

ACRP 2019
April 12-15, 2019 | Nashville

Additional Event Details Available Online via the Official ACRP 2019 Event App ([Get the App!](#))

Friday, Apr 12 6:30 AM - 6:30 PM, Outside of Exhibit Hall A2, Music City Center

Registration Desk Open

Friday, Apr 12 8:00 AM - 12:00 PM, Meeting Room 202BC

ACRP Quality Congress: Quality and Risk Management through Industry Collaboration

This event requires a separate registration fee. Details available [online](#).

Friday, Apr 12 8:00 AM - 5:15 PM, Meeting Room 209A

(SOLD OUT) Workshop: A Clinical Trial Financial Management Review – A Paradigm of Front End and Back End Revenue

This session will provide a thorough review of the entire financial process of a clinical trial from a programmatic consideration. How do you manage the budget so when the funds are received, you have your costs covered? Evaluate your budget process while analyzing the paradigm shift occurring with lower dollars in our research program. If you have personnel doing coverage analysis for your site, you will benefit attending this 8 hour session!

Learning Objective 1: Analyze how to build foundational principles necessary to build a profitable research site

Learning Objective 2: Understand how to manage research program accounts receivable

Learning Objective 3: Explain issues related to reporting the results of a research program to executive management

Learning Level: Intermediate

Primary Competency: Study and Site Management

Secondary Competency: Communication and Teamwork

Credit Type: 8.00 ACRP

Kelly Willenberg, Kelly Willenberg & Associates; Deena Bernstein

Friday, Apr 12 8:00 AM - 5:15 PM, Meeting Room 209C

(SOLD OUT) Workshop: Clinical Project Management Excellence and Best Practices

This 8 hour course will provide learners with a solid foundation in clinical project management best practices and standards. By combining Project Management Institute best practices with a focused clinical research application and good communication and leadership skills, learners will leave the course with tangible tools to improve their application of project management principles. The ideal attendee will have experience in project management and a heavy focus of project management in their current role.

Learning Objective 1: Identify Strategic Project Decisions to Increase R&D productivity in a Global Context

Learning Objective 2: Discover how to efficiently develop a critical path, task duration and effort, how to use the Gantt chart and manage resources over-allocation

Learning Objective 3: Discuss and Analyze critical concepts that will help you maintain Best Project Management Standards and Practices.

Learning Level: Intermediate

Primary Competency: Leadership and Professionalism

Secondary Competency: Communication and Teamwork

Credit Type: 8.00 ACRP

Eric Morfin, Critical Skills Inc.

Friday, Apr 12 8:00 AM - 5:15 PM, Meeting Room 207A

(SOLD OUT) Workshop: “Let’s Get Clinical: A Research Bootcamp”

This full day pre-conference session is based on the popular and successful “Fundamentals of Research” and “CRC Bootcamp” ACRP training programs. The session includes four modules composed of a didactic session followed by a workshop. The didactic sessions cover a comprehensive yet concise review of the topic along with relevant group discussion. The workshops will follow the educational theme presented in the didactic session prior to dividing into small groups to work on solutions to practical exercises. Several trainers will circulate around the room providing feedback, tips, and comments before a large group debrief with the opportunity for one member of each group to discuss their solutions. The four modules are: 1. Informed Consent 2. Obtaining and Reporting Adverse Events 3. Essential Documents 4. Soft Skills

Learning Objective 1: Describe the general requirements for obtaining Informed Consent

Learning Objective 2: Recognize when to report a symptom, sign, or syndrome

Learning Objective 3: Evaluate task priority in managing a busy schedule

Learning Level: Beginner

Primary Competency: Study and Site Management

Secondary Competency: Clinical Trials Operations (GCPs)

Credit Type: 8.00 ACRP

John Rowell, LSU Health Shreveport; Cindy Foss, ACRP

Friday, Apr 12 8:00 AM - 5:15 PM, Meeting Room 209B

(SOLD OUT) Workshop: Best Practices to Become a Preferred Site

Mirror, Mirror, on the wall, who's the fairest site of all? Most noncompliance stems from inadequate and inconsistent documentation at sites. Learn techniques to better manage your regulatory files and prepare to answer sponsors and inspectors regarding screening/enrollment numbers, subject withdrawal, informed consent, recruitment efforts, delegation of authority, PI oversight, protocol violations and adverse events through the use of adequate source. Explore methods by which one can assess feasibility to determine if a study is a good fit for your site. Tips for managing the regulatory file will be provided through tools/worksheets/templates and interactive activities. Over 200 pages of templates and tools will be provided. These techniques and tools will position your site to be best prepared for a monitoring visit or site audit/inspection. Be prepared and be preferred!

Learning Objective 1: Recognize the importance of quality in clinical trials by identifying key areas for improved documentation and communication.

Learning Objective 2: Manage study documents and minimize the potential for document inconsistencies proactively.

Learning Objective 3: Discuss the criteria for evaluating a site from both the sponsor and site perspectives.

Learning Level: Intermediate

Primary Competency: Study and Site Management

Secondary Competency: Clinical Trials Operations (GCPs)

Credit Type: 8.00 ACRP

Janet Holwell, Independent Consultant; Deborah Rosenbaum, Sarrison Clinical Research

Friday, Apr 12 2:00 PM - 2:45 PM, Meeting Room 207D

techXpo: Powering New Possibilities for Site-Sponsor Collaboration with the Shared Investigator Platform (Sponsored by Cognizant)

Larissa Comis, Cognizant Life Sciences

Please Note: This session does NOT offer ACRP Contact Hours or CEUs of any kind.

Friday, Apr 12 3:15 PM - 4:00 PM, Meeting Room 207D

techXpo: How to Ensure Investigator Adoption of Site Technology - A Panel Discussion (Sponsored by Florence Healthcare)

Please Note: This session does NOT offer ACRP Contact Hours or CEUs of any kind.

Friday, Apr 12 4:15 PM - 5:00 PM, Meeting Room 207D

techXpo: A Shifting World of Work (Sponsored by Kelly Services)

Harvey Yau, Kelly Services

Please Note: This session does NOT offer ACRP Contact Hours or CEUs of any kind.

Friday, Apr 12 5:00 PM - 6:30 PM, Exhibit Hall A2

KPS Opening Night Celebration (Sponsored by KPS Life)

Friday, Apr 12 6:45 PM - 9:00 PM, Omni Nashville, Broadway Ballroom F-K

ACRP Awards & Recognition Ceremony (Sponsored by Syneos Health)

Saturday, Apr 12 7:00 AM - 5:00 PM, Outside of Exhibit Hall A2, Music City Center

Registration Desk Open

Saturday, Apr 13 8:00 AM - 9:00 AM, Grand Ballroom C

'Signature Series' - Evolution of the Clinical Research Workforce for the Future

Learning Level: Intermediate

Primary Competency: Leadership and Professionalism

Secondary Competency: Communication and Teamwork

Credit Type: 1.00 ACRP

Jim Kremidas, Association of Clinical Research Professionals (ACRP); Andy Lee, Merck, Virginia Nido, Genentech, a Member of the Roche Group; Donald A. Deieso, WCG

Saturday, Apr 13 9:00 AM - 10:00 AM, Exhibit Hall A2

Expo Hall Open / Coffee Break

Saturday, Apr 13 9:15 AM - 9:45 AM, Exhibit Hall

Learning Lab: Maximizing Enrollment at Your Site (Sponsored by Bio-Optronics)

Sandy Swistak, Bio-Optronics, Inc.

Please Note: This session does NOT offer ACRP Contact Hours or CEUs of any kind.

Saturday, Apr 13 10:15 AM - 11:15 AM, Meeting Room 207ABC

Knock, Knock....FDA is here; Be Prepared for a Regulatory Inspection

Track: Site Management

What do you do when a regulatory Agency knocks on the door? Turn off the lights? Panic? If you're prepared, it should be an exercise to ensure your systems are working the way you designed them. We will briefly look at FDA Inspections and how to prepare for the inevitable knock, and discuss resources available to you.

Learning Objective 1: Learn how to prepare for a regulatory inspection, before the "knock on

the door.”

Learning Objective 2: Learn what should be in your quality system to be prepared.

Learning Objective 3: Understand what resources are available for you prior to, during, and after regulatory inspections.

Learning Level: Intermediate

Primary Competency: Clinical Trials Operations (GCPs)

Secondary Competency: Ethical and Participant Safety Considerations

Credit Type: 1.00 ACRP, CNE

Eric Pittman, FDA , Office of Bioresearch Monitoring Operations, Office of Regulatory Affairs

Saturday, Apr 13 10:15 AM - 11:15 AM, Meeting Room 209AB

EFS is the new OUS strategy for Early-Phased Medical Device Clinical Trials

Track: Project Management/Device

This session will provide the participant with several real-world examples of the benefits and risks of conducting early-phased medical device clinical trials, and the strategies involved in optimizing this avenue for regulatory submissions. The participant will obtain tools to develop successful clinical and regulatory strategies for new devices and indications.

Learning Objective 1: Define FDA's Early Feasibility Study (EFS) Program.

Learning Objective 2: Outline the risks/benefits of participating in the EFS program for early-phased clinical trials.

Learning Objective 3: Outline strategies to leverage EFS protocols for PMA and 510 submissions.

Learning Level: Intermediate

Primary Competency: Study and Site Management

Secondary Competency: Scientific Concepts and Research Design

Credit Type: 1.00 ACRP

Christopher Cain, Conformal Medical, Inc.; Victor Chen, Kaiser Permanente; Maureen Dreher, US Food and Drug Administration, Center for Devices & Radiological Health

Saturday, Apr 13 10:15 AM - 12:15 PM, Meeting Room 202

Applying Six-Sigma Tools and Concepts to Your Clinical Research Activities

Track: Project Management/Device

Six Sigma is a certification that can be achieved but it's also concepts and practices to apply to everyday activities. The way regulated processes, documents and work practices are handled and executed offer opportunities on a daily basis.

Learning Objective 1: 1. Recognize and understand the concepts of Lean Six Sigma

Learning Objective 2: 2. Identify key questions to consider when determining if a process is lean

Learning Objective 3: 3. List specific actions to lean the document management processes

Learning Level: Beginner

Primary Competency: Study and Site Management

Secondary Competency: Clinical Trials Operations (GCPs)

Credit Type: 2.00 ACRP

Betsy Fallen, BAFallen Consulting LLC; Bridget Gonzales, ACRP

Saturday, Apr 13 10:15 AM - 11:15 AM, Meeting Room 208

Building Relationships & Collaboration: Sponsors and Sites

Track: Leadership

Currently, there is often confusion or lack of understanding regarding the roles of the CRC and CRA. We need to take the time to understand each other's backgrounds and expertise, and then align these competencies in effective collaboration. Taking the time to do this by the CRC and CRA would make the best use of our limited time together promoting a quality and timely work product. We have often heard from CRCs that they look to CRAs as their first point of Sponsor contact, a guide and support, not just a someone to verify data against source documents. CRAs look to CRCs for their expertise at implementing a protocol at the site. How can we maximize our roles to effectively reach our individual goals while supporting each other?

