29TH ANNUAL CONFERENCE

ELEVATING THE CLINICAL RESEARCH PROFESSION AND TRANSFORMING THE WORLD OF CLINICAL RESEARCH

SEPTEMBER 23-26, 2020 | VIRTUAL PROGRAM

CONFERENCE SCHEDULE

Wednesday, September 23
Opening Plenary Sessions

Thursday, September 24 - Friday, September 25
Breakout Sessions by Educational Track

Saturday, September 26
Closing Plenary Sessions

Over 50 CE across 8 Educational Tracks

Advanced Management
Behavioral Health
Compliance / Noncompliance
Data Management / EDC
Device Research
Enrollment / Retention /
Informed Consent
Research Ethics

Finance and Billing
GCP and Audit Preparedness
Health Disparities
International Trials and ICH
Investigator-Initiated Research
Monitoring / Monitoring
Effectiveness
Oncology Research
Pediatric Research

Project Management
Quality Management
Responsible Conduct of Research
Risk Management
Site Management
Training Techniques

www.socra.org | 530 West Butler Avenue, Suite 109, Chalfont, PA 18914 USA | 215.822.8644
2020 ANNUAL CONFERENCE
SEPTEMBER 23-26, 2020 | VIRTUAL PROGRAM

We look forward to hosting this year's Annual Conference virtually! We may not be headed to Las Vegas, but we will still welcome clinical research professionals from across the world. This four day virtual program will offer current information and tools, best practices, and training to assure that you’re up-to-date and compliant in your clinical research practice. Through a digital platform we look forward to offering engaging presentations, insightful Q+A, opportunities for continuing education, and ways to interact and connect with fellow attendees, speakers, sponsors and exhibitors.

OPENING SESSION PLENARY SPEAKERS

Quincy Byrdsong, EdD, CCRP, CIP
Amy Jo Jenkins, MS, CCRP
Anne Johnson, BA
Christopher Trudeau, JD
Rachele Peterson, MS, CCRP, CRA

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REGISTRATION FEES:

For Registrations Confirmed prior to August 20:
Member Fee - $450 / Non-Member Fee*- $525
*Non-Member Fees include a non-refundable one-year SOCRA membership

For Registrations Confirmed on or after August 20:
Member Fee - $475 / Non-Member Fee*- $550
*Non-Member Fee includes a non-refundable one-year SOCRA membership

To register, please visit www.socra.org/annualconference

SCHEDULE OF EVENTS

WEDNESDAY, SEPTEMBER 23, 2020
Opening Plenary Session
11:00 am to 3:20 pm - Welcome, Introduction, Opening Plenary Sessions - Join us for the live stream opening of the event!

THURSDAY, SEPTEMBER 24, 2020
Breakout Sessions by Educational Track
11:00 am to 4:10 pm - Join us for the broadcasting of the breakout sessions in all 8 educational tracks featuring live Q+A!

FRIDAY, SEPTEMBER 25, 2020
Breakout Sessions by Educational Track
11:00 am to 3:20 pm - Join us for the broadcasting of the breakout sessions in all 8 educational tracks featuring live Q+A!

SATURDAY, SEPTEMBER 26, 2020
Closing Plenary
11:00 am to 3:20 pm - Closing Plenary Sessions and Awards - Join us for the live stream closing event!

CONTINUING EDUCATION CREDITS:
SOCRA designates this educational activity for a maximum of 50+ Continuing Education Credits for SOCRA CE and Nurse CNE.

ACCREDITATION STATEMENTS:
CME for Physicians: The Society of Clinical Research Associates is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. (Accreditation continued on next column)

CME for Nurses: Society of Clinical Research Associates is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center’s Commission on Accreditation.

