**Breakout Session Descriptions**

**Friday, October 6, 2017**

**TRACK 1**  
**Quality Management**  
Location: Yucatan Ballroom  
Moderator: Sandhya Patel

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

Leaving the Past in the Past: Analyzing Common FDA Findings to Build Quality into Current Clinical Study Management

Dr. Mansfield will discuss common FDA and clinical audit findings and what these findings mean. Dr. Mansfield will also present common practices to help avoid common issues.¹⁰⁹

Presenter: **Bryce Mansfield, PhD**, Associate Director, Gilead Sciences

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

The Evolution of a Quality Assurance Program for Clinical Research at an Academic Research Hospital

Ms. Filice will discuss institutional activities aimed to establish and maintain quality assurance (QA) and regulatory compliance in the conduct of clinical research at and on behalf of an academic research hospital. The presentation will examine changes in the regulatory landscape in Canada and their impact to the institution’s QA program. Ms. Filice will provide the audience with strategies for program development and sustainability, including a risk-based approach for implementation that is driven by an analysis of trends used to mitigate both institutional and study participant risks.¹¹¹

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

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

Hands On Quality: Implementing a QA Knowledge Transfer Program on an Institutional Level

Ms. Li will discuss the idea and implementation of an initiative to promote quality in clinical research conduct. In the ‘Hands On Quality’ program, clinical research staff from across the institution were invited to take part in conducting a real-life quality assurance (QA) review to learn the QA methodology and transfer their learning back to their home departments. Ms. Li will share her experience in leading this initiative, areas of success, lessons learned, and future planning.¹¹³

Presenter: **Jennifer Li, BSc, CCRP**, Quality Assurance Supervisor, Princess Margaret Cancer Centre

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

How to Ensure Trial Master File (TMF) Quality from Beginning to End

The FDA’s case for quality initiative has shown that companies who spend more time and money on improving product quality spend less time and money on remediation. Ms. Ehdaivand will discuss how this applies to the Trial Master File (TMF).¹¹⁵

Presenter: **Sholeh Ehdaivand, BA**, President and CEO, LMK Clinical Research Consulting LLC

**TRACK 2**  
**Monitoring**  
Location: Fiesta 5  
Moderator: Angela Rock

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

The Empathetic Monitor

Monitors often miss opportunities to understand site errors, performance issues, and other clinical study conduct issues by not listening to site challenges and observing site cues that may explain changes in performance. Additionally, monitors may routinely be seen as the “police” of the clinical trials process instead of a part of the trial team due to their necessary but often off-putting rigidity and curtness when presenting findings or recommendations. By doing this, both monitors and sites lose multiple opportunities to identify root causes of errors, implement tailored corrective action plans, and build beneficial relationships that will help decrease errors, improve performance, and create a more proactive dynamic between site staff and monitors.²⁰⁹

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

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

The Value of Centralized Monitoring

Regulatory agencies are advocating sponsors to take risk-based approaches in various clinical trial related activities especially in the area of monitoring. Sponsors are looking at and beginning to use “centralized monitoring”. Learn what this means and entails to enhance data quality on clinical trials.²¹¹

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

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

Beyond Sampling - Risk-Based Quality Auditing

Ms. Dilis will focus on the process and methodology for establishing a data-driven Risk-Based Quality Auditing (RBQA) program at sponsors and CROs. The benefits of the proactive RBQA versus the traditional reactive approach to QA auditing will be discussed. A case study will be presented.²¹³

Presenter: **Alexandra Dilis, JD**, Executive VP of Quality and Compliance, SFJ Pharmaceuticals Group

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

Remote Monitoring: Here and Now

Remote monitoring is no longer a futuristic idea, it is a current necessity. Medical facilities are now required to use an electronic medical records system. Most research studies use electronic data capture/remote data capture systems now instead of the paper case report forms. With many electronic medical record systems, sponsors now have the ability to monitor studies remotely. Sites’ IT departments assign ID/passwords and a link to the monitor and give monitors read-access only to a cohort of study patient records. The cohort of patients is requested by the coordinator, and with the link/ID/password can be monitored without the field-CRA having to travel to the site. Remote monitoring decreases travel costs for the sponsor, and assists the sites by not having to keep office space available for field monitors. Remote monitoring can also be done by in-house CRAs so that adverse events may be reviewed more quickly as well. Remote monitoring is time saving and cost effective.²¹⁵

Presenter: **Kristi Pinkston, BS, MA,RN, CCRP**, Senior Field Clinical Research Associate, Abbott
Breakout Session Descriptions

Friday, October 6, 2017

**TRACK 3**
**Adverse Event Reporting**
Location: Fiesta 6
Moderator: Patricia Beers Block

Time: 1:15 to 2:00  Track: Adverse Event Reporting

**Adverse Drug Events - What They Are and Are Not**

All drugs have the potential to cause adverse events. During clinical trials an adverse event must be differentiated from an adverse disease symptom. Dr. Arbit will discuss the various definitions describing adverse events; the time frames for reporting; what information must be reported to the FDA, the IRB, and study participants; and who is responsible for the reporting. 309

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

Time: 2:05 to 2:50  Track: Adverse Event Reporting

**AE/SAE Reporting - Best Practice to Improve Regulatory Compliance**

Mr. Furlong will discuss best practice guidelines to improve regulatory compliance and streamline reporting activities. He will use the successful assessment of subjects for the occurrence of adverse events. 311

Presenter: John Furlong, RN, CCRP, Senior Field Clinical Research Associate, Abbott

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**TRACK 4**
**Training**
Location: Fiesta 7-10
Moderator: Anatoly Gorkun

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

**The Training Cycle: From Theory to Practice**

The purpose of this session is to provide a simple but effective practical overview of the training cycle for clinical research professionals who need to operate in complex training environments. This will include analyzing the training needs, designing, developing, implementing, and evaluating effectiveness of the training solutions. 409

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

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

**Integrating Standardized Patients into IRB and Clinical Research Training**

This session will focus on the divide between classroom learning and the real-life challenges of the informed consent encounter. Standardized patient simulations have been utilized in medical education with excellent results but are less frequently employed in researcher and IRB training. Benefits and challenges will be discussed as well as implementation strategies. Participants will have the opportunity to experience working with short video vignettes of standardized patient simulations to gain a better understanding of the interactive component of the training experience. 411

Presenter: Mary Cataletto, MD, MMM, Institutional Review Board Member, Winthrop University Hospital

