Friday, September 28, 2018

Opening Plenary

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. 001

Presenter: **Tammy Neseth, MA, CCRP, CIP,** Operations Manager, Mayo Clinic Integrity and Compliance Office
Presenter: **Jamie Harper, MHA, CCRP,** Director of Clinical Research, Illinois CancerCare PC

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

Rethinking Research Ethics: Considerations for Pragmatic Clinical Trials

Pragmatic clinical trials, including comparative effectiveness research, are becoming increasingly prevalent. These trials aim to answer important research questions for multiple stakeholders and may be less expensive than conventional clinical research. In addition, these "real-world studies", which are typically embedded in health care settings, often pose minimal incremental risks and burdens to participants. This suggests that the full range of protections employed for conventional research subjects may not be appropriate. However, designing and conducting pragmatic research has been associated with a surprisingly vexing array of ethical and regulatory challenges. Dr. Sugarman will describe the nature of pragmatic clinical trials, some of these challenges, and ways to address them. 002

Presenter: **Jeremy Sugarman, MD, MPH, MA,** Professor of Bioetics and Medicine, Johns Hopkins University

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

Precision Medicine versus Precision Health: Transformative Opportunities in the Digital Era

Advances in precision medicine are accelerating treatment discoveries that are more targeted and effective. Yet successful interventions for diseases such as Alzheimer's disease remain elusive. Consider that in the US about 86% of diseases treated are chronic diseases, which means that the path from normal to disease is a long one – taking years, if not decades to progress to the level of severity in which medical treatment is needed. Emerging technologies offer the opportunity of preventing disease from happening altogether and potentially lead to a paradigm shift in healthcare from a focus on precision medicine to one on precision health. Further, centering on optimizing brain health as an alternative to disease treatment may prove the most efficacious route for not only solving the problem of Alzheimer's disease but also other common chronic disorders. 003

Presenter: **Rhoda Au, PhD, MBA,** Professor of Anatomy & Neurobiology, Neurology and Epidemiology
Boston University Schools of Medicine & Public Health

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

Improving Informed Consent

In January, 2017, a final rule was published in the Federal Register to revise a variety of provisions of the Common Rule (the main set of federal regulations designed to protect research participants). In particular, some of those changes relate to improving informed consent. This session will discuss the ways in which the most significant of these changes are intended to operate and how they will lead to a more ethical process for obtaining informed consent from prospective research participants. 004

Presenter: **Jerry Menikoff, MD, JD,** Director, Office for Human Research Protections, Department of Health & Human Services

Friday, September 28, 2018

Breakout Session Descriptions

Track 1 Compliance/Noncompliance

Time: **1:15 to 2:00** Track: **Compliance / Noncompliance**

The Dangers and Consequences of Fraud and Misconduct in Clinical Research

The US Office of Research Integrity (ORI) conducts oversight of research misconduct and has identified 23 significant issues that pertain to misconduct. Ms. Wintering will present an overview of the prevalence, risks, and consequences of misconduct. Historical examples and scenarios will be presented. Topics will include ORI significant issues, disbarment and exclusion, publication retraction, and, your rights and responsibilities. 109

Presenter: **Nancy Wintering, MSW, LCSW, CCRP,** Assistant Director of Research, Thomas Jefferson University

Time: **2:05 to 2:50** Track: **Compliance / Noncompliance**

Compliance, Auditing and GCP Challenges

Investigator Initiated Trials (IITs) present unique regulatory and clinical operational challenges and risks. Specialized skills and knowledge are required for auditing and achieving compliance leading to successful trial completion. Ms. Portier will share auditing plans and techniques to address the challenges of IITs. 111

Presenter: **Wendy Portier, MSN, RN, CHRC, CHC,** Consultant Kelly Willenberg & Associates, LLC

Track 1 Data Management/EDC

Time: **3:25 to 4:10** Track: **Data Management / EDC**

Trial Master File: Transition from Repository to Study Management Tool

Following the release of ICH GCP E6 and the draft EMA guidance on the Trial Management File (TMF) the industry is transitioning from a repository which should be complete at the end of a study to a study management tool for communication, management and oversight. Ms. Malia will discuss how this change came about and considerations for companies as they move forward. 113

Presenter: **Joanne Malia, BS, MS, MS,** Associate Director, Clinical Documentation Management, Regeneron Pharmaceuticals

Time: **4:15 to 5:00** Track: **Data Management / EDC**

Electronic Clinical Trial Management Systems: The Basics, Needs, and Outputs

Mr. Wieczerzak will discuss the basic structure, need, and importance of having an electronic clinical trial management system at the sponsor/CRO level. The various benefits of using an integrated CTMS system such as linking other systems, running reports, and other various outputs will be presented as well as the requirements and regulations needed when using an electronic CTMS. 115

Presenter: **Michael Wieczerzak, BS, MS, CCRP,** Clinical Trial Lead EMD Serono Inc.

Breakout Session Descriptions

Track 2 / Device Research

Time: **1:15 to 2:00** Track: **Device Research**

Total Product Life Cycle

Understanding and planning for the Total Product Life Cycle of your medical device is becoming increasingly more important. This talk will dive into some key areas of TPLC and how that might impact your IDE and PMA. Ms. Pack will also go over the "life after PMA approval" and some tips for managing this process. 209

Presenter: **Lindsay Pack, BSE,** Head of Quality
Philips Healthcare

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

Data & Safety Monitoring Committees: The Important Role They Play

This presentation will provide an overview of the Data & Safety Monitoring Committee: its purpose, importance, and the critical role it plays in investigator initiated trials. Ms. Lockhart will emphasize the importance of submitting clean and applicable data. Examples will be provided on how investigators, coordinators, regulatory and data managers play an integral role in providing data validation. Best practices currently utilized at the University of Miami Sylvester Comprehensive Cancer Center will serve as a focal point. 211

Presenter: **LaShanna Lockhart, MBA-HA, MS, CCRP**
Manager, Research Support
University of Miami Sylvester Comprehensive Cancer Center

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

How Innovation in Medical Products Will Impact the Design and Conduct of Clinical Trials

Personalized medicine, wearables, sophisticated diagnostics, and nanotechnology are all now a reality of the healthcare field, and will require an innovative approach to designing and running clinical trials. This presentation will include overviews of innovative technologies and what was required to get them to market. 213

Presenter: **Athena Thomas-Visel, MA, ME, RQAP-GCP, CCRP, PMP, RD,** Chief Quality Officer & Principal Consultant
Cliq Solutions, LLC

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

Lessons Learned: Navigating the Medical Device Regulatory Process and the Implications of the Quality System and Design Controls

This presentation will be an interactive session discussing aspects of medical device classification, investigational studies, Quality System- Design Controls and CDRH's Small Business Certification Program. 215

Presenter: **Donna Headlee, BSN, RN, CCRP**

Track 3 / Quality Management

Time: **1:15 to 2:00** Track:**Quality Management**

Utilizing the Research Ethics Review Process as a Method to Incorporate Quality by Design

Mr. Staios will describe the actions taken to incorporate quality by design principles into the conduct of human participant research at the Centre for Addiction and Mental Health. A framework of the approach and the main outcomes of this process change will be presented. 309

Presenter: **Gregory Staios, MSc, CCRP,** Manager
Research Ethics, Centre for Addiction and Mental Health