PROGRAM LEARNING OBJECTIVES
Upon completion of this course the attendee should be able to:

• Discuss how to better connect with patients while better complying with new regulations that promote participant understanding
• Discuss what to consider when planning and managing behavioral health research
• Discuss the requirements for including neonates and children in research
• Discuss creating a Clinical Evaluation Report (CER) that meets international regulators’ expectations
• Discuss key areas in monitoring and assessment tools to evaluate monitoring adequacy
• Describe informed consent unanticipated problems and provide strategies to prevent
• Discuss how to revise or re-negotiated a budget with confidence
• Discuss strategies to minimize risk and improve quality for investigator-initiated trials
• Discuss ideas to streamline the start-up process in a Clinical Trials Office in an academic institution or other similar setting
• Discuss FDA’s expectations and regulations when selected for an FDA audit
• Discuss best practices and potential approaches to managing projects involving complex data collection structures
• Discuss practical methods for conducting foreign trials that rely upon the United States for regulatory purposes
• Discuss European legislation updates
• Discuss ways to work with study team members and other stakeholders to implement quality assurance within an academic organization
• Discuss factors that promote as well as hinder research compliance and integrity and practices that may help protect against research integrity violations
• Discuss how to seek professional mentorship and effectively network in the field of clinical trials/translational research
• Discuss the various aspects regarding eligibility criteria and study procedures of oncology investigator-initiated interventional clinical trial protocols
• Discuss how to organize and complete the study start up quickly and accurately to ensure compliance
• Discuss unique community engaged research recruitment and tools to set up a research initiative at a large scale event
• Discuss high level planning of the enrollment and how the resources can be well-managed
• Discuss tools to oversee vendors and mitigate risk
• Discuss opportunities and challenges with internal collaboration
• Discuss the value of in-home visits and understand the basics
• Discuss common questions related to the revised Rule and implementation of the requirements for informed consent in the revised Common Rule
• Discuss identifying and resolving key risk issues in clinical trial agreements in a proper and efficient manner
• Discuss the requirements and strategies required to develop the Clinical Research Response Toolkit (CCRT) and how to customize it to fit the rapid response needs for conducting clinical research during an infectious disease outbreak
• Discuss viable and economic alternatives for educating a highly efficient workforce
## 2020 ANNUAL CONFERENCE SCHEDULE

**SEPTMBER 23, 24, 25, AND 26, 2020 | VIRTUAL PROGRAM**

### OPENING SESSION

**Wednesday, September 23, 2020**

**Time/Track:** Track 1

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<td>Finance and Billing</td>
<td>GCP and Audit Preparedness</td>
<td>International Trials and ICH</td>
<td>Responsible Conduct of Research</td>
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<td>Project Management</td>
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<td>11:50-12:40</td>
<td>Health Disparities</td>
<td>Device research</td>
<td>Finance and Billing</td>
<td>GCP and Audit Preparedness</td>
<td>International Trials and ICH</td>
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<td>2:30-3:20</td>
<td>Investigator Initiated Research</td>
<td>Device Research</td>
<td>Finance and Billing</td>
<td>International Trials and ICH / Canadian</td>
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### BREAKOUT SESSIONS

**Thursday, September 24, 2020**

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**Saturday, September 26, 2020**

**Closing Plenary - General Session**

**Time/Track:** Track 1

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**Wednesday, September 23, 2020**

**Opening Plenary - General Session**

**Time: 11:00**

**Welcome and Introduction**

The speakers will describe issues related to the practice of clinical research in the current regulatory environment and how SOCRA works to promote education and training within the clinical research community.

**Presenter:** Quincy Byrdsong, EdD, EdD, CRCP, Associate VP for Research Administration, WellStar Research Institute

**Time: 11:20**

**Current FDA Organizational Developments and Oversight Initiatives**

The presentation will cover organizational developments including personnel updates, key indicators and performance measures in the OBIMO program.

**Presenter:** Anne Johnson, BA, Program Division Director OBIMO East, FDA, Philadelphia District Office

**Time: 12:10**

**From Data to Discoveries: Creating a Research Program for All of Us**

The National Institutes of Health (NIH) All of Us Research Program is among the most ambitious research efforts our nation has ever undertaken. It is an historic effort to gather data from one million or more people living in the United States to accelerate research and improve health. By taking into account individual differences in lifestyle, environment, and biology, researchers will uncover paths toward delivering precision medicine. Unlike research studies that focus on one disease or group of people, All of Us is building a diverse database that can inform thousands of studies on a variety of health conditions as part of a new era in which researchers, health care providers, technology experts, community partners, and the public work together to develop individualized health care.

