Time: **10:50 to 11:35**

**Can Useful Research Be Conducted in Integrative Medicine at a Community Clinic?**
This session will discuss how a family clinic, which includes a comprehensive integrative medicine program and treats many low-income patients, has successfully participated in three research studies on chronic pain in patients receiving acupuncture, chiropractic, and osteopathic care. Dr. Spar will discuss challenges and lessons learned, in addition to study outcomes.

Presenter: **Myles Spar, MD, MPH**, Director of Integrative Medicine, Simms-Mann Health & Wellness Center/Venice Family Clinic

Time: **11:40 to 12:25**

Nutrition can greatly impact the course of disease and is an important adjunctive therapy for many diseases. Research that aims to provide evidence for nutritional intervention in various disease states comes with a unique set of challenges. Ms. Cole will discuss lessons learned during the development and implementation of a clinical trial for high dose topical vitamin D supplementation in individuals with cystic fibrosis. This presentation will delve into the challenges facing clinical nutrition research as they arise within the confines of the current research environment, which historically separates traditional medicine from the fields of nutrition and complementary medicine.

Presenter: **Abigail Cole, BS**, Graduate Student, University of Minnesota

Time: **8:30 to 9:15**

**Track 3: Research Ethics**

**Informed Consent - It’s How Many Pages?**
Informed consent is one of the most important parts of a clinical trial. It’s an open discussion where patients, and many times families and friends, get an understanding of the full scope of the trial and what is involved. It can be a tough discussion, not just due to the complexity of the trial, but in the emotional effect of the diagnosis. In addition to the essential elements of informed consent, Ms. Barnick will discuss considerations when presenting a trial, educating patients about a trial, and assessing patient understanding of what is being discussed.

Presenter: **Elizabeth Barnick, BS, CCRP**, Research Coordinator/Clinical Operations Lead, Carle Clinic Association

Time: **1:40 to 2:25**

**Informed Consent and the Human Experience**
This presentation will focus on the aspects of informed consent “beyond the regulations” that involve human experience and interactions. Ms. Thomas will review positive and negative feedback received from research participants to illustrate commonly found issues. In addition, she will share participant suggestions which can improve comprehension and the overall informed consent experience.

Presenter: **Cheryl Thomas, MS, CGC**, Research Subject Advocate, Mayo Clinic

Time: **2:30 to 3:15**

**Empathy, Communication, and Informed Consent**
This presentation will review the history of informed consent, the ethical principles underlying informed consent, and the relationship between a patient’s health literacy, informed consent, and empathy. While those who manage research studies are often aware of the ethical principles underlying informed consent, many are unaware of how health literacy affects study participants’ ability to truly give informed consent. One of the solutions to improve consent processes is empathy, which is shown through improved communication between the study participant and the investigators and research staff.

Presenter: **Tammy Swenson Lepper, PhD**, Chair / Professor, Winona State University

Time: **3:45 to 4:30**

**What Would You Do?**
Ms. Neseth and Ms. Knowlton will present scenarios on the topic of consenting subjects at a research site. Participants will be asked to share feedback related to the scenarios and suggest tactics to address the situations presented. This interactive session will consider best practices related to the informed consent process.

Presenter: **Tammy Neseth, BS, CCRP**, Manager of IRB Regulatory Compliance, Mayo Clinic

Time: **4:35 to 5:20**

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**TRACK 4**
**Device Research**

**Time: 8:30 to 9:15**
**Track: Device Research**
**From Volume to Value: What Payment Changes Under ACA Mean to You**
The transition from a volume-based to a value-based payment system is moving healthcare providers from a risk-free business model (‘if I deliver the services, I get paid’) to a risk-bearing business model. Ms. Townsend will discuss how significant changes in reimbursement methodology, including shared savings programs; payments for quality; penalties for readmissions; penalties for health care acquired infections; and valued-based purchasing, are subjecting providers to unprecedented levels of risk and impacting potential revenue. A value-driven, outcomes-based payment model requires population management, i.e., monitoring and managing higher cost populations such as frail elders and individuals with multiple chronic conditions or mental/behavioral health issues. Population health management requires access to actionable information to intervene with the appropriate patients and to monitor and report on their outcomes (which will then tie to payment). This session will review new opportunities to bridge clinical research and evidence based practice. 417

