opening plenaryFriday, September 27, 2019

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

Welcome and Introduction
Ms. Harper and Ms. Jenkins will describe issues related to the practice of clinical research in the current regulatory environment and how SOCRA works to promote education and training within the clinical research community. 001

Presenter: Jamie Harper, MHA, CCRP, Director of Clinical Research, Illinois CancerCare PC
Presenter: Amy Jo Jenkins, MS, CCRA, CCRC, CCRP, Executive Director, Translational Research Institute
University of Arkansas for Medical Sciences (UAMS)

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

OHRP’s Thinking on Key Revisions to the Common Rule
Compliance to the revised Common Rule became effective on January 21, 2019. Dr. Lau will provide updates on OHRP’s thinking on key revisions. 002

Presenter: Yvonne Lau, PhD, MBBS, MBHL, Director, Division of Education and Development, U.S. Department of Health and Human Services, Office of Human Research Protections

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

Creating and Sustaining Diverse Study Enrollment: Towards a Quantifiable Science of Recruitment
Many, if not most, clinical trials struggle to complete study enrollment on time and within budget. Similarly, diversity in clinical trial enrollment remains elusive for most study teams, in spite of determined, thoughtful, and concerted efforts. Common barriers to recruitment as well as recent efforts to concretize a scientific study of applied research recruitment will be discussed. Dr. Jackson will illustrate how recruitment science operationalizes efforts to develop, compare, and generalize best practices in study accrual, drawing on principles of engagement with underserved communities to improve recruitment and retention for all populations in clinical research. 003

Presenter: Jonathan Jackson, PhD, Director, CARE Research Center, Massachusetts General Hospital & Harvard Medical School

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

FDA’s Bioresearch Monitoring Program - Foreign Inspections and Program Updates
Ms. Wright will provide an overview of international inspections conducted in support of FDA’s Bioresearch Monitoring Program and discuss the implementation of a dedicated inspectional cadre. Recommendations for supporting protocol compliance through Good Documentation Practices will also be reviewed. 004

Presenter: Barbara Wright, BGS, Supervisory Investigator, Foreign Inspection Cadre, Office of Bioresearch Monitoring, U.S. Food and Drug Administration

Friday, September 27, 2019

Breakout Session Descriptions

Track 1  Oncology Research

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

Oncology Investigator Initiated Clinical Trial Protocols: A Comprehensive Review of Eligibility Criteria and Study Procedures
A clinical trial protocol provides details regarding design, recruitment, treatment plan, regulatory requirements and logistics of a study. Ms. Mukit will go deeper into two specific sections of the protocol: ‘eligibility criteria’ and ‘study procedures’. This presentation will be a beginners level presentation based on oncology investigator initiated interventional clinical trials. Ms. Mukit will focus on the specifics of universal eligibility criteria and how they can be presented effectively. She will also shed light on the most commonly used study procedures and cover the vital specifics that need to be stated with each study procedure. The impact of these two sections on the ‘Recruitment and Retention’ capacity of a clinical trial will also be discussed. 109

Presenter: Sabeeha Mukit, MBBS, MS, Medical Writer, Northwestern University

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

Intratumoral Injection Trials: IR Experience
Injecting cancer treatments have shown promise in clinical trials, whether through vaccines or direct intratumoral injections. This presentation is an overview of the management and coordination of intratumoral injection trials wherein procedures were performed by faculty members of the Interventional Radiology Department of MD Anderson Cancer Center. In the past couple of years, the IR Department has been challenged with the growing demands of Phase I and Phase II intratumoral injection trials, which were primarily driven by different departments such as Investigational Cancer Therapeutics/Phase I, Melanoma, Sarcoma and others. 111

Presenter: Maria Briones, MD, CCRP, Clinical Research Team Lead, Interventional Radiology, UT MD Anderson Cancer Center

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

Putting Everything in Perspective: What You Need to Know to Survive in Clinical Trial Management
Ms. Stewart will discuss information from the data management side and regulatory side of managing clinical trials. Ways to navigate requests from sponsors/CROs will also be presented. 113

Presenter: Diandra Stewart, BS, CCRP, Clinical Research Associate, Cancer Centers of SW Oklahoma

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

Complementary and Alternative Medicine Pros and Cons
Nowadays an increasing number of patients from various age groups are moving to integrative medicine (IM). IM is a coordinated approach that uses Complementary and Alternative Medicine (CAM), and conventional therapies. Patients may not discuss its use with their healthcare providers. These therapies may enhance or interfere with traditional cancer treatments. Healthcare providers should focus on strategies for effective communication with patients to discuss the use of CAM and notify about risks and benefits associated with it. 115

Presenter: Rashmi Pande, BDS, MS, CCRP, Clinical Research Coordinator
**Track 2 / Ethics in Research**

**Vulnerable Subjects: Challenges of Conducting Research Under Difficult Circumstances**
Researchers are often faced with a number of difficult situations during the course of conducting human research. Often, the solutions are also not easy or apparent. There are many circumstances where participants are vulnerable to coercion, dependent, and may have decreased autonomy due to developmental disabilities and cognitive impairments, which may violate their freedom to choose and, hence, cannot exercise the right to refuse to participate in research.

**Presenter:** Muhammad Waseem, MD, MS, CCRP, CIP, CHSE-A, Research Director/Professor Emergency Medicine, Lincoln Medical Center

**Words Matter - Dehumanization in the Past...and Today?**

Words matter. Historically, words have been used to dehumanize, allowing “researchers” to study “objects” or “animals” instead of humans, which contributed to the atrocities of Nazi Germany and Imperial Japan. Ms. Oeser will review words currently used to describe people who participate in research--are they dehumanizing too?

**Presenter:** Annette Oeser, BS, MLAS, CCRP, Clinical/Translational Research Coordinator III, Vanderbilt University Medical Center

**The Reason Why Emerging Countries are Attractive Places for Clinical Research**

Clinical research has become more global in the past few years, therefore the number of conducted clinical trials has increased worldwide, especially in emerging countries. This presentation will discuss reasons for the increasing number of trials in African countries.

**Presenter:** Vanessa Struveuer, MSc, Research Assistant, University of Applied Sciences and Arts

**Ethics of Placebo Use in Randomized Controlled Trials**

An ethical schism amongst placebo use in clinical trials remains, despite the latest revision of the Declaration of Helsinki, to include a systemic approach towards the design of placebo-controlled trials. Disparity in the interpretation of the current international guidelines led to conflicting arguments for and against placebo use in the presence of existing standard treatment. This presentation shall evaluate these differing notions objectively and provide a better understanding of the underlying justifications for the ethical framework supporting placebo use in randomized controlled trials. Alternative study designs which allow comparison of the novel therapy with placebo and active treatment while mitigating existing risks will also be examined. An overview focused on the Declaration of Helsinki revisions shall throw light on the historical perspective of the ethics of placebo use in clinical trials.

