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.

Presenter: Jeromy Sugarman, MD, MPH, MA, Professor of Bioethics and Medicine, Johns Hopkins University

Time: 10:30 to 11:15

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.

Presenter: Tammy Neseth, MHA, CCRP, Operations Manager, Mayo Clinic Integrity and Compliance Office

Time: 9:15 to 10:00

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.

Presenter: Tammy Neseth, MHA, CCRP, Operations Manager, Mayo Clinic Integrity and Compliance Office

Time: 9:15 to 10:00

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.

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

Time: 11:15 to 12:00

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, risk, 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.

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

Time: 1:15 to 2:00

Compliance / Noncompliance, 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. Porter will share auditing plans and techniques to address the challenges of IITs.

Presenter: Wendy Portier, MSN, RN, CHRC, CHC, Consultant

Time: 2:05 to 2:50
**Track 2 / 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: 1:15 to 2:00

**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: 2:05 to 2:50

**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
Clqi Solutions, LLC

Time: 3:25 to 4:10

**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

Time: 4:15 to 5:00

---

**Track 3 / 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: 1:15 to 2:00

**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 has 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: 2:05 to 2:50

**Methods 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: 1:15 to 2:00

**Methods 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

---

**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

Time: 3:25 to 4:10

**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: 3:25 to 4:10

**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

Time: 4:15 to 5:00

---
**Breakout Session Descriptions**

**Track 4  Oncology Research**

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

**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.

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

**Time: 2:05 to 2:50**

**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.

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

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

**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.

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

**Track 5  Training**

**Time: 2:05 to 2:50**

**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.

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

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

**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.

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

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

**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.

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

**Track 6  Therapeutic Areas in Research**

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

**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.

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

**Track 5  Training**

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

**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.

**Presenter:** Melissa McLennon, MPH Monitoring & Compliance Officer, Memorial Healthcare System
Lessons Learned from Research Misconduct Cases

John Kessler, BS Pharm, PharmD, Presenter:

Dr. Kessler will review the strategies that have made clinical research more effective tools 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: 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: 2:05 to 2:50 Track: Responsible Conduct of Research
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

Time: 2:05 to 2:50 Track: Responsible Conduct of Research
Understanding Research Wrongdoing: Lessons from the PI Program and PSI Lab

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: 2:05 to 2:50 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

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: 2:05 to 2:50 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

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: 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
Track 8 / Monitoring

Time: 2:05 to 2:50

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

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

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

Track 1 / Poster Session

Time: 8:30 to 10:05

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 / Poster Session

Time: 1:40 to 2:25

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

Track 1 / Behavioral Health

Time: 10:50 to 11:35

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

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: 11:40 to 12:25

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

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

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

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: 10:50 to 11:35

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

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

Time: 1:40 to 2:25

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

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

Time: 3:45 to 4:30

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
**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 Trial 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 / 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: 4:35 to 5:20**  
**Track: Finance and 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.**

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/Algorkics

**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
**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 pediatric 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 / Integrative Medicine/CAM**

**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

---

**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 Selte, 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 overarching 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
4:35 to 5:20

**Track 6 / 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.

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

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

**Track 7 / 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. The people who face the operational challenges hold the key to the answer. 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 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 set the agenda.

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

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

---

**Track 6 / Ethics in Research**

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

**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 been used. 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.

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

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

---

**Track 7 / 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.

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

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

---

**Track 6 / Ethics in Research**

**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. Setting Your Team Up for Success will show how to use HCD to improve the recruitment, retention, and operational success of your projects.

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

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

---

**Track 7 / Advanced Management**

**Using Human-Centered Design in Clinical Trial Operations:**

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. Setting Your Team Up for Success will show how to use HCD to improve the recruitment, retention, and operational success of your projects.

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

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

---

**Track 6 / Ethics in Research**

**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.

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

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

---

**Track 7 / 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.

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

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

---

**Track 6 / Ethics in Research**

**Designer of the Human Experiments - Dr. Henry Beecher**

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 been used. 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.

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

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


---

**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 / Project Management**

**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, CRCP, CIP, Clinical Research & Regulatory Specialist II, Children’s Hospital Colorado
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 learned and allow attendees to learn from others' mistakes. 901
Presenter: Barbara Wright, BGS, Bioresearch Monitoring Specialist, Food and Drug Administration

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

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

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

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