Learning Objective 1: Identify the expectations of CRAs

Learning Objective 2: Identify the expectations of CRCs based on feedback from active sites

Learning Objective 3: Identify skills and provide tips to improve this relationship

Learning Level: Intermediate

Primary Competency: Communication and Teamwork

Secondary Competency: Clinical Trials Operations (GCPs)

Credit Type: 1.00 ACRP

Marian Fisher, Boston Scientific; Mary Sophy Yohannan, Boston Scientific, Inc

Saturday, Apr 13 10:15 AM - 11:15 AM, Meeting Room 209C

Getting Multicenter Studies Under Control with Technology

Track: Technology

You've just been handed a project: An investigator-initiated study with 20 sites on a tight deadline, and here's the kicker: It's up to your small team to manage it on top of all your other work. The three panelists before you have all faced this situation... and triumphed. In this session, learn how they did it. Topics explored include: • Strategic approaches to spread work equitably across study teams • Tips for the most critical phases of your study: Startup, monitoring/QC, ongoing communications and closeout In house tools that give you the leverage to "build it once, use it lots" • Purpose-built tools that enable secure collaboration of documents and tasks • What I'd do differently next time: Learn from our mistakes

Learning Objective 1: Launch a multi-center study using a lean team

Learning Objective 2: Get buy-in on use of new technologies

Learning Objective 3: Improve GCP through remote oversight

Learning Level: Intermediate

Primary Competency: Clinical Trials Operations (GCPs)

Secondary Competency: Communication and Teamwork

Credit Type: 1.00 ACRP

Ryan Jones, Florence Healthcare; Melissa Bolton, University of Utah, Department of Pediatrics;
Jessica Rodriguez, Department of Neurosurgery- Mount Sinai Health System

Saturday, Apr 13 10:15 AM - 11:15 AM, Meeting Room 207D

How to Create a Culture of Quality at a Research Site

Track: Site Management

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. We will describe our experience creating a culture of quality using an integrative approach in a team environment. Our easy to implement techniques include quality assurance checks, office guidelines, checklists, and lessons learned. We will explore the challenges of implementing a quality management system and how to overcome any setbacks.

Learning Objective 1: After the presentation, participants will be able to take ownership of their culture of quality using practical tools and advice. Participants will have practical tools to help their site own quality.

Learning Objective 2: Participants would better understand quality assurance and its challenges.

Learning Objective 3: Participants will be able to use info presented to implement site quality management system.

Learning Level: Beginner

Primary Competency: Clinical Trials Operations (GCPs)

Secondary Competency: Study and Site Management

Credit Type: 1.00 ACRP

Sergey Nikitin, Prime Site Research Solutions Inc.; Jessica Pinder, Prime Site Research Solutions

Saturday, Apr 13 10:15 AM - 11:15 AM, Meeting Room 205

Integrating Quality into Investigator-Initiated Clinical Trials

Track: Site Management

There are many steps that must be taken to assess risk and integrate quality when developing, initiating and conducting a clinical trial. These steps are crucial for every type of clinical trial. This session will describe how to apply those principles to investigator-initiated clinical trials utilizing tips, tools and templates available to help along the way.

Learning Objective 1: Identify quality standards, and areas of risk, for clinical trials

Learning Objective 2: Describe measures to incorporate quality into study design and initiation of Investigator-Initiated Trials (IITs)

Learning Objective 3: Examine ways to assess quality during IIT study conduct

Learning Level: Intermediate

Primary Competency: Clinical Trials Operations (GCPs)

Secondary Competency: Study and Site Management

Credit Type: 1.00 ACRP, CME, CNE

Neala Lane, Indiana University

Saturday, Apr 13 10:15 AM - 12:15 PM, Meeting Room 201

Post-ICH GCP E6 R2: Institution/Investigator Qualification and Oversight of External Parties in Clinical Trials

Track: Site Management

Since the publication and global implementation of ICH GCP E6 R2, Institutions and Investigators are grappling with the appropriate and adequate approaches for qualifying external parties (e.g., testing facilities [clinical laboratories, radiology centers, medical specialists [ophthalmologist]]) and implementing oversight of delegated trial-related duties, functions, activities and tasks. This session reviews the requirements and includes a panel discussion with experts in institutional research administration, operations and compliance, GCP compliance and a clinical investigator on how to implement the requirements, and how the sponsor/CRO Study Managers and Site Monitors are to monitor and manage the investigator/site.

Learning Objective 1: Evaluate external parties responsibilities and contributions to the study in order to accurately design and implement investigator supervision and oversight of the work performed and data generated for the trial.

Learning Objective 2: Discuss the Investigator/Institution ICH GCP E6 R2 requirements for the qualification and oversight of an individual/party (external parties).

Learning Objective 3: Analyze healthcare organization qualification standards and approaches for both a facility and medical practitioners to leverage in clinical research for the ICH GCP E6 R2 requirements.

Learning Level: Intermediate

Primary Competency: Study and Site Management

Secondary Competency: Clinical Trials Operations (GCPs)

Credit Type: 2.00 ACRP, CME, CNE

Liz Wool, Wool Consulting Group Inc.; Erika Stevens, Recherche Transformation Rapide, LLC; Lionel Lewis, Dartmouth Medical School

Saturday, Apr 13 11:30 AM - 12:30 PM, Meeting Room 209C

Transformational Technologies in Pharma – What’s here, What’s Coming – and Why Now?

Track: Technology

Technology is changing at light speed and the automobile, retail, airline, finance and many other industries have made a concerted effort to adapt to such. The pharmaceutical industry has been a lagger in adapting to newer technologies and clinical trial processes have evolved very little in two decades. However, the regulatory authorities are embracing an effort to transformation clinical trials and change is now inevitable for sponsors, CROs, clinical sites and patients. How are/will wearables, digital therapeutics, digital medicine, real world data, machine learning, artificial intelligence and telemedicine impacting the future of clinical trials; are we all ready for it – is the real question.

Learning Objective 1: 1. Describe the changing regulatory landscape specific to data collection and technologies.

Learning Objective 2: 2. Identify technologies that are shifting and reshaping clinical trial processes for patients and sponsors, and why?

Learning Objective 3: 3. Define the value proposition of leveraging transformational technologies for patients in clinical trials; what’s in it for them?

Learning Level: Intermediate

Primary Competency: Technology

Secondary Competency: Leadership and Professionalism

Credit Type: This session does NOT offer ACRP Contact Hours or CEUs of any kind.

Debbie Profit, Otsuka Pharmaceutical Development & Commercialization

Saturday, Apr 13 11:30 AM - 12:30 PM, Meeting Room 207ABC

Effective Project Management to Streamline your Clinical Trial Workload

Track: Project Management/Device

In clinical trials, studies are complex, time-intensive and leave little to no room for error. Particularly when conducting concurrent studies with limited resources, it can be difficult to ensure quality and timely data collection and entry on every study. This can lead to stress and unhappiness with staff despite the meaningful work they contribute to improve treatment options. Clear and effective project management can make or break the success of a clinical trial, and project planning and management are a key part of achieving quality clinical data.

Learning Objective 1: Describe essential factors needed for effective project management of clinical trials.

Learning Objective 2: Assess your workload to determine how to effectively tackle items

Learning Objective 3: Identify tools to assist with streamlining tasks and work efficiently

Learning Level: Intermediate

Primary Competency: Study and Site Management

Secondary Competency: Clinical Trials Operations (GCPs)

Credit Type: 1.00 ACRP, CNE

Vatche Bartekian, Vantage BioTrials

Saturday, Apr 13 11:30 AM - 12:30 PM, Meeting Room 205

Expanded Access vs. "Right to Try"; Navigating Disparate Pathways for Desperate Patients

Track: Site Management

Expanded access to investigational drugs and devices has been available for decades through special pathways provided by the FDA. More recently, two federal actions have widened this access. 1. A federal law allowing for the "right to try" these same unapproved products has been enacted by US Lawmakers. 2. The previous rules governing expanded access have been modified to streamline the process to expedite such access. How do they differ? How should regulatory and research professional advise and/or assist patients faced with these choices? This session will provide a current and complete description of the two pathways, their advantages and challenges.

Learning Objective 1: Describe the fundamental differences between the "Right to Try" law and Expanded Access provisions

Learning Objective 2: Discern the challenges presented by each pathway.

Learning Objective 3: Provide guidance to desperate patients and their clinicians seeking access to unapproved therapies.

Learning Level: Advanced

Primary Competency: Clinical Trials Operations (GCPs)

Secondary Competency: Ethical and Participant Safety Considerations

Credit Type: 1.00 ACRP, CME, CNE

Robert Romanchuk, Advarra IRB

Saturday, Apr 13 11:30 AM - 12:30 PM, Meeting Room 209AB

Implementing a Competency Based Onboarding Program for Clinical Research Nurses and Coordinators

Track: Career Growth

This presentation will provide an overview of the key concepts a clinical research nurse or coordinator should know prior to independently managing their own clinical research project and how they should be incorporated into a clinical research training program. Identifying the right tactics to engage adult learners is often a trial and error process and this presentation will explore multiple methods to provide learners with the content they need to know and the pros and cons of each. Attendees will receive checklists, competency scales and week by week guides used in the onboarding program being utilized at Nationwide Children's Hospital.

Learning Objective 1: Identify key concepts to be included in a clinical research training program

Learning Objective 2: Explore various training methods to improve comprehension of concepts presented

Learning Objective 3: Discuss tools that aid in evaluating individual competence in a given content area to predict future performance

Learning Level: Intermediate

Primary Competency: Clinical Trials Operations (GCPs)

Secondary Competency: Study and Site Management

Credit Type: This session does NOT offer ACRP Contact Hours or CEUs of any kind.

Grace Wentzel, Nationwide Children's Hospital

Saturday, Apr 13 11:30 AM - 12:30 PM, Meeting Room 208

The Missing Links in CRA Training...How Do We Fix the Chain?

Track: Monitoring

This session will examine the most frequent errors witnessed at a study site due to lack of/poor training on the part of the Clinical Research Associate. Training tips and remediation ideas along with a comprehensive dialogue on how to improve training will be presented. Session participants will be asked to share their viewpoints and experiences as to what they have seen

and implemented at their study sites.

Learning Objective 1: List the most common oversights encountered at a study site due to a lack of adequate CRA (Clinical Research Associate) training

Learning Objective 2: Identify solutions and training tips for filling in the training gaps to ensure compliance and decrease the 'slip-ups'

Learning Objective 3: Discuss with session attendees what is currently 'working' and what is 'not working' on the training forefront at their study sites

Learning Level: Intermediate

Primary Competency: Study and Site Management

Secondary Competency: Communication and Teamwork

Credit Type: This session does NOT offer ACRP Contact Hours or CEUs of any kind.

Annette Bernstein, Johnson & Johnson; Sandra Hines, PRA Health Sciences

Saturday, Apr 13 11:30 AM - 12:30 PM, Meeting Room 207D

Unveiling the Mystery of Quality Tolerance Limits

Track: Project Management/Device

This session focuses on answering the questions of what quality tolerance limits (QTLs), risk indicators, and thresholds are by defining them and discussing how to establish them. We will look at examples of QTLs, and thresholds and discuss appropriate responses to breaches in the thresholds. In addition, documentation of breaches will be reviewed, reporting expectations and long-term plans for the QTLs, and thresholds. Key take-aways will include examples of QTLs, and thresholds to help one get started with establishing QTLs at their organization.

Learning Objective 1: Define quality tolerance limits, risk indicators, and thresholds

Learning Objective 2: Describe how to formulate quality tolerance limits, risk indicators, and thresholds

Learning Objective 3: Discuss the maintenance of QTLs, reporting expectations, and long term plans

Learning Level: Beginner

Primary Competency: Clinical Trials Operations (GCPs)

Secondary Competency: Study and Site Management

Credit Type: 1.00 ACRP

Susan Leister, Barnett International

Saturday, Apr 13 12:30 PM - 2:00 PM, Exhibit Hall

Exhibit Hall Open / Lunch Served

Saturday, Apr 13 12:45 PM - 1:15 PM, Exhibit Hall

Learning Lab: Complion eRegulatory: From Complexity to Compliance (Sponsored by Complion)

Please Note: This session does NOT offer ACRP Contact Hours or CEUs of any kind.

Saturday, Apr 13 1:30 PM - 2:00 PM, Exhibit Hall

Learning Lab: The Shared Investigator Platform; Past, Present, and Future (Sponsored by TransCelerate Biopharma)

Please Note: This session does NOT offer ACRP Contact Hours or CEUs of any kind.