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

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**Track 3 / Site Management**

**Unpacking the FDA Clinical Investigator Inspection Process in order to Maximize the Probability of Successful Inspection Outcomes**

Conducting clinical research in an FDA inspection-ready environment is crucial and is arguably the best predictor for a positive FDA inspection outcome. As such, understanding the FDA inspection process should motivate an investigator’s clinical research-related processes. Lastly, navigating the FDA inspection process from inception to complete resolution often relies on a savvy understanding of how to best respond whenever 483-worthy findings are noted.

**Presenter:** T. Che Jarrell, BSPh, MPIA, RAC, Proprietor & Principal Consultant, Milestone Regulatory Experts, LLC

**Source Documentation: Common Pitfalls and Site Monitoring Visit Findings**

Source documentation issues is one of the most common findings cited by clinical site monitors. The source document should speak to the patient’s progression in the trial and how the data is initially obtained. Missing or inadequate source documentation jeopardizes the patient’s safety and eligibility, and the accuracy and reliability of the data. To avoid common pitfalls and cited monitoring findings, source documentation should be clearly defined and agreed upon by the site PI, research staff, and sponsor/CRO prior to trial initiation.

**Presenter:** Taylor Swankie, Public Health Analyst/Clinical Research Coordinator, RTI International

**How to Use Excel to Coordinate Your Studies**

Learn to use the features in Excel to coordinate studies and patients. Use Excel to manage complicated studies, track patient visits and required observations. Use date fill features, conditional formatting, worksheets, and formulas.

**Presenter:** Amy Rowell, MS, CCRP, Quality Assurance Coordinator, UT Southwestern

**Private Practice Research Culture and Compliance Transformation**

Ms. Iovanni will focus on research culture transformation efforts at a community, non-academic, private, medical practice, with a for profit partner. Challenges, successes and strategies that are easily transferrable to a variety of research site types, will also be discussed.

**Presenter:** Linda Iovanni, MBA, BSN, RN, COO, Research Director, Maryland Oncology
**Friday, September 27, 2019**

**Track 4  GCP and Audit Preparedness**

**Investigator / Investigational Site Responsibilities**
Mr. Rashti will highlight the importance of investigator and investigational site responsibilities, and relate Good Clinical Practice compliance to successful completion of clinical studies in support of New Drug Applications. Mr. Rashti will describe how to prepare for an audit by FDA staff, most common deficiencies observed, and how to avoid them. Past audit experiences will be shared.

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

**Dealing with an FDA Inspection: Expectations, Outcomes & Consequences**
This session will describe the preparation of a site for an FDA inspection and how to successfully host an audit. Mr. Hamrell will cover the audit from different perspectives and focus on helpful hints and procedural issues regarding what to do if chosen for an FDA inspection. There will be a discussion on how to host the inspection and how best to prepare for the actual event. The audience will be taught some of the dos and don’ts of a successful inspection and will learn from actual case examples and inspections.

**Presenter:** Michael Hamrell, PhD, RAC, FRAPS, RQAP-GCP, CCRA, FACRP, President, MORIAH Consultants

**What to Expect from an FDA Inspection**
The FDA notifies you they are coming to inspect. What do you do next? This presentation will go over what to plan for, before the FDA Inspector arrives on site, what to expect during the inspection process, and what to expect at the conclusion of the inspection.

**Presenter:** Donna Williams, BS, CCRP, RN, Project Administrative Officer of Clinical Trials, SUNY Upstate Medical Hospital / Cancer Center

**Study Team Training as a Result of Audit Findings in Oncology Trials**
We all love audits. How can we make the results of audits productive and informative? Ms. Rowell and Ms. Chang will help attendees learn how to take oncology clinical trial audit findings and create study team trainings to fulfill the corrective action plan and not have issues in the future.

**Presenter:** Amy Rowell, MS, CCRP, Quality Assurance Coordinator, UT Southwestern

**Presenter:** Jenny Chang, BA, Quality Assurance Coordinator, UT Southwestern

**Track 5  Integrative Medicine / CAM**

**Applying Behavioral Science in the Clinical Research Workplace: Tools to Improve Personal and Site Performance**
Clinical research professionals are commonly presented with high stress work situations due to workload, competing priorities, and interpersonal communication challenges within teams. This presentation will outline how various methods can improve an individual’s resiliency, to aid in the ability to focus more effectively and to be more assertive in their roles as they advocate for improved practices in clinical research. Mr. Staios will include a brief guided meditation session and highlight the key principles of emotional intelligence that individuals can incorporate into their daily work and personal lives.

**Presenter:** Gregory Staios, MSc, CCRP, Manager, Research Quality & Privacy, St Michael’s Hospital, Applied Health Research Center

**Improving Quality by Using Stress Management in a GCP Environment**
Working in clinical research can be stressful for sponsors, CROs, and sites and have an impact on quality. Ms. Wintering will discuss behavioral and social factors that contribute to errors and reduce quality and performance in research settings and organizational cultures. Learn strategies to recognize stressors and how to build resilience and reduce errors.

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

**Clinical Trials of FDA-IND Natural Bioactive Components for Bone Health**
Bone loss is a natural process of aging. Mitigating the progress of bone loss has become a major public health issue. Nutrition and bone health are closely linked. This session will review the role of dietary natural bioactive components on promotion of bone health. Dr. Shen will discuss how to study dietary natural bioactive components (green tea polyphenols and tocotrienols) for bone health through translational approaches from animal studies to clinical trials. Examples illustrating design of appropriate animal models, FDA IND application, communication between FDA and funding agency (federal and industry), and follow-up IND reports will also be provided.