**Presenter: Kimberly Townsend, JD, MBA, MPA, CPA, President and Chief Executive Officer, Loretto**

**Time: 9:20 to 10:05**
**Track: Device Research**
**Utilizing Human Factors Engineering Principles to Optimize Clinical Performance**
Discovering a problem with the user’s ability to safely and/or effectively use a medical device or combination product in the clinic puts patients at risk and can lead to costly delays in bringing a life-saving therapy to market. Integrating human factors principles, including the conduct of usability evaluations, throughout the development process optimizes the device design and reduces the risk of performance issues arising during a clinical evaluation. This session will provide critical guidance to the manufacturers of combination products, illustrating the importance of introducing human factors engineering principles to ensure patient safety as well as maximize efficiency and control costs for the product development process. 419

** Presenter: Cynthia Nolte, PhD, RAC, Director, Medical Device Regulatory Services, Aptiv Solutions**

**Time: 10:50 to 11:35**
**Track: Device Research**
**Investigator GCP Responsibilities in Device Trials**
This presentation will review how to identify common device good clinical practice (GCP) risks for investigator/sponsor studies, such as reviewing current device GCP trends for investigators, identifying common device GCP risks for investigator/sponsor studies, investigating issues of device GCP noncompliance among academic health centers (AHC), and examining AHC device case studies and corrective action. 421

**Presenter: Erika Stevens, MA, BA, Senior Manager Advisory Services, Ernst & Young, LLP**

**Time: 11:40 to 12:25**
**Track: Device Research**
**A Look at Today’s 510(k)**
Ms. Rosecrans, former Director of the 510(k) program at FDA, will provide an update of the 510(k) program. The session will provide insight into how to best approach and work with the FDA. 423

**Presenter: Heather Rosecrans, BS, VP, Medical Devices & Combination Products, Greenleaf Health LLC**

**Time: 1:40 to 2:25**
**Track: Device Research**
**Randomized Clinical Trials: “The Hard and Soft Sell”**
Mr. Gavin will provide an overview of different types of randomized device trials. In addition, this session will outline specific advantages and disadvantages of conducting each type of trial. Attendees will review how to identify important factors to consider and evaluate if a trial is right for your target population. 425

**Presenter: Stephen Gavin, BSN, CCRP, RN, System Wide Administrative Director, Ochsner Clinic Foundation**

**Time: 2:30 to 3:15**
**Track: Device Research**
**US/OUS Clinical Data Requirements**
Clinical data is needed for many medical devices prior to placing the device on the market in the US and outside the US (OUS). Dr. Frestedt will review the types of clinical data typically collected for medical device regulatory submissions. 427

**Presenter: Joy Frestedt, PhD, CCTI, RAC, FRAPS, President and CEO, Frestedt Inc**

**Time: 3:45 to 4:30**
**Track: Device Research**
**Budgets from a Sponsor’s Perspective**
Ms. Hankee will describe the development of a device sponsor study budget; from the determination of fair market value, the development of a needs assessment document, and finally, the budget itself. Representatives from both clinical sites and from sponsor companies will benefit from attendance. 429

**Presenter: Keli Hankee, BSc, CCRA, Manager of Clinical Operations, Biomet Orthopedics**

**Time: 4:35 to 5:20**
**Track: Device Research**
**The Modern Multi-Talented Cardiac Device**
Ms. Hale will provide an overview of the advancement in cardiac devices and how care for device patients has changed (such as remote monitoring, etc.). Discussion will also include information about how pacemakers and implantable cardioverter defibrillators (ICDs) have advanced and are no longer limited to patients with bradycardia and ventricular tachycardia. The presentation will also review specific studies that illustrate how cardiac devices have branched out to be used in other therapeutic areas. 431

**Presenter: Leslie Hale, CCRP, CT, Cardiac Device Technician, Vanderbilt University Medical Center**

**JOIN US**
for the 23rd Annual Conference

**WELCOME AND NETWORKING RECEPTION**

**Thursday**
**September 18, 2014**
**6:00pm - 7:00pm**

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**BREAKOUT SESSION DESCRIPTIONS**

**TRACK 5**

**Canadian Regulatory**

**Time: 8:30 to 9:15**

**Track: Canadian Regulatory**

**Promoting YOUR Site - Strategies, Facts, and Fiction**

Sites need to promote themselves in order to be site selected for a study. Strategies and ideas will be introduced. These strategies will be critiqued from both the sponsor and site perspective – the facts versus fiction. Successes and non-successes will be shared, supported by some of the thinking, rationale, and reason for the outcomes. 517