Time: **2:05 to 2:50** Track: **Quality Management**

Enhancing Safety and Efficiency Through Implementation of Electronic Tools

The Investigational Drug Service (IDS) is a component of the Hospital Pharmacy Services at the University of Illinois Hospital and Health Sciences System (UI Health). It is charged to assist and support clinical drug research within UI Health in providing safe, high-quality, and cost-effective care that is core to a patient-centered organization. IDS actively engages in continuous quality improvement initiatives to advance patient care, education, and research. This presentation highlights several Window-based electronic tools IDS had developed and implemented to promote workflow efficiency and to enhance safety. 311

Presenter: **David Chan, PharmD, PhD, BCOP, CCRP,** Clinical Pharmacist, Univ of Illinois Hospital & Health Sciences System

Time: **3:25 to 4:10** Track: **Quality Management**

Tools and Techniques for Effective Clinical Research Start-up at an Academic Medical Center

Activating a clinical research project at an academic medical center requires significant planning and effort from study teams. Research sponsors often have difficulty understanding a process lacking in transparency, and so start-up becomes a barrier to study enrollment. This talk breaks down that barrier by advocating specific project management and communication techniques and tools that accelerate the start-up process without sacrificing quality. 313

Presenter: **Michael Mapel, CCRP,** Clinical Research Lead
UCLA Pediatrics, Office of Finance & Research

Time: **4:15 to 5:00** Track:**Quality Management**

The Internal Research Quality Audit Experience: Lessons Learned So Far

Ms. Marzinotto will provide an overview of the internal research quality audit process. The speaker will discuss the most common audit findings and the identification of educational needs. Development of an educational series for researchers to improve the quality of the conduct of clinical research will be elaborated. 315

Presenter: **Velma Marzinotto, BScN, RN, CCRP**
Senior Research Compliance & Education Specialist
St. Michael's Hospital

Breakout Session Descriptions

Track 4
Oncology Research

Time: **1:15 to 2:00** Track: **Oncology Research**

Immunotherapy and Nursing Implications on Patient Care

As immunotherapy continues to grow as a treatment option within cancer types, identifying and managing adverse events of these treatments are much more important when caring for cancer patients. Nurses are often the initial point of contact for cancer patients, especially when reporting adverse events. It is therefore important for nurses to become knowledgeable in identifying immune-mediated events as well as providing education to patients who are receiving treatment. 409

Presenter: **Cynthia Bocaya, RN, CON(C),** Practice Lead
Princess Margaret Cancer Centre

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

Research at the VA - Is it Really that Different?

This presentation will discuss the conduct of clinical research in the VA setting which serves a unique population. Ms. Chase will discuss the special criteria and approvals which need to be put in place, examine potential challenges, and share solutions to overcome them. 411

Presenter: **Margaret Chase, BSN,** Research Clinical Coordinator
Hematology-Oncology, VACCHCS - Fresno

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

Don't Let Basket Trials Make You a Basket Case

This presentation is an overview of management of basket trials within the clinical trial framework. Common pitfalls as well as key strategies will be discussed. Examples of trials will be incorporated. 413

Presenter: **Melissa Ford, PhD,** MSN, RN, Manager
Research Projects
Vanderbilt University Medical Center/Ingram Cancer Center

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

CAR T Therapy: Side Effects and Management

Ms. Dudley will discuss expected side effects and how to safely manage them. 415

Presenter: **Channing Dudley, MSN, RN,** Manager, Hematology Clinical Trials Program, Vanderbilt-Ingram Cancer Center
aspects of clinical risk-based planning, analytics, and data monitoring. 429

Track 5
Training

Time: **1:15 to 2:00** Track: **Training**

Sink or Swim: Research Training to Keep Your Team Afloat

All too often, new staff are thrown into a research role without the proper training and frequently feel like they're sinking with no life vest. The regulations are lengthy, the language is difficult and there typically isn't a mentor to walk them through the process and bring them up to speed. This presentation will guide you with setting up a comprehensive training for different members of your team and how to allocate dedicated time to properly train on the research regulations, requirements and rescue. 509

Presenter: **Melissa McLennon, MPH**
Monitoring & Compliance Officer, Memorial Healthcare System

Track 5
Training

Time: **2:05 to 2:50** Track: **Training**

Communication in Clinical Research: Is There Something to Improve?

We recognize that effective communication skills in clinical research are vitally important. However, due to many conflicting priorities, we may not have time for management of soft skills. If that's the case, there is a danger that something may go wrong. Dr. Gorkun will review real-life examples from clinical research environments where communication problems affected deliverables or compliance. The principles of effective communication styles will be discussed, and the attendees will have the opportunity to brainstorm ideas on how to improve communication once a problem has been identified. 511

Presenter: **Anatoly Gorkun, Chartered MD, PhD, MCIPD**
Senior Manager, Clinical Management, PPD

Time: **3:25 to 4:10** Track: **Training**

Introducing Generation Z: Who They Are and How They Will Impact the Clinical Workplace

Generation Z, the Post Millennials, are the latest addition to the extremely generationally-diverse American clinical workplace. Their preferences for critical workplace parameters, including work place engagement, communication, leadership approaches and flexibility, differentiate them from even their most closely age-aligned colleagues, the Millennials. This presentation will discuss these preferences and how to optimize their integration into the current clinical research workplace, 513

Presenter: **Barbara van der Schalie, MS**
Clinical Training Manager, Leidos Biomedical Research Inc.

Time: **4:15 to 5:00** Track: **Training**

Coaching Beyond the Goal: The Hidden "I" in Team

This training will assist the individual on career development as an individual contributor to a team. In addition, it will provide the framework for the need for solid coaching and feedback for study teams through mentoring. Lastly, it will demonstrate how individual development translates into quality site management and performance to deliver quality study data. 515

Presenter: **Avie Banks, MBA, MHA, CCRA,** Director
Project Management, PPD

Track 6
Therapeutic Areas in Research

Time: **1:15 to 2:00** Track: **Therapeutic Areas in Research**

Current Trends: The Renaissance of Ophthalmic Research

Ms. Grewal will provide updates from the vast area of ophthalmic research to assist monitors and site staff on ensuring a successful trial. Pitfalls and pearls from the ophthalmic arena to shed light on this unique clinical trial space will be discussed. 609

Presenter: **Jaspreet Grewal, MSc, CCRP,** Principal
JK Grewal Consulting, Inc.

Track 6
Therapeutic Areas in Research

Time: **2:05 to 2:50** Track: **Therapeutic Areas in Research**

A New Foot Soldier in the Opioid Addiction War: Medical Device Implantation and Management for Chronic Long-Term Pain

Medical device implantation is a proven, safe and effective way to curb opioid use for chronic pain control. Explanation of the devices used and the pain controlled by each device describes this effective tool in preventing and curbing opioid addiction in patients with chronic pain syndrome. 611

Presenter: **Melba Isom, ASB, CCRP,** Clinical Trials Specialist
Vanderbilt University Medical Center

Time: **3:25 to 4:10** Track: **Therapeutic Areas in Research**

Using Music Relaxation Techniques for Cardiovascular Health

Vascular Management Associates works with vascular surgery and cardiovascular disease prevention practices to prevent, diagnose, treat, and manage cardiovascular disease in patients. One of the ways we assist our patients is through the use of music relaxation techniques. Ms. Cross will discuss the music relaxation group session, and how it assists patients with cardiovascular disease. 613

Presenter: **Connie Cross, BS, CCRP,** Vice President
Vascular Management Associates, Inc.