Saturday, Apr 13 2:00 PM - 3:00 PM, Grand Ballroom C

'Signature Series' - Set Extraordinary Expectations

Kristin Smedley is proof that a change in perception can drive one person to impact an entire field. Eighteen years ago Kristin was on course to achieve her dream: Teacher of the Year. However, fate had an unanticipated outcome for her destiny. Her two sons were diagnosed soon after birth with a rare blindness. Although Kristin was initially paralyzed with fear, she launched an extraordinary mission to change their bleak future. Kristin will demonstrate how the power of perceptions and expectations drives your outcomes and discuss components necessary to ignite your own extraordinary journey through her (often hilarious) real life stories and examples.

Learning Objective 1: Discover how the power of perception and expectations can drive your outcomes.

Learning Objective 2: Learn the components necessary to ignite your own extraordinary journey

Learning Objective 3: Discover key developments in rare diseases that are currently being

developed

Learning Level: Beginner

Primary Competency: Leadership and Professionalism

Secondary Competency: Communication and Teamwork

Credit Type: 1.00 ACRP

Kristin Smedley, Curing Retinal Blindness Foundation

Saturday, Apr 13 3:15 PM - 4:15 PM, Meeting Room 208

Digital Health: A Clinical & Regulatory Update

Track: Technology

Software as a Medical Device (SaMD) is performing a larger and more impactful role in patient care than ever before, and new technologies present new regulatory and development challenges. This presentation explores Digital Health technologies and the challenges and opportunities they present to industry, health care providers, and global regulators. After a brief review of the regulatory approaches used for Digital Health technologies across multiple international venues, the US FDA's Digital Health Precertification Program will be explored. The underlying principles, philosophy and challenges to digital health tech development will be presented, the real and potential "value" of SaMD will be defined, and implications for research and regulatory professionals will be discussed.

Learning Objective 1: 1. Identify at least 3 different types of digital technologies that are being developed today and their potential impact on patient health and healthcare.

Learning Objective 2: Discuss how the "value" of a digital technology is assessed.

Learning Objective 3: Describe FDA PreCert regulatory framework for the development and approval of digital health technologies.

Learning Level: Intermediate

Primary Competency: Medicines Development and Regulations

Secondary Competency: Clinical Trials Operations (GCPs)

Credit Type: This session does NOT offer ACRP Contact Hours or CEUs of any kind.

Robin Newman, Johnson & Johnson Medical Devices

Saturday, Apr 13 3:15 PM - 5:15 PM, Meeting Room 202

A Deeper Dive: What Makes a Great CRA

Track: Monitoring

Join the continued discussion from ACRP 2018 session with data from session participants to gain insights regarding skills and competencies of today contrasted to those of tomorrow for a CRA. This session included a 360 perspective and discussion of what makes a great CRA. Through the proposed session discussion and data, it is a conversation to be continued through a deeper dive into a few key areas. These areas include technology skills, regulatory knowledge and RCA competency. During this session, our team will reconvene to discuss and share specific recommendations for how to ensure CRAs, employers of CRAs and research sites engaging with CRAs are best prepared to support and optimize the performance of individuals who are undergoing a shift within a long-established role for our industry.

Learning Objective 1: Understand resources available to advance skills of CRAs

Learning Objective 2: Understand and apply the application of root cause analysis to the CRA scope of responsibilities.

Learning Objective 3: TBD

Learning Level: Intermediate

Primary Competency: Communication and Teamwork

Secondary Competency: Study and Site Management

Credit Type: 2.00 ACRP

Jaylene Weigel, Children's Mercy; Lynn King, PPD; Patricia Cataruozolo, Pfizer; Tegan Mead, Javara Inc.

Saturday, Apr 13 3:15 PM - 4:15 PM, Meeting Room 205

2019 Regulatory Update

Track: Leadership

Join us for a stimulating presentation that offers a high level overview of the recent changes to laws, regulations, policies and trends that affect our industry. Many of these are from FRDA and OHRP but many are intended mostly for healthcare operations that are unintentionally (or intentionally) bleeding over into research operations.

Learning Objective 1: identify several new and updates to laws and regulations that affect our

industry

Learning Objective 2: recall summaries of the relevant parts that may affect our industry

Learning Objective 3: hypothesize on how these regulations may impact operations

Learning Level: Advanced

Primary Competency: Study and Site Management

Secondary Competency: Ethical and Participant Safety Considerations

Credit Type: 1.00 ACRP, CME, CNE

David Vulcano, HCA

Saturday, Apr 13 3:15 PM - 4:15 PM, Meeting Room 209C

Thinking ahead - Enterprise-Wide Implementation of a Clinical Research Management System

Track: Technology

Duke invested in a new clinical research management system (CRMS) to improve quality and support reworked business processes that create administrative simplicity and operational excellence. The CRMS is the central tool to track the clinical research operations portfolio. Its integration with the electronic IRB system (a 1:1 match on protocols, including exemptions) is critical to understanding the diverse clinical research activities across the institution. This required Duke to: implement system-wide workflows, create pathways for heavy and infrequent users, and develop tools for monitoring non-compliance and data completeness. The CRMS has been integral in helping study teams use standardize workflows. Nearly a year post-go live, this presentation will review key success factors, decision points, challenges and successes of an enterprise-wide adoption of Forte's CRMS, OnCore.

Learning Objective 1: Identify key success factors with an enterprise-wide implementation of OnCore

Learning Objective 2: Recognize Recognize potential benefits of multisystem approach to clinical research management

Learning Objective 3: Identify technology adoption approaches and key success factors for a variety of users

Learning Level: Intermediate

Primary Competency: Technology

Secondary Competency: Clinical Trials Operations (GCPs)

Credit Type: This session does NOT offer ACRP Contact Hours or CEUs of any kind.

Denise Snyder, Duke University Medical Center; Orla Mester, Forte Research Systems, Inc.

Saturday, Apr 13 3:15 PM - 4:15 PM, Meeting Room 209AB

Clinical Misconduct: Examples and Implications for your Clinical Staff

Track: Site Management

The Buck Stops with the PI... or Does It? Regulation states that ultimate responsibility for a clinical trial rests with the principal investigator. This session will provide information on the implications and consequences of investigator and staff misconduct in clinical research. Using case studies and actual findings, participants will learn about clinical trials compliance, what kinds of misconduct have occurred in the past and the consequences of a finding of misconduct. Reasons for committing fraud will be explored.

Learning Objective 1: Define Scientific misconduct in clinical research

Learning Objective 2: List three case examples of investigator and coordinator misconduct

Learning Objective 3: Describe the consequences of misconduct

Learning Level: Advanced

Primary Competency: Clinical Trials Operations (GCPs)

Secondary Competency: Ethical and Participant Safety Considerations

Credit Type: 1.00 ACRP

Michael Hamrell, MORIAH Consultants; Janet Holwell, Independent Consultant

Saturday, Apr 13 3:15 PM - 5:15 PM, Meeting Room 201

Risk Management, the Crash Course

Track: Project Management/Device

Are you prepared for the risk management requirements in ICH GCP E6 (R2)? This session will provide a high-level walk through of quality risk management, the key components of a risk management program, and how to conduct a risk assessment at the system and protocol level. We will review the key steps of the process: risk identification, assessment, control, review, reporting, management, and communication. Having an effective risk management program not only ensures compliance with the ICH GCP E6 R2 requirements, but also ensures continuous improvement strategies for your clinical trials. Practical take-aways will be shared along with sample tools.

Learning Objective 1: Define Quality Risk Management (ICH GCP E6 R2 & ISO 31000)

Learning Objective 2: Describe the framework for a risk management program

Learning Objective 3: Describe the key steps of risk assessment at the system and protocol level

Learning Level: Beginner

Primary Competency: Clinical Trials Operations (GCPs)

Secondary Competency: Study and Site Management

Credit Type: 2.00 ACRP, CME, CNE

Susan Leister, Barnett International

Saturday, Apr 13 3:15 PM - 4:15 PM, Meeting Room 207ABC

The Impact of Disruptive Change in the Clinical Trials Industry on Research Sites

Track: Site Management

As we head towards the end of the second decade of the twenty first century a great deal has changed about the way research is done at the site level particularly as it relates to the many disruptive technology driven changes that have evolved. Or has it? After 13 years managing sites and taking the investigator view followed by thirteen years in the CRO industry taking the sponsor view, the author will look at what has changed in over a quarter of century and the future holds for clinical research sites. In particular he will look at the site landscape through the lens of four, supposedly major, disruptive changes

Learning Level: Intermediate

Primary Competency: Study and Site Management

Secondary Competency: Ethical and Participant Safety Considerations

Credit Type: 1.00 ACRP, CNE

Paul Evans, Velocity Clinical Research

Saturday, Apr 13 4:30 PM - 5:15 PM, Meeting Room 207D

techXpo: The Paperless Site – eREG and eSOURCE (sponsored by RealTime Software Solutions)

Rick Greenfield, RealTime Software Solutions, LLC

Please Note: This session does NOT offer ACRP Contact Hours or CEUs of any kind.

Saturday, Apr 13 4:30 PM - 5:30 PM, Meeting Room 209C

Insights from Industry Technology Competency and Adoption Survey – What This Means for You and Your Organization

Track: Technology

ACRP and Forte have recognized that there is a critical need improve tech adoption in clinical trial operations and to define and refine the technology-related skill sets and competencies. Such competencies will more effectively adapt and develop job descriptions, hiring practices, and training programs that enable a more tech-savvy and more sustainable workforce. Therefore, the two organizations collaborated to launch the Technology Competency and Adoption survey in early 2019. We will be sharing highlights from the survey results with a focus on discussing: • Barriers to competency achievement and technology adoption • How individuals can enhance their individual competency • Best practices for how organizations can foster improved adoption of clinical research technologies

Learning Level: Intermediate

Primary Competency: Technology

Secondary Competency: Clinical Trials Operations (GCPs)

Credit Type: This session does NOT offer ACRP Contact Hours or CEUs of any kind.

Beth Harper, ACRP; Wendy Tate, Forte

Saturday, Apr 13 4:30 PM - 5:30 PM, Meeting Room 209AB

7 Breakthrough Behaviors for Clinical Research Project Managers

Track: Career Growth

Clinical Project Managers (CPMs) can spend a considerable amount of time “firefighting”. This talk will present 7 behaviors that CPMs can internalize and demonstrate to prevent firefighting. The discussion will also include real-world examples and tried-and-true techniques that will help avoid some of the pitfalls, along with the hefty benefits garnered when the behaviors are embraced.

Learning Objective 1: Define strategic and soft-skill behaviors clinical project management, agnostic of process or organizational framework.

Learning Objective 2: Employ essential behaviors that, when internalized and demonstrated, can obviate the need for Clinical Project Managers to spend a significant time firefighting.

Learning Objective 3: Cite real-world examples and tried-and-true techniques that will help avoid some of the pitfalls of clinical project management.

Learning Level: Intermediate

Primary Competency: Study and Site Management

Secondary Competency: Communication and Teamwork

Credit Type: 1.00 ACRP

Dalfoni Banerjee, 3Sixty Pharma Solutions LLC.

Saturday, Apr 13 4:30 PM - 5:30 PM, Meeting Room 205

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

Track: Leadership

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

Learning Objective 1: Understand how to use the state and federal False Claims Acts as fraud enforcement tools.

Learning Objective 2: Discuss the recent cases brought under the False Claims Act for fraud in clinical research.

Learning Objective 3: Understand how to protect yourself, the company and clinical studies by detecting and reporting fraud.

Learning Level: Beginner

Primary Competency: Ethical and Participant Safety Considerations

Secondary Competency: Leadership and Professionalism

Credit Type: 1.00 ACRP, CME, CNE

Shauna Itri, Berger & Montague PC

Saturday, Apr 13 4:30 PM - 5:30 PM, Meeting Room 207ABC

US FDA Submission Process for Medical Devices

Track: Project Management/Device

Regulatory submissions are a result of teamwork, often occurring over many years. Each person involved in the testing, organization, or clinical studies is integral to the success of the submission. This session will take a step by step approach to walk attendees through what is required in the 510(k) and PMA submission process; and how you can best support the process. In order to commercialize, additional FDA establishment registration and device listings are required; these registration/listings help the FDA plan facility inspections. Participants of this session will get a broad appreciation of the submission process and some best practices to support your team in the regulatory submission process.