**Presenter:** Stephen Garland, BA

**Time: 9:20 to 10:05**

**Track: Canadian Regulatory**

**Health Canada/Food and Drug Administration: Risk Based Monitoring**

Mr. Martin will review and update Health Canada/Food and Drug Administration’s views and guidance on risk based monitoring. 519

**Presenter:** Delonce Martin, BSN, CCRN, BCLS, ACLS, Senior Clinical Research Associate III, Quintiles

**Time: 10:50 to 11:35**

**Track: Canadian Regulatory**

**Quality Assurance - What Is It?**

Ms. Patel will review essential components of a quality assurance program. The aim of a quality assurance program is to ensure compliance with regulations, institutional policies, procedures and processes in order to mitigate risks to participants, as well as promote data integrity and high quality research overall. The presentation will discuss lessons learned in developing and implementing a quality assurance program that includes monitoring, auditing, and continuous quality improvement. In addition to identifying challenges and barriers to change, Ms. Patel will share approaches to effectively implement solutions and best practices and to foster cooperation and sharing of expertise among a research team. 521

**Presenter:** Sandhya Patel, BScN, Director, Research Quality Assurance, Centre for Addiction & Mental Health

**Time: 11:40 to 12:25**

**Track: Canadian Regulatory**

**Is It Worth Conducting Clinical Research in Canada?**

Why conduct trials in a country that only has 34 million people? Mr. Huizinga will discuss compelling research, medical, and data reasons for conducting clinical research in Canada. 523

**Presenter:** Robert Huizinga, MSc, RN, CNeph(C), Vice President, Clinical Affairs, Aurinia Pharmaceuticals Inc

**Time: 1:40 to 2:25**

**Track: Canadian Regulatory**

**Successful Collaboration Between Site Operations & Delegated Monitoring Representative Responsibilities**

This session will identify what is expected to make a project successful at a site with high recruitment, from both the site and monitor perspectives, while working together to ensure that Health Canada regulations are followed. Ms. Appelman-Eszczuk will provide tools to aid both the site staff and monitor in working together. Scenarios will include suggestions for implementation and illustrate possible outcomes. Participants will review strategies for resolution when the relationship is not seeing eye to eye. 525

**Presenter:** Sharon Appelman-Eszczuk, BScN, RN, CCRP, Director of Operations - GILDR Group, University of Alberta

**Presenter:** Cathy Laferriere, BA, Senior CRA, Quintiles Canada

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**Saturday - September 20, 2014**

**Time: 2:30 to 3:15**

**Track: Canadian Regulatory**

**Clinical Program Outsourcing in Canada: A Canadian CRO's Perspective**

This presentation will focus on the role of the CRO in clinical outsourcing and the need for such organizations to look for new paradigms in managing sites and programs. 527

**Presenter:** Michael Cornelius, BS, Manager, Clinical Site Management, Robarts Clinical Trials

**Time: 3:45 to 4:30**

**Track: Canadian Regulatory**

**Sponsor-Investigator Led Medical Device Trials: Determining When an Investigational Testing Authorization (ITA) is Required**

The Medical Device Regulations (1998) define specific investigational testing authorization (ITA) requirements for the sale and importation of medical devices for use in human clinical trials in Canada. Specifically, the regulations outline the necessary components of an ITA for each class of device. However, the regulations provide little detail to assist sponsor-investigators in determining when an application to Health Canada is required. This is of particular importance as academic institutions and investigators are initiating more trials using medical devices that have been developed in-house, medical devices that are used outside of their Canadian licensed indication(s) for use, and secondary/additional devices that are required for the licensed/primary device to be used. This presentation will review information gleaned from 10 years of experience in facilitating sponsor-investigator led medical device trials in Canada. Additionally, Ms. Filice will review scenarios to assist participants in their understanding of when an ITA is required. 529

**Presenter:** J. Michelle Filice, BPHE, CCRA, Manager, Research Quality and Risk Management, Hospital for Sick Children

**Time: 4:35 to 5:20**

**Track: Canadian Regulatory**

**Mandatory Training Program for Quality Research**

Ms. Johnston will discuss the development, implementation, and lessons learned from the creation of a mandatory and supplementary clinical research education and training program. The aims of such a program are to ensure that all research conducted is consistently performed to high ethical and scientific standards and to support compliance with regulatory requirements, research best practices, and institutional policies and standards. Ms. Johnston will discuss developing a gap analysis (assessing the current culture), benchmarking, and developing strategies to maximize existing resources. This presentation will examine how to identify barriers, as well as offer solutions, for developing and implementing effective training and knowledge-sharing techniques and the process for implementing a mandatory research training policy. 531