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

**The Importance of Mentoring - Connecting the Dots**

This session will provide learners with a comprehensive overview of various mentoring models for clinical research coordinators that can be utilized to enhance outcomes for conducting clinical research studies. The CRC is a vital component of ensuring protection of human subjects, conducting meaningful research, and mitigating risk. It is imperative that the CRC is knowledgeable, efficient, confident, and has access to the appropriate resources when conducting research. Ms. Smith will “connect the dots” between the importance of implementing a mentoring process for clinical research coordinators and successful research outcomes. 413

Presenter: Melinda Smith, BSN, RN, CCRC, Clinical Research Coordinator-RN, Nationwide Children’s Hospital

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

**Managing Up in the Clinical Arena**

The relationship with your boss and those “above you” is one of the most important in the workplace; a relationship that influences every aspect of your professional development, progression, success, and satisfaction. This highly interactive presentation explores the diverse aspects of this critical relationship including style, timing, context, urgency, and expectations. 414

Presenter: Barbara van der Schalie, MS, Clinical Research Coordinator-RN, Nationwide Children’s Hospital

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**TRACK 3**
**Data Management / EDC**
Location: Fiesta 6
Moderator: Patricia Beers Block

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

**Practical Strategies for Managing Electronic Clinical Data**

Managing clinical data from multiple sources can be a daunting task. It is important to identify and understand the challenges related to the generation, transmission, and parsing of clinical data that stream from multiple and frequently remote locations and stakeholders. Ms. Beers Block will address these challenges as well as strategic methods for ensuring data compatibility, regulatory compliance, and data quality parameters are met. 313

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

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

**Considerations When Implementing e-Consent**

Investigative sites are the linchpins in the adoption of e-consent. This presentation will present an overview of FDA guidelines to e-consent together with e-consent components that address the guidelines. Investigators reported that the helpful characteristics of e-consent include version tracking, electronic handwritten signatures, and availability on a tablet device. Experience shows that regardless of perceptions of benefits from e-consent, the importance of site preparation and attention to the needs of the site staff cannot be overlooked. Dr. Brink will provide lessons learned through implementation of e-consent at clinical sites for numerous clinical trials. Specific examples of actions that can be taken to aid sites during initial stages of adoption will be shared. 315

Presenter: Susan Brink, DrPH, MSHA, Strategic Advisor, DrugDev Patient Solutions

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Presenter: Susan Brink, DrPH, MSHA, Strategic Advisor, DrugDev Patient Solutions
This presentation is designed for those unfamiliar with the Medical Safety Role: A Device Sponsor’s Perspective.

CEO, Frestedt Inc

We’ll request “so much information” related to Adverse Events. We’ll discuss roles and responsibilities of the Medical Safety team as they apply to clinical research, review and assessment of Adverse Events, and interaction with cross-functional partners.

513

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

Comparing ICH E6 and ISO 14155 for Drug and Device Clinical Trials

Dr. Frestedt will review the international pharma GCP standard ICH E6 (R2) for clinical trials and the medical device international GCP standard for clinical trials (ISO14155). Audience participation will be solicited to see how these standards are working today in the field.

510

Presenter: Erika Stevens, MA, BA, Vice President of Research, Northwell Health

Device Research

Location: Coronado A-C

Moderator: Kathi Durdon

Time: 1:15 to 2:00

Research Administration Operational Transformation: People, Process and Technology

This session describes research administration operational transformation. Reviewing organizational capabilities and streamlining multiple systems and workflows throughout research administration expedites performance. Identifying key stakeholders fosters champions for change and eliminates roadblocks for implementation success. Building a detailed roadmap for implementation to include milestones provides organizations with transformation success. This step-by-step session analyzes processes for effective transformation of research administration to include people, process and technology.

510

Presenter: Tina Noonan, MBA, CHRC, CIP, Executive Director of Research, St. Vincent Health

Time: 2:05 to 2:50

Device Research

Time: 3:25 to 4:10

Medical Safety Role: A Device Sponsor’s Perspective

This presentation is designed for those unfamiliar with the Medical Safety Analyst role and who want to understand why sponsors request “so much information” related to Adverse Events. We’ll discuss roles and responsibilities of the Medical Safety team as they apply to clinical research, review and assessment of Adverse Events, and interaction with cross-functional partners.

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Presenter: Cheryl Eichenauer, BS, MS, RN, CCRA, CCRP, Principal Medical Safety Analyst, Boston Scientific CRM

Time: 4:15 to 5:00

Device Research

Time: 3:25 to 4:10

Medical Device Case Study: Lessons Learned

This presentation will be an interactive session discussing aspects of medical device investigational studies, applications, and lessons learned. Topics will include IDE, PMAs, and GCP and compliance strategies.

515

Presenter: Donna Headlee, BSN, RN, CCRP, Branch Chief Premarket Programs Branch

Drug Development

Location: Coronado D-G

Moderator: Jamie Harper

Time: 1:15 to 2:00

Sponsor Readiness for an FDA Inspection

The participants will learn how to interact with FDA inspectors and how to prepare their study documents when they are selected for an audit. They will learn their responsibilities and commitments. Additionally, Mr. Rashti will explain the most common deficiencies observed during FDA audits, how to avoid them, and how to be in compliance with the GCP regulations. 610

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

Time: 2:05 to 2:50

Drug Development

Ethics in Research

Location: Coronado D-G

Moderator: Jamie Harper

Time: 3:25 to 4:10

Ethics of Open Label Extension Trials

Open Label Extension Trials are often used after a Phase III randomized controlled investigative drug study. Ethical issues arise when the option to be a part of the open label extension influences the subject’s decision to enter the main trial. Informed consent is compromised when participants do not know which arm (placebo or active drug) of the main trial they were enrolled in before starting the extension phase.

613

Presenter: Margaret McCormick, MS, RN, CNE, Clinical Associate Professor, Towson University

Time: 4:15 to 5:00

Ethics in Research

Emphasis on Protection: Beyond the Regulations

On August 20, 1947, the judges delivered their verdict of guilty in the “Doctors’ Trial” against 23 physician-scientists for war crimes committed in Germany. These war crimes involved human experimentation in concentration camps and the details of the verdict and associated descriptions of permissible medical experiments became known as the Nuremburg Code. Since the Nuremburg Code, human experimentation has become increasingly more regulated. These regulations have become more sophisticated and cover virtually every scenario, but have resulted in a dependence on regulation and a reduced focus on human protection. This talk will engage the attendees in a thoughtful discussion on how we renew our emphasis on protection beyond the regulations.