Learning Objective 1: Characterize the steps in the submission process.

Learning Objective 2: Discuss the Device Establishment Registration & Medical Device Listing as defined in 21 CFR Part 807.

Learning Objective 3: Define the timeline that needs to be followed to register a device and the steps a foreign company needs to follow to register and appoint a US Agent.

Learning Level: Intermediate

Primary Competency: Medicines Development and Regulations

Secondary Competency: Medicines Development and Regulations

Credit Type: 1.00 ACRP, CNE

Angela Mallery, NAMSA

Saturday, Apr 13 4:30 PM - 5:30 PM, Meeting Room 208

Write Like an 8th grader! Improving Readability in Clinical Research

Track: Monitoring

How do you ensure that your clinical research materials are readable for the audiences you want to reach? This session will help you learn how to measure and improve the readability of your clinical research communications to a participant and public-facing audience. We will discuss the importance of readability and explore the pros and cons of tools you can use. Case examples from the Duke Clinical Research Institute including informed consent forms, recruitment materials, and lay summaries will highlight how to use free and existing resources to improve your communication.

Learning Objective 1: Understand our national readability problem and how it affects the public's understanding of science and medicine.

Learning Objective 2: Diagnose and improve readability in your communications materials, including informed consent language, recruitment materials, and all participant-facing materials.

Learning Objective 3: Know about existing resources to help you write in plain language and templated language for various grade levels.

Learning Level: Beginner

Primary Competency: Ethical and Participant Safety Considerations

Secondary Competency: Communication and Teamwork

Credit Type: 1.00 ACRP

Jennifer Cook, Duke Clinical Research Institute

Saturday, April 13 5:30 PM - 6:30 PM, Exhibit Hall

Expo Hall Happy Hour

Sunday, Apr 14 7:00 AM - 5:00 PM, Outside of Exhibit Hall A2, Music City Center

Registration Desk Open

Sunday, Apr 14 8:00 AM - 9:00 AM, Grand Ballroom C

'Signature Series' - The Reality of Change

What would happen if you transformed your view on change? What if you learned how to master positive change and lead others through the process? The impact of this transformation will surprise you. Your ability to embrace and engage in meaningful change will extend into all areas of life. The Reality of Change Leadership will become a catalyst for positive change in your

organization and beyond.

Learning Level: Beginner

Primary Competency: Leadership and Professionalism

Secondary Competency: Communication and Teamwork

Credit Type: 1.00 ACRP, CME, CNE

Fred Johnson, InitiativeOne

Sunday, Apr 14 9:00 AM - 10:00 AM, Exhibit Hall

Expo Hall Open / Coffee Break

Sunday, Apr 14 9:15 AM - 9:45 AM, Exhibit Hall

Learning Lab: Leveraging Technology to Improve Monitoring in Clinical Trials (Sponsored by Covance)

Kristin Stallcup, Covance

Please Note: This session does NOT offer ACRP Contact Hours or CEUs of any kind.

Sunday, Apr 14 10:15 AM - 11:00 AM, Meeting Room 207D

techXpo: Curing Patient Burden: Site-Centric Telemedicine (Sponsored by VirTrial)

Kim Kundert, VirTrial; Amanda Rangel, VirTrial

Please Note: This session does NOT offer ACRP Contact Hours or CEUs of any kind.

Sunday, Apr 14 10:15 AM - 11:15 AM, Meeting Room 205

An Introduction to Gene Therapy Research

Track: Site Management

Gene therapy studies are becoming increasingly common as the US FDA and other countries have begun issuing approvals for gene therapies, particularly in the field of oncology. Gene

therapy studies pose exciting advancements for clinical research but also involve additional risks and regulatory requirements. Gene therapy studies receiving federal funds or taking place at sites receiving federal funds, require review by both an IRB and an Institutional Biosafety Committee prior to registering with the National Institutes of Health (NIH). Further review may be required by the NIH Recombinant DNA Advisory Committee (RAC). This presentation will summarize the current state of gene therapy research and the associated risks. Attendees will learn how to obtain the necessary regulatory approvals and prepare sites to conduct gene therapy research.

Learning Objective 1: Understand what is gene therapy research and the associated federal requirements.

Learning Objective 2: Understand how to request approval for gene therapy research.

Learning Objective 3: Understand the challenges in preparing sites for approval to conduct gene therapy research.

Learning Level: Beginner

Primary Competency: Ethical and Participant Safety Considerations

Secondary Competency: Medicines Development and Regulations

Credit Type: 1.00 ACRP, CME, CNE

Daniel Eisenman, Advarra

Sunday, Apr 14 10:15 AM - 11:15 AM, Meeting Room 209AB

Working Smarter, Not Longer

Track: Career Growth

Looking to find new ways to organize and increase your workload without becoming overwhelmed? This session will break down how you can better understand your strengths and utilize them to improve productivity. We will cover how this can be applied in the patient setting to provide the best care for your patients before, during and after the visit. We will also cover how you can use these skills to improve communication and data deadlines with sponsors. Lastly, this session will cover tips and examples where organization and multitasking can improve the amount of work being completed.

Learning Objective 1: Understanding your strengths

Learning Objective 2: Utilizing those strengths to complete tasks with excellence

Learning Objective 3: Tricks of Multitasking & Organization

Learning Level: Beginner

Primary Competency: Communication and Teamwork
Secondary Competency: Study and Site Management

Credit Type: 1.00 ACRP

Jennifer Pruitt, Arizona Pulmonary Specialists, Ltd

Sunday, Apr 14 10:15 AM - 11:15 AM, Meeting Room 208

Cybersecurity: Is Your Clinical Research Data Protected?

Track: Site Management

Maintaining the confidentiality, integrity, and availability of data and systems is critical in healthcare. A cybersecurity incident could result in the compromise of critical information or systems, disruption of operations, and even harm to patients. For these reasons, multiple layers of security defenses are needed to protect our people, data, devices, systems, and networks. People in all roles need to understand the critical part they play and how to utilize processes and technology to protect our ecosystem.

Learning Objective 1: Understand key cybersecurity risk considerations for clinical research

Learning Objective 2: Identify key defense principles to protect against cyber threats

Learning Objective 3: Understand actions each person can and should take to defend against cyberattacks

Learning Level: Beginner

Primary Competency: Ethical and Participant Safety Considerations

Secondary Competency: Technology

Credit Type: 1.00 ACRP

Paul Connelly, HCA

Sunday, Apr 14 10:15 AM - 11:15 AM, Meeting Room 207ABC

Advancing Medical Device Innovation and Safety: An FDA Perspective

Track: Site Management

CDRH's vision is that patients in the US have access to high quality, safe and effective medical

devices of public health importance first in the world. Ten years ago, the medical device regulatory landscape was perceived to have limited options for bringing new therapies and devices to patients in a timely manner. Today, however, that outlook has changed due in part to the significant efforts that FDA has taken to advance medical device innovation and safety by focusing on our vision. This presentation will provide an overview of multiple CDRH initiatives across the total product lifecycle ranging from streamlined regulatory approaches for clinical studies to new programs for expediting review of devices which address unmet medical needs, and increased opportunity for using real world evidence to support regulatory submissions.

Learning Objective 1: 1. The available FDA initiatives to bring safe and effective medical devices to patients in a timely manner

Learning Objective 2: 2. The alignment of FDA initiatives for increasing patient access to medical devices with the total product lifecycle

Learning Objective 3: 3. How to engage with FDA through these programs in a collaborative and interactive approach to facilitate innovative medical device development.

Learning Level: Intermediate

Primary Competency: Scientific Concepts and Research Design

Secondary Competency: Clinical Trials Operations (GCPs)

Credit Type: 1.00 ACRP, CNE

Maureen Dreher, US Food and Drug Administration, Center for Devices & Radiological Health

Sunday, Apr 14 10:15 AM - 12:15 PM, Meeting Room 201

Inspection Readiness – Beginning with the End in Mind

Track: Site Management

Sponsors, CROs, and Investigator sites are all too aware of the stress of preparing for a health authority inspection. The challenge is that most organizations begin preparing for an inspection when a drug is filed for approval or they receive notification of an inspection. The key to a successful inspection is preparing at the start of the study. Ensuring that your Investigator Site File (ISF) and Trial Master File (TMF) are built in a way that the complete documentation tells the story of the study, will ensure that you are ready come inspection day. The session will also include common GCP violations that are evident in the TMF/ISF and can result in findings.

Learning Objective 1: Identify 4 strategies for ensuring that their organization is inspection ready through-out the life of the study

Learning Objective 2: Identify 2 current trends in health authority inspections of both the investigator site and the sponsor/monitor organization

Learning Objective 3: Identify 3 techniques for ensuring that their study documentation tells the story of the study

Learning Level: Intermediate

Primary Competency: Clinical Trials Operations (GCPs)

Secondary Competency: Study and Site Management

Credit Type: 2.00 ACRP, CME, CNE

Donna Dorozinsky, Barnett International

Sunday, Apr 14 10:15 AM - 11:15 AM, Meeting Room 209C

Leveraging Technology at the Site: Putting the Humanity back in Clinical Trials

Track: Technology

We spend too much time in Clinical Research battling the technology that is supposed to be there to help us. That's time taken away from caring for the patient. By utilizing available solutions that are designed to align current technologies across siloes, we can ease the burden on the research staff, so that Investigators and staff can get back to the disciplines that drew them to the healing arts in the first place. This session will address the technology options available to sites, and participants should walk away empowered, knowing that it's not an "either-or", but an "and"; that they can support the patient and still not be shackled by the technology involved.

Learning Objective 1: Identify the barriers that Sponsor-provided technology creates and how to solve them.

Learning Objective 2: Have a Working knowledge of current technologies and how to leverage them to be able to keep your focus on your patient.

Learning Objective 3: Zero in on the identification of time-wasting elements within clinical research and how to begin eliminating them.

Learning Level: Beginner

Primary Competency: Study and Site Management

Secondary Competency: Technology

Credit Type: 1.00 ACRP

Stephanie Abbott, Western Washington Medical Group

Sunday, Apr 14 10:15 AM - 12:15 PM, Meeting Room 202

The Path of Least Resistance – Managing Opposition to Change

Track: Site Management

One of the biggest challenges to implementing change in an organization is employee resistance to change. This session introduces participants to the challenges and obstacles that resistance poses and presents research-based change management practices to mitigate resistance to change. A real-world case study will be used to demonstrate the principles and will be followed throughout the session. Through structured and guided exercises and small group discussion, participants will have the opportunity to apply the learning to a change they are experiencing in their own organization.

Learning Objective 1: Identify resistance to change within your organization as well as within yourself

Learning Objective 2: Apply established practices to minimize/manage resistance

Learning Objective 3: Develop a strategy to manage resistance within your scope of work

Learning Level: Intermediate

Primary Competency: Communication and Teamwork

Secondary Competency: Leadership and Professionalism

Credit Type: 2.00 ACRP

Ryan Bailey, Rho; Heather Kopetskie, Rho; Shann Williams, Rho

Sunday, Apr 14 11:30 AM - 12:15 PM, Meeting Room 207D

techXpo: eSource: Save Time and Improve Your Site's Workflow (Sponsored by Clinical Research IO)

Eric Elander, Clinical Research IO

Please Note: This session does NOT offer ACRP Contact Hours or CEUs of any kind.