**Presenter:** Rachelle Peterson, MS, CCPR, CRA, Director of Healthcare Provider Organization Engagement, All of Us Research Program / Vibrant Health

**Time: 1:40**

**Connecting while Complying: The Regulatory Trend Towards Clear Communication in Clinical Trials**

This session will explore the global regulatory trend towards improving participant understanding in clinical trials. It will focus on aspects of the Revised Common Rule, GDPR, EMA Policy 0070, and the EU-US Privacy Shield that mandate clear communication with trial participants. Mr. Trudeau will discuss best practices for better connecting with participants while still also complying with new regulatory requirements.

**Presenter:** Christopher Trudeau, JD, Associate Professor, University of Arkansas at Little Rock, Bowen School of Law

**Time: 2:30**

**Question and Answer Session**

Moderated Q&A session with live questions from the audience.

**Moderator:** Quincy Byrdsong, EdD, EdD, CRCP, Associate VP for Research Administration, WellStar Research Institute

**Time: 11:00**

**Using Patient Stories in Research to Address Disparities and Change Lives**

Dr. Bailey will focus on the importance of patient stories and qualitative research in designing pragmatic and patient-centered outcomes and research interventions to address health disparities. Dr. Bailey will highlight experience from his team’s Patient-Centered Outcomes Research Institute (PCORI) funded study, Management of Diabetes in Everyday Life (MODELL), in using patient input to develop and implement patient-centered interventions to improve diabetes self-care among African American people living in medically underserved areas of the Mid-South.

**Presenter:** James Bailey, MD, MPH, FACP, Director, Center for Health System Improvement, University of Tennessee Health Science Center

**Time: 11:50**

**Behavioral Health Strategies for Social & Behavioral Research**

Ms. Wintering will present on key areas to consider when planning and managing behavioral health research. She will identify what are treatment based interventions, patient centered approaches and the Readiness for Change Model and skills through scenarios to work more effectively with difficult situations. The participant will learn strategies to manage a stressful workload, utilize self-care, assess effectiveness while maintaining quality and consistency.