**Presenter:** Lisa Johnston, BScN, RN, CCRP, Research Training Coordinator, Centre for Addiction & Mental Health
**Saturday - September 20, 2014**

**BREAKOUT SESSION DESCRIPTIONS**

**Time: 2:30 to 3:15**  
**Track: Site Management**  
**Digital Strategies for Recruitment & Retention**  
This session will cover use of digital media in patient recruitment and retention and strategies for planning recruitment campaigns.  
**Presenter: Nariman Nasser, BS, Founder / Digital Strategist for Product Development, Only For Good / Genetech**

**Time: 3:45 to 4:30**  
**Track: Site Management**  
**Creative Site Strategies to Reach Targeted Enrollment Goals for Studies with Increasingly More Stringent Inclusion / Exclusion Criteria**  
With inclusion and exclusion criteria for clinical trials becoming increasingly stringent, it is important to structure recruitment strategies to identify, locate, and recruit the subject group long before the study commences. Always underestimate the efficacy of a given recruitment technique and utilize multiple strategies in your design. Although it is important to identify the customary recruitment techniques that are available, the more creative subject recruitment plans will most frequently bring success. Ms. Jeanfreau will offer specific examples to provide ideas, encourage creativity, and help participants gain confidence in reaching enrollment goals.  
**Presenter: Andrea Jeanfreau, BSN, MHA, RN, CEO, MedPharmics**

**Chapter Orientation Luncheon**  
**Sat., Sept. 20 - 12:40 - 1:30**

**Chapter Orientation - North America**  
**Wendy Lloyd, BA, CCRP, LPN, CIP Regulatory Compliance Analyst**  
**Vanderbilt University Medical Center-IRB**  
Wendy Lloyd will review successful examples of how to provide clinical research education at the local level through SOCRA chapters.  

**Chapter Orientation - International**  
**Joanne Goldberg, MSc, BSc, pht, CCRP**  
**Associate Director, Institute of Aging**  
**Canadian Institutes of Health Research**  
Joanne Goldberg will share examples of mechanisms for clinical research education for international members.

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**Time: 8:30 to 9:15**  
**Track: Site Management**  
**Clinical Research Overview (A Method to the Madness)**  
Ms. Tucker will present an overview of clinical research from site initiation to site closure for the new or inexperienced site coordinator. The session will review sponsor/site responsibilities, regulatory requirements, intellectual property issues, procedures for scheduling subjects and subject visits, recruitment/retention procedures, documentation requirements, and study site closure procedures.  
**Presenter: Cynthia (Cindy) Tucker, CCRP, RN, Clinical Trials Coordinator, Dermatology, Laser & Vein Specialists of the Carolinas**

**Time: 9:20 to 10:05**  
**Track: Site Management**  
**Site Management / Continuous Improvement**  
This session will focus on improving site efficiency by defining the roles and responsibilities of site staff. Ms. Patel will discuss issues related to coordinating clinical studies including regulatory affairs, ethics board and sponsor communication, development of processes for effective practice, and the use of a systematic approach to conduct clinical trials. The information will be based on the real-life experience of a site which began in chaos, and through the use of the continuous improvement approach for processes and systems, became a very efficient and highly sought out site conducting Phase II and III trials.  
**Presenter: Sandhya Patel, BScN, Director, Research Quality Assurance, Centre for Addiction & Mental Health**

**Time: 10:50 to 11:35**  
**Track: Site Management**  
**Become a Preferred Site: Quality and Documentation Tips for Compliance for the CRC**  
Learn techniques to better manage your regulatory files and prepare to answer sponsors, auditors, and inspectors regarding screening/ enrollment numbers, subject withdrawal, informed consent, recruitment efforts, delegation of authority, investigator oversight, protocol violations, and adverse events through use of adequate source.  
**Presenter: Janet Holwell, CCRC, CCRA, Independent Consultant**