615

Presenter: Quincy Byrdsong, EdD, CIM, CIP, CCRP, VP for Academic Planning & Strategic Initiatives, Augusta University

Ethics in Research

Location: Coronado D-G

Moderator: Jamie Harper

Time: 3:25 to 4:10

What is the Value of the Laboratory and Electrocardiogram Data Throughout the Drug Development Process in Subject Safety

With the increasing frequency of FDA audits and complexity of Investigational Medicinal Products (IMPs), the wise are paying more attention to including a full range of lab tests and cardiovascular testing to ensure investigational agent and therefore public safety.

Which lab values outside of the reference range are to be reported as AEs and the relationship of lab data to “Adverse Event” determination is the decision of the investigator guided by what is in the protocol. The section on “Safety Monitoring” includes the array of lab tests taken at prescribed intervals adjudged to answer safety questions. Whereas evaluation of this safety data is the investigator’s responsibility, the whole team and the sponsor must be on board.

Presenter: Charles Pierce, MD, PhD, FCP, CPI, Director, Pierce One Consulting

Time: 2:05 to 2:50

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Ethics in Research

Location: Coronado D-G

Moderator: Jamie Harper

Time: 3:25 to 4:10
The 2014 outbreak of Ebola virus disease (EVD) in West Africa was declared a public health emergency of international concern by the WHO, eventually claiming over 11,000 lives. The catastrophic mortality rates impelled Liberian and US scientists to rapidly initiate a Phase II/III randomized-controlled EVD vaccine trial. The Clinical Monitoring Research Program (CMRP) within Leidos Biomedical Research (LBR), Inc. was tasked to support NIAID’s Conduct of Ebola Emergency Protocols in West Africa, Integrated Project Management Approach in Facilitating the Conduct of Ebola Emergency Protocols in West Africa. CMRP has facilitated combining solid project management methodology with persistence in Liberia in only three months, despite the financial, political, and institutional setting where initiating a Phase II/III randomized-controlled EVD vaccine trial was declared a public health emergency of international concern by the WHO.

The project manager is often the primary point of contact for research studies for subjects, regulatory agencies and IRBs, funders, and project team members. However, many studies lack adequate planning and the development of a comprehensive communication strategy to address these audiences. Clear and comprehensive communication is a valuable tool for any project to run smoothly. A comprehensive communication strategy can provide information to research subjects, research sites and public inquiries. It can also be utilized to obtain feedback from stakeholders to help research projects to operate more efficiently. In addition, a communication plan includes developing a relationship with the media to promote funding awards, results reporting, and dissemination efforts. Ms. Holtz will provide session participants with tools to develop a communication plan for studies and sites.

PROJECT MANAGEMENT ROLE

All Other Duties as Assigned, Including Communications in the Project Management Role

Integrated Project Management Approach in Facilitating the Conduct of Ebola Emergency Protocols in West Africa

The 2014 outbreak of Ebola virus disease (EVD) in West Africa was declared a public health emergency of international concern by the WHO, eventually claiming over 11,000 lives. The catastrophic mortality rates impelled Liberian and US scientists to rapidly initiate clinical trials on experimental vaccine and treatment candidates. The Clinical Monitoring Research Program (CMRP) within Leidos Biomedical Research (LBR), Inc. was tasked to support NIAID’s Division of Clinical Research Emergency Ebola Response Initiatives. From concept to enrollment, CMRP was instrumental in initiating a Phase II/III randomized-controlled EVD vaccine trial in Liberia in only three months, despite the financial, political, and healthcare challenges posed by a national state of emergency. By combining solid project management methodology with persistence and partnership under aggressive timelines, CMRP has facilitated the conduct of six clinical studies in West Africa, including multiple studies of experimental EVD vaccine and treatment candidates and a natural history study.

Presenter: Laura Holtz, BS, CCRP, Senior Research Manager, IU Ctr for Aging Research, Regenstrief Institute

Time: 2:05 to 2:50
Track: Project Management

Risk Management

Navigating a Risk-Based Auditing Program

Monitors are a vital asset to the clinical trial, yet auditors tend to be forgotten until a notice arrives for a regulatory inspection. Some see auditing as an unnecessary burden or added expense to a clinical trial budget. This session will discuss the benefits of risk-based clinical trial auditing. Dr. Leister will review a risk-based audit strategy that has been successfully implemented for multiple clients and discuss how other organizations can do the same. How to make your clinical quality audits more effective and value added to both the organization and sponsor will also be discussed.

Presenter: Susan Leister, PhD, MBA, BS, CQA, CSSBB, Director of Quality Assurance, Technical Resources International, Inc.

Time: 3:25 to 4:10
Track: Risk Management

One Solution for Health Disparities

We Can Do It: Enrolling Women into Clinical Trials

All things considered, women’s role has been a little slow to infiltrate the medical world. In fact, until the 1990’s, women were underrepresented in Clinical Research. This talk will discuss the implications of gender disparity in clinical trials on current medical practice as well as common hurdles that can be overcome to increase female participation in clinical trials.

Presenter: Heather Caro, RN, CCRC, Nurse Educator, Quintiles

Time: 4:15 to 5:00
Track: Health Disparities

The Rise of Electronic Consent in the Information Age

According to the Pew Internet Project, 90% of American adults own a cell phone and 42% of American adults own a tablet computer as of January 2014. Sixty-four percent of American adults owned a smart phone in the same year, an increase from only 35% in 2011. Given this rise in use, mobile devices and smart phones are now being used much more frequently to consent research subjects. Dr. Young will go over the types of e-consent used, the challenges associated with e-consent, and how to work with the IRB in order to allow e-consent.

Presenter: Jonathan Young, PhD, CIP, CCRP, Senior IRB Consultant, Rush University Medical Center

Time: 4:15 to 5:00
Track: Risk Management

Case Studies in the Responsible Conduct of Research

Can Clinical Research Learn from the Patient Safety Movement?

Since 1999, the patient safety movement in the USA has made important advances in preventing patient harm by learning from its mistakes, identifying the quality gap between best practices and care as it is commonly given, and developing structured systems that track and analyze risk, harm and potential harm. Dr. Kessler will identify lessons from these reports that could be applied to the responsible conduct of research.