**Presenter:** Nancy Wintering, MSW, LCSW, CCRP, Assistant Director of Research, Thomas Jefferson University
Pathology, Texas Tech University Health Sciences Center, Professor of guidelines outlined in USP.115 for Clinical Research Units regarding the safe handling and will discuss the process of developing, implementing, and are considered hazardous by the new guidelines. Ms. Trost that are still within the FDA approval process, and therefore, available. The field of nursing research utilizes many agents must be considered hazardous until more information becomes healthcare setting, but previous guidelines for safe handling unintended occupational exposure to Hazardous Drugs (HDs) and potentially HDs have been widely discussed in the health care setting, but previous guidelines for safe handling of HDs have not been objectively outlined nor are enforceable. Former HD recommendations have addressed only chemotherapy agent handling and administration whereas, new, enforceable, USP guidelines state that if the information available on an agent is deemed insufficient to make an informed decision regarding precautions, that agent must be considered hazardous until more information becomes available. The field of nursing research utilizes many agents that are still within the FDA approval process, and therefore, are considered hazardous by the new guidelines. Ms. Trost will discuss the process of developing, implementing, and evaluating a formalized, multidisciplinary training program for Clinical Research Units regarding the safe handling and administration of investigational agents based upon the guidelines outlined in USP.115. Presenter: Ashley Trost, MSN-Ed, RN, Clinical Education Coordinator, Northwestern Memorial Hospital Time: 1:40
Track 2 Device Research
Track: Investigator-Initiated Research
Track: Device Research
Program and the Breakthrough Devices Program
The average time from medical device concept to marketing approval has been reported as three to seven years. If alternative treatments are not available, this is problematic for patients with serious or life-threatening diseases. Expanded access permits patients with life-threatening conditions who are not eligible to participate in clinical trials to receive investigational devices before formal product approval. This presentation will provide an overview of multiple programs at CDRH that enable patient access to important devices. This presentation will introduce the Expanded Access Program, and the Breakthrough Devices Program.41
Presenter: Donna Headlee, BSN, RN, CCRP Time: 1:40
Track: Device Research
Track: In Vitro Diagnostics as Companion Diagnostics: Studies Within Studies
From prototype lab tests to a fully developed assay, in vitro diagnostics (IVD) are used in all phases of clinical research and often as companion or companion diagnostics (CDx) to a pharmaceutical test. In oncology in particular, these tests allow pharmaceutical companies to identify trial populations that have the greatest chance of clinical benefit and/or the least exposure to hazardous side effects. Ms. Hazzel will discuss the lifecycle of an IVD CDx project from prototype development through to successful Premarket Application.41
Presenter: Kellie Hazzel, BS, MA, PMP, ACRP-CP, Manager, Clinical Affairs, Illumina Time: 2:30
Track: Device Research
Track: Asia Pacific and European (MDR & IVDR) Clinical Evaluation Reports and Latest Requirements for Post Market Reporting
As Europe transitions to the MDR/IVDR and Asia Pacific Regulations (including Australia and China), this topic focuses on clinical evidence, creating a Clinical Evaluation Report (CER) that meets international regulators’ expectations is becoming increasingly complex. Mr. Jimenez will review MEDDEV 2.7/1 revision 4 guidelines will be shared. This topic will also cover areas of focus for manufacturers and sponsors, based on recent feedback from EMA and Notified Bodies as well as recent EU and US regulatory changes. Presenter: Luis Jimenez, MBA, Vice President, Business Development, Brandwood CKC Time: 1:10
Track: Device Research
Track: Workforce Development 2020: Paradigm Shift from ‘Training’ to ‘Performance Management’ - Back to the Job’
Ms. Stevens and Ms. Wool will describe workforce development and the shift from training, back to job performance. Leveraging Kirkpatrick’s theory for learning evaluation, incorporating knowledge and skills gained from training on the job, enables improved performance. Identifying methods (technology, performance review, peer assessment, etc.) to capture job performance in ‘real-time’.41
Presenter: Erin Stevens, MA, MA, BA, Principal, Recherche Transformation Rapide Liz Wool, BSN, RN, CCRA, CMT, President, Wool Consulting Group Inc. Time: 11:50
Track: Device Research
Track: Expanded Access to Medical Device for Patients: Expanded Access Program and the Breakthrough Devices Program
Front End and Back End Billing – Revenue Compliance
Ms. Willenborg will help attendees understand foundational principles necessary to build a profitable research site. They will understand financial management in clinical trials from front end to back end. They will be able to discuss issues related to reporting results of a research program to executive management.48
Presenter: Kelly Willenborg, DBA, RN, CHCR, CHC, CCERP, CHO, Kelly Willenborg LLC Time: 11:40
Track: Device Research
Track: Finance and Billing
Management Clinical Research Revenue Cycle by Understanding Financial Strategies and Budget Negotiations- Improving the Bottom Line
Dr. Verma will help participants succeed in optimizing financial performance in research billing and revenue cycle processes. The tools needed to deal with billing compliance in the course of oncology cancer trials and be effective in performing them right from the beginning will be discussed.41
Presenter: Sachit Verma, MD, MD, MBA, FAPCR, CRCP, RDMS, RVT, SSGB, Director, Research Revenue and Billing, Inova Health System, Office of Research Time: 1:40
Track: Finance and Billing
Track: Navigating Industry-Sponsored Clinical Trial Budgets and Finance: Setting the Sites up for Success
Developing a site or network of sites to conduct industry-funded clinical trials is no small task. There are many challenges in achieving operational and financial success. This talk will address some of the key considerations for sites related to budgeting, planning, and execution of clinical trials. Solutions and best practices will be shared with a focus on covering staffing costs, as well as creating and managing a diversified staffing model that optimizes cost-effective site operations.41
Presenter: Jennifer Goldfarb, MSN, RN, CCERP, Vice President, Clinical Research, The IM Group Time: 2:30
Track: Finance and Billing
Track: How to Successfully Renegotiate a Budget and Predict Future Budgets Based on Actual Experience
Dr. Sult will discuss budget renegotiations, how it is successfully done, how to apply those learning situations to future budgeting, and what a sponsor or CRO is looking for to have a successful renegotiation. Dr. Sult will provide practical tips that can be taken away and applied for successful re-negotiations.41
Presenter: Mark Sultik, PharmD, CCRP, Director, Rocky Mountain Clinical Research Time: 1:10
Track: Finance and Billing
Track: Front End and Back End Billing – Revenue Compliance
Access Program and the Breakthrough Devices Program
The dangers and negative health risks associated with unintentional occupational exposure to Hazardous Drugs (HDs) and potentially HDs have been widely discussed in the health care setting, but previous guidelines for safe handling of HDs have not been objectively outlined nor are enforceable. Former HD recommendations have addressed only chemotherapy agent handling and administration whereas, new, enforceable, USP guidelines state that if the information available on an agent is deemed insufficient to make an informed decision regarding precautions, that agent must be considered hazardous until more information becomes available. The field of nursing research utilizes many agents that are still within the FDA approval process, and therefore, are considered hazardous by the new guidelines. Ms. Trost will discuss the process of developing, implementing, and evaluating a formalized, multidisciplinary training program for Clinical Research Units regarding the safe handling and administration of investigational agents based upon the guidelines outlined in USP.115. Presenter: Ashley Trost, MSN-Ed, RN, Clinical Education Coordinator, Northwestern Memorial Hospital.
Thursday, September 24, 2020
BREAKOUT SESSIONS