**Time: 11:40 to 12:25**  
**Track: Site Management**  
**Organization to Save Your Sanity: Helpful Research Management Tactics**  
Ms. Allen will present successful and helpful organizational tactics to assist in managing important aspects of clinical research trials, whether a single-site or a multi-site study. These tactics will promote success in recruitment and retention, communication with the IRB, and oversight of regulatory needs, participant safety, as well as encourage teamwork and ease in workflow.  
**Presenter: Janelle Allen, MS, CCRP, CHAMP Study Assistant Project Manager, Cincinnati Children’s Hospital Medical Center**

**Time: 1:40 to 2:25**  
**Track: Site Management**  
**Key Considerations: Working with a CRO - Delivering on Subject Recruitment and Enrollment Promises**  
This session will identify key strategies for successful site management to implement when working with a CRO on a clinical trial. Case studies will be shared demonstrating what does and does not work when designing your site’s subject recruitment plan prior to study startup of a new research project with a CRO.  
**Presenter: Carolyn Rugloski, MSc, CCRP, Director Project Management, Worldwide Clinical Trials (WCT)**

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**Adverse Events in Oncology Research**

This session will cover the various ways of reporting, recording, and coding adverse events in an oncologic setting, specifically within the confines of clinical trials. Specific topics to be covered include regulatory reporting requirements, navigating the common toxicity criteria for adverse events (CTCAE, the oncology version of MedDRA), serious adverse events, and pre-existing medical conditions.

**Presenter:** Lindsay Philip, BSc, CCRP, Education Specialist / Quality Assurance Coordinator, Princess Margaret Cancer Centre

**Time:** 8:30 to 9:15

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**What Is Quality?**

Quality is an integral part of the work we do in research, and is directly tied to regulations and requirements. Quality is not just a mark or measure of excellence but a tool to be used by each of us as we care for our patients and provide data in clinical studies. This session will explore the concept of quality in research and discuss issues related to quality in oncology clinical research.

**Presenter:** Hether Seifert, MSM, BS, Audit / Compliance Program Coordinator, Mayo Clinic/NCCTG Alliance

**Time:** 9:20 to 10:05

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**Quality Assurance in Oncology Trials**

This session will review quality assurance in the conduct of oncology clinical trials. Ms. Li will describe common coding systems used to quantify observations, how to develop clear and succinct corrective action and preventive action plans, and discuss trends of findings and how these feed into the development of training and education.

**Presenter:** Jennifer Li, BSc, CCRP, Quality Assurance Coordinator, University Health Network

**Time:** 10:50 to 11:35

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**Incorporating Metrics into Your Clinical Research Program**

This session will focus on how to establish a metrics program, lessons learned in establishing a program, and how to start using metrics to aid in process improvement and program management.

**Presenter:** Heather Cole, BSc(Hons), Metrics and Process Improvement Manager, University Health Network

**Time:** 11:40 to 12:25

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**The History of Pediatric ALL: How We Have Reached the Current Survival Rates**

This session is a historical review of the research that has been completed to improve the outcomes of therapy in pediatric acute lymphoblastic leukemia (ALL). Dr. Dvorak will illustrate how good, systematic research practices can result in superior outcomes.

**Presenter:** Andrea Dvorak, MD, Assistant Professor of Pediatrics, SUNY Upstate Hospital

**Time:** 1:40 to 2:25

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**Management of Pediatric Biological Specimens for Clinical Trials**

The presentation will provide important information regarding the management of biological samples; understanding the need to establish proper procedure for collecting and processing human samples at the hospital/clinical site and for transporting samples to the central laboratory during a clinical trial for an investigational new drug or for improved therapy. The necessary steps involved with the handling of study biological samples, including information required for the study protocol, sample volume for ethics board approval, sample collection, processing, storage, and shipping will be discussed. Emphasis will be placed on the essential source documents collected during sample processing to ensure good documentation throughout the study and for certifying the validity and integrity of the study data.

**Presenter:** Dewi Clark, BSc, CCRP, Clinical Research Coordinator, Hospital for Sick Children

**Time:** 3:45 to 4:30

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**“Free” Research Assistants 15 Hours a Day - It’s Not Just a Dream!**

Ms. Crudden will discuss the successes and challenges of running a student volunteer research assistant program in a pediatric hospital using an established research volunteer model.

**Presenter:** Johanna Crudden, Clinical Research Manager, Hospital for Sick Children

**Time:** 4:35 to 5:20

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**Communities of Practice in Pediatric Clinical Research**

Are you a small research enterprise that could benefit from collaboration with others who participate in the same type of research you do? This presentation will discuss the creation of a national CRA Community of Practice in hematology/oncology. Ms. Devine will share examples of how a little self help goes a long way in supporting improvements in clinical research practices in pediatrics.