Time: **4:15 to 5:00** Track: **Therapeutic Areas in Research**

ABC's of Establishing an Ethically-Sound BioBank

This talk will focus on the importance of biobanking to advance clinical and translational research. The speaker will cover the development of infrastructure, SOPs, staffing, financial modeling, etc. to build a successful biobank. The final portion will cover the specific ethics and regulations pertaining to biobanking protocol and ICF/Assent development. Mr. Ratti will share personal experiences and successes. 615

Presenter: **Pukar Ratti, MSHCM, MSChE, CIM, CCRP, FACMPE**
System Director of Research
CHRISTUS Inst for Innovation & Adv Clinical Care

Track 7
Responsible Conduct of Research

Time: **1:15 to 2:00** Track: **Responsible Conduct of Research**

Lessons from the National Patient Safety Movement that are Applicable to Clinical Research

Dr. Kessler will review the strategies that have made clinical care safer and examine how clinical research has adopted these strategies. 709

Presenter: **John Kessler, BS Pharm, PharmD,** Chief Clinical Officer, SecondStory Health, LLC

Time: **2:05 to 2:50** Track:**Responsible Conduct of Research**

Lessons Learned from Research Misconduct Cases

This presentation will use case studies and lessons learned to discuss research integrity and the consequences of a scientific enterprise that rely solely on a "self-correcting" model of peer review and independent validation of results. An updated model of actively promoting research integrity and encouraging the safe reporting of problems will be presented that is based on tools and strategies adopted from patient safety movement and a "just culture." Approaches will be discussed for moving beyond a "reactive" mode of responding to questionable research practices and more serious issues of research misconduct to a "proactive" setting where all components of the research enterprise are involved in, responsible for, and accountable to a community standard of integrity. A focus on re-mediation not only of individuals but also of factors in the institutional setting where questionable practice or misconduct may have been facilitated or gone undetected will be discussed. 711

Presenter: **Donna Kessler, PhD,** Research Integrity Officer
Duke University

Track 7
Responsible Conduct of Research

Time: **3:25 to 4:10** Track: **Responsible Conduct of Research**

Research Misconduct in Clinical Trials

Ms. Parrish will discuss US administrative and institutional actions when research misconduct is alleged, journal activism when allegations are made, and best practices for managing corrections and retractions will be reviewed. 713

Presenter: **Debra Parrish, JD,** Partner, Parrish Law Offices

Time: **4:15 to 5:00** Track: **Responsible Conduct of Research**

Understanding Research Wrongdoing: Lessons from the PI Program and PSI Lab

This presentation will explore factors that increase the risk of research integrity violations or serious noncompliance. It will draw upon data from the first 60 participants in the PI Program, which serves investigators following professional lapses. It will also draw from recent studies in the Professional and Social Issues (PSI) Lab at Washington University, involving more than 950 NIH-funded researchers. These studies have examined professional decision-making in research and its relationship to culture, values, RCR education, and personality traits such as cynicism, narcissism, and moral disengagement. Finally, Dr. DuBois will examine a series of lab management practices associated with research exemplars—practices that may help protect against research integrity violations. 715

Presenter: **James DuBois, DSc, PhD,** Director, PI Program & Ctr for Clinical Res Ethics, Washington University School of Medicine

Track 8
Monitoring

Time: **1:15 to 2:00** Track: **Monitoring**

Unique Monitoring Experiences - How to Effectively Manage Challenging Situations

Experiential learning is pivotal in clinical research; gaining knowledge from others' professional tenure is one of the best ways to advance an individual's proficiency. Ms. Statler will draw upon her 9 years of monitoring experience to directly inform the topics that will be discussed. Challenging scenarios will be presented and resolutions will be offered. 809

Presenter: **Abby Statler, MPH, MA, CCRP,** Research Regulatory Quality Assurance Coordinator, Cleveland Clinic

Breakout Session Descriptions

Friday, September 28, 2018

Track 8 / Monitoring

Time: **2:05 to 2:50** Track: **Monitoring**

Creating Effective Communication Strategies and Relationships with Sites in a Remote Monitoring Environment

The new focus on remote monitoring has provided sites, sponsors, and monitors with many benefits, including less travel, expense, and more real-time data review of critical endpoints. Unfortunately, the change in environment for more on-site training and monitoring can lead to strained and underdeveloped relationships between site staff and monitors. The lack of proper communication may lead to additional challenges in meeting study-related targets, additional errors, and a generally less engaged study team. By learning how to adapt on-site communication and training practices to the remote environment, sponsors, sites, and monitors can equally benefit from a more productive and engaged study team. 811

Presenter: **Grace Morgan-Holmes, BS, CCRP, CCRA**
Senior CRA and Protocol Specialist, Westat

Time: **3:25 to 4:10** Track: **Monitoring**

Our Risk Based Monitoring (RBM) Model for Device Studies - A Team Approach

BIOTRONIK uses a grading model and heat map model to determine which sites need monitor visits on a more frequent basis, as well as the regular visits dictated in the Monitoring Plan. Device data and other CRFs are centralized monitored by both in house CRAs and RCRAs. This allows for less frequent monitor visits to be dictated in the MP, as well as less on site time for the RCRA team when on site. 813

Presenters:
Phil Moll, MS, Statistical Programmer, Clinical Studies BIOTRONIK
Sarah Deer, CCRA, Regional CRA Manager, BIOTRONIK

Time: **4:15 to 5:00** Track: **Monitoring**

Monitoring Plan Development and Key Considerations

Ms. Doherty will focus on Monitoring Plans for clinical trials. Topics will include the importance of having a clear Monitoring Plan at study start and key elements of the plan, such as source data verification and escalations. 815

Presenter: **Lauren Doherty, CCRP,** Clinical Trial Manager TESARO

Saturday, September 29, 2018

Track 1 / Poster Session

Time: **8:30 to 10:05** Track: **Poster Session**

Poster Session Presentations

Selected poster presenters will present a synopsis of their work related to Clinical Trials and Clinical Trials Management. 117

Presenter: **Joanne Goldberg, MSc, pht, CCRP,** Assistant Director, CIHR Institute of Aging
Presenter: **Bryce Warren, PhD,** Chairman, L. H. Warren Foundation for Science

Saturday, September 29, 2018

Track 1 / Behavioral Health

Time: **10:50 to 11:35** Track: **Behavioral Health**

Conducting Behavioral Health Research

Mr. Gepty will address issues to consider when conducting behavioral health research with adult and adolescent populations in a clinical and community setting. Topics to be discussed include ethical considerations, logistics, methodology, statistics, and clinical issues. 121

Presenter: **Andrew Gepty, BA,** Doctoral Student
George Washington University

Time: **11:40 to 12:25** Track: **Behavioral Health**

Implementing Quality Assurance in Behavioral Health Research

Too often we focus on quality assurance in medical research due to increased risk. However, we neglect to acknowledge that quality assurance is needed in social behavioral research. Ms. Rowe will describe QA processes that have been implemented at a school of nursing where the research is predominately behavioral. 123

Presenter: **Jessica Rowe, MA, MS, CCRP,** Research Quality Improvement Manager, University of Maryland, Baltimore