**Track 5**
International Trials and ICH

**Time: 11:00**
Track: International Trials and ICH

Local Medical Needs in Selected African Countries vs Clinical Research Activities - Do They Fit?
The African continent offers many good conditions for conducting clinical trials, but a diverse population of potential patients, many patients have not been previously exposed to any kind of pharmaceutical drugs and are deemed naive patients. In addition, a diverse number of patients – particularly those defined as neglected and tropical are endemic in certain parts of Africa. Certainly, it makes sense to run clinical trials for drugs that would treat such diseases in the areas most affected by them. But do strategies to include African countries in global clinical research address the local medical need? A project at the University of Applied Sciences and Arts in Hannover, Germany, did investigate if clinical research geared to the health priorities of African countries.

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

**Time: 11:50**
Track: International Trials and ICH

Pacific South American Countries: Essential Tips to Successful Research Projects
Dr. Polo will explain why Peru, Ecuador, and Chile are countries of opportunity for clinical research. Essential tips for managing research projects will be shared.

**Presenter:** Elizabeth Polo, MD, CCRP, CQA
President, EPP Consulting

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**Track 6**
Responsible Conduct of Research

**Time: 11:00**
Track: Responsible Conduct of Research

Lessons Learned from Case Studies of Research Misconduct
Dr. Kessler will use case studies and lessons learned to discuss research integrity and the impact of wrongdoing on the research enterprise. Provocative intentions aimed at raising awareness, promoting a culture of integrity, and encouraging the early detection and reporting of problems will be presented.

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

**Time: 11:50**
Track: Responsible Conduct of Research

Responsible Conduct of Research/Research Misconduct – a Year in Review
Ms. Parrish will provide a primer for research misconduct including the primary agencies and definitions, and will highlight the most important developments in the preceding year (litigation, agency findings, criminal prosecution, revision of COPE guidelines). An attendee should be conversant and current after attending the session.

**Presenter:** Debra Parrish, JD
Director of Clinical Operations, HBT Labs

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**Track 7**
Oncology Research

**Time: 11:00**
Track: Oncology Research

Oncology Investigator Initiated Clinical Trial Protocol: A Comprehensive Review of Eligibility Criteria and Study Procedures
A clinical trial protocol provides details regarding design, recruitment, treatment plan, regulatory requirements and logistics of a study. Ms. Mulk will go deeper into two specific sections of the protocol: ‘Eligibility criteria’ and ‘Study procedures’. This presentation will be a beginners level overview of how to investigate investigator-initiated interventional clinical trials. It will focus on the specifics of some universal eligibility criteria and how they can be presented effectively. It will also shed light on the most commonly used study procedures and cover the vital specifics that need to be stated with each study procedure. The impact of these two sections on the ‘Recruitment and Retention’ capacity of a clinical trial will also be discussed. Supplemental handouts will be provided. The presentation will conclude with an interactive session focusing on some interesting case studies or scenarios.