Sunday, Apr 14 11:30 AM - 12:30 PM, Meeting Room 205

Understanding Regulatory Guidance for Gene Therapy Development

Track: Site Management

It has been a big year for gene therapy. In the past 12 months, three gene therapy products received approval from FDA. In July 2018, FDA Commissioner Scott Gottlieb released a statement on the FDA's efforts and commitment to advance gene therapy. The statement included the announcement of six new or revised guidance documents related to the development of gene therapy products. In this presentation, Dr. Vaughn will review Commissioner Gottlieb's statement, provide an overview of the six guidance documents, and discuss the implications for clinical development of new gene therapy products.

Learning Objective 1: Identify the six new draft guidance documents recently released by the FDA in the area of gene therapy

Learning Objective 2: Understand the basic recommendations the FDA has for sponsors and researchers working in the area of gene therapy

Learning Objective 3: Describe general differences between the development of gene therapy products and traditional pharmaceutical products

Learning Level: Intermediate

Primary Competency: Medicines Development and Regulations

Secondary Competency: Scientific Concepts and Research Design

Credit Type: 1.00 ACRP, CME, CNE

Meagan Vaughn, Rho; Mallory Hicks,

Sunday, Apr 14 11:30 AM - 12:30 PM, Meeting Room 209AB

Rapid-Fire: 'Certify'ably Confused: Certifying Source Documentation

Track: Career Growth

This one-hour session will consist of seven, 5-minute presentations, on hot topics in the clinical research industry. The sessions will be designed to differentiate between myth and fact, guidance on hot topics and fun inspirational stories.

Credit Type: This session does NOT offer ACRP Contact Hours or CEUs of any kind.

David Vulcano, LCSW, MBA, CIP, RAC | Dalfoni Banerjee, B.A. | Stephanie Abbott, PharmD | Romiya Barry, M.Sc. | Katie Dry, PT, DPT, MS | Gina Remington, RN, MSN

Sunday, Apr 14 11:30 AM - 12:30 PM, Meeting Room 208

Leading Clinical Research Workforce Transformation

Track: Leadership

Research affects care. Without clinical research, we have standard of care. However, the clinical research landscape is complicated and increasingly burdensome to clinician scientists. To better handle the evolution of the research landscape, the role of the clinical research professional has become even more important; employing a top-notch clinical research workforce is critical. Our AMC prioritized the role of the workforce by using a competency-based framework, developed by the Joint Taskforce for Clinical Trial Competency (JTF), for many related initiatives: to 1) overhaul job classifications, 2) create advancement through a tiering process, 3) establish a professionals network, 4) align competencies with on-boarding and training, 5) create pipelines for clinical research positions, 6) centralize a hiring service, – all an institution-wide workforce strategic initiative called Workforce Engagement & Resilience (WE-R).

Learning Objective 1: Review the path of clinical research job competency implementation at a large academic medical center

Learning Objective 2: Describe the stakeholder engagement needed for competency adoption, institutional buy-in and sustainability

Learning Objective 3: Discuss the impact of overhauling job classifications and ROI as it relates to national efforts for improvement

Learning Level: Intermediate

Primary Competency: Leadership and Professionalism

Secondary Competency: Communication and Teamwork

Credit Type: 1.00 ACRP

Denise Snyder, Duke University Medical Center; Deborah Hannah, Duke University Medical Center

Sunday, Apr 14 11:30 AM - 12:30 PM, Meeting Room 207ABC

Project Review- A Transformational Change in Project Delivery

Track: Project Management/Device

It is critical to manage the performance on a project through key operational indicator metrics.

Those metrics assess the current operational and financial health of the project. The project team is responsible for ensuring the project delivery against the contracted statement of work. Through this ongoing review process, the team is able to proactively identify risks and develop a specific, actionable plan. Key operational indicators are critical during start-up, maintenance and close-out. The project manager is able to share this data with the Sponsor to ensure clear visibility and accountability on the project. The goal is to achieve flawless execution on a project by managing to the scope of work and providing quality deliverables within the required timeline.

Learning Objective 1: Review key operational indicators for assessing the health of a project

Learning Objective 2: Describe how to develop an action plan to improve execution of a project

Learning Objective 3: Discuss how to assess the risk associated with specific key operational indicators

Learning Level: Intermediate

Primary Competency: Study and Site Management

Secondary Competency: Leadership and Professionalism

Credit Type: 1.00 ACRP, CNE

Cynthia Venendaal, Clinipace

Sunday, Apr 14 11:30 AM - 12:30 PM, Meeting Room 209C

Vendor Management- Selecting, Budgeting, and Managing

Track: Project Management/Device

This presentation will focus on selecting the best vendors for a specific study, including vendor costs in the study budget, and how to successfully collaborate with the vendors from startup to close out. (This session will not cover qualification of vendors.) I will review the most common types of vendors needed for clinical research studies, what information each type will request from the study sponsor, and how to develop vendor budgets. There will be a discussion on how to review vendor proposals to determine the best fit for the study. Once selected, I will review methods to ensure oversight of the vendor during the length of the study.

Learning Objective 1: Identify criteria for selecting a vendor for a study

Learning Objective 2: List 2 sources of budgeting figures for early budget development

Learning Objective 3: Develop a plan for managing vendors from start up to close out

Learning Level: Advanced

Primary Competency: Study and Site Management
Secondary Competency: Clinical Trials Operations (GCPs)

Credit Type: 1.00 ACRP

Jill Petro, Janssen R&D

Sunday, Apr 14 12:30 PM - 2:00 PM, Exhibit Hall

Expo Hall Open / Lunch Served

Sunday, Apr 14 12:45 PM - 1:15 PM, Exhibit Hall

Learning Lab: Contract and Budget Negotiations - How to Maximize the Potential of Every Study (Sponsored by Clin-Edge)

Scott Palmese, BTC Network

Please Note: This session does NOT offer ACRP Contact Hours or CEUs of any kind.

Sunday, Apr 14 1:30 PM - 2:00 PM, Exhibit Hall

Learning Lab: Operationalizing the Single IRB Mandate: The Yale University Approach (Sponsored by WIRB-Copernicus Group (WCG))

Linda Coleman, Yale University; Stuart Horowitz, WIRB-Copernicus Group; Madeleine Williams, Huron Consulting Group

Please Note: This session does NOT offer ACRP Contact Hours or CEUs of any kind.

Sunday, Apr 14 2:00 PM - 3:00 PM, Grand Ballroom C

'Signature Series' - State of the Industry

Join Kenneth A. Getz, MBA, Director of Sponsored Research Programs & Research Associate Professor, Tufts Center for the Study of Drug Development, as he examines the forces shaping the current and future state of the clinical research industry. Explore the individual dynamics of technology, process, and workforce on the industry and their effect on each other.

Learning Level: Beginner

Primary Competency: Clinical Trials Operations (GCPs)
Secondary Competency: Study and Site Management

Credit Type: 1.00 ACRP, CME, CNE

Kenneth A. Getz, CSDD, Tufts University

Sunday, Apr 14 3:15 PM - 4:15 PM, Meeting Room 207ABC

Office of Regulatory Affairs (ORA) Update

Track: Leadership

This session will focus on an overview of the Office of Regulatory Affairs "Program Alignment" initiative including new divisions, what the initiative will mean for your next (or first) inspection, and who to contact with concerns. This session will also provide a review of current metrics associated with the Bioresearch Monitoring (BIMO) program, including common regulatory violations. Finally, recently released guidance documents and regulations changes related to good clinical practice will be discussed.

Learning Objective 1: Explain ORA's "Program Alignment" initiative

Learning Objective 2: Summarize bioresearch monitoring metrics

Learning Objective 3: Describe recent finalized guidance documents and regulations

Learning Level: Intermediate

Primary Competency: Clinical Trials Operations (GCPs)

Secondary Competency: Medicines Development and Regulations

Credit Type: 1.00 ACRP, CNE

Chrissy Cochran, FDA , Office of Bioresearch Monitoring Operations, Office of Regulatory Affairs

Sunday, Apr 14 3:15 PM - 4:15 PM, Meeting Room 209C

Identifying, Documenting, and Implementing Corrective Action Plans to Improve Site Compliance from a CRO Perspective

Track: Monitoring

This session will provide an overview on how to appropriately identify, document, and address

compliance issues noted at sites, from monitoring and Sponsor perspectives. There will be an overview of common monitor findings and a discussion about appropriate next steps for developing effective CAPAs. The escalation of issues to the Sponsor will be discussed along with how to adequately document compliance issues in monitoring reports and follow-up letters. Possible ways in which the Sponsor can handle noncompliances will be addressed, as well as the consequences and risks to the Sponsor and study if compliance issues are not addressed. The objective of this session will be to review site compliance from a CRO perspective, while also discussing practical and effective corrective actions from both the monitor's and Sponsor's view.

Learning Objective 1: 1. Identify appropriate Corrective and Preventative Action Plans (CAPAs) for common monitoring findings discuss ways to effectively implement CAPAs with sites.

Learning Objective 2: 2. Understand how to appropriately escalate issues to the Sponsor and the importance of properly documenting compliance issues in monitoring reports and follow-up letters.

Learning Objective 3: 3. Critically examine ways in which the Sponsor can attempt to secure compliance at a site where compliance issues have been identified.

Learning Level: Intermediate

Primary Competency: Study and Site Management

Secondary Competency: Communication and Teamwork

Credit Type: 1.00 ACRP

Stephani Hulec, IMARC Research Inc.; Meghan Kulaszewski, IMARC Research

Sunday, Apr 14 3:00 PM - 4:15 PM, Meeting Room 205

Regulatory and Legal changes, the Common Rule, and GDPR: How they can impact study data flow based on real and perceived changes to the privacy of information

Track: Site Management

The session will allow the audience to identify and anticipate compliance issues associated with the privacy concerns around the revised Common Rule. It will help the audience understand the reasons why institutions may require steps to help ensure privacy that will no longer be legally required by the revised Common Rule but may be required by research institutions because of ethical concerns. It will also provide the audience with information on the privacy concerns to anticipate when research involves or could involve data covered by the GDPR

Learning Objective 1: Understand the privacy implications of the revised Common Rule and GDPR on studies

Learning Objective 2: Identify the implications of the changes to the Common Rule and the implementation of GDPR on privacy considerations for studies

Learning Objective 3: Anticipate why study sites might not be willing to embrace the Common Rule changes as part of their oversight, even when the Common Rule permits less oversight of studies in some instances

Learning Level: Intermediate

Primary Competency: Data Management and Informatics

Secondary Competency: Ethical and Participant Safety Considerations

Credit Type: 1.00 ACRP, CME, CNE

Marti Arvin, CynergisTek

Sunday, Apr 14 3:15 PM - 4:15 PM, Meeting Room 209AB

Who's on First: Developing the Best Inspection Team

Track: Leadership

We are participants in the development process, impacting the lives of patients and improving the human condition. Global regulators expect us to comply with requirements to ensure data integrity and subject safety throughout the development life-cycle. When they come to review the processes, paper and people involved we must be ready. This visit is expected with known methods so why is there so much angst for an inspection? Taking a team approach, identify the strengths of your resources and aligning those to an inspection "game plan" brings confidence to any inspection team.

Learning Objective 1: Understand the roles and responsibilities of the different inspection team members

Learning Objective 2: Think critically to identify key inspection team members

Learning Objective 3: Propagate a confident inspection readiness culture

Learning Level: Intermediate

Primary Competency: Communication and Teamwork

Secondary Competency: Medicines Development and Regulations

Credit Type: 1.00 ACRP

Kara Harrison, FDA Quality and Regulatory Consultants, LLC; Michelleanne Bradley, Metis Consulting Services

Sunday, Apr 14 3:15 PM - 5:15 PM, Meeting Room 201

A Five Step Approach to Device Risk Management

Track: Project Management/Device

Companies are faced with challenges to make medical devices safe for human use. Risk management is an integral part of the medical device product development lifecycle. It helps medical device developers ensure that the product is reliable, works as expected and causes no harm to the patients, operators or the environment. In other words, the main purpose of the risk management cycle is to reduce or mitigate the chances of failure in the product. In this session participants will look at a five step approach to risk management. In this interactive session participants will gain knowledge into the identification, assessment, evaluation, reduction, control and monitoring of risk that are essential to device risk management. Speakers will provide tools, guidance, and some tips on developing a risk management strategy.