Track 1
Enrollment/Retention & Informed Consent

Time: **1:40 to 2:25** Track: **Enrollment/Retention & Informed Consent**

Community Based Recruitment

Traditionally, trials have taken place in a clinical setting, but that is changing as technology allows us to take our research out into the community. Ms. St. Romain will discuss various recruitment methods that have been successful for community (as well as clinic) based trials. Ways to use what you have internally, such as leveraging staff schedules and skill sets, developing recruitment/marketing plans, and considerations for recruitment channels and materials will also be discussed. 125

Presenter: **Mary Jessica St. Romain, BS,** Community Based Project Manager, Pennington Biomedical Research Center

Time: **2:30 to 3:15** Track: **Enrollment/Retention & Informed Consent**

Creating a Community that Supports Recruitment for Alzheimer's Disease Research

Various efforts supported by the Global Alzheimer's Platform (GAP) Foundation have greatly increased referrals to Alzheimer's disease clinical trials being conducted across the GAP network of clinical research sites. The GAP Novel Recruitment Model and lessons learned from implementation in select communities will be highlighted. Ms. Cordell will detail how to build a community culture to support AD research to interact with, educate, and prescreen potential research participants to improve rates of enrollment/randomization for specific clinical studies. 127

Presenter: **Cyndy Cordell, BS, MBA,** Vice President, Provider Relations, The Global Alzheimer's Platform Foundation

Breakout Session Descriptions

Track 1
Enrollment/Retention & Informed Consent

Time: **3:45 to 4:30** Track: **Enrollment/Retention & Informed Consent**

Automated Documentation of the Informed Consent Process

With the migration from paper to electronic health records, electronic systems are being used frequently to provide documentation of informed consent. The purpose of this session will describe developing and using an electronic system to easily document the unique features of each informed consent discussion. 129

Presenter: **Joan Whitted, BS, CCRC,** Quality Management Education & Training, Sylvester Comprehensive Cancer Center

Time: **4:35 to 5:20** Track: **Enrollment/Retention & Informed Consent**

Transitioning to eConsenting-Implementing New Technology to Increase Efficiency within a Research Study

This presentation will focus on sharing the experience of transitioning from a paper consent process to an electronic process using REDCap. Relevant background information including current industry perspectives and guidance on eConsenting as well as a detailed account of how moving to an electronic system impacted the data flow of the study and increased efficiency for the study team will be discussed. Benefits and drawbacks of eConsenting for this project would also be discussed as well as how this pilot program will impact future research projects. 131

Presenter: **Elizabeth Solinger, MS, CCRP,** Senior Clinical Research Coordinator, The Ohio State University

Track 2 / Device Research

Time: **8:30 to 9:15** Track: **Device Research**

Navigating the FDA 510(k) Submission Process to Successful Medical Device Clearance

Ms. Davagian will provide an understanding of the classification of medical devices and FDA 510(k) submission process for marketing clearance in the United States. The presentation will also give an understanding of how the 510(k) submission can harm the market value of a medical device. Overviews of strategies for successful 510(k) submissions will also be discussed. 217

Presenter: **Jennifer Davagian,** President, Cristcot LLC

Time: **9:20 to 10:05** Track: **Device Research**

IDE Infrastructure Mapping

Ms. Seidl will discuss how to develop a robust study infrastructure that incorporates the requirements of the FDA, sponsor/CRO SOPs, IRB/EC requirements and needs of the site into one project plan. The session will demonstrate how to develop ins and outs of the infrastructure including but not limited to a project map, plan, master document list and task list. Having an infrastructure in place reduces the time to study start up and ensures project set up stays on track and considers every phase of a clinical trial. 219

Presenter: **Caitlyn Seidl, BS, CCRP,** Director Clinical & Regulatory Affairs, K2M, Inc.

Track 2 / Device Research

Time: **10:50 to 11:35** Track: **Device Research**

Mobile Medical Devices in Research

Dr. Young will go over regulations and guidance related to mobile medical devices. Examples will then be given, which will include mobile apps. Finally, some mention will be given to possible risks or controversy that may arise from the use of such devices. 221

Presenter: **Jonathan Young, PhD, MS, CIP, CCRP**
Senior Research Regulatory Operations Analyst
Rush University Medical Center

Time: **11:40 to 12:25** Track: **Device Research**

Balancing the (Clinical Trial) Budget

Approaches to developing, negotiating and managing clinical trial budgets will be discussed with an emphasis on maximizing site reimbursement and managing sponsor expectations. 223

Presenter: **Tammy Floore, BSN, MBA, CCRP, RN, CPC-A**
Research Nurse Coordinator, UCLA

Track 2 / GCP Audit Preparedness

Time: **1:40 to 2:25** Track: **GCP Audit Preparedness**

So You Think You Know GCP….

There are many component parts to GCP including FDA regulations, FDA guidance documents, state laws and international standards. There is so much information to digest on GCP that it is easy to get confused on what GCP actually requires and what is simply recommended. This presentation will use a quiz show format to challenge audience members with GCP questions on a variety of topics including informed consent, monitoring, source documentation, subject recruitment, and IRB's. Even experienced clinical research professionals might be surprised by what they think they know and what is actually true. 225

Presenter: **Paul Below, MS, CCRA,** Director
GCP Training Specialists LLC

Time: **2:30 to 3:15** Track: **GCP Audit Preparedness**

Delegation of Authority: The Importance of Qualifications and Training of Investigator Site Staff

Mr. Purnell will discuss the importance of qualifications and training of delegated site staff including the purpose of the delegation log and investigator oversight, review of expectations outlined in ICH GCP, and examples of what the FDA looks for during regulatory inspections. An exercise in verifying compliance for participants will be provided. 227

Presenter: **Terrence Purnell, MS, CCRP, RQAP-GCP**
Senior Quality Assurance Auditor, CSL Behring

Time: **3:45 to 4:30** Track: **GCP Audit Preparedness**

The FDA is Coming - How to Prepare Clinical Sites

This presentation describes the FDA inspection process and provides the tools to prepare for a regulatory inspection at your clinical trial sites. Ms. Miller will review the FDA's most recent warning letters for noncompliance issues noted during FDA site inspections, and examine the FDA compliance programs relevant to investigators, sponsors, and CRO's. 229

Presenter: **Gloria Miller, BS, RAC-US, CQA-ASQ**
GCP Compliance Manager, Esperion Therapeutics

Breakout Session Descriptions

Track 2 / GCP Audit Preparedness

Time: **4:35 to 5:20** Track: **GCP Audit Preparedness**

What to Do When the FDA Just Shows Up

We have all heard that the FDA can show up at our site at any time. Most of the FDA visits we hear about start with a phone call or notification which in turn allows the site some time to "prepare". What do you do when the FDA just shows up? 231

Presenter: **Jasmine Neumann, BS, CCRP,** Regulatory Affairs Coordinator Manager, Banner MD Anderson Cancer Center

Track 3 / Canadian Regs/Inspections

Time: **8:30 to 9:15** Track: **Canadian Regs / Inspections**

Negotiating a Reasonable Allocation of Risk in Clinical Trial Agreements

Negotiating the liability sections of a CTA is often the most challenging task facing CTA negotiators. Mr. Rajakaruna will identify and describe how to negotiate a reasonable allocation of risk and liabilities for your site. Topics covered will include subject injury reimbursement, indemnification, insurance and limitation of liability. For attendees not involved in CTA negotiations, this presentation may still be of value, especially for study personnel who want to know if the CTA properly protects their interests. 317

Presenter: **Marlon Rajakaruna, BA, MBA, LLB, CRCP,** Partner Global & Nat'l Co-Leader of Life Sciences, Dentons

Time: **9:20 to 10:05** Track: **Canadian Regs / Inspections**

Negotiation of Clinical Trial Agreements with Canadian Sites

Dr. Feldman will focus on Clinical Trial Agreements and requirements Canadian sites expect from sponsors. 319

Presenter: **Anat Feldman, PhD, CCRP,** Senior Business Development Officer, StemCell Technologies Inc.