**Presenter:** Chwan-Li (Leslie) Shen, PhD, CCRP, Professor of Pathology, Texas Tech University Health Sciences Center
Track 5  
Integrative Medicine / CAM

Time: 4:15 to 5:00  
Track: Integrative Medicine/CAM/Behavioral Health

Acupuncture and Pain Management
Dr. Zhang will briefly introduce the history of traditional Chinese medicine roots and current practice of acupuncture in the US. Dr. Zhang will also review the clinical research evidences of acupuncture for various pain conditions and examine the issues related to such research. At the end, Dr. Zhang will discuss relevant clinical implications of acupuncture based on the evidences. 515

Presenter: Yan Zhang, PhD, LAc, Associate Professor, Texas Tech University Health Sciences Center

Track 6  
Monitoring

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

A Changing Role in a Changing Landscape - How the Role of the CRA Will Evolve in the Next 5 Years
The role of the CRA in the future is evolving to one with less on-site data verification and increased focus on consultative problem solving through data driven insights. Mr. Leray will share experiences and facilitate a discussion with the research community on how to jointly prepare for what is to come. 613

Presenter: Eric Leray, MSc, Senior Director, IQVIA

Ensuring Success Through Smarter Site Selection and Study Feasibility
Site Selection is a complex dance between sponsors and sites. The wrong choice can have serious consequences, impacting quality, time and finances for both the sponsor and investigator. Steps for site selection and feasibility will be discussed. This session will explore best practices for both sponsors and sites during the selection process. Sponsors will learn the most critical questions to ask an investigator and staff to ensure quality and timely data as well as appropriate enrollment for the proposed clinical trial. Sites will learn how they can be proactive in the selection process and how to ensure a study is feasible by considering logistics, resources, and staffing. The whole process of site feasibility and selection will be outlined with key decision points for both sponsors and sites. Sites and sponsors will also learn what tools can help sites become “preferred” and achieve quality in the execution of a clinical trial. 609

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

Checking the Eligibility Checklist
This discussion will review the eligibility checklist elements of management and review process. Recommendations to ensure that the eligibility checklist is created, used, managed, and executed properly will be provided. The importance of dedicating adequate resources to enforce proper eligibility checklist management through developing, implementing, and maintaining a real-time participant eligibility verification process, which will ensure that clinical trial registrations are conducted according to regulations, will be reviewed. Mr. Granobles will examine the importance of having an independent review (administrative quality assurance), aside from the study team, and systems that can be used to improve this important quality assurance process. 611

Presenter: Adrian Granobles, MS, CCRP, Clinical Research Team Lead, Monitoring, Memorial Sloan Kettering Cancer Center (MSK)

Track 7  
Device Research

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

Top 5 Clinical Trends in the Medical Device Industry in 2019
New trends in technology are transforming the medical device industry, particularly in the way data is managed during clinical trials. Advanced technology is making clinical data management easier, so regulatory agencies are raising their expectations regarding clinical studies, primarily with trial master file (TMF) management. Specifically, more regulatory focus will be on accuracy, security, integrity, and inspection readiness of all TMF components. Also, the industry is trending toward managing all clinical activities electronically, making it more critical for companies to establish the TMF as a single point of truth. 709

Presenter: Patricia Santos-Serrao, RAC, Director, Product Strategy-Pharma and Biologics, MasterControl, Inc.
Clinical Validation for a Medical Device Design Update

Ms. Downing will describe the R&D efforts that were required to enhance the capabilities of the Welch Allyn Spot Vision Screener (a device that objectively screens for the 6 risk factors of amblyopia). She will also cover the clinical validation that was required to prove that the updates were effective and that the device was still accurate. 713

Presenter: Lindsay Downing, BS, MS, CCRP, Senior Specialist, Clinical Affairs, Welch Allyn

Building Quality Clinical Data into Premarket Approval (PMA) Applications

Devices that present the highest risk (Class III) to patients are generally regulated under the Premarket Approval (PMA) Program. The PMA review process is a scientific and regulatory review to evaluate the reasonable safety and effectiveness of a new Class III medical device. This evaluation is based on valid scientific evidence. It is critical that valid scientific evidence is supported with high quality data. This session will provide an introduction to the premarket program, valid scientific evidence and elements, and strategies of quality data. 715

Presenter: Donna, Headlee, RN, BSN, CCRP

Managing Risks for Medical Device Clinical Trials and Their Products

Medical device clinical trial managers must manage risks (i.e., things that could potentially go wrong) in their trials, and may also be involved in the product risk management process (as per ISO 14971, the harmonized standard for medical device in vitro diagnostic product risk management) for the device under evaluation. This session will provide an overview of a) Project Management Institute’s® project risk management process and how it can be executed to achieve clinical trial objectives, b) the ISO 14971 product risk management process and how it is executed, and c) the vital roles of clinical data and the clinical trial manager for the product risk management process. 711

Presenter: Claudia Campbell-Matland, MS, PMP, Consultant & Managing Member, CNCM Consulting LLC

International Variations in the Uptake and Governance of Genetic Research, Research on Gametes and Stem Cells and Cloning

The past two decades have witnessed huge leaps in medical research, particularly with regard to stem cell research that continues to promise life and a cure for patients with a wide spectrum of disorders such as cancer and multiple sclerosis. Cloning has opened a whole new gate for restorative medicine and, as the case has always been in history, science and research confront traditions, beliefs and societal norms. Dr. Elmorsy will focus on the international differences governing stem cell research, cloning, and genetic research will be compared among the USA, Europe, Saudi Arabia, a country from the Far East and another from Latin America. Such information is very important when planning multinational research in the current era when new clinical research frontiers are badly needed. 813

Presenter: Soha Elmorsy, MD, PhD, Associate Professor, Faculty of Medicine, Cairo University

Quality Control Principles and Practices to Oversee Research Projects in South America

This presentation will address the importance of a commitment to Total Quality principles and practices as the key to successful research projects in Latin America. It provides an overview of training and general elements for running a quality control program and offers recommendations for addressing the unique challenges encountered in multisite projects. Creating a culture of quality through commitment, training, and continual improvement can enhance team performance from site selection to study closeout. Tips, tools, and best practices will be shared, along with suggestions on how to apply them in different scenarios. Ms. Wright will discuss strategies, common barriers and opportunities, and the role of the United States in partnerships for leading and monitoring investigation projects. This presentation will be based on tuberculosis trials conducted in Peru and Brazil since 2008, drawing from insights gained through training and leading clinical research personnel in multisite projects in both countries. 815

Presenter: Alicia Wright, MS, CCRP, Program Manager, Vanderbilt University Medical Center

The EU GDPR has been constituted to harmonize European data protection regulations. It has an impact on any company worldwide with revenue-generating processes based on using personal data of EU citizens. The GDPR protects data of every EU citizen, no matter where in the world the data is processed and stored. GDPR protects a broad variety of types of data, including health and research related data! GDPR was officially released in April 2016. After a two-year transition phase, the date of enforcement was May 25 in 2018. Unlike most EU regulations, GDPR is in effect without undergoing ratification of the EU member states first. The presentation covers in short, what you should know about the new regulation and how and where it affects your daily business. 811

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

Being Prepared - The EU General Data Protection Regulation (GDPR)