Learning Objective 1: • Describe the five steps in a risk management process and how to implement these steps though out the life cycle of the device.

Learning Objective 2: • Define two key aspects of device risk management.

Learning Objective 3: • Define how to measure what is an acceptable risk/benefit ratio and implement a risk matrix for a medical device.

Learning Level: Advanced

Primary Competency: Medicines Development and Regulations

Secondary Competency: Clinical Trials Operations (GCPs)

Credit Type: 2.00 ACRP, CME, CNE

Suheila Abdul-Karrim; Victor Chen, Kaiser Permanente

Sunday, Apr 14 3:15 PM - 4:15 PM, Meeting Room 207D

Scope - What Is It and Why Should I Care

Track: Project Management/Device

While most of us intuitively understand the concept of scope, many do not firmly understand how project managers use the terms "scope", "scope creep", and "scope change". After defining these terms, we will review parameters that most commonly define the scope of a project from both a sponsor, CRO, and site perspective. The importance of tracking scope

changes and monitoring for scope creep will be shown using examples of how these could impact on studies.

Learning Objective 1: Define the term "scope", "scope creep", and "scope change"

Learning Objective 2: List common parameters used to define the scope of a project

Learning Objective 3: Identify 3 common impacts of scope change

Learning Level: Intermediate

Primary Competency: Study and Site Management

Secondary Competency: Clinical Trials Operations (GCPs)

Credit Type: 1.00 ACRP

Jill Petro, Janssen R&D; John Rowell, LSU Health Shreveport

Sunday, Apr 14 3:15 PM - 4:15 PM, Meeting Room 208

The Evolution of Source Documents

Track: Site Management

This presentation is for a new coordinator or for coordinators who would like a refresher. The presentation will address the creation of comprehensive source documents and how to incorporate source documents within the electronic medical record system without creating more work. Source documentation is critical for obtaining accurate data. The number one cause of FDA 483s reported is that sites are not following the protocol. Therefore, developing well written source documents will provide detailed instructions on the information that must be collected. The presentation will also discuss utilizing the electronic case report form manual to identify additional data points to include in their documentation. Source documents should be organized in such a way that anyone is able to complete a visit without missing essential data points.

Learning Objective 1: define ALCOA/CCEA

Learning Objective 2: apply the skills for completing comprehensive source document templates

Learning Objective 3: identify inconsistencies with protocols compared with the electronic data capture system instructions to capture all requested data points

Learning Level: Beginner

Primary Competency: Clinical Trials Operations (GCPs)

Secondary Competency: Communication and Teamwork

Credit Type: 1.00 ACRP

Jennifer Kennedy, JAEB Center for Health Research

Sunday, Apr 14 3:15 PM - 5:15 PM, Meeting Room 202

Clinical Research Management Transformation: Infrastructure, Process, and Technology

Track: Technology

Clinical research program management is highly complex and requires coordination, communication and cooperation among multiple stakeholders, departments, and teams. Improving research management workflows is a priority for research programs. Reviewing organizational capabilities and streamlining multiple systems and workflows throughout the research program infrastructure expedites performance. Transforming research management infrastructure, processes, and technology enables efficiencies, and is key to improving cycle times and reducing redundancies. Identifying and effectively communicating with key stakeholders fosters champions for change and eliminates roadblocks for implementation success. Participants in this Master Session will learn practical, step-by-step transformational strategies and tools, and have the opportunity for hands-on practice using these tools through case studies.

Learning Objective 1: Assess current clinical research management processes and develop a gap analysis

Learning Objective 2: Analyze key processes for developing a future clinical research management model and roadmap; including identification of, and effective communication with, appropriate stakeholders

Learning Objective 3: Evaluate clinical research program transformation case studies using the provided strategies and tools

Learning Level: Advanced

Primary Competency: Leadership and Professionalism

Secondary Competency: Communication and Teamwork

Credit Type: 2.00 ACRP

Tina Noonan, Ascension St. Vincent Health System; Erika Stevens, Recherche Transformation Rapide, LLC

Sunday, Apr 14 4:30 PM - 5:30 PM, Meeting Room 207ABC

Legal and Regulatory Changes: A Year in Review

Track: Leadership

A lot has happened this year! Get up to speed with this overview session designed to bring you the highlights and breaking news since last year's ACRP Conference. How are recent legal and regulatory changes fundamentally affecting research? What should research sites and institutions be ready for in the coming months and years? Get answers to these questions and more through this session's issue-spotting exploration and analysis of changes in laws, regulations, and standards promulgated by FDA, DHHS, the NIH, and ICH.

Learning Objective 1: Identify recently proposed and adopted legislative and regulatory initiatives affecting research.

Learning Objective 2: Illustrate likely impact on current practices and evaluate importance of change.

Learning Objective 3: Evaluate whether further change is necessary or likely forthcoming.

Learning Level: Intermediate

Primary Competency: Medicines Development and Regulations

Secondary Competency: Clinical Trials Operations (GCPs)

Credit Type: 1.00 ACRP, CNE

Mitchell Parrish, Quorum Review

Sunday, Apr 14 4:30 PM - 5:30 PM, Meeting Room 208

Innovative Solutions. Best Practices. Excellence in Cancer Research

Track: Site Management

Dr. Skip Burris will present some of the challenges in Oncology research and some of the innovative solutions that he and his team at Sarah Cannon Research Institute have implemented to overcome these challenges. He will share some best practices and resources that can be utilized by other institutions and most of all he will share his key takeaway in clinical research that you won't want to miss.

Learning Objective 1: 1. Identify the key challenges that oncology research sites encounter and some innovative solutions that may foster success at your site.

Learning Objective 2: 2. Describe best practices for an oncology clinical research

organization/site.

Learning Objective 3: 3. Discuss key resources to provide additional guidance to your clinical research organization/site.

Learning Level: Intermediate

Primary Competency: Leadership and Professionalism

Secondary Competency: Study and Site Management

Credit Type: 1.00 ACRP

Howard Burris, Sarah Cannon

Sunday, Apr 14 4:30 PM - 5:30 PM, Meeting Room 209C

ALCOA-C Redefined: Writing Effective Site Monitoring Visit Reports

Track: Monitoring

Detailed and accurate documentation, source or otherwise, is crucial in clinical research and yet the site monitoring visit report is often perceived as a "B-list" actor when compared with the superstar, source documentation. Nothing could be further from the truth. The monitoring visit report not only documents observations at the site but is one of the main avenues for communicating important information to key stake holders in the clinical research process: study and site issues to the sponsor and facilitating sponsor oversight of the investigator and clinical study; issues of concern and corrective actions to the site staff, and site GCP compliance to regulatory authorities, especially during an audit. The importance of the monitoring visit report must be understood and guidance provided on how to write it effectively.

Learning Objective 1: Understand the role and importance of the site monitoring report in clinical research

Learning Objective 2: Identify the key information key stakeholders need in the site monitoring report

Learning Objective 3: Provide guidance for writing an effective site monitoring visit report

Learning Level: Beginner

Primary Competency: Communication and Teamwork

Secondary Competency: Clinical Trials Operations (GCPs)

Credit Type: 1.00 ACRP

Roslyn Hennessey, Westat

Sunday, Apr 14 4:30 PM - 5:30 PM, Meeting Room 209AB

Clinical Project Schedule Management: Successful Start-Up Planning

Track: Project Management/Device

Successful clinical trial projects don't happen, they require effective planning and processes at both the site and sponsor/CRO to meet timelines. The use of a project management tool, a Work Breakdown Structure (WBS) to define clinical trial start-up tasks, timelines, and assignments is an effective method to improve project success. Instruction on how to implement a WBS for clinical trial start-up planning will be mapped out along with best practices to ensure successful communication between the investigative site departments responsible for timely deliverables to the sponsor/CRO.

Learning Objective 1: Identify three benefits of defining clinical trial start-up processes and planning

Learning Objective 2: Create a clinical trial start-up Work Breakdown Structure (WBS) to monitor and control clinical trial start-up activities

Learning Objective 3: Describe effective communication tools to enhance clinical trial start-up planning

Learning Level: Intermediate

Primary Competency: Study and Site Management

Secondary Competency: Communication and Teamwork

Credit Type: 1.00 ACRP

Marla Hoelle, Barnett International

Sunday, Apr 14 4:30 PM - 5:30 PM, Meeting Room 205

GCP Auditing Techniques: Using the FDA Compliance Program Guidance Manuals (CPGMs)

Track: Site Management

While GCP Quality Assurance (QA) in clinical research settings is not an FDA regulatory requirement, the FDA, research sites and industry are trending towards implementing quality assurance programs. The ICH E6(R2) guideline also raises expectations for QA and conveys the expectation that GCP auditing will be performed. Do you know what you need to know about quality assurance auditing? Implementing a GCP QA program closes the loop between quality

control (QC) and quality management. Learn how QC and QA compliment each other. Together they allow for greater assurance of GCP compliance and that data being presented within a regulatory submission will be accurate and defensible. We will introduce GCP auditing, review the FDA's CPGM for Investigators, Sponsors and IRBs, and relevant sections of the ICH E6(2) Guideline.

Learning Objective 1: List the primary components of a GCP audit program and rationale for its use

Learning Objective 2: Describe the basic steps for conducting an audit

Learning Objective 3: Discuss the purpose of the FDA's Compliance Program Guidance Manual and how it can be used to prepare for Inspections

Learning Level: Intermediate

Primary Competency: Clinical Trials Operations (GCPs)

Secondary Competency: Study and Site Management

Credit Type: 1.00 ACRP, CME, CNE

Glenda Guest, Assured of Quality Consulting & Training; Lee Truax-Bellows, NCRA

Sunday, Apr 14 4:30 PM - 5:30 PM, Meeting Room 207D

Pediatric Research: FDA's 2017 Adopted Version of ICH E11 Resulting in E11(R1)

Track: Monitoring

ICH E11 original and R1 both considerably changed the environment of drug development for children. They were written specifically to harmonize, promote, and facilitate high-quality and ethical clinical research for children within the ICH regions, i.e., the United States of America (USA), the European Union (EU), and Japan. In August 2017 several key topics within the E11 (R1) Addendum received new recommendations from the FDA. The scope of the 2000 policies, however, remains unchanged and still apply. In this discussion we will discuss E11 (R1) and the FDA issues pertaining to pediatric research. These topics included ethical considerations, age subgroups, pediatric formulations, and drug development research.

Learning Objective 1: Discuss the FDA's input into ICH E-11 and the rationale for E11(R1)

Learning Objective 2: Recite four ethical considerations for pediatric studies

Learning Objective 3: Debate the use of chronological age versus categories for clinic research

Learning Level: Intermediate

Primary Competency: Clinical Trials Operations (GCPs)

Secondary Competency: Ethical and Participant Safety Considerations

Credit Type: 1.00 ACRP

John Rowell, LSU Health Shreveport

Sunday, Apr 14 5:30 PM - 6:30 PM, Exhibit Hall

Expo Hall Happy Hour

Sunday, Apr 14 6:45 PM - 8:00 PM, Meeting Room 207D

ACRP/Academy Annual Business Meeting (Open to ACRP and Academy Members Only)

Monday, Apr 15 7:00 AM - 2:00 PM

Registration Desk Open

Monday, Apr 15 8:00 AM - 9:00 AM, Grand Ballroom C

'Signature Series' - The Future of the Clinical Research Industry: Where are we Headed and What it Means to You

Enjoy a paneled discussion on the future of our industry with perspectives from the FDA, CRO, Site and TransCelerate. Gain knowledge on what the future may look like in each of our panelists perspectives and how they are preparing and how you may want to prepare.

Learning Objective 1: Define the key changes our industry will likely encounter over the next 5 years.