Time: **10:50 to 11:35** Track: **Canadian Regs / Inspections**

The Tri-Council Policy Statement: Understanding Canada's "Common Rule" for Human Research

Mr. Letendre will explore the Tri-Council Policy Statement (TCPS) and its application to clinical trials in Canada. He will present the scope of the TCPS, its application, and how it differs from and how it complements ICH-GCP. 321

Presenter: **Martin Letendre, LLB, LLM,** President Ethica Group of Companies

Time: **11:40 to 12:25** Track: **Canadian Regs / Inspections**

Health Canada's Clinical Trail Compliance Program

An overview will be provided of Health Canada's Clinical Trial Compliance Program, including compliance trends, program updates, transparency, and Canada's implementation of ICH E6 (R2). 323

Presenter: **Alicja Kasina, PhC, MSc,** Senior Regulatory Advisor, Clinical Trial and Biological Product Compliance Health Canada

Track 3 / Canadian Regs/Inspections

Time: **1:40 to 2:25** Track: **Canadian Regs/ Inspections**

Participant Recruitment Strategies in the Canadian Clinical Trials Environment

Recruiting study participants is a critical component of the clinical trial process; it can also be one of the most challenging as well. It is crucial that participant recruitment strategies are well planned and meet protocol requirements including budget, timelines, and awareness of the Canadian regulatory/legislative environment. It is imperative to identify what are the potential challenges for recruitment to a study, including barriers to the participant, as well as recognizing that 'one size' strategy does not fit all studies. During this session, Ms. Johnston will look at various strategies that offer alternative solutions to the usual recruitment posters but also recognizing the added complexities around privacy with these solutions. 325

Presenter: **Lisa Johnston, BScN, RN, CCRP**
Clinical Research Facilitator, Ottawa Hospital Research Institute

Time: **2:30 to 3:15** Track: **Canadian Regs / Inspections**

Inspection of Clinical Investigator: Conducting Clinical Trials in Canada

Mr. Rashti will explain how FDA selects their clinical study sites in Canada, the differences between US and Canadian sites, FDA's foreign cadre, Bioresearch Monitoring Program, deviations observed in Canadian sites, FDA 483 and Warning Letters, and how to be prepared for the agency audit. 327

Presenter: **Mike Rashti, BS,** President
BIMO Auditor and Trainer, LLC

Track 3 / Health Disparities

Time: **3:45 to 4:30** Track: **Health Disparities**

Trust and Willingness to Participate in Research: Implications for Enrollment of Hard to Reach Populations

The NIH has set guidelines for the inclusion of women and minorities in research. However, this is a population that can be difficult to engage in research. Dr. Dawson will discuss how levels of trust can influence willingness to participate in research. Findings regarding participant willingness to participate in various types of research (i.e., oral medications, IV injections, genetic testing) will be presented, along with variations in trust associated with each type of research. This data was collected in a typically hard-to-reach population where trust in medical researchers is a potential enrollment issue. 329

Presenter: **Leah Dawson, PhD, CCRP, CHES,** Postdoctoral Fellow University of Arkansas for Medical Sciences

Track 3 / Health Disparities

Time: **4:35 to 5:20** Track: **Health Disparities**

Health Disparities: Why Inclusion and Health Equity Matters in Clinical Research

With advancements in biomedical research and genomics, inclusive conduct of research can reduce bias and improve outcomes for the benefit of society as a whole. Parity and diversity enhances the depth and complexity of research. Ms. Wintering will discuss the historical, social and cultural indicators and consequences of inequality in clinical research. 331

Presenter: **Nancy Wintering, MSW, LCSW, CCRP,** Assistant Director of Research, Thomas Jefferson University

Track 4 / Finance & Billing

Time: **8:30 to 9:15** Track: **Finance and Billing**

Effective Management of Clinical Trial Finances

Ms. Sarafin will discuss how to create and negotiate a comprehensive clinical trial budget, then move to best practices for daily financial management of clinical trials. How to work with your clinical team to track activity and invoiceables, renegotiate when needed, and ensure full payment from sponsors will be presented. 417

Presenter: **Sandra Sarafin, BA, CCRP,** Director
Research Finance Office, Ohio State University

Time: **9:20 to 10:05** Track: **Finance and Billing**

Financial Management of a Clinical Trial at an Academic Institution: Lessons Learned

This presentation will include discussion points related to a centralized clinical trial finance management department at an academic institution. Points to be covered will include; the department's organizational structure, electronic systems utilized, collaboration with clinical and other research administration departments, challenges/successes, and lessons learned since the department originated. 419

Presenter: **Veronica Kain, MBA,** Director, Clinical Trials Financial Management, Children's Hospital of Philadelphia

Time: **10:50 to 11:35** Track: **Finance and Billing**

Leveraging CTMS and HER to Build a Compliant Research Billing Program

Attendees will learn the essential elements of building a compliant research billing program and will understand foundational elements of a research billing program. The session will provide attendees with helpful tools, techniques and resources to establish a research billing program. 421

Presenter: **Mary Veazie, MBA, CPA, CHC, CHRC,** Executive Director
The University of Texas MD Anderson Cancer Center

Time: **11:40 to 12:25** Track: **Finance and Billing**

Successfully Allocating, Managing, and Paying for Study Coordinator Time on Industry-Sponsored Clinical Trials

Ms. Goldfarb will discuss strategies utilized by the centralized staffing core at a pediatric institution to successfully manage coordinator time and effort, while recovering upwards of 100% of the true cost for coordinator services. This discussion will

Track 4 / Finance & Billing

focus on the model created and employed by the staffing core to successfully manage coordinator time and effort, including how to create a proactive staffing plan, monitor your progress, and make adjustments throughout the life cycle of the clinical trial for best operational and financial outcomes. 423

Presenter: **Jennifer Goldfarb, MSN, CCRP, RN,** Senior Director Clinical Research Support Office
Children's Hospital of Philadelphia

Time: **1:40 to 2:25** Track: **Finance and Billing**

Increase Revenue By Billing Compliantly

This session will provide a broad overview of clinical trial billing compliance. Ms. Willenberg will review revenue cycle integrity and research administration to increase your research brand. 425

Presenter: **Kelly M. Willenberg, DBA, RN, CHRC, CHC, CCRP,** CEO
Kelly Willenberg LLC

Time: **2:30 to 3:15** Track: **Finance and Billing**

Charging Patients for Costs Associated with Clinical Trials and Expanded Access Uses: Understanding FDA Limitations and Requirements

FDA regulations impose strict limits on the circumstances in which a researcher can recover costs from a patient, as well as the types of costs that can be recovered. In addition, prior written authorization from FDA must be obtained for any cost recovery. Ms. Backfield will help researchers understand the key standards and procedures for patient cost recovery in the context of both clinical trials and expanded access usage. 427