The EU GDPR has been constituted to harmonize European data protection regulations. It has an impact on any company worldwide with revenue-generating processes based on using personal data of EU citizens. The GDPR protects data of every EU citizen, no matter where in the world the data is processed and stored. GDPR protects a broad variety of types of data, including health and research related data! GDPR was officially released in April 2016. After a two-year transition phase, the date of enforcement was May 25 in 2018. Unlike most EU regulations, GDPR is in effect without undergoing ratification of the EU member states first. The presentation covers in short, what you should know about the new regulation and how and where it affects your daily business. 811

Presenter: Gerhard Fortwengel, PhD, MPH, MSc, Professor, University of Applied Sciences and Arts, Hannover
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 Research Management. 117/119

**Moderator:** Joanne Goldberg, MSc, phd, CCRP, Assistant Director, CIHR Institute of Aging

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

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Track 1 / Finance and Billing

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

**Business Building Blocks of a Billing Process**

This session will discuss the purpose of having a good business practice in place for doing trials. Understand the elements needed and how your site can better provide the infrastructure necessary for revenue integrity. 127

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

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**Track 1 / Risk Management**

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

**The State of Industry Adoption of Risk-Based Monitoring: Survey Results**

OmniComm represents the eClinical Forum in reporting survey results of diverse organizations that currently have, or plan to, adopt risk-based monitoring related to clinical research risk based planning, analytics, and data monitoring. Mr. Light will share those findings. 121

**Presenter:** Kenneth Light, MS, BS, Executive Vice President, Corporate Strategy

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**Timeline Reduction: Contract Review and Negotiation Process**

Ms. Burch-Williams will discuss document quality management processes in conjunction with collaborative efforts. The collaboration workspace will be targeted in this presentation to identify appropriate timelines and process streaming. This allows for document tracking and visibility to eliminate bottlenecks in the process while allowing all associated parties to weigh in on content. 129

**Presenter:** Tamara Burch-Williams, BS, MS, Clinical Software Implementation Manager, MasterControl

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**Track 1 / Finance and Billing**

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

**Leveraging Data to Drive Decisions & Maximizing the Health System Revenue Cycle**

Data is a powerful tool that can be leveraged to drive key decisions for the health system. Ms. Veazie will discuss various data elements, metrics, and key performance indicators that aid the health system with making key decisions about their research portfolio. Using denials management is one example of leveraging the data to build robust Medicare coverage analysis; thus, increasing revenue for the health system. The presentation will provide attendees with information to develop staffing models and productivity models. 131

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

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Track 2

**Responsible Conduct of Research**

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

**Lessons Learned from Case Studies in Research Misconduct**

This presentation will use case studies and lessons learned to discuss research integrity and the impact of wrongdoing on the research enterprise. Proactive interventions aimed at raising awareness, promoting a culture of integrity, and encouraging the early detection and reporting of problems will be presented. Approaches will be discussed for moving beyond a “reactive” mode of responding to misconduct to a “proactive” setting where all components of the research enterprise are engaged in, responsible for, and accountable to a community standard of integrity. 217

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

Track 2 / Investigator Initiated Research

Time: 10:05 to 10:50 Track: Investigator Initiated Research

Investigator Initiated Trials - The Tale of Two Roles in One
Unlike industry sponsored trials focused on regulatory approval of new medications, investigator initiated trials (IITs) are developed and executed under the direction of 3rd party investigators who are physician researchers, often within an academic institution. Biopharmaceutical companies are using them as a creative and cost-effective way to innovate and further improve patient safety. Yet, these trials do come with some risks, potentially for the investigator and institutions. What is the guidance available and what are ways to ensure subject protection, data integrity, and ethical quality research? 225

Presenter: Cynthia Clark, PhD, MSN, CRNP, CCRC, Director of Research Operations Dermatology, Perelman Center for Advanced Medicine, Hospital of the University of Pennsylvania

Time: 11:00 to 11:45 Track: Investigator Initiated Research

Investigational Product Management: Understand Your Responsibilities as a Sponsor/Investigator to Ensure Compliance
Ms. O’Malley will review the responsibilities of the sponsor-investigator related to investigational product management, when performing investigator-initiated research. Ms. O’Malley will include a discussion of tools to manage investigational products and considerations around dose management/escalation, and the decision to utilize an investigational pharmacy. 229

Presenter: Kathleen O’Malley, RN, BSN, CCRP, Associate Director of Education and Training, Jefferson Clinical Research Institute, Thomas Jefferson University

Time: 11:45 to 12:30 Track: Investigator Initiated Research

Meeting with Regulatory Authorities
Early, proactive, and productive communication with regulatory agencies can benefit many areas of investigator-initiated research. Many times, sponsor-investigators may have questions about IND or IDE related investigations that require a more detailed review or discussion than the information found in procedural guidance. Ms. Talley will review what types of mechanisms are available to request a meeting with specific centers or offices at the FDA and the purposes of each, how this relates to different types of IITs or investigator-driven technology development, and the benefit of doing so. The following meeting and communication types will be discussed: administrative, product-related (CDER, CBER, CDRH), safety/product inquiries. 231

Presenter: Christina Talley, MS, RAC, CCRP, CCRC, Director, Regulatory Affairs & Translational Management, Houston Methodist Research Institute

Track 2 / Responsible Conduct of Research

Time: 9:00 to 9:45 Track: Responsible Conduct of Research

Research Misconduct In Clinical Trials: Landmark Cases and the Role of Journals
Ms. Parrish will discuss the landmark cases (i.e., those that highlighted the problem in a dramatic manner and prompted reform) of research misconduct and will also discuss journal activism in addressing allegations of research misconduct. 219

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

Time: 10:00 to 10:45 Track: Responsible Conduct of Research

Becoming a SMART Whistleblower: Strategies for How to Respond to Suspicious Behavior and Suspected Wrongdoing
Dr. McIntosh will showcase how decision making strategies can be used to navigate situations when someone 1) receives an inappropriate request to engage in suspicious or questionable behavior, or 2) observes suspicious or questionable behavior. These social-cognitive decision-making strategies—seeking help, managing emotions, anticipating consequences, recognizing context, and testing assumptions—support effective information gathering, professional decision-making, and whistleblowing practices. Additional considerations for making the decision to become a whistleblower will also be discussed, including how to identify whether misconduct has occurred, deciding who to involve, and choosing a course of action. 221

Presenter: Tristan McIntosh, PhD, Instructor in Medicine, Washington University School of Medicine

Time: 11:00 to 11:45 Track: Responsible Conduct of Research

Responsible Conduct of Research
This presentation will explore factors that promote as well as hinder research compliance and integrity. Dr. Dubois will draw upon data from the first 85 participants in the PI Program, which serves investigators following professional lapses, and also draw from recent studies in the Bioethics Research Center (BRC) at Washington University, involving more than 1200 NIH-funded researchers. Finally, Dr. Dubois will examine a series of lab management practices associated with research exemplars—practices that may help protect against research integrity violations. 223