**Presenter:** Susan Devine, CCRP, Senior Manager, Hospital for Sick Children

**Time:** 4:35 to 5:20
BREAKOUT SESSION DESCRIPTIONS

**TRACK 8  
MONITORING / AUDIT**

**Time: 8:30 to 9:15**  
**Track: Monitoring / Audit**

**Planning and Executing Successful Not-For-Cause Audits**

Ms. Smith will discuss how to set the stage for success by planning an audit report from the start. Discussion will focus on developing a collegial audit strategy, being prepared for difficult situations, and approaching the audit as an advocate for the study team's success.  
Presenter: **Lynn Smith, JD, CIP**, Director, Clinical Research Services, Huron Consulting Group

**Time: 9:20 to 10:05**  
**Track: Monitoring / Audit**

**FDA Inspection Preparedness**

The overall goal of this training is to establish a basic understanding of FDA inspections, the general purpose of the inspection, preparation strategies, and outcomes to assist clinical sites in developing an inspection readiness culture of compliance. In addition to reviewing key terms and responsibilities, Dr. Leister will discuss possible outcomes of an FDA inspection and how to respond to the FDA. This session will also include helpful tips for the inspection.  
Presenter: **Susan Leister, PhD, MBA, BS, CQA, CSSBB**, Director of Quality Assurance, Technical Resources International Inc

**TRACK 8  
INVESTIGATOR-INITIATED RESEARCH**

**Time: 10:50 to 11:35**  
**Track: Investigator-Initiated Research**

**Using Placebos in Cancer Clinical Trials - Perceptions of Health Care Providers**

Patients' willingness to participate in a clinical trial is affected by the use of placebos in the study design. Moreover, patients rely on their healthcare providers when making decisions related to participation in clinical trials. This session will discuss how healthcare providers' perceptions of the use of placebos in cancer clinical trials affect their willingness to refer patients to such trials, and, therefore can affect patients' decisions regarding whether to participate in a clinical trial.  
Presenter: **Khalid Al Moaikel, MS, MBA, PhD Candidate**, Clinical Trials Fellow, VA Cooperative Studies Program

**Time: 11:40 to 12:25**  
**Track: Investigator-Initiated Research**

**Investigator-Initiated Research: Strategies for Project Planning**

Before the first subject is enrolled, preparation and planning are essential to success in investigator-initiated research. This session will present strategies regarding IRB and FDA submissions, who to list on the 1572, ClinicalTrials.gov registration, feasibility planning, standard of care vs. research, endpoints and data capture, selecting investigators, building the research team, communication and expectations, training, planning the study flow, evaluating risks, and safety. Ms. Wintering will focus on strategies to apply before enrollment begins.  
Presenter: **Nancy Wintering, BA, MSW, LCSW, CRC, CCRP**, Research Program Manager, Thomas Jefferson University

**TRACK 8  
BEHAVIORAL RESEARCH**

**Time: 1:40 to 3:15**  
**Track: Behavioral Research**

**The Language of Behavioral Clinical Trials: A Practical Thesaurus for Clinical Researchers**

Staff from the National Institutes of Health will give a brief introduction to the most common behavioral interventions tested in clinical trials to improve health, including those meant to educate, teach skills and boost motivation. Using the drug-development paradigm as a foundation, the presenters will describe key steps in developing and testing behavioral interventions. Among the key steps to be discussed are protocol development, implementation, data capture, and quality control. Commonalities and differences between drug-development and behavioral clinical trials at each step will be highlighted.  
Presenter: **Michelle Culp, BSN, MPH, CCRP**, Director, Office of Clinical Trial Operations & Management, NIDCR, NIH
Presenter: **Melissa Riddle, PhD**, Branch Chief, NIH / National Institute of Dental and Craniofacial Research

**Time: 3:45 to 4:30**  
**Track: Behavioral Research**

**Clinical Challenges in Behavioral Research**

Ms. Wintering will present strategies to conduct behavioral research and to manage unexpected clinical behaviors. Learn to recognize and manage clinical behaviors that arise to improve subject accrual and retention. Challenges include understanding psychological, social and cultural barriers; assessing and stimulating subject motivation and protocol adherence; and establishing a rapport with the subject to ensure good quality data. An overview of frequently used psychological assessments and instrumentation considerations will be provided. Methodology and feasibility issues related to working as a member of a multidisciplinary team in a behavioral health treatment setting will be discussed.  
Presenter: **Nancy Wintering, BA, MSW, LCSW, CRC, CCRP**, Research Program Manager, Thomas Jefferson University