Presenter: **Katlin Backfield, JD,** Attorney and Consultant
Backfield PLLC

Track 4 / Risk Management

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

The Latest Industry Pulse on Risk Based Monitoring

OmniComm represents the eClinical Forum, to review RBM member adoption levels and leading practices related to certain aspects of clinical risk-based planning, analytics, and data monitoring. 429

Presenter: **Abby Abraham, MPharm, PGDHHM,** Vice President eCF/OmniComm/Algorics

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

Chaos to Structure

The talk will focus on improving site efficiency by defining roles with respect to tasks involved in Clinical trials (Clinical Coordinating of studies , Regulatory affairs, REB and sponsor communication), creating processes for effective practices and using a systematic approach to conducting clinical trials. The information will be based on real life experience of a site which was in chaos and with continuous improvement approach of processes and systems was very efficient in conducting Phase 2 & 3 trials and was a highly sought out site by sponsors. 431

Presenter: **Sandhya Patel, BScN, BSc,** Consultant

Breakout Session Descriptions

Track 5 / Pediatric Research

Time: **8:30 to 9:15** Track: **Pediatric Research**

Initiating a Pediatric Research Program

Attendees will gather tactics and techniques to initiate pediatrics research within a private practice setting or within an academic center. Sometimes getting started with your first study is the biggest challenge. This presentation will help you initiate getting involved or becoming better known as a location for pediatric research. 517

Presenter: **Janelle Allen, BS, MS, CCRP,** Director, Clinical Research Operations, Quality & Education, I-ACT for Children

Time: **9:20 to 10:05** Track: **Pediatric Research**

Enrollment in Pediatric Research: What Works and What Does not Work

Dr. Waseem will discuss the challenges in pediatric research. How the enrollment is different from adult research and what techniques can be used to improve enrollment of children will be highlighted. 519

Presenter: **Muhammad Waseem, MD, MS, CCRP**
Attending Physician, Lincoln Medical & Mental Health Center

Time: **10:50 to 11:35** Track: **Pediatric Research**

The Importance of Affirmative Assent in Pediatric Clinical Trials

Children are considered vulnerable subjects and therefore entitled to added protection under federal regulations. This requires not only parental permission but affirmative assent of the child. Dr. Cataletto will discuss the developing capacity that occurs during childhood and the circumstances that affect enrollment in clinical trials. 521

Presenter: **Mary Cataletto, MD, MMM**
Professor of Clinical Pediatrics, NYU Winthrop Hospital

Time: **11:40 to 12:25** Track: **Pediatric Research**

Building Networks to Support Pediatric Research

Building networks and relationships is key to creating a robust, quality research program. This talk will focus on building and maintaining internal and external networks to support projects and overall objectives. 523

Presenter: **Emily Owens Pickle, BS, CCRP,** Pediatric Neuro-Oncology Coordinator, Orlando Health Inc. / Arnold Palmer Hospital

Time: **1:40 to 2:25** Track: **Pediatric Research**

Strategies for AE and SAE Tracking in Pediatric Clinical Trials

Effective monitoring and reporting of adverse events and serious adverse events is vital to ensuring participant safety. This presentation will share some practical strategies to accomplish this work in pediatric clinical trials, including how to prepare your source documents, how to effectively work with care teams, and how to ensure reporting requirements are met. 525

Presenter: **Amanda Galster, MPH, CCRP,** Clinical Research Program Director, University of Minnesota

Track 5 / Pediatric Research

Time: **2:30 to 3:15** Track: **Pediatric Research**

Managing Complex Pediatric Trials

Planning and managing early phase, experimental pediatric research studies requires a whole team approach. This presentation will discuss the challenges faced when undertaking feasibility assessments and accurately costing for the work to be undertaken. Ms. Hodson and Ms. Rowley will provide examples and tools to aid in planning these complex studies using a whole system approach to ensure patient safety, quality, and efficient allocation of resources. 527

Presenters: **Christy Rowley, BA, MSc,** Clinical Research Facility Operations Manager, Great Ormond Street Hospital for Children
Lorraine Hodsdon, BSc, MSc, RN, Head of Nursing Clinical Research, Great Ormond Street Hospital for Children

Track 5 / Integrative Medicine/CAM

Time: **3:45 to 4:30** Track: **Integrative Medicine / CAM**

Complementary and Alternative Therapies: Using Reporting Standards for Nonpharmacologic Trials to Explore Research Design Issues

This presentation will provide a brief overview of complementary and alternative medicine (CAM) and challenges encountered in designing clinical trials of these therapies. Differences between drug trials and CAM trials will be highlighted using reporting standards specific to non pharmacologic trials, which include additional elements to be considered when designing such studies. The focus will be on mind-body intervention studies, with examples drawn from meditation and yoga trials. A basic meditation technique will be presented, giving attendees an opportunity to gain direct experiential knowledge of a mind-body intervention used in clinical trials. 529

Presenter: **Terry Selfe, PhD, DC, PhD, CCRP,** Translational Research & Impact Librarian, University of Florida HSC

Time: **4:35 to 5:20** Track: **Integrative Medicine / CAM**

Ayurvedic Approach to Chronic Diseases

Dr. Bhargava will present an overview of the Ayurvedic principles of diagnosis and treatment. He will then share his experiences as a patient turned healer. Finally he will discuss the opportunities and challenges in integrative medicine research. 531

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

Track 6 / International Trials and ICH

Time: **8:30 to 9:15** Track: **International Trials and ICH**

Now It's Time for a Change - What You Should Know About the EU Regulation for Clinical Trials

It is important to know the new procedures associated with clinical trials in the EU-region. The current system for clinical trials in the EU will be shortly reviewed before the changes under the new Clinical Trial Regulation will be addressed. The new Regulation will change the way pharmaceutical companies handle clinical trials with sites located in the EU, and sponsors and investigators need to be prepared for it. 617

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

Time: **9:20 to 10:05** Track: **International Trials and ICH**

Challenges in Managing Clinical Trials in Asia

Escalating research costs and limited patient pools have forced biotech and pharmaceutical companies to seek out emerging markets in Asia. However, the successful implementation of clinical trials in Asia can be impeded by issues arising from managerial, ethical, clinical/scientific, and regulatory aspects, as well as physicians/investigators and research participants. This talk will focus on efficient trial management strategies from the Asian perspective, and how various stakeholders related to clinical research can take a proactive approach to shape the emerging markets in Asia and ride this changing wave of drug discovery. 619

Presenter: **Xinmei Shi, MS, CCRP,** Research Manager
National University Cancer Institute, Singapore

Time: **10:50 to 11:35** Track: **International Trials and ICH**

The History of Clinical Research in Jamaica West Indies and Nutraceutical Development Including Cannabinoid Therapy

This talk will review historical studies and therapeutic areas researched in Jamaica, the emergence of medical marijuana research in Jamaica, and operating a CRO in this new environment. 621

Presenter: **Francine Campbell-Hakim, BSc,** CEO/Founder
Caribbean Clinical Research Associates, Limited

Time: **11:40 to 12:25** Track: **International Trials and ICH**

Self-Medication - A Too Little Regarded Aspect in Medical Research?