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

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

Health Disparities

One Solution for Health Disparities

People of underserved populations may hesitate to enroll in clinical research for a variety of cultural and historical reasons. However, a community-based approach to understanding and engaging with underserved populations can improve the quality of all research engagement. Ms. Simpson will discuss a case study of an urban Native American health clinic with an emphasis on community-based participatory research and research principles as they present one path to advocating for, and engaging with persons who are underserved in research.

Presenter: Rachel Simpson, MA, CCRP, Coordinator, Medicine Office of Research, National Jewish Health

Time: 3:25 to 4:10
Track: Health Disparities

Responsible Conduct of Research

Track: Risk Management

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Presenter: Jonathan Young, PhD, CIP, CCRP, Senior IRB Consultant, Rush University Medical Center

Time: 4:15 to 5:00
Track: Risk Management

Case Studies in the Responsible Conduct of Research

Dr. Kessler will use case studies and lessons learned to discuss research integrity and the consequences of a scientific enterprise that relies solely on a “self-correcting” model of peer review and independent validation of results. This session will focus on remediation not only of individual issues but also of factors in the institutional setting where unethical or questionable practice or misconduct may have been facilitated or gone undetected will be discussed.

Presenter: Donna Kessler, PhD, Research Integrity Officer and Chair, IRB, Duke University School of Medicine

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

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Breakout Session Descriptions

**TRACK 1**

**Poster Session**

**Location:** Yucatan Ballroom

**Moderators:** Bryce Warren and Joanne Goldberg

**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.117-119

Presenter: Joanne Goldberg, MSc, CCRP, Assistant Director, CIHR Institute of Aging

Presenter: Bryce Warren, PhD, Chairman, L. H. Warren Foundation for Science

**Track:** Pediatric Research

**Location:** Yucatan Ballroom

**Moderator:** Susan Devine

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

**Track:** Pediatric Research

**Regulatory Aspects of Inclusion of Children in Research**

Ms. Devine will review current rules and regulations pertaining to pediatric populations and research. Discussion will include when children may be included in research, consent/assent requirements, age of majority, and re-consent.121

Presenter: Susan Devine, CCRP, Research Consultant

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

**Track:** Pediatric Research

**Pathways for Medical Devices in Pediatrics**

The FDA regulations for medical devices are complex, and the appropriate pathways for unapproved pediatric devices is not always clear. Ms. Galster will review regulations 21 CFR 812 (IDEs) and 21 CFR 814 Subpart H (HDEs/HUDs), as well as the FDA Guidance for Expanded Access to Unapproved Devices. The presentation will conclude with some practical tips for managing typical pediatric scenarios that have been seen.123

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

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

**Track:** Pediatric Research

**Pediatric Clinical Trial Toolbox**

The time between study commitment and open to accrual is critical for being prepared to adequately conduct and monitor a study. Both general and study-specific tools help us construct the pieces of our research study. Ms. Owens Pickle will share personal experiences, case studies, and tools created that have resulted in higher quality research work. The talk will focus on all pediatric specialties.125

Presenter: Emily Owens Pickle, BS, CCRP, Pediatric Neuro-Oncology Coordinator, Orlando Health Inc

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

**Track:** Pediatric Research

**Pediatric Emergency Medicine and Barriers to Enrollment: What Makes it so Unique?**

Emergency medicine research recruitment and follow-up is a unique department in which to conduct clinical trials. Almost all ED studies have a short enrollment time, and there can often be many barriers to enrolling subjects. Ms. Runyan will discuss some barriers that a study can encounter and how to prepare for them.127

Presenter: Chasity Runyan, CCRP, Clinical Trials Coordinator, Children’s Mercy Hospital

**Track:** Advanced Management

**Location:** Fiesta 5

**Moderator:** Lisa Benson

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

**Track:** Advanced Management

**Responsible of an IND Sponsor-Investigator**

Mr. Jarrell will provide attendees with an overview of how one compiles, submits, and conducts (in a regulatory-compliant fashion) a sponsor-investigator IND trial.217

Presenter: T. Che Jarrell, BPhS, MIPI, RAC, Proprietor & Principal Consultant, Milestone Regulatory Experts, LLC

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

**Track:** Advanced Management

**How to Lead a Team**

This presentation will discuss how to lead a team of CRAs, research coordinators, and research personnel. Dr. Mohammad will give insight and personal experience of leading a research team of 20+ personnel to conduct global studies and help research staff across more then 50 sites be successful.219

Presenter: Atif Mohammad, MD, Clinical Trial Manager, PPD

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

**Track:** Advanced Management

**Understanding the Challenges of Conducting Clinical Trials in Rare Diseases**

Mr. Ksiazek will detail some of the major challenges in rare disease research and how one could mitigate these circumstances. Mr. Ksiazek will give real life examples and experiences and will also discuss the importance of rare disease research in the world today.221

Presenter: Adam Ksiazek, CCRP, Manager, Clinical Operations, Alexion Pharmaceuticals, Inc.
Breakout Session Descriptions

Tracker 2: Advanced Management
Location: Fiesta 5
Moderator: Susan Corl

Time: 11:40 to 12:25

Protecting Patient Data in Rare Disease Clinical Studies - Challenges and Special Considerations

The presentation will highlight potential challenges encountered in the protection of subject data in rare disease populations. Challenges with de-identification of rare disease patient data will be presented.

Presenter: Gloria Miller, BS, RAC-US, CQA-ASQ, Associate Director, US QARC, Premier Research

Time: 1:40 to 2:25

The Overlooked Price We Pay for Using Paper in Clinical Research

Despite the availability of advanced electronic information systems, paper is still primary source for data management. This can significantly impact research budgets, time, space, personnel and the natural environment. We attempted to assess the volume, costs and environmental impact of using paper in clinical stroke research at the Ottawa Hospital Research Institute (OHRI) between 2011 and 2016.

Presenter: Rany Shamloul, PhD, MBBC, MBA, CCRP, Senior Clinical Research Associate, Ottawa Hospital Research Institute

Time: 2:30 to 3:15

Living on the Edge (of Research) – One Center’s Experience with Expanded Access and Other Specialty Programs

As researchers, we sometimes find ourselves responsible for managing projects that are not, strictly speaking, research. Our approach to establishing and managing programs that fall under the umbrellas of Expanded Access, enforcement discretion, and other innovative activities that bridge the gap between routine clinical care and research must necessarily differ from our usual approach to new projects. Mr. Smith will discuss one site’s experience navigating the regulatory environment surrounding these activities, review lessons learned in their implementation, and provide information about how— and why—to get started in this important field.