Presenter: James DuBois, DSc, PhD, Director, PI Program & Center for Clinical Research Ethics, Washington University School of Medicine

Track 2 / Investigator Initiated Research

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

Investigator Initiated Trials - The Tale of Two Roles in One
Unlike industry sponsored trials focused on regulatory approval of new medications, investigator initiated trials (IITs) are developed and executed under the direction of 3rd party investigators who are physician researchers, often within an academic institution. Biopharmaceutical companies are using them as a creative and cost-effective way to innovate and further improve patient safety. Yet, these trials do come with some risks, potentially for the investigator and institutions. What is the guidance available and what are ways to ensure subject protection, data integrity, and ethical quality research? 225

Presenter: Cynthia Clark, PhD, MSN, CRNP, CCRC, Director of Research Operations Dermatology, Perelman Center for Advanced Medicine, Hospital of the University of Pennsylvania

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

Understanding Monitoring and Auditing in the Context of Investigator-Initiated Research
This presentation will provide an overview and define the activities of monitoring and auditing in clinical research. Beyond that, Ms. Gaskin will provide a guideline for how to structure these activities in investigator-initiated research with limited infrastructure and resources. 227

Presenter: Jennifer Gaskin, BA, CCRP, CMQ-OE, Director, Karyopharm

Time: 3:45 to 4:30 Track: Investigator-Initiated Research

Investigational Product Management: Understand Your Responsibilities as a Sponsor/Investigator to Ensure Compliance
Ms. O’Malley will review the responsibilities of the sponsor-investigator related to investigational product management, when performing investigator-initiated research. Ms. O’Malley will include a discussion of tools to manage investigational products and considerations around dose management/escalation, and the decision to utilize an investigational pharmacy. 229

Presenter: Kathleen O’Malley, RN, BSN, CCRP, Associate Director of Education and Training, Jefferson Clinical Research Institute, Thomas Jefferson University

Time: 4:35 to 5:20 Track: Investigator-Initiated Research

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Early, proactive, and productive communication with regulatory agencies can benefit many areas of investigator-initiated research. Many times, sponsor-investigators may have questions about IND or IDE related investigations that require a more detailed review or discussion than the information found in procedural guidance. Ms. Talley will review what types of mechanisms are available to request a meeting with specific centers or offices at the FDA and the purposes of each, how this relates to different types of IITs or investigator-driven technology development, and the benefit of doing so. The following meeting and communication types will be discussed: administrative, product-related (CDER, CBER, CDRH), safety/product inquiries. 231

Presenter: Christina Talley, MS, RAC, CCRP, CCRC, Director, Regulatory Affairs & Translational Management, Houston Methodist Research Institute
Track 3  
**Advanced Management**

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

**Retention Rates of Clinical Research Associates – A Global Perspective**

Clinical research associates are crucial to the success of any research program. Common factors that contribute to high turnover rates in the US and other countries will be discussed. Strategies to combat their loss will be outlined. 317

**Presenter:** Mike Brunet, PhD, ATC, CHRISTUS Regional Director of Research, CHRISTUS Health

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

**How To Motivate and Retain Your Clinical Research Staff**

Learn what motivates employees and how to manage millennials. Ms. Adair will present creative ways to recognize and reward employees as well as how to lead change. 319

**Presenter:** Takisha Adair, MBA, CCRP, Clinical Operations Manager, Covance

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

**The Benefits of a Cooperative and Functional Interdepartmental Relationship at Your Site**

This discussion will help research professionals, especially research coordinators, use their resources accurately and efficiently, and help everyone to run their clinical trials in an effective and efficient way. How to establish cooperative and functional relationships with your IRB, pathology department, laboratory department, radiology department, research finance department, and medical records department will all be outlined. 321

**Presenter:** Ramon Adams, BA, CCRP, Clinical Research Associate, University Hospitals Cleveland Medical Center

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

**Study Feasibility: More than an Exercise in Futility**

Ms. Graham will review common approaches to study feasibility assessment and explore ways to improve feasibility prior to time and resource commitments. 323

**Presenter:** Tammy Graham, MBA, BSN, RN, CPC-A, CCRP, Clinical Research Nurse, UCLA

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

**Using Simulation for Research**

The integration of simulation into healthcare has recently been gaining momentum. Simulation refers to the re-creation of an actual event that has previously occurred or could potentially occur. It allows learners to test new clinical procedures and to enhance both individual and team skills before involving “real” participants. The simulation also allows learners to acquire the skills and valuable experience they need in a variety of clinical settings without putting patients at risk. Since all of the elements of the simulated environment can be standardized, simulation provides an extremely powerful research methodology for studying clinically relevant issues in a controlled manner. Simulation is well suited to conduct research that is otherwise difficult to accomplish in the real clinical environment. Dr. Waseem will discuss lessons learned from research performed in the simulated environment and how it can be applied to the real clinical environment to optimize patient care and outcomes. 325

**Presenter:** Muhammad Waseem, MD, MS, CCRP, CIP, CHSE-A, Research Director/Professor Emergency Medicine, Lincoln Medical Center

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

**Expanded Access Drug: From Bench to Bedside**

Ms. Ingersoll will outline the process and application requirements for an expanded access approval from the FDA and an IRB. Ms. Ingersoll will provide valuable lessons learned during the process that could reduce timelines and improve compliance. 327

**Presenter:** Sara Ingersoll, MS, CCRP, Regulatory/Data Coordinator, St. Barnabas Medical Center

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Track 3  
**Compliance/Noncompliance**

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

**Beyond the Matrix - A Quantitative Approach to Compliance Program Management**

Every research program, regardless of size, has some level of exposure to compliance risk. One of the challenges of managing this risk is to know how to prioritize limited compliance resources to achieve the most efficient allocation of effort. Mr. Smith will discuss approaches to identify, stratify, and analyze compliance risks. Ways to apply the analysis to management of compliance, education, and operations to establish—and document—an environment of continuous improvement will also be covered. 329

**Presenter:** Kevin Smith, MS, MBA, CCRP, Research Administrator, Cleveland Clinic

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

**The FDA is Here - Now What**

The FDA’s relationship with the regulated industry seems to be evolving into a dynamic that most companies are still struggling to fully grasp. Ms. Johnson will cover key aspects that only someone who has managed the FDA inspections program, as a Lead FDA Inspector, can provide. This session will be direct, concise, engaging and informative. 331