Self-medication is a common form of healthcare practiced in most parts of the world. It can lead to waste of health resources, drug resistance and adverse reactions. The presentation focuses on a development of a calculation model and results of a study in which the model was applied to investigate the antibiotic self-medication rate in several geographical areas of a predefined country. 623

Presenter: **Dnyanesh Limaye, PhD, Mpharm, MS**
Professor and Scientist, University of Applied Sciences and Arts

Track 6 / IRB Issues - Solutions - Methods

Time: **1:40 to 2:25** Track: **IRB Issues - Solutions - Methods**

Establishing a High Quality Human Research Protection Program (HRPP): the AAHRPP Model

At the turn of the 21st century, it became apparent that the most effective way to help ensure research participant safety and welfare was through an over arching human research protection program (HRPP) dedicated to that mission. The Association for the Accreditation of Human Research Protection Programs (AAHRPP) accreditation provides an excellent model for achieving a robust HRPP. AAHRPP, Inc., founded by PRIM&R and six other research-focused organizations in 2001, is an international nonprofit organization that accredits high quality human subject protection programs. It provides peer-based, collaborative, collegial, and educational evaluations of HRPPs, based on applicable standards and elements. During this session, Ms. Summers and attendees will review the elements of a robust HRPP, review the process of achieving or maintaining AAHRPP accreditation, discuss AAHRPP's approach to cutting edge issues in the human research enterprise, and become familiar with AAHRPP staff and web resources available to all wishing to maintain or achieve a overarching system of human research protections. 625

Presenters:
Elyse Summers, JD, President and CEO, AAHRPP
Michelle Feige, MSW, Executive Vice President, AAHRPP

Time: **2:30 to 3:15** Track: **IRB Issues - Solutions - Methods**

Centralized IRB Review of Multi-Site Clinical Research. Do you have Single/Central IRB questions? Ask the panel of experts

The moderator will provide a brief overview of centralized IRB review of multisite clinical research. Each panelist will highlight their experience with IRB's of record. The moderator will entertain questions from the audience. 627

Moderator: Wendy Lloyd, BA, LPN, CCRP, Translational Research Navigator, Vanderbilt University Medical Center

Panelists:
Michelle Culp, BSN, MPH, CCRP, Vice President for Research People-Centered Research Foundation
Rebecca Abel, MA, CIP, Regulatory Manager
Vanderbilt Ingram Cancer Center
Debra Cunningham, ASN, CCRP, RN, Research Nurse
Dayton Children's Hospital
Megan Singleton, JD, Associate Director od Eduaction and Training, University of Pennsylvania
Jennifer Beadles, MEd, CIP, Single IRB Operations Manager
VUMC Human Research Protections Program
Michelle Feige, MSW, Executive Vice President, AAHRPP

Breakout Session Descriptions

Track 6 / Ethics in Research

Time: **3:45 to 4:30** Track: **Ethics in Research**

Ethical Considerations in the Genetic Testing of Human Research Subjects

Understanding how genetic factors and the variability in the human genome impact an individual and community's health has the potential to shape the future of health care and how we approach medicine. However, because genetic research identifies specific information about an individual, there are ethical issues that go beyond the potential population health benefit. Dr. Teeple will highlight some of the ethical issues related to genetic testing of human subjects including informed consent, data storing and sharing, privacy and confidentiality, and payment and commercialization. Attendees will gain an understanding of the current regulatory environment and potential future implications of genetic testing in human subject. 629

Presenter: **Wrenda Teeple, PharmD,** Senior Regulatory Affairs Specialist, Arbit Consulting LLC

Time: **4:35 to 5:20** Track: **Ethics in Research**

Human Experimentation in the United States: Before, During and After the Beecher Article - Are We Learning From Our Mistakes?

In June of 1966, Dr. Henry Beecher, an anesthesiologist at Harvard Medical School, published the landmark article entitled "Ethics and Clinical Research" in the New England Journal of Medicine. The article highlighted 22 examples of unethical human experimentation and led to the development of the early iterations of federal regulations currently used to govern human subjects research. Although, these regulations were clear in describing expectations for research, it is less clear how the regulations have actually affected the conduct of human subjects research. Dr. Byrdsong will chronicle the history of human subjects research in the United States and inspect the current state of human subjects research over 50 years after the Beecher article. 631

Presenter: **Quincy Byrdsong, EdD, CCRP, CIP**
Executive Director for Research Administration
WellStar Health System/WellStar Research Institute

Track 7 / Advanced Management

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

Optimizing Investigational Pharmacy Operations in Support of Clinical Trials

Dr. Parr will provide a review of workflows leading to efficient and safe processing of investigational drug orders; strategies to establish synergy between research coordinators, study teams, and pharmacy; and establishing productive pharmacy-sponsor relationships. 717

Presenter: **Douglas Parr, PharmD,** Clinical Pharmacist Lead
Dartmouth-Hitchcock Medical Center

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

Investigator Responsibilities - Explaining FDA's Guidance Document

Investigator responsibilities (21 CFR 312.60) are some of the most important obligations in a clinical trial. The FDA's guidance document will be reviewed and expanded with examples of what study related tasks can be delegated, what constitutes adequate training, what constitutes adequate supervision, and responsibilities for oversight of the study team. This is done in the name of protecting the rights, safety, and welfare of the study subjects. 719

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

Track 7 / Advanced Management

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

Single and Central IRB Review - Helpful Hints for Coordinators

What information does a single or central IRB need to conduct its review? How can the study materials accurately capture the information for an IRB committee? How can teams operationalize single IRB review for study coordination? Ms. Abel will address single and central IRB review in terms of what a study coordinator needs to know to submit and manage a study for single or central IRB review. 721

Presenter: **Rebecca Abel, MA, CIP,** Regulatory Manager
Vanderbilt Ingram Cancer Center

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

Human-Centered Design in Clinical Trial Operations: Setting Your Team Up for Success

Solutions to challenges in clinical research operations must be business viable, technology feasible, and humanly desirable to create real and lasting impact. Using Human-Centered Design (HCD) in clinical trial operations engages the team at the heart of operations to come up with a range of solutions to the challenges they face each day. Sponsors, CROs and sites already use HCD to recruit and retain subjects in their trials by researching population characteristics to inform trial design and marketing campaigns and fully informed consent to be sure subjects are engaged and understand how to participate successfully in the trial. Using HCD in clinical operations would increase job-ownership and satisfaction, decrease turn-over and training costs, decrease start-up and enrollment periods, and decrease team performance redundancies. This could change the tide for many clinical trial organizations. The people who face the operational challenges hold the key to the answer. 723

Presenter: **Heather Baldwin, MPH, CM,** Principal Consultant
Frog bottom Consulting, LLC

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

Fraud, Waste, and Abuse in Clinical Research and the False Claims Act

The federal and state False Claims Acts (or Whistleblower Acts) play an important role in detecting fraud, waste and abuse. A person who "knows" of fraud, waste, or abuse being committed against the government can file a lawsuit on behalf of the government and, in some cases, receive a reward for bringing original information about a violation to the government's attention. Because of the importance of the False Claims Acts in clinical research, this presentation will provide a primer on the False Claims Acts, address fraud enforcement trends and the various "hot button" issues in clinical research. The presentation will also discuss how non-compliance compromises not only the financial and operational viability of current trials, but may result in (1) a loss of funding, (2) a risk of fines and penalties imposed by oversight agencies, (3) settlement costs and/or damages arising from actions, and (4) diminution of the organization's reputation. 725