**Presenter:** Sahibeha Mulk, MBBS, MD, Medical Writer, Northwestern University

**Time: 11:50**
Track: Oncology

Common Queries: Strategies for Prevention and Resolution in Oncology Clinical Trials
Identifying common oncology research queries and trends can provide added efficiency in addressing them. Understanding the rationale for frequently asked questions can provide insight into methods by which they can be prevented. Finally, understanding how to successfully resolve queries is a critical skill for any clinical research professional.

**Presenter:** Rachel Kingsford, MS, CCRP
Training and Mentorship Manager, Huntsman Cancer Institute

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**Track 8**
Project Management

**Time: 11:00**
Track: Project Management

7 Breakthrough Behaviors For Clinical Research Project Managers
Clinical Project Managers (CPMs) can spend a considerable amount of time “firefighting.” Ms. Banerjee 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.

**Presenter:** Dalfoni Banerjee, BA, Principal Consultant & CEO, 3 Sixt Pharma Solutions LLC

**Time: 11:50**
Track: Project Management

Successful Vendor Oversight
Ms. Gaskin will provide an overview of best practices for overseeing vendors while not duplicating work. The talk will outline best practices, tips, and processes for vendor oversight.

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

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**Track 8**
Advanced Management

**Time: 1:40**
Track: Advanced Management

Patient Leaders: A Pathway to Organizational Learning and Thriving
An interdisciplinary team approach as well as partnering with patients is crucial for improving patient care. Ms. Arsovskova will discuss findings concerning “How a healthcare team at an organizational level can work with patients to increase patient understanding and management of their disease. Lessons learned as a research manager and coordinator will be discussed. Organizing an annual patient education event leading to a Patient Advisory group and volunteering with a provincial working group to find ways to disseminate results to patients will be addressed.

**Presenter:** Olga Arsovskova, MA, BSc, CCRP
Research Lead, Vancouver General Hospital

**Time: 2:30**
Track: Advanced Management

Organ Donation and Clinical Research
Ms. Gray will discuss how organ donors become a part of clinical research and what that means in terms of IRB, FDA, and organ procurement.

**Presenter:** Kayla Gray, MS, CCRP
Research Coordinator
Donor Network of Arizona
Time: 11:00    Track: Pediatric Device Research Learning Your A, B, C’s, D’s: The Regulations of Research in Children (A Deep Dive into Subparts A, B, and D) Ms. Galster will closely examine the regulations pertinent to conducting research in neonates and children. This will include a deep dive into Subparts B and D. How understanding these regulations can help you develop better IRB submissions, and how they should frame your informed consent conversations with families will be discussed.

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

Time: 11:50    Track: Pediatric Technology in Pediatric Trial Management & Success Ms. Allen will review technological approaches to best facilitate and manage pediatric clinical research trials. She will stimulate discussion of helpful technology-based tactics and encourage efficiencies through electronic systems.

Presenter: Janelle Allen, BS, MS, CCRP, Director, Clinical Research Operations, Quality & Education, Institute for Advanced Clinical Trials for Children

Time: 1:40    Track: Pediatric Successful Study Recruitment and Retention in Pediatric Trials (Site Perspective) Focus will be on communication, team cohesion, support/ buy in, understanding of WHY, best practices in working with varying departments/providers, and recruiting in difficult situations/diverse populations. Ms. Wrenn’s session will be key to site level study coordinators, and can be tailored for CRA’s monitors as well.

Presenter: Samantha Wrenn, MHA, CCRP, Project Lead, Duke Clinical Research Institute

Time: 2:30    Track: Pediatric Compliance and Accountability: A ‘How To’ Guide for the Pediatric Population Dr. Duke Endevs will cover topics related to investigator product, research pharmacies, and pediatric considerations as related to study drugs. The topics will be tailored for both pharmacists and research coordinators that do not have a research pharmacy involved in their operations. Some specific topics that will be covered include compliance monitoring with calculation examples, accountability basics that will result in positive FDA audits, and teaching administration techniques to the pediatric population.