Learning Objective 2: Discuss the infrastructure, training, or preparation that may be needed.

Learning Objective 3: Determine what you may need to plan for in order to prepare for the changes.

Learning Level: Intermediate

Primary Competency: Leadership and Professionalism

Secondary Competency: Study and Site Management

Credit Type: 1.00 ACRP, CME, CNE

John Neal, PCRS Network, LLC; David Burrow, Center for Drug Evaluation and Research, FDA; Jamie Macdonald, Parexel International; Dalvir Gill, TransCelerate BioPharma, Inc.

Monday, Apr 15 9:00 AM - 10:00 AM, Outside Session Rooms (Level 2)

Coffee Break

Monday, Apr 15 10:15 AM - 12:15 PM, Meeting Room 201

FDA Inspections: Understand the Process and Manage the Consequences

Track: Site Management

This interactive program is designed for regulatory professionals who deal with complex issues, need to understand the latest developments, and can contribute their own front-line experiences. We will cover important GCP topics and preparation for audits and regulatory inspections. Bring your own GCP questions and dilemmas. Part 2 will employ hands-on activities to create corrective and preventive Actions (CAPAs), utilizing root cause analysis (RCA) procedures to address FDA citations in warning letters and 483s.

Learning Objective 1: Describe at least 3 regulatory actions FDA can take following an inspection

Learning Objective 2: Discuss appropriate strategies for responding to inspection findings

Learning Objective 3: Implement realistic and appropriate Corrective and Preventive Actions to successfully resolve inspection findings

Learning Level: Intermediate

Primary Competency: Clinical Trials Operations (GCPs)

Secondary Competency: Study and Site Management

Credit Type: 2.00 ACRP, CME, CNE

Janet Holwell, Independent Consultant; Glenda Guest, Assured of Quality Consulting & Training

Monday, Apr 15 10:15 AM - 4:30 PM, Meeting Room 207D

ACRP ICH Gap Analysis: Are you ready for the certification exam?

Track: Career Growth

This interactive 4 hour session will navigate you through the main ICH guidelines (E2a, E6 R2, E8, E9, E11) and the Declaration of Helsinki which are noted on the ACRP certification exams. The session will help you create an analysis of where you may need to focus your studies. A discussion of the exam format and valuable strategies for exam preparation will be discussed. This session is not intended for those that are preparing to take the exam in the Spring cycle as this is merely a gap analysis to help prepare you for the format of the exams and where you may want to focus in preparation for any of the ACRP main certification exams (CCRA, CCRC, CPI, ACRP-CP).

Learning Objective 1: Define 3 Effective Strategies for Exam Preparation

Learning Objective 2: Create an individual Gap Analysis of the 6 relevant guidelines

Learning Objective 3: Develop an understanding of the exam format and how to evaluate each question and answer

Learning Level: Beginner

Primary Competency: Clinical Trials Operations (GCPs)

Secondary Competency: Ethical and Participant Safety Considerations

Credit Type:

John Rowell, LSU Health Shreveport; Cindy Foss, ACRP

Monday, Apr 15 10:15 AM - 11:15 AM, Meeting Room 207ABC

CDER BIMO Compliance and Enforcement: What You Need to Know

Track: Leadership

Join FDA personnel from the Center for Drug Evaluation and Research as they discuss key opportunities for the clinical research industry to make their FDA inspection experience a positive one. The speaker will outline recent inspection trends and identify key strategies to build quality into clinical research in order to prevent critical compliance issues. When problems do occur, inspected entities should be able to respond appropriately. Take away practical approaches to working with the FDA during an inspection, responding to 483s after an inspection, and responding to subsequent regulatory correspondence.

Learning Objective 1: Identify recent trends in CDER-BIMO inspections of clinical investigators, sponsors, and IRBs.

Learning Objective 2: Describe key strategies for building quality into clinical trials.

Learning Objective 3: Describe key strategies for responding to FORM FDA 483s and Warning Letters.

Learning Level: Intermediate

Primary Competency: Clinical Trials Operations (GCPs)

Secondary Competency: Medicines Development and Regulations

Credit Type: 1.00 ACRP, CNE

David Burrow, Center for Drug Evaluation and Research, FDA

Monday, Apr 15 10:15 AM - 11:15 AM, Meeting Room 209C

Big Data, RWD & RWE – what’s the difference and how is it changing the research landscape?

Track: Monitoring

Real world data (RWD) involves data collected outside of clinical trials, and produces real world evidence (RWE), becoming actionable when powered by analytics, machine learning & artificial intelligence (AI). RWE provides insight beyond traditional clinical trial data, adding potential to link data from different sources; improve trial efficiency; identify new indications, and a real-world perspective of risks/benefits to make informed decisions beyond traditional clinical trials. This session reviews RWE regulatory and market impact including the updated FDA guidelines requiring RWE use in regulatory decisions and how AI and information exchange can be securely managed. It will also highlight ethical and privacy concerns, reviewing recent big data consent guidelines and how to clinically integrate RWD. This session shows best practices from a clinical setting that has multiple RWE publications.

Learning Objective 1: Identify what benefits RWD and RWE have beyond traditional clinical trial data

Learning Objective 2: Know how to align with FDA, consent and ethical guidelines when collecting RWD

Learning Objective 3: Integrate these concepts within electronic health records and clinical settings

Learning Level: Intermediate

Primary Competency: Scientific Concepts and Research Design

Secondary Competency: Study and Site Management

Credit Type: 1.00 ACRP

Karri Venn, LMC Manna Research

Monday, Apr 15 10:15 AM - 11:15 AM, Meeting Room 208

Careers in Clinical Research: Charting a Path for CRO Professionals

Track: Career Growth

A career in clinical research as a CRO professional has many advantages – plentiful demand, good compensation, and the ability to make a positive impact – but investigating and exploring these career opportunities can be difficult for those unfamiliar with contract research organizations. In this presentation, we'll look at a number of different career path options available at CROs, identify how to get started on these paths, and discuss the skills and knowledge you'll need to progress along those paths. The presentation will include real world examples including those who start their professional careers at a CRO, those who transition from other jobs and industries, some common career paths, and some not so common ones.

Learning Objective 1: Describe various career paths in clinical research available at CROs

Learning Objective 2: Identify skills needed to pursue common career paths

Learning Objective 3: Understand non-traditional career paths in clinical research and how to transition from other careers, organization types, and industries

Learning Level: Beginner

Primary Competency: Leadership and Professionalism

Secondary Competency: Communication and Teamwork

Credit Type: This session does NOT offer ACRP Contact Hours or CEUs of any kind.

Ryan Bailey, Rho; Brook White, Rho

Monday, Apr 15 10:15 AM - 11:15 AM, Meeting Room 209AB

Compliant Clinical Trial Contracting- Sponsor and Site Perspectives

Track: Site Management

Emily Pauli, PHRMD, Director of Research at Clearview Cancer Institute (in Huntsville, AL) and Amy Schmidt, DBA, MBA, CCRC, Compliance Manager, AbbVie (Mettawa, IL) will provide the perspective of both the Sponsor and the Site regarding FMV, SOC and Subject/Travel Reimbursement in clinical study budgets. There are 2 vantage points to contracting and this session will allow the audience to hear from both regarding their processes and how they mirror and possibly conflict....and suggestions how to have a positive outcome for both parties.

Learning Objective 1: Understand the Fair Market Value (FMV) assessment process

Learning Objective 2: Awareness of the implications to Standard of Care (SOC) being added to a study budget

Learning Objective 3: Travel and Subject Reimbursement considerations

Learning Level: Advanced

Primary Competency: Clinical Trials Operations (GCPs)

Secondary Competency: Study and Site Management

Credit Type: 1.00 ACRP

Amy Schmidt, AbbVie; Emily Pauli, Clearview Cancer Institute

Monday, Apr 15 10:15 AM - 11:15 AM, Meeting Room 205

With Great Power Comes Great Responsibility: What to Consider in Conducting the Physician-Sponsored IDE

Track: Project Management/Device

Physician-Sponsored IDE (PS-IDE) offers an ability for the physicians to design the study to treat patients with the unapproved medical devices without the industry support or oversight. The unapproved devices may be born out of physician's innovation (new devices) or innovative practice such as using the commercially available devices for unapproved indication (i.e., off-label use) or customizing/modifying the approved devices (altered device is considered a new device). Although there is a lot of freedom for the physician to design and conduct his or her own PS-IDE study, it is important to understand the regulatory requirements in every aspect of the trial that you will be personally responsible for. The study site will also have a unique challenge as it must incorporate sponsor obligations into their practices.

Learning Objective 1: Explain the definition of PS-IDE

Learning Objective 2: Understand the Physician's regulatory responsibilities in conducting a PS-IDE

Learning Objective 3: Understand the logistics of the PS-IDE

Learning Level: Intermediate

Primary Competency: Study and Site Management

Secondary Competency: Study and Site Management

Credit Type: 1.00 ACRP, CME, CNE

Yuki Kuramochi, Cleveland Clinic; Denise Sweeney, Cleveland Clinic, HVI Research

Monday, Apr 15 10:15 AM - 12:15 PM, Meeting Room 202

You want me to do WHAT?": Building Lasting Sponsor/Site Relationships Part Deux

This session is brought to you by a generous educational grant, courtesy of Veeva Systems.

Track: Leadership

"Coming together is a beginning. Keeping together is progress. Working together is success." - Henry Ford
How do you build a solid sponsor-site working relationship from site identification to closeout and beyond? We introduced this topic at ACRP 2018, but strongly believe it deserves a deeper look, as these relationships can have significant impact on overall study success. Through an interactive session, we aim to identify the framework that builds a successful sponsor-site relationship beyond a single clinical research project.

Learning Objective 1: Tips to build successful, long-term site/sponsor working relationships

Learning Objective 2: Through examples and team exercises, explore effective and ineffective communications

Learning Objective 3: Understand and incorporate the steps to achieve conflict resolution

Learning Level: Advanced

Primary Competency: Communication and Teamwork

Secondary Competency: Leadership and Professionalism

Credit Type: 2.00 ACRP

Marcus Stone, Spine Institute of Louisiana; Jane Jacob, Orthofix Inc.; Kelly Van Schouwen (Frank), Spine Institute of Louisiana

Monday, Apr 15 11:30 AM - 12:30 PM, Meeting Room 209C

Workforce Innovation Award Finalists: Top 5 Share their Ideas

Track: Leadership

Come see the top 5 Workforce Innovations Finalists share their innovative ideas in workforce development and have the opportunity to ask questions for your own idea creations.

Learning Level: Intermediate

Primary Competency: Leadership and Professionalism

Secondary Competency: Communication and Teamwork

Credit Type: This session does NOT offer ACRP Contact Hours or CEUs of any kind.

Beth Harper, ACRP

Monday, Apr 15 11:30 AM - 12:30 PM, Meeting Room 208

GPS for Study Startup: The Importance of the Critical Path

Track: Technology

Site activation cycle times within the industry are now worse than they were over a decade ago by an average of 4 to 6 weeks. Large, global organizations and small ones alike struggle more than ever to manage the complexities of today's trials and activities on the critical path to activation are always changing. This session will provide practical information on how technologies, best practices, and KPIs can proactively lead life-science organizations towards an entirely different approach to managing study startup.

Learning Objective 1: Upon completion of this session, participants should be able to understand various tactics for managing the critical path during site activation

Learning Objective 2: Upon completion of this session, participants will be able to identify how technology can aid in a more proactive approach to managing critical path activities

Learning Objective 3: Upon completion of this session, participants will understand how to measure one's progress against the original plan and use performance measurements to inform future planning

Learning Level: Advanced

Primary Competency: Technology

Secondary Competency: Study and Site Management

Credit Type: This session does NOT offer ACRP Contact Hours or CEUs of any kind.