Presenter: **Shauna Itri, JD, MA, BS,** Attorney
Berger & Montague PC

Track 7 / Advanced Management

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

Improved Site Management Through the Lens of Training and Education

This presentation will describe the role of education and training to improve site management and overcome barriers to clinical research at an urban academic medical center. Ms. O'Malley will present methods to improve compliance, support clinical research personnel in their roles, and increase retention of effective clinical research staff. There will be a discussion of tips and tools to define processes, improve access to required systems, and optimize online resources. 727

Presenter: **Kathleen O'Malley, BSN, RN, CCRP,** Manager of Education and Training, Jefferson Clinical Research Institute

Track 7 / Adverse Event Reporting

Time: **3:45 to 4:30** Track: **Adverse Event Reporting**

Operationalizing the Serious Adverse Event Process

Are you capturing the SAEs at your site? At our site, we have developed the policies and flow for serious adverse events - from clinical, billing, accounting, and budgeting capture! Join Ms. Popp to learn how to operationalize SAEs at your own site. 729

Presenter: **Tracy Popp, MBA, CRCP, CCRP,** Director Research Financial Operations, Norton Healthcare, Inc.

Time: **4:35 to 5:20** Track: **Adverse Event Reporting**

Adverse Event Reporting

Presenter: **TBD**

Track 8 / Site Management

Time: **8:30 to 9:15** 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, PI oversight, protocol violations, and adverse events through use of adequate source. Tools will be provided. 817

Presenter: **Janet Ellen Holwell, BA, CCRC, CCRA, TIACR, FACRP,** Clinical Research Consultant

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

5 Key Strategic Decisions for Research Sites

The business of clinical research has changed over the past 10 years. Mr. Snyder will examine the top 5 most important strategic and tactical decisions that apply to every site. Participants will review new approaches that are key to all successful sites. 819

Presenter: **Andrew Snyder, MBA, PMP, CRCP,** Director, Clinical Trials Office, HealthEast Medical Research Institute

Track 8 / Project Management

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

Project Management: Introduction to Tools and Templates

Project management involves many complex components and moving parts. Prior to initiating a trial, various types of project tools and templates can be used to successfully plan and execute a clinical trial. During the presentation, Mrs. Harris will demonstrate tools readily available for project management including Microsoft Excel, Access, Visio, Outlook, and SharePoint, as well as web-based applications. Monitoring progress through various tracking mechanisms ensures successful clinical trial execution from recruitment through retention and follow up. 821

Presenter: **Melissa Harris, BS, MPA, CCRP**
Director of Interventional Resources
Pennington Biomedical Research Center

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

Committee Project Management

Ms. Houser will discuss strategies for successfully implementing and managing committees involved in clinical trials. Committees include: Executive/Steering, Data and Safety Monitoring Boards (DSMBs), National Lead Investigators (NLIs), and Clinical Endpoint Committees (CECs). There will be additional discussion on meeting efficiency, philosophy of the committee purpose, pitfalls and opportunities, and selecting face to face vs. web based meeting formats. 823

Presenter: **Stacey Houser, BA, CCRP**
Committees Operations Manager II, CPC Clinical Research

Track 8 Investigator-Initiated Research

Time: **1:40 to 2:25** Track: **Investigator-Initiated Research**

So Your Investigator Wants to Run a Multi-Site Investigator-Initiated Research Study?

Investigator-initiated trials are a central part of clinical research, but opening these types of trials at other sites comes with its own set of challenges… and headaches! This talk will address points to consider, responsibilities, and logistical tips to best support your investigator's ambitions. include: trial funding, vetting the other institutions, study trial master file, drug supply, site initiation vists (SIVs), subject registration, adverse event/serious adverse event (AE/SAE) reporting, onsite monitoring versus remote, electronic data capture (EDC), etc. 825

Presenter: **Christine Jerome, BS, CCRP,** Director
QA & Process Improvement Unit
Sidney Kimmel Cancer Ctr at Jefferson

Time: **2:30 to 3:15** Track: **Investigator-Initiated Research**

How to Prepare for an FDA Audit

The presentation is geared towards CRCs and PIs of FDA-regulated Investigator-Initiated clinical trials. Dr. Eder will provide an introduction to the FDA Bioresearch Monitoring Program and describe when an FDA inspection is likely to be scheduled. The talk will include the steps of an FDA inspection, expand on what the FDA inspector is evaluating based on the investigator's responsibilities per 21 CFR 312.60 and Form FDA 1572. 827

Presenter: **Astrid Eder, PhD, CCRP, CIP,** Clinical Research & Regulatory Specialist II, Children's Hospital Colorado

Closing Plenary

Time: **8:40 to 9:25** Track: **Closing Plenary**

Lessons Learned: A Review of Common GCP Deficiencies and Examination of Warning Letters Issued to Clinical Investigator Sites

Ms. Wright will review commonly cited deficiencies in clinical investigator inspections, using examples drawn from recent Warning Letters issued to clinical investigators. The session will focus on lessons learn and allow attendees to learn from others' mistakes. 901

Presenter: **Barbara Wright, BGS,** Bioresearch Monitoring Specialist, Food and Drug Administration

Time: **9:25 to 10:10** Track: **Closing Plenary**

Implementing the Changes to the Common Rule

Significant revisions to the Common Rule took effect January, 2017. The target audience for this presentation is individuals who are at research sites that conduct federally funded research. There have been several presentations discussing the changes to the Common Rule. This discussion will differ in that Ms. Gates will present actions needed to implement the changes at a research site and institutional review board. 903

Presenter: **Cynthia Gates, JD, ADN, CCRP, CIP,** Director, IRB Administration, University of California, Davis

Time: **10:30 to 11:00** Track: **Closing Plenary**

Learning Compliance From Living It - What I Discovered When My Husband Died

This session will cover what I learned from my husband dying in 2017. I learned a great deal from organ donation, donating tissue for research, and being on the receiving end of healthcare. After 30 years in research, I learned what you need to be aware of on the front line, taking into account privacy, HIPAA, and compliance needs when people die during your care. 904

Presenter: **Kelly Willenberg, DBA, RN, CHRC, CHC, CCRP,** CEO, Kelly Willenberg LLC

Time: **11: 00 to 11:30** Track: **Closing Plenary**

Clinical Trial Recruiting - A Partnership Between Site and Sponsor

Clinical trials are daunting no matter the age of the patient, but they are critical to advance treatments. How do you communicate that importance? How do you connect with patients that may not see the traditional advertisements? How do you overcome the fear factor? Ms. Damji will cover these topics and discuss how sites and sponsors can work together to positively drive patient recruitment. 905

Presenter: **Jzaneen Lalani, JD,** Chief Operating Officer, Curemark, LLC

Time: **11:30 to 12:00** Track: **Closing Plenary**

eConsent and eSource - The Revolution is Here: Now What?

Dr. Khan will define eConsent and eSource and review their variations as well as the history of regulatory guidance and adoption challenges over the past 15 years. Why we are seeing adoption improve with both sponsors and sites will be explored. The talk will discuss ways to optimize adoption of eConsent while maintaining a focus on compliance. 906

Presenter: **Irfan Khan, MD, FACC, FHRS,** Founder, Chief Strategy Officer, Circuit Clinical