Presenter: Julie Duke Endevs, PharmD, BA, CCRP, Investigational Drug Services Pharmacist, Nemours Children’s Hospital

Time: 11:00    Track: Device Best Practices in Scientific Database Searching The MEDDE2 2.7/1 Rev 4 (June 2016) and EU Regulation 2017/745 (2017) have placed a new, renewed focus on the planning and execution of literature search reports for the description of current practice / state of the art and the safety and performance of a device under evaluation. Ms. VanWyk will address best practices in scientific database search techniques that can be applied in the development of such reports but also in the day-to-day discovery of peer-reviewed literature for application in evidence-based practice. It will be accompanied by real case studies that exemplify how informed changes to a search string can yield more targeted results.

Presenter: Sara VanWyk, BS, MPH, CCRP, RAC, Senior Regulatory Specialist, Regulatory & Quality Solutions

Time: 11:50    Track: Device Sponsor Roles and Responsibilities for Medical Devices Ms. Yani will discuss the roles and responsibilities of the sponsor for medical devices and cover roles and responsibilities as defined in 21 CFR 812 Subpart C. Topics will include the selection of informants, proper monitoring, and UADE reporting. The relationship between the sponsor and the site will also be discussed.

Presenter: Sivan Yani, Clinical Research Associate, Align Technologies

Track 2  Monitoring

Time: 1:40    Track: Monitoring Monitoring the Informed Consent Process – Challenges and Proposed Solutions Monitoring the informed consent process presents unique challenges; the variability of human interaction directly impacts the success of the process, complicating the practice of obtaining fully-compliant informed consent. Dr. Statler will draw upon her 10 years of monitoring experience, presenting real research pharmacist interviews to illustrate the challenges associated with each example will be highlighted and solutions will be offered. Specific recommendations regarding protocols and monitors can help their study team avoid anticipated problems within the context of informed consent will be emphasized.

Presenter: Abby Statler, PhD, MPH, MA, CCRP, Director, Research Quality and Safety, Dartmouth-Hitchcock Medical Center

Time: 2:30    Track: Monitoring Recognizing Mr. Hyde: Misconduct in Clinical Research Research misconduct not only endangers subjects; it raises legal and compliance risks that range from human subject protection to false claims liability. This session will discuss characteristics of research misconduct, the establishment of a culture that supports disclosure of possible misconduct, and approaches to investigation through the discussion of case studies.

Presenter: Melissa Markey, JD, CISSP, Attorney / Shareholder, Hall Rendar

Time: 11:00    Track: Device Integrating Quality into Investigator-Initiated Clinical Trials Ms. Lane will define the general quality standards and areas of risk for clinical trials, focusing on those with high impact on investigator-initiated trials (IITs). She will then describe measures to incorporate those quality standards into the study design, including study initiation process for IITs, and approaches to mitigate potential risks during the trial’s conduct.

Presenter: Neala Lane, MS, CRC, Associate Director, Quality Improvement Office, Indiana University

Track 3  Site Management

Time: 11:50    Track: Site Management Establishing a Regulatory Support Program-Steps to Success Dr. Arbit will discuss the importance of regulatory support for IRB in an academic health center along with involving the research support and providing the necessary services. Hurdles to avoid and keys to success will also be discussed.

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

Time: 1:40    Track: Site Management Challenges for Consenting when Enrolling Children in Research In this presentation, Dr. Waseem will highlight the challenges and barriers for effective and adequate consenting for pediatrics using research tool based data that will demonstrate practical mechanisms for obtaining appropriate assent and consent when conducting research involving pediatric patients, so as to not cause harm to this unique population.

Presenter: Muhammad Waseem, MD, MS, CCRP, CIP, Research Investigator/Professor Emergency Medicine, Lincoln Medical Center

Time: 2:30    Track: Site Management Improvements in the Start-Up Process in an Academic Clinical Trials Office Ms. Wheeler will discuss some innovative ways to work through study start-up, beginning with study feasibility through budget/contract negotiation. Process maps, workflows, and checklists to streamline start-up and reduce work re-direction will be discussed.