Presenter: Kevin Smith, MS, MBA, CCRP, Research Program Manager, Cleveland Clinic

Tracker 3: Canadian Regs / Inspections
Location: Fiesta 6
Moderator: Helen Darwin

Time: 8:30 to 9:15

Research-Related Injury: A Hypothetical Case Study

This presentation will use a fictional case study involving injury to a research subject. It will involve a walk-through of the interplay between the liability, limitation of liability, insurance and other sections of a clinical trial agreement and how the case study would likely play out in court.

Presenter: Marlon Rajakaruna, BA, MBA, LLB, CRCP, Partner, Global & National Co-Leader of Life Sciences, Dentons

Time: 9:20 to 10:05

Surviving and Thriving in a Regulatory Inspection: Lessons Learned

This presentation will discuss how internal quality risk management personnel can assist with preparing, facilitating, and supporting the investigative site before, during, and after a routine regulatory inspection. Ms. Marzinotto will discuss the development of effective corrective and preventative actions in response to regulatory inspection observations. The speaker will also outline best practices for the conduct of clinical trials to ensure research teams are always audit ready.

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

Time: 10:50 to 11:35

Navigating Canadian Medical Device Regulations

Mr. Bartekian will discuss the current regulations governing medical devices in Canada. How Health Canada is structured and the Investigational Testing Authorization (ITA) application and review process will also be presented along with the similarities and differences of ITA (device) versus CTA (drug) studies.

Presenter: Vatche Bartekian, BSc, MSc, President, Vantage BioTrials, Inc.

Time: 11:40 to 12:25

Health Canada’s Clinical Trial Compliance Program

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

Presenter: Chad Sheehy, ND, BSc, National Manager, Clinical Trial Compliance, Health Canada

Time: 1:40 to 2:25

Inspection Strategy for Clinical Trials Health Canada Guidelines

This presentation will promote awareness of Canadian regulatory requirements within the clinical research community, which integrates the rules of conduct of Good Clinical Practices (GCP) as described in International Conference on Harmonisation guidance document E6 and is adopted by the Health Products and Food Branch.

Presenter: Aarti Sidana, MBBS, RPSGT, CSE, Clinical Sleep Educator, Somni Research
### TRACK 3
**Canadian Regulations / Inspections**

**Investigator Responsibilities in 2017: Helping Investigators Understand Their Responsibilities in a Changing Landscape**

In Canada, clinical research regulatory, operational, contractual, privacy, knowledge translation, patient engagement, and ethical requirements for investigators are dynamic and ever changing. Our investigators participate in both industry sponsored studies as site investigators and as the sponsor in academic investigator-initiated studies. We have been working with our vast network of investigators to help them understand their obligations and will share our tools for coaching both junior and senior investigators.  

**Presenter:** Erin Cherban, MSc, CCRP, Chief Clinical Research Officer, Centre for Health Evaluation & Outcome Sciences  
**Time:** 8:30 to 9:15  
**Track:** Canadian Regs / Inspections

### TRACK 4
**GCP Audit Preparedness**

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<td>10:50 to 11:35</td>
<td>GCP Audit Preparedness</td>
<td>Fiesta 7-10</td>
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<td>1:40 to 2:25</td>
<td>International Trials and ICH</td>
<td>Fiesta 7-10</td>
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**Quality Assessment of Research Conduct: Auditing Yourself Before They Do**

Why wait for the sponsors or regulatory agencies to audit you? Auditing your own study conduct is a way to determine if you are conducting your study accordingly, identifying areas of weakness or gaps, and instituting quality improvement measures to address those gaps.  

**Presenter:** Patricia Ivery, BSN, MSN, RN, QI and Education Specialist, McLaren Health Care  
**Time:** 11:40 to 12:25  
**Track:** GCP Audit Preparedness

**Clinical Trial Inspection - When and What to Prepare**

Preparing for a clinical site inspection starts long before the inspector arrives. Utilizing a checklist for inspection preparation, Ms. Baxendale will discuss the crucial steps from study start up to site closeout. Implementing and maintaining quality assurance systems, such as a checklist for audit preparedness, will ensure essential documents are in compliance with GCP and readily available for inspection by regulatory authorities.  

**Presenter:** Darlene Baxendale, BScn, RGN, CCRP, Research Coordinator, IWK Health Centre  
**Time:** 10:50 to 11:35  
**Track:** GCP Audit Preparedness

### TRACK 4
**International Trials & ICH**

**Challenges of Conducting Clinical Trials in Asia**

The clinical trials market is growing in Asian countries. Dr. Sheraz will discuss regulatory factors, ethical issues, cultural issues, operational issues, infrastructure related and future challenges. SWOT (Strengths, Weakness, Opportunity, Threats) analysis for the emerging clinical trial market in Asia will be discussed. Dr. Sheraz will also review the disparity in approval times between regulatory authorities and ethical committees in Asian countries.  

**Presenter:** Sheraz Ali, PharmD, MPH, Researcher, King Saud Medical City, Ministry of Health  
**Time:** 1:40 to 2:25  
**Track:** International Trials and ICH

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**Source Documentation: What Does an Auditor Look For?**

Mr. Purnell will discuss the importance of good documentation at clinical investigator sites including facts regarding regulatory inspection findings, what’s the purpose of source documentation, definitions of source data and source documents, good documentation principles of ALCOA, and FDA inspection warning letter findings.  

**Presenter:** Terrence Purnell, MS, CCRP, RQAP-GCP, Senior Quality Assurance Auditor, CSL Behring  
**Time:** 9:20 to 10:05  
**Track:** GCP Audit Preparedness

**Common Sponsor/FDA Audit Findings and How to Avoid Them**

Ms. Thomas-Visel will cover the most frequent audit findings made at clinical research sites, what practices lead to these issues, and systems that can be implemented by both sites and sponsors to prevent them from occurring.  

**Presenter:** Athena Thomas-Visel, MA, ME, RQAP-GCP, RQP, RD, CCRP, Chief Quality Officer & Principal Consultant, Cliq Solutions, LLC  
**Time:** 8:30 to 9:15  
**Track:** GCP Audit Preparedness
Significant and Non-Significant Risk Determination

Ms. Ingersoll will outline the roles of the sponsor, IRB, and the FDA in risk determination of medical device studies. She will discuss examples of significant risk versus non-significant risk devices. The presentation will also examine best practices that can be adapted to ensure better compliance. The regulations and guidance that address how best to understand the process of risk determination for device studies will also be reviewed.  