**Time: 4:35 to 5:20**  
**Track: Behavioral Research**

**Treatment Fidelity in Community-Based Intervention Studies**

A key factor in effective dissemination is treatment fidelity, which refers to implementing an intervention in a manner consistent with an established manual. Quantitative observational data from a clinical trial of family therapy for adolescent substance abuse illustrate the importance of documenting fidelity, while qualitative data help to identify likely stumbling blocks in exporting a complex behavioral intervention to community settings.  
Presenter: **Michael J. Rohrbaugh, PhD**, Clinical Professor of Psychiatry and Behavioral Sciences, George Washington University,

© SoCRA 2014 Annual Conference - Page 13
Ten Things You Should Do to Prepare for an OCR HIPAA Audit

The Health Information Technology for Economic and Clinical Health (HITECH) Act requires that the U.S. Department of Health & Human Services, Office for Civil Rights (OCR) conducts audits to determine whether a covered entity has HIPAA required processes, controls, and policies in place. This session will cover the requirements for audits, the audit process, and the actions that can result from an audit. This session will also present the ten items that OCR will access during the audit and will provide ten important steps to take in preparation for the audit.

Presenter: Cynthia Gates, JD, RN, CIP, Associate Director, IRB Administration, University of California, Davis

What's New in Clinical Research - An Overview of the Latest Guidance Documents and Trends

What did they change now? Navigating the federal regulations can be confusing enough, so understanding the current regulatory environment and thinking can help. This presentation will cover the latest guidance documents and trends from FDA and OHRP, with an emphasis on high-level updates for sponsors, investigators, and institutional review boards (IRBs).

Presenter: Daniel Redline, BA, CCRP, CIP, Director, IRB Administration, University of California, Davis

Problematic Aspects of Clinical Trials from a Scientific Perspective

The vast majority of critiques of clinical trial methodology focus on statistical or experimental design issues. Yet substantial problems can arise from non-statistical or non-design related issues such as impaired drug bioavailability and intra- and inter-subject variability, among others. New drugs are almost invariably less bioavailable than older drugs and correspondingly more difficult to formulate in conventional dosage forms, let alone drug delivery systems. This presentation will address these drug, dosage form, and patient-related concerns in the context of staging effective clinical trials.

Presenter: Lawrence Block, PhD, Professor Emeritus of Pharmaceutics, Duquesne University

Informed Consent Forms: Stepping Back to Redefine its Mission

Ms. Zafonte will discuss why we have informed consent forms, review the evolution and current landscape related to the informed consent process, and explore how and where advancements in the informed consent form may have subverted its original intention. This session will be based on a clinical project comparing two sister divisions at an institution, metrics set by ANPRM by HHS, and related literature. Where should we go from here? Possible future directions and developments for informed consent will be discussed.

Presenter: Stephanie Zafonte, MSN, RN, CCRP, Clinical Project Manager, NIH/NIAID/DMID/EHDB

Effective Employee Training in a Multi-Generational Workforce

As the clinical research landscape becomes more generationally diverse and FDA scrutiny of clinical research professional qualifications increases, the need for appropriate and effective employee training is becoming more important. This presentation will highlight current research on whether generational differences matter; and if so, how to manage and even leverage these differences. Ms. van der Schalie will review the challenges of training design and delivery and present a blueprint for optimization of multi-generational training.

Presenter: Barbara van der Schalie, MS, Clinical Training Manager, SAIC-Frederick Inc

Give Back Event at the 23rd Annual Conference

This year SOCRA is partnering with Bert's Big Adventure, a 501(c)(3) nonprofit organization that provides a magical, all-expenses-paid, five-day journey to Walt Disney World® for children with chronic and terminal illnesses and their families. Following the trip, Bert’s Big Adventure provides year-round support through initiatives such as the Reunion Adventures, the Fairy Godparent volunteer program and additional charitable services. Since it’s inception, Bert’s Big Adventure has served more than 130 children with chronic and terminal illnesses and their families.

For More Information, visit www.socra.org/annual-conference/2014-conference-information/give-back-event/ or stop by the SOCRA Registration Desk at the Annual Conference for more information.