**Presenter:** Sylvia Johnson, BS, MS, MBA, President/CEO, Ji-Solutions LLC

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

**The Importance of Quality Management in Behavioral Research**

This presentation will discuss the importance of quality management in behavioral research. As behavioral risk carries less compared to clinical intervention, the need for quality management is often underestimated. However, quality management is an essential component of conducting quality research and protecting the rights, safety, and welfare of human subjects. Ms. Rowe will discuss the importance of quality management and the methods for quality assurance, quality control, and quality improvement. 417

**Presenter:** Jessica Rowe, MA, MS, CCRP, Research Quality Improvement Manager, University of Maryland, Baltimore
## Track 4 / Quality Management

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

**Track: Quality Management**

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**Creating a Comprehensive Quality Assurance Program for Human Subject Research**

This session will evaluate investigator/site performance, IRB performance, and address complaints and concerns from the research community. Managing reports of investigator and IRB performance will also be discussed. 419  
**Presenter:** Jessy Thomas, DMFT, MS, Assistant Director, Quality Assurance, University of Minnesota

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

**Track: Quality Management**

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**Deviations, CAPA, and Root Cause Analysis**

Developing an effective system to track deviations, implement CAPAs, and identify root causes will be presented. 421  
**Presenter:** Monika Schmuck, BSc, Quality Assurance Coordinator, University Health Network

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

**Track: Quality Management**

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**How to Create a Culture of Quality at a Research Site**

Sites are so busy nowadays that quality assurance is often overlooked and is only a focus when issues arise or when there is an audit. Creating a culture of quality using an integrative approach in a team environment will be discussed. Easy to implement techniques include quality assurance checks, office guidelines, checklists, and lessons learned. Challenges of implementing a quality management system and how to overcome any setbacks will be explored. 423  
**Presenter:** Sergey Nikitin, MBA, BSc, President and Director, Prime Site Research Solutions, Inc.  
**Presenter:** Jessica Pinder, BSc, CCRP, PMP, Research Coordinator, Prime Site Research Solutions

## Track 4 / Pediatric Research

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

**Track: Pediatric Research**

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**Developing a Pediatric Clinical Research Center – Lessons Learned at the University of Minnesota**

In 2018 the University of Minnesota Department of Pediatrics began an effort to open an outpatient research center for pediatric research visits. Key stakeholders included not only researchers and research staff, but also hospital administration, clinic operations, university research leadership, and the medical school dean’s office. In 2019 much work continues to be done to ensure the PedCRC is successful. In this talk Ms. Galster will share with you the steps taken in planning, parties involved, challenges faced, structure developed, and what the team would have done differently. 425  
**Presenter:** Amanda Galster, MPH, CCRP, Clinical Research Program Director, University of Minnesota

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

**Track: Pediatric Research**

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**The Community Basis of Optimal Pediatric Recruitment**

Ms. Allen will present an overview of recruitment in pediatric trials. Recruitment is a challenging endeavor, and this seminar will help attendees best utilize their system to aid in useful recruitment. This talk will stimulate discussion around helpful community-based recruitment tactics. 427  
**Presenter:** Janelle Allen, BS, MS, CCRP, Director, Clinical Research Operations, Quality & Education, Institute for Advanced Clinical Trials for Children

## Track 5 / Enrollment/Retention and Informed Consent

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

**Track: Enrollment/Retention and Informed Consent**

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**Building a Referral Partner Network – Developing Partnerships with Primary Care Physicians, Specialists and Other Medical Professionals to Support Enrollment into your Clinical Trial Program**

Clinical trial centers often reach out to primary care providers, specialists, and other medical professionals to provide information about open and enrolling clinical trials in the hope they will receive potential participant referrals. Ms. Jackson-Pope will review how to create successful referral partner relationships and provide tips for building engagement opportunities that will ensure success in the referral process. Examples of how referral networks have been built to support a clinical trial site will be discussed. 517  
**Presenter:** Lenore Jackson-Pope, ADN, BSN, MSM, RN, CCRP, Co-Director of Primary Care Outreach at the Center for Alzheimer Research and Treatment (CART), Brigham and Women’s Hospital

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

**Track: Enrollment/Retention and Informed Consent**

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**Knowing Your Study Subjects on Day One: Artificial Intelligence (AI) with Clinical Trials**

Anyone involved in clinical research today understands that clinical trial recruitment is expensive, making up to one-third of the total cost of trial costs. Clinical recruitment is also slow, expensive and inefficient. With 86% suffering delays (11 months on average), and 50% of trial sites failing, in any other industry this would be unacceptable. AI is a game-changer when evaluating clinical trial feasibility. Mr. Brusselaers will provide case study examples illustrating how applying AI to medical records can pinpoint eligible patients for clinical trials in minutes not months, and will explore the effectiveness of analytics versus AI. Mr. Brusselaers will also show how combining different techniques drastically speeds up subject identification and augments patient recruitment. 519  
**Presenter:** Wout Brusselaers, MA, CEO, Deep 6 AI
Track 5 / Project Management

Time: 3:45 to 4:30  Track: Project Management
Define the meaning of the word ‘project’ as per PMI. Review the 10 knowledge areas and 5 processes of PMI Project Management. Illustrate and discuss the interactions of the processes and how they work together to provide best practices/guidelines for managing individual projects. 529

Presenter: Barbara Kosky, MASc, CCRP, PMP, Clinical Research Project Coordinator, Interventional Cardiology, Sunnybrook Health Sciences Centre

Time: 4:35 to 5:20  Track: Project Management
Implementing Integrated Project Management Framework: Lessons Learned from Ebola Rapid Response Efforts in West Africa
At a large clinical research organization, project management approaches can vary greatly across many functional groups. Functional project and program management approaches under fragmented organizational structures can result in many different solutions to similar problems, each with its own pros and cons. While these functional group-specific PM approaches are often a key priority within each function to maintain excellent clinical research support services, program-wide planning, operational, and administrative support can stagnate significantly. However, integrating the most effective project management approaches from all involved at the functional and program level can have an immediate impact. The LBR/CMRP project team will share its experience and lessons learned from key customers while implementing and expanding the best integrated project management framework in support of a dozen Ebola clinical trials initiated by NIAID’s Division of Clinical Research Program during and after the outbreak Ebola virus disease in West Africa in 2014. 531

Presenter: Jiwan Giri, MSPM, MSIS, PMP, Clinical Project Manager II, Leidos Biomedical Research, Inc.
Presenter: Sara Albert, MPH, Clinical Project Manager II, Leidos Biomedical Research, Inc.
Time: 8:30 to 9:15
Leadership and Line Management in Clinical Research
Whys and what of line management through leadership will be discussed using real life examples to show how it can support clinical research and you. 617
**Presenter:** Anatoly Gorkun, MD, PhD, Chartered MCIPD, Senior Manager, Global Clinical Development, PPD UK