Presenter: Sara Ingersoll, MS, CCRP, IRB Coordinator, St. Joseph’s Regional Medical Center

Sponsored Medical Device Registries and 21 CFR

A Medical Device Registry Study provides the manufacturer, clinician, and study subjects’ device performance information by collecting data that proves the effectiveness or lack of such for a medical device used to treat a specific patient population by disease and device implant. The sponsor’s success of the registry is dependent on long term data collection from the implanting physician and the consented subject. 21 CFR outlines the provisions approved for Medical Device Registry participation. Included are general provisions, application and administrative, sponsor and investigator responsibilities, IRB approvals and reviews, and records and reporting. These provisions are necessary in order to access private health information of the consented subject and provide correct feedback to the sponsor.

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

How to Develop Successful Market Adoption Evidence: A Case Study

This presentation will guide listeners through the process of developing successful market adoption studies once a product has been approved. Ms. Stebbs and Ms. Shukla will review the consumer market adoption process and detail how to use this process to develop claims, generate clinical evidence to support these claims, and then present study results effectively to the right audience in the best format. Background information will be illustrated in a real-world case study describing a clinical investigation with a vision screener. The case study will help highlight key points in the market adoption process.

Presenter: Naguline Shukla, PNP-BC, CCRP, Senior Clinical Researcher, Welch Allyn Inc

LDTs (Lab Developed Tests) - Past, Present, Future

LDTs have evolved from simple, single analyte reporting such as a sodium or potassium value to multi-analyte assays that report disease risk scores to next generation sequencing of large gene panels. CLIA certification is a requirement for laboratories to bill government payers for LDTs, but CLIA oversight is limited to an assurance that testing procedures are controlled. FDA proposes to classify LDT risk similar to the risk stratification of medical devices and regulate LDTs as medical devices.

Presenter: Wendy Schroeder, BSN, CCRC, CCRP, RN, Director, Clinical & Regulatory Programs, VisionGate
Breakout Session Descriptions

**TRACK 5**

**Behavioral Health**

Location: Coronado A-C

Moderator: Nancy Wintering

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

**Track:** Behavioral Health

Research Beyond Medical Center Walls – Why We Need Behavioral and Community-Based Research

Dr. Dawson will focus on the need for community-based research and how behavioral research in communities is generally conducted. Topics will include: surveys and self-reporting, engaging communities and other methods to collect data in behavioral studies. This talk will highlight some of the similarities and differences between pharmaceutical research and behavioral research and will how both play their unique roles in furthering scientific knowledge of disease. 529

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

Time: 4:35 to 5:20

**Track:** Behavioral Health

Behavioral Health: Assessing Behavioral Engagement in Clinical Research

Research personnel are presented with study populations that exhibit a wide variety of behaviors. By taking a proactive approach, research personnel can plan, prepare, identify and address the behavioral needs of individual research participants or particular patient populations. Ms. Wintering will provide attendees with an adaptive assessment tool to evaluate the psychological, physiological, cognitive, social and functional strengths and the need for necessary supports and accommodations. Attendees will have the opportunity to use the screening tool in an interactive session.

With planning, a behavior management strategy can be developed to evaluate the needs of individuals or patient populations to ensure greater success in protocol planning and protocol adherence. 531

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

**TRACK 6**

**Finance & Billing**

Location: Coronado D-G

Moderator: Jennifer Goldfarb

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

**Track:** Finance and Billing

Site Financial Management

This presentation will help owners and site directors manage the business side of their sites in order to maximize efficiency. Key indicators to watch to understand site financial health will be discussed as well as elements to build a business plan and financial statements. 621


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

**Track:** Finance and Billing

Innovative Ways to Combine Quality and Financial Assurance Monitoring

The Research Coordination and Management (RCM) Program is a fee-for-service program that provides study coordination and management to researchers at the Medical University of South Carolina. In order to ensure regulatory compliance and data integrity across all RCM conducted studies, an internal quality assurance monitoring program was developed. This program quickly expanded to include the development and implementation of a financial assurance component to monitor each study’s expenditures and income as well as incorporating review of hospital and professional billing charges related to the study to ensure regulatory and research billing integrity. A combined quality and financial assurance monitoring plan, electronic tracking, monitoring, and reporting tools as well as program tracking forms were developed to facilitate the implementation and ongoing monitoring of RCM quality and financial metrics. 622

Presenter: **Cullen McWhite, BS, CCRC,** Prospective Reimbursement Analysis Manager, Medical University of South Carolina

Presenter: **Ricardo Cantu, BS, CCRC**, Lead Clinical Research Coordinator, Medical University of South Carolina

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

**Track:** Oncology Research

Oncology Research Compliance Infrastructure in an Academic Cancer Institute: Implementation and Challenges

Ms. Chadaram will discuss compliance oversight infrastructure at an academic cancer institute for cancer-related clinical research to assure data integrity and maximize human subject protection. A successful research compliance plan is contingent upon robust institutional infrastructure to foster research, resources and education. The NCI Data Safety and Monitoring Plan (DSMP), institutional policies, and standard operating procedures (SOPs) are utilized as a guide to recognize areas of research noncompliance and define processes to address findings and implement corrective action plans in a supportive and timely manner to enhance research integrity. 625

Presenter: **Vijaya Chadaram, MSN, RN, CCRP**, Clinical Trials Operations Manager, Duke Cancer Institute

**Time:** 2:25 to 3:10

**Track:** Oncology Research

Clinical Research Compliance Infrastructure: Challenges and Solutions

Ms. Willenberg will explore how to avoid expensive claims submission errors by coding your clinical trial subjects correctly. Learn how to evaluate submission errors quickly and why denials occur because of improper coding. Formulate a coding agenda for your site for clinical trial billing. 619

Presenter: **Kelly Willenberg, DBA, MBA, BSN, CHC, CHCRC, CCRP**, CEO, Kelly Willenberg LLC