Ashley Davidson, Veeva Systems

Monday, Apr 15 11:30 AM - 12:30 PM, Meeting Room 207ABC

Clinical Research Site Culture & the Impact on Adverse Event Reporting

Track: Site Management

Site culture is a significant, yet under-addressed factor on the impact of timely and complete adverse event (AE) reporting; a large component of patient safety and execution of quality clinical trials. AE collecting, documenting and reporting seems straightforward process that can be covered with a standard operating procedure. In reality, the process itself is impacted by the site culture and effective communication among all of the employees at the site. Quality sites also have a culture that recognizes that clinical trials and their participants are complex, thus requiring checks and balances between the team. This presentation will define the negative impact of strained site cultures on adverse event reporting, identify internal and external pressures, and strategies for improving culture, communication, and adverse event reporting.

Learning Objective 1: Understanding the impact of site culture on clinical research operations

Learning Objective 2: Identify 3 culture related barriers to timely and complete adverse event reporting

Learning Objective 3: Identify 3 strategies to improve open adverse event reporting.

Learning Level: Intermediate

Primary Competency: Communication and Teamwork

Secondary Competency: Ethical and Participant Safety Considerations

Credit Type: 1.00 ACRP, CNE

Molly Downhour, Medix; Nicole Mills, Medix

Monday, Apr 15 12:30 PM - 1:30 PM, Exhibit Hall A1

Lunch

Monday, Apr 15 1:30 PM - 3:30 PM, Meeting Room 202

Business Development Best Practices: How to Make your Site Stand Out in an Increasingly Competitive Landscape

Track: Site Management

With the clinical trial landscape becoming increasingly complex and competitive, it is essential that clinical research sites position themselves in a way to stand out from the “competition.” Factors such as a downturn in the volume of trials being conducted in sites’ primary indications leads to increased competition for each study and a potential downturn in the number of active trials at a site. We will discuss industry trends that impact R&D, the key factors that drive them, and the implications for research sites. We will discuss insightful strategies for staying ahead of the curve, such as therapeutic expansion and increasing patient access within existing key

indications. Finally, we will discuss key tactics for developing and strengthening CRO & sponsor relationships in order to become a “go-to” site.

Learning Objective 1: Discuss industry trends and the implications for research sites

Learning Objective 2: Discuss proactive site-level strategies for staying ahead of the curve

Learning Objective 3: Discuss key tactics for developing and strengthening relationships with sponsors and CROs

Learning Level: Beginner

Primary Competency: Study and Site Management

Secondary Competency: Clinical Trials Operations (GCPs)

Credit Type: This session does NOT offer ACRP Contact Hours or CEUs of any kind.

Riley Kammer, ClinEdge

Monday, Apr 15 1:30 PM - 2:30 PM, Meeting Room 208

Achieving the Patient Experience and Site-Sponsor Relationship of the Future

Track: Technology

During this interactive session, leaders from TransCelerate Member Companies will candidly share their experiences collaborating to create solutions that will bring about innovative change, and address some of our industry’s greatest challenges. They will discuss a suite of initiatives that, using innovative digital efforts, has the potential to transform the end-to-end clinical trial experience. TransCelerate has been developing solutions to allow patients to easily find trials, understand studies and provide consent, participate in trial information exchange, utilize electronic medicine labels, provide feedback on their experiences, and ultimately own their digital medical records. The audience will learn how the use of patient technologies, The Registry of the Future, eConsent, eLabels, and electronic health records can advance clinical research and create the patient experience of the future.

Learning Objective 1: Understand opportunities to improve the speed, quality and efficiency for all stakeholders in the industry by introducing consistent digital solutions in Clinical Research

Learning Objective 2: Discuss five key industry initiatives that, using innovative digital efforts, will transform clinical trials

Learning Objective 3: Recognize how the use of patient technologies, The Registry of the Future, eConsent, eLabels, and electronic health records can advance clinical research

Learning Level: Beginner

Primary Competency: Study and Site Management
Secondary Competency: Communication and Teamwork

Credit Type: This session does NOT offer ACRP Contact Hours or CEUs of any kind.

Lisa Moneymaker, Amgen; Brian Egan, TransCelerate Biopharma

Monday, Apr 15 1:30 PM - 3:30 PM, Meeting Room 201

Risky Business: Impact of a Risk-Based, Study-Specific Training Program on Research Coordinator Competency in an Emergency Department Setting

Track: Site Management

This session will describe three important steps to assure RC competency in study procedures at the beginning of a trial: risk assessment, development of a competency based training program, and implementation of that program. Participants will gain an understanding of how to conduct a risk assessment for a clinical trial. They will also learn how to develop and implement this type of program for their studies in order to help increase study procedure awareness and CRC competence. Take-aways will include a training checklist template that can be applied to clinical trial study start-up and a toolkit describing our program.

Learning Objective 1: Demonstrate the process for conducting a risk assessment for a clinical trial.

Learning Objective 2: Develop a competency-based training program using a risk based approach.

Learning Objective 3: Apply a risk-based competency checklist and competency check off to study-specific training in order to help increase study procedure awareness and CRC competence.

Learning Level: Intermediate

Primary Competency: Study and Site Management
Secondary Competency: Clinical Trials Operations (GCPs)

Credit Type: 2.00 ACRP, CME, CNE

Jessica Saunders, Nationwide Children's Hospital; Sally Jo Zuspan, University of Utah; Melissa Metheny, University of Utah

Monday, Apr 15 1:30 PM - 3:30 PM, Meeting Room 209C

Top Tips for the New Patient Advocacy and Recruitment

Track: Technology

Social Media has been a new highly innovative and disruptive technology to many industries, but most importantly clinical trials. Our latest talk on social media breaks down, step-by-step, the latest techniques for patient recruitment, retention and advocacy across the new and old platforms including: Snapchat, Instagram and Facebook.

Learning Objective 1: Use social media to boost patient enrollment.

Learning Objective 2: Effectively use mobile devices to communicate with patients.

Learning Objective 3: Boost screenings by 300%

Learning Level: Beginner

Primary Competency: Technology

Secondary Competency: Clinical Trials Operations (GCPs)

Credit Type: This session does NOT offer ACRP Contact Hours or CEUs of any kind.

Jerome Chiaro, StudyKIK

Monday, Apr 15 1:30 PM - 3:30 PM, Meeting Room 207ABC

Combating Increasing Complexity of Clinical Trial Data with Expanded Skill Sets and More Teamwork

Track: Career Growth

The number of data sources in clinical trials is increasing and the data coming from those sources are more complex than ever. According to a recent Tufts study, there has been a 20% reduction in EDC as the single source of clinical trials data. What does that mean for the future of data handling and interpretation? It is a broad problem that touches many more areas than just traditional clinical data management. This session will address how skill sets across multiple clinical research disciplines including bioinformatics, statistics, project management and clinical operations will need to broaden, and discuss why greater teamwork, cross-functional collaboration, and minimization of organizational silos are needed.

Learning Objective 1: Identify new sources of data and data complexity related to clinical trials

Learning Objective 2: Describe how changes in data sources, data source diversity and complexity, and shifts in the functional areas themselves impact the knowledge needed by various roles and disciplines within clinical research

Learning Objective 3: Understand how changes in the sources and complexity of clinical trial

data increase the need for teamwork and cross-functional collaboration

Learning Level: Intermediate

Primary Competency: Communication and Teamwork

Secondary Competency: Data Management and Informatics

Credit Type: 2.00 ACRP, CNE

Heather Kopetskie, Rho; Derek Lawrence, Rho; Rachel Berry, Rho

Monday, Apr 15 1:30 PM - 3:30 PM, Meeting Room 205

Tools for Advancing Patient-Centered Medical Device Clinical Trials

Track: Project Management/Device

Industry, FDA and patient groups recognize the importance and value of patient input in the ideation, design, testing and approval of new medical device technologies, but often struggle to elicit and incorporate patient input in a meaningful way. Patients can identify outcomes that are meaningful, risks that they would be willing to tolerate, and practices that can decrease the burden of participation in clinical trials. MDIC is developing a suite of tools to help medical device companies solicit input from patients and patient groups on clinical trial design elements that are aligned with patients' real-world priorities. Panel attendees will learn about the development of these tools that they can implement in their own clinical trials to develop clinical trials that measure what matters to patients and that patients can complete.

Learning Objective 1: Describe a model for using patient preference information to inform the protocol development and statistical design of clinical trials

Learning Objective 2: Understand methodologies for involving patients in study design to reduce barriers of participation

Learning Objective 3: Identify practices that can maximize retention and compliance of patients in clinical trials

Learning Level: Intermediate

Primary Competency: Scientific Concepts and Research Design

Secondary Competency: Clinical Trials Operations (GCPs)

Credit Type: 2.00 ACRP, CME, CNE

Stephanie Christopher, Medical Device Innovation Consortium; Matthew McCarty, ICON, plc; Michael Otlewski, MED Institute, Inc.

Monday, Apr 15 2:30 PM - 3:30 PM, Meeting Room 208

Extreme Make-Over! How the TransCelerate Common Protocol Template Makes Your Job Easier

Track: Site Management and Study Coordination

Learning Level: Intermediate

Primary Competency: Clinical Trials Operations (GCPs)

Secondary Competency: Scientific Concepts and Research Design

Credit Type: This session does NOT offer ACRP Contact Hours or CEUs of any kind.

Virginia Nido, Genentech, a Member of the Roche Group; Tanya Fleege, Astellas Pharma Global Development

Monday, Apr 15 3:30 PM - 4:30 PM, Meeting Room 202

Why do Surgical Placebo Controlled Trials?

Track: Site Management

In this session, the rationale for surgical placebo-controlled trials will be reviewed. One example of such a trial is the world first randomised placebo-controlled trial to evaluate the efficacy and cost-effectiveness of decompressive surgery for lumbar spinal stenosis, which is currently being conducted in Australia. A variety of techniques have been used to address ethical and safety considerations including the unusual step of recruiting a consumer and ethicist to act in advisory roles to provide input on the practicalities of the study design. This session will provide attendees with a high level overview of the trial together with highlighting key learnings about protocol design, consent form drafting and collection of consent, recruitment of surgeons, working with private healthcare providers, and other relevant site level activities.

Learning Objective 1: Understand the underlying rationale and practical complexities in conducting surgical placebo controlled trials

Learning Objective 2: Understand the ethical and safety components to patients enrolling in a surgical placebo controlled trial

Learning Objective 3: Understand the need for a consumer and ethicist to act in advisory roles to assist with delivery of the trial (such as providing input into the flow of the study and reviewing study documentation)

Learning Level: Intermediate

Primary Competency: Scientific Concepts and Research Design

Secondary Competency: Ethical and Participant Safety Considerations

Credit Type: 1.00 ACRP

Renata Yong, George Clinical

Monday, Apr 15 3:30 PM - 4:30 PM, Meeting Room 201

Practical Aspects of Study Initiation

Track: Site Management

Purpose: focuses on practical aspects of the preparation and execution of clinical study initiation; identifying and describing key activities, processes, and critical personnel. Methods: provides a practical overview of the significant processes in starting research at a site and a clear understanding of the main components of study initiation: document management, logistics, and people management. Guidance, tools, and resources help the primary investigator and coordinator perform efficiently and understand how their responsibilities tie together with the tasks and duties of others. Conclusions: Organization and adequate time for the initiation process are critical to successful studies. Multiple activities must be orchestrated and performed concurrently, requiring use of study tools and efficient processes. Identification and use of numerous research resources improve efficiency of study initiation and decrease work load and frustration.

Learning Objective 1: Identify the three main components of study initiation

Learning Objective 2: identify five startup activity processes

Learning Objective 3: Describe preparations for a Site Initiation visit

Learning Level: Beginner

Primary Competency: Study and Site Management

Secondary Competency: Clinical Trials Operations (GCPs)

Credit Type: 1.00 ACRP, CME, CNE

Susan Alderman, University of Texas Houston, Cizik School of Nursing/McGovern Medical School