Time: 9:20 to 10:05
Workforce Resource Management: Managing Onboarding and Training for Key Functional Area Roles
In today’s fast-paced clinical research industry with heightened expectations of quality and qualified staff, effective on-boarding (beyond company orientation) requires a systematic review and analysis of key functional roles to strategically align and allocate resources for the development of efficient on-boarding practices across the enterprise. Management of resources to effectively meet competing clinical research activities necessitates a quality systems approach. Creating a process of continuous improvement to actively engage and positively impact the organization requires realignment, re-deployment and restructuring. This session reviews methods and analysis practices for deployment of on-boarding and training to include realignment when necessary, based upon organizational needs. 619
**Presenter:** Erika Stevens, MA, BA, Principal, Recherche Transformation Rapide

Time: 10:50 to 11:35
Optimizing Personal Communication in the Clinical Research Arena: Passive, Aggressive, Assertive, Which Are We and When?
Collaborative communication with colleagues of all levels is a critical professional skill as the clinical research enterprise expands. This presentation will provide an overview of the aggressive, passive, and assertive communication styles, including characteristics, impact on professional progression, and how it looks in a professional environment as well as an inventory tool that allows the participant to adjust their communication style to support their professional goals. 621
**Presenter:** Barbara van der Schalie, MS, Clinical Training Manager, Leidos Biomedical Research Inc

Time: 11:40 to 12:25
From Clinical Trials Poster to Peer-Reviewed Publication
This session is designed to teach poster presenters how to convert their poster content into a manuscript suitable for submission to a peer-reviewed journal. It is particularly suited for those presenting in the clinical trials track who are inexperienced at composing articles for publication. Dr. Selfe will cover choosing an appropriate journal, structuring the manuscript according to International Committee of Medical Journal Editors (ICMJE) recommendations (i.e., introduction, methods, results, and discussion), finding and using the applicable reporting standard (e.g., CONSORT for randomized controlled trials) as a blueprint to make composing a manuscript with the appropriate content a clear-cut task and attainable goal. 623
**Presenter:** Terry Selfe, PhD, DC, CCRP, Translational Research & Impact Librarian, University of Florida HSC

Time: 1:40 to 2:25
Research Investment and Staff Enrichment (RISE)
A core objective of RISE is to “develop a highly trained, innovative, and skilled workforce” and “legitimize” research staff as a valued and career-worthy pathway. Currently there is no defined advancement strategy, and one’s advancement through existing career pathways is often restricted because of reasons unrelated to merit or knowledge, skills, and abilities. RISE is a formal mentorship platform to help individuals identify personal strengths and work toward career goals. The result will be a diverse network of knowledgeable and skilled staff dedicated to producing high-quality research. Anticipated benefits are 1) job satisfaction and retention among research staff by providing career advancement guidance and professional development opportunities, 2) demonstrated value of contributions and professional development of research staff, and 3) legitimize research staff careers. 625
**Presenter:** Gloria Harrington, MBA, LMSW, CCRP, Research Operations Manager, University of Michigan

**Presenter:** Angela Lyden, MS, Science Coordinator, University of Michigan

Time: 2:30 to 3:15
Cultivating an Effective Research Team through the Application of Team Science Principles
The technique of team science allows us to draw from theory driven principles to inform how to build an effective and efficient research team. Inherent in these principles are recognizing team member differences and welcoming diversity in an effort to integrate knowledge to solve complex problems. Ms. Helm will present the basics of team science and how they may be applied to creating a highly productive research team across the study continuum including research administration, budget developers, investigators, and research coordinators. The development of mutual trust, a shared vision, and open communication are crucial elements to a successful research team and project. The use of a case study to illustrate this approach will be presented. 627
**Presenter:** Shirley Helm, MS, CCRP, Manager of Clinical Research Administration, Virginia Commonwealth University

Time: 3:45 to 4:30
Career Progression in Clinical Research: Transitioning from a CRC to a Sponsor CRA
Mr. Boothby will focus on the direct experiences of what, how, and when to make the transition from CRC to a sponsor CRA. With over 15 years of clinical research experience as both a CRC and a CRA, Mr. Boothby will provide individuals attending this presentation with a checklist that will act as a roadmap to help make this a smooth transition. 629
**Presenter:** Thomas Boothby, MSc, CCRP, Clinical Research Associate II, Boston Scientific
Saturday, September 28, 2019

**Track 6 / Training**

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

**Track: Training**

**How Do You Ensure Clinical Trial Quality in Investigator-Initiated Studies?**

**Training for Research Professionals in Monitoring Concepts!**

Establishing and maintaining a rigorous quality management system in clinical trials helps to protect human subjects and ensures data collected is accurate and valid. Monitoring, an essential and routine quality function in industry sponsored trials, is often lacking in investigator-initiated trials conducted in academia. We find that only approximately 65% of investigator-initiated trials are monitored when we poll research professionals locally and nationally. Findings from literature and web-based searches revealed that although numerous GCP training resources are available, most require fees or institutional affiliations. Moreover, many lack the practical approaches to meet the complex requirements of monitoring. To address this gap, the University of Southern California is developing a series of self-study modules that will be readily accessible by all research professionals to be used to establish a pool of research coordinators who can cross-monitor and cross-audit studies they do not coordinate. Ms. Spinrad will share her approach, experience and findings in an interactive session.

**Presenter:** Amelia Spinrad, Regulatory Knowledge Support Administrator, University of Southern California

**Track 7 / Device Research**

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

**Track: Device Research Early Device**

**Documentation and Management Practices for Successful Post Marketing Regulatory Compliance**

Early documentation in medical device design and research can lead to successful post-market launch regulatory compliance. Setting up a quality management system with regular review and surveillance is key to compliance.

**Presenter:** Jennifer Davagian, CCRP, President and CEO, Cristcot LLC

**Track 7 / Emergency Research**

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

**Track: Emergency Medicine Research**

**Somebody Call 911! The Challenges of Emergency Medicine Research**

An overview of the typical challenges faced in emergency medicine research will be provided, as well as examples of studies that have posed unique hurdles and how those hurdles were jumped (or fumbled) over.