**Time:** 3:15 to 4:00

**Track:** Oncology Research

Breakout Session Descriptions

**Time:** 4:05 to 4:50

**Track:** Oncology Research

**Time:** 4:55 to 5:40

**Track:** Oncology Research
### TRACK 6
**Oncology Research**
Location: Coronado D-G  
Moderator: Susanna Sellmann

**Integrated Care Model: Partnership of Cancer Center Clinic and Clinical Research Office**  
Ms. Byatt will provide an overview of the development, impacts, and lessons learned of an integrated care model in an oncology clinic involving nurse navigators, research nurses, and clinic nurses to impact clinical trial accruals.  
Presenter: Leslie Byatt, CPhT, CCRC, Clinical Research Manager, New Mexico Cancer Care Alliance  
Time: 2:30 to 3:15

**Immunotherapy**  
Immunotherapy has been rapidly growing as a treatment option for cancer patients. New treatments using a patient’s own T-cells have shown success over recent years. This session will provide an overview of CAR-T (chimeric antigen receptor T-cells) and TILs (tumor-infiltrating lymphocytes) and how they are used as cancer treatments.  
Presenter: Jamie Harper, MHA, CCRP, Director of Research and Clinic Support, Illinois CancerCare  
Time: 3:45 to 4:30

### TRACK 7
**Site Management**
Location: Coronado H  
Moderator: Amy Jo Jenkins/ Quincy Brydsong

**Clinical Study Agreements**  
Mr. Hudalla will first provide an overview of the contractual relationships that arise out of a clinical study agreement. A description of the common contractual provisions that comprise a clinical study agreement will then be provided.  
Presenter: Nicholas Hudalla, JD, Attorney, Hogan Marren Babbo & Rose, Ltd  
Time: 8:30 to 9:15

**Integrating Research into the Clinical Practice**  
This talk will look at the methods utilized to integrate the research department into the clinical practice, including increased communication with all departments and enhanced training. Ms. Garner will discuss how these methods led to improved efficiency and efficacy of the research department through fewer queries and improved patient satisfaction.  
Presenter: Madeline Garner, BS, CCRC, CCRP, Clinical Research Associate/Graduate Student, Docs Global/Boston Scientific  
Time: 9:20 to 10:05

### TRACK 7
**Site Management**
Location: Coronado H  
Moderator: Amy Jo Jenkins/ Quincy Brydsong

**Oncology Research**
Location: Coronado D-G  
Moderator: Susanna Sellmann

**Clinical Study Agreements**  
Mr. Rajakaruna will identify and describe the top 10 risk-related issues in clinical trial agreements (CTAs). He will then provide the attendees with suggestions of how to mitigate these risks by properly negotiating CTAs.  
Presenter: Marlon Rajakaruna, BA, MBA, LLB, CRCP, Partner, Global & Nat’l Co-Leader of Life Sciences, Dentons  
Time: 10:50 to 11:35

**Site Management**
Location: Coronado H  
Moderator: Amy Jo Jenkins/ Quincy Brydsong

**Site Clinical Trial Costs**  
With nearly 50% of industry clinical trial budgets allocated to pay for research site activities, sponsors are aware of the true cost of doing business. When it comes to site management, however, many sites do not understand their actual costs which can lead to ineffective budgeting and underpayment for their services. This session will review in-depth cost analysis, sponsor negotiating tips and overall financial management strategies for clinical trials.  
Presenter: Jeffrey Kurland, MBA, CPA, Director of Research Financial Operations, Cook Children’s Health Care System  
Time: 11:40 to 12:25
### TRACK 7
**Therapeutic Areas in Research**

**Location:** Coronado H  
**Moderator:** Virginia Doran

**Time:** 4:35 to 5:20  
**Track:** Therapeutic Areas in Research

**Jumping the Hurdles of Patient Recruitment and Retention in Rare Disease Clinical Trials Through Innovative Strategies and Creative Problem Solving**

Patient recruitment is a primary reason for missing clinical trial timelines. About 30% of the Phase III studies fail due to enrollment challenges. Even though rare disease clinical trials have a smaller sample size, recruitment and retention is even more challenging. The geographic spread of rare disease patient populations across the globe, along with the fact that most of the rare diseases affect the pediatric population, are the major factors that impede recruitment. A patient-centric and innovative approach is needed rather than traditional methods. Using specific examples Mr. Jaggumantri will show how technology, specifically big data and social media, can be used to map the location of these rare disease patients to optimize site selection and recruitment. Patient-centric approaches around reducing burdens like home care nursing and travel concierge that folks conducting rare disease clinical trials can implement to jump these hurdles will be presented. 731

Presenter: **Venkata Jaggumantri, BS, CCRA**, Clinical Scientist, Rare Diseases, PRA Health Sciences

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### TRACK 8
**Investigator Initiated Research**

**Location:** Monterey Ballroom  
**Moderator:** Milton Marshall

**Time:** 8:30 to 9:15  
**Track:** Investigator Initiated Research

**Real Time/Risk Based Monitoring of Investigator-Initiated Clinical Trials**

Investigator-Initiated Trials (IITs) fall into the highest category of institutional risk for academic medical centers. With ever increasing regulatory, scientific and protocol complexities, compliance, and human subjects protections are a large responsibility and concern. Innovative academic level treatment concepts are vital to the continued cause of finding cures and optimal/improved treatment options for our patients. A dynamic, risk-based driven monitoring program is essential in maintaining research quality compliance and excellence in conducting such high priority projects such as IITs. 817

Presenter: **Daniel Otap, BS, CCRP**, Associate Director, Regulatory Affairs, Columbia University/Herbert Irving CCC

**Time:** 9:20 to 10:05  
**Track:** Investigator-Initiated Research

**Sponsor-Investigator Initiated Investigational New Drug (IND) Application**

Ms. Mancenido will discuss the submission process of filing for an Investigational New Drug Application (IND) with the Food and Drug Administration (FDA) as a sponsor-investigator. Compliance requirements of conducting a study under an IND at an academic medical institution will be explored. 819

Presenter: **Denesy Mancenido, BA, CCRP**, Assistant Director of Research, Hospital for Special Surgery

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

**Protocol Development - The Making of the Master Document**

Ms. Mukit will address the process of protocol development of Investigator-Initiated Trials (using the Northwestern University RHLCC oncology protocol template as an example), discuss the essential elements of a protocol, and the common non-scientific flaws. It will also include an interactive session to engage the audience. 821

Presenter: **Sabeaha Mukit, MBBS, MS**, Medical Writer, RHLCC, Northwestern University

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### TRACK 8
**Enrollment/Retention and Informed Consent**

**Location:** Monterey Ballroom  
**Moderator:** Lenore Jackson-Pope

**Time:** 11:40 to 12:25  
**Track:** Enrollment/Retention and IC

**Expectations from Supporters for Quality and Compliant Investigator-Initiated Research**

Investigator-initiated sponsored research requires multiple layers of support to be conducted properly. The panel will discuss these layers of support. Included will be a discussion of who should provide the support and what can happen if there is inadequate support. Examples of warning letters and negative press will be offered. 823

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

Presenter: **Charles Pierce, MD, PhD,FACP, CPI**, Director, Pierce One Consulting

Presenter: **Ashley Wills, BS**, Senior Manager, Medical Affairs-Research, TESARO

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**Enrollment Strategies to Optimize Enrollment and Retention**

One of the first challenges in clinical trials is finding the right subjects for your study. Keeping them involved and engaged throughout the study requires a whole different skill set. Ms. McFarland will discuss how to optimize subject enrollment and reduce ineligibility. Strategies to minimize dropout and maximize retention will also be presented. 825

Presenter: **Christine McFarland, BA, BS**, Research Coordinator, University of Pittsburgh Medical Center

**Winning at Patient Recruitment: Achieving Enrollment Goals Through Outbound Telephone Screening**

The telephone remains an important outreach tool for patient recruitment. In many cases, what’s missing are the proper tools and techniques to use the telephone effectively. Ms. Miller will focus on how to conversationally recite from IRB-approved study scripts, navigate through confidentiality issues, and maintain a professional demeanor and high-degree of sensitivity when asking health-related questions during the telephone screening. The session will include scenarios and mock-screening calls. 827

Presenter: **Deborah Miller, MBA, CCRC**, Independent Consultant

**Alzheimer’s Association Efforts to Help Accelerate the Pace of Enrollment into Clinical Trials**

Ms. Tierney will outline the tools and outreach efforts conducted throughout the US by the Alzheimer’s Association towards connecting our constituents with potential opportunities to enroll in Alzheimer’s research. 829

Presenter: **Martha Tierney, LCSW**, Associate Director of Research Volunteer Program, Alzheimer’s Association

**How Artificial Intelligence is Transforming Clinical Trials**

Finding and matching patients to trials is traditionally a slow manual process requiring extensive outreach efforts and in-depth review of medical records by trained clinical staff as 90% of the information is free-form text (unstructured data), which cannot easily be searched. Advances in artificial intelligence (AI) are making it faster and easier to identify patients for clinical trials. AI has the ability to quickly understand massive amounts of unstructured data and learn from users over time. This level of AI understands not just words, but also relationships between medical concepts. It then mines such relationships to identify patients that match extensive trial criteria at least 22 times faster than manual methods. The possibilities are endless as such a system can be trained to identify potential relationships from available data, which can guide areas of clinical research in the future – leading to new drug therapies and customized treatments. 831

Presenter: **Wout Brusselaers, MA**, CEO, Deep 6 AI
Updates to ICH E6: Are You Ready?
During this session attendees will expand their understanding of the recent revisions to ICH E6 GCP, this includes a general review of the major changes and how to address them. Dr. Leister will discuss key topics such as clinical monitoring, software validation, quality management, and risk management. As we dive into the changes she will discuss potential implementation strategies as well as challenges one might encounter during the change process. By the end of the session, you will be familiar with the revisions to ICH E6 GCP as well as having a better understanding of how to effectively implement the necessary changes within your organization to be in compliance with the updates to ICH E6.  

**Presenter:** Susan Leister, PhD, MBA, BS, CQA, CSSBB, Director of Quality Assurance, Technical Resources International, Inc.

The Emergence of Biologics and Biosimilars within the United States Regulatory Landscape
Traditional medications are made through chemical processes, while biologic products are developed from living organisms. Biologics are often made from large complex molecules requiring tightly controlled manufacturing processes. A biosimilar is a biologic product that is highly similar to an already approved reference biologic with no clinically meaningful difference in terms of safety, purity, and potency. While Europe has been approving biosimilars since 2006, no regulatory pathway existed in the United States until 2010. As of August 2017, the FDA has approved only 5 biosimilar products without an interchangeability designation. The development of biosimilars and their potential to be interchangeable with reference biologics may be critical for introducing competition into the high cost biologic market, improving medication access, and lowering overall healthcare costs.  

Dr. Smith will present a high-level overview of the biologic regulatory landscape and the current state of the biosimilar market.  

**Presenter:** Julia Smith, PharmD, Manager, Pharmacy Strategies, UnitedHealthcare Pharmacy

Minimally Disruptive Research: A Respectful Approach to Conducting Clinical Studies
The design and conduct of clinical studies must achieve the research goals while minimizing the work allocated to participants (clinicians and patients). Research must impose the smallest positive footprint on clinical care activities. We have come to call this, Minimally Disruptive Research. Our adherence to this new standard requires participants (both patients and clinicians) as research partners to engage with investigators at every step of the research process to ensure that all procedures result in CAREFUL and KIND Research.  

**Presenter:** Sara Dick, MSc, CCRP, Clinical Research Coordinator, Mayo Clinic

The Changing Landscape of Human Subjects Protection
Understanding context is key to understanding and implementing regulatory requirements. This session will explore the historical context and events which shaped the current human subjects regulations, and discuss how changes in human subjects research and public perception have impacted the proposed revisions to the human subjects regulations. The session will conclude with an overview of the recently-released revision to the Common Rule and its impact on research.  

**Presenter:** Amy Waltz, JD, CIP, Associate Director, Reliance, Regulatory Affairs & Outreach, Indiana University

How Patient Advocacy Can Support and Advance Research
Patient advocacy has the power to advance and influence policy with the power of the authentic voice. Learn about the collaboration between the Massachusetts General Hospital Frontotemporal Disorders Unit, family advocates, and community partners to give the patient a positive experience meaning while supporting continued advancement in clinical care and research efforts.  

**Presenter:** Katie Brandt, MM, BA, Community Resource Specialist, Mass General Hospital, Frontotemporal Disorders Unit

The Social Media Blueprint: Top 3 Tips for New Patient Advocacy and Recruitment
Social media has been a highly innovative and disruptive technology for many industries, but most importantly for clinical trials. Mr. Chiaro will touch on social media breaks down, step-by-step, the latest techniques for patient recruitment, retention, and advocacy across newer and older platforms such as Snapchat, Instagram, and Facebook.  

**Presenter:** Jerome Chiaro, BA, Vice President of Clinical Site Operations, StudyKIK