**Presenter:** Natalie Bidad, BSN, RNCC, ENPC, MOAB, Assistant Director of EMRAP, University of Vermont Medical Center

**Track 7 / Data Management / EDC / 21 CFR 11**

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

**Track: Data Management / EDC / 21 CFR 11**

**Where Did My Data Go and Who Does it Concern, Anyway? Using Results from Pharmaceutical Clinical Research Trials Beyond the NDA**

Ms. Elsaid will demonstrate how pharmaceutical organizations use results obtained from Phase I – III clinical trials other than for the purposes of obtaining NDA and product monograph publishing. Several industry-initiated, medical and commercial programs will be reviewed. The examples of such programs will include medical education programs, advisory board meetings, medical ambassador programs, speaker tours, detail aids, patient focus groups, and educational initiatives. Furthermore, Ms. Elsaid will discuss how the pharmaceutical industry interacts with healthcare workers, key opinion leaders (KOLs) and patients. Clinical research professionals who attend the presentation will also be able to learn and understand how their expertise can be used beyond clinical operations.

**Presenter:** Sonja Elsaid, MSc, CCRP, Medical Affairs Consultant, MaRS

**Track 7 / Succeeding with CTMS**

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

**Track: Data Management / EDC / 21 CFR 11**

**Succeeding with CTMS**

Integrating clinical research data collected through divergent software applications can be a challenge. Knowing how and when to use clinical trial management software/systems (CTMS) and how to integrate data from other e-clinical systems can help ensure successful trial execution. This presentation will highlight what you can expect from a modern CTMS including successful integration ideas and techniques.

**Presenter:** Jan Nielsen, BS, PMP, Senior Project Manager & Community Manager CTMS, BSI Business Systems Integration AG
Time: 8:30 to 9:15 Track: Canadian Regs / Inspections
**Top 10 Mistakes Commonly Made When Drafting and Negotiating CTAs…..What You Need to Know**
Negotiating a CTA is often a challenging task for CTA negotiators. This presentation will identify and describe key mistakes commonly made when drafting and negotiating CTAs. Topics covered will include CTAs with foreign sponsors, CTAs with CROs, privacy, 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.

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

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Time: 9:20 to 10:05 Track: Canadian Regs / Inspections
**Health Canada's New Guide-0100: Helping Researchers to Know the Rules! Follow the Rules!**
Health Canada has recently released GUIDE-0100 to help researchers conducting clinical drug trials to be compliant with regulations and guidelines, specifically Part C, Division 5 of the Food and Drug Regulations and ICH E6(R2). This talk will give an overview of the new GUIDE-0100. Methods to integrate Part C, Division 5 and ICH E6(R2) into practice to ensure compliance will be discussed.

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

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Time: 10:50 to 11:35 Track: Canadian Regs / Inspections
**Integrating Health Canada Division 5 Requirements with Pharmacy Best Practices Rules**
Investigational Drug Services (IDS) is a specialized area of pharmacy practice that requires adherence to standard best practices and regulations governing both the pharmacy profession and clinical trial conduct. This talk will provide an overview of the practical challenges and solutions in applying Division 5 requirements to everyday practice of an IDS pharmacy, covering topics that include drug labeling and preparation for audits/inspections.

**Presenter:** Jeffrey Doi, HonBSc, BSPharm, RPh, BCPS, Clinical Trials Pharmacist, Princess Margaret Cancer Centre, UHN

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Time: 1:40 to 2:25 Track: Canadian Regs / Inspections
**Conducting an International Trial – The Canadian Sponsor Perspective**
The purpose of this presentation is to discuss the structure and processes required to manage an international clinical trial. Ms. Clarke will also review the challenges and successes to date in conducting a clinical trial with a Canadian site as the sponsor.

**Presenter:** Rosemarie Clarke, BScN, MHM, RN, CCRP, CHE, Research Nurse Manager/Project Manager, University Health Network

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Time: 2:30 to 3:15 Track: Canadian Regs / Inspections
**Cross-Border Clinical Trials: Are You Prepared?**
Conducting cross-border/international clinical trials increases the complexity of an already complex task exponentially. Key differences in areas such as clinical, regulatory, ethical, and operational, must all be clearly identified as early as possible. Ensuring that these (and more) issues are addressed appropriately across all sites helps secure the rigor of your trial data while simultaneously ensuring participant safety.

**Presenter:** Amr Sharaf, HBSc, CCRP, Clinical Site Monitor, Bristol-Myers Squibb

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**SAVE THE DATE**
**2020 Annual Conference**
Las Vegas NV
September 25 - 27
**Closing Plenary**

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

**Applying the Principles of the Science of Safety to Improve Subject Safety in Clinical Research: Actionable Practices to Identify and Minimize Risk**

Dr. Kessler will use case studies to illustrate and describe 1) selected practices in the management of investigational drugs and the consent process that are potentially unsafe and increase the risk to subjects, 2) enhanced reporting strategies to identify potential risks, and 3) enhanced ways to learn from deviations/mistakes that occur.

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

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

**The Evolution of Vulnerability – The Ethics of Equitable Subject Selection**

In April of 1979, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research published the Belmont Report. The Report summarized ethical principles and guidelines for research involving human subjects. Three core principles were identified: respect for persons, beneficence, and justice. While all three principles consider the rights of the research subjects, the justice principle focused primarily on subject selection. The spirit of the justice principle describes the protection of subjects vulnerable to unethical research. However, vulnerability in 1979 is markedly different from vulnerability today. This talk will chronicle the history of vulnerability in human subjects research and compare and contrast how this vulnerability is now manifested in today’s research environment.

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

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

**Including Vulnerable Subjects with Cognitive Impairment in Research**

This talk will review the new common rule definition of vulnerable subjects including “individuals with impaired decision making ability.” It will discuss why inclusion of this vulnerable population is needed in research studies, especially for diseases such as Alzheimer’s research. Finally, it will review the ethical guidelines and discuss practical strategies for obtaining informed consent for subjects who may lack decision making capacity.

**Presenter:** Laura Holtz, MS, CCRP, Senior Research Manager, IU Center for Aging Research, Regenstrief Institute

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

**Sharing De-Identified Data**

Ms. Balch will discuss Count Me In, a nonprofit that allows researchers to work directly with patients and advocacy groups, along with software engineers and computational scientists, to collect, analyze, and share de-identified data in order to transform cancer care.

**Presenter:** Sara Balch, BS, Project Manager, Count Me In and the Broad Institute of MIT and Harvard

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

**The Reality of Enrollment Expectations**

Louis Lasagna was the founder of the Tufts Center for the Study of Drug Development at Tufts University where he became Dean of the Sackler School of Graduate Biomedical Sciences. Lasagna’s Law states “The incidence of patient availability sharply decreases when a clinical trial begins and returns to its original level as soon as the trial is completed.” Why is this true? Can it ever be changed? If not, why not?

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

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