Presenter: Katrina Wheeler, BS, CCRP, Clinical Project Manager, UC Davis School of Medicine

Time: 3:20    Track: Site Management A Journey from Inspection Fear to ‘No Observations’ Surprised or announced, QA or operations, everyone fears for the dos and don’ts, handling observations and implementing CAPAs such that re-finding is avoided.

Presenter: Priyand Gajiwala, MPharm, CCRP, QA Analyst KGRC Science inc.

Track 4  Research Ethics

Time: 11:00    Track: Ethics Regulatory Aspects of Clinical Research – A Lesson in History Ms. Tongul will provide a detailed overview of the history of regulatory aspects of clinical research, and what our history has taught us about running clinical research. The presentation will provide a historical account of the historical events that paved the way for our current clinical research practices – not only the well known major events in history, but also the minute details in between.

Presenter: Joyce Tongul, BS, CCRP, Clinical Research Associate, Duke University

Time: 11:50    Track: Ethics The Bucket with the PL… or Does it? CRC Gone Wrong He’s Back Stops with the PL… or Does it? Regulation states that ultimate responsibility for a clinical trial rests with the principal investigator. What happens when a coordinator goes rogue and is guilty of misconduct? Ms. Holwell will explore the definition of misconduct in clinical trials and the possible consequences of CRC intentional misconduct. Actual cases will be used to delineate CRC sanctions and punishments, and reasons for committing fraud will be explored.

Presenter: Janet Ellen Holwell, BA, CCRC, CCRA, TIACR, FACR, Clinical Research Consultant/Trainer

Time: 1:40    Track: Ethics Good Reporting Practices: Describing Your Research So Other Researchers Can Replicate It; Clinicians Can Implement Transparency in reporting research findings is vitally important. Reporting standards, guidelines that inform the content to be included in a well written journal article, are available for numerous study types including case reports, systematic reviews, and randomized trials. In this presentation, Dr. Waseem will highlight the challenges and barriers for effective and adequate consenting for pediatrics using research tool based data that will demonstrate practical mechanisms for obtaining appropriate assent and consent when conducting research involving pediatric patients, so as to not cause harm to this unique population.

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

Time: 2:30    Track: Ethics The Trials Experience in the United States, Africa, and South America Recruitment and retention is an essential part of any successful research trial. Potential challenges that have been addressed effectively will be presented based on more than eleven years of experience conducting trials conducted in the United States, Africa, and Latin America. The speaker will discuss practical and cultural differences between research sites and how to optimize participant enrollment and reduce ineligibility. Strategies to reduce withdrawals and maximize retention will also be explored. Ms. Wright will examine challenges that are unique to infectious disease research with implications in public health, included impact from COVID-19 Pandemic. She will include scenarios, the roles played by team members across functional areas of the research project, collaborations, and the importance of a Quality Management Program to improve patient recruitment and retention.

Presenter: Alicia Wright, MS, CCRP, Program Manager, Vanderbilt University Medical Center
11:00 Awards Ceremony
Presentation of the Presidents Award and the Special Recognition Poster Program Award
Presenter: Quincy Byrdsong, EdD, EdD, CCRP, CIP, Associate VP for Research Administration, WellStar Research Institute
Presenter: John Petroch, MS, RPh, Investigational drug Service Manager, Cleveland Clinic Foundation

11:20 In Case You Were Wondering: Common Questions About the Revised Common Rule, a Year Later
Ms. Anderson will share reactions, recurring questions, issues, etc. that OHRP has seen since the revised Common Rule became effective. She will answer typical questions related to informed consent under the new rule, and will discuss the associated changes to the informed consent process, as well as the ethical basis of those changes. 901
Presenter: Misti Ault Anderson, MS, MA, Senior Advisor for Public Health Education, HHS Office for Human Research Protections

11:50 FDA Clinical Trials: A Review of Regulations and Responsibilities
Dr. Garmendia will review regulations and responsibilities with regard to human subject research, both IND and non-IND clinical trials. Topics to be covered include but are not limited to: clinical investigator responsibilities; the Common Rule; documentation requirements (ALCOA+C); electronic documentation; FDA inspections; FDA clinical investigator compliance program; Form FDA 1572; informed consent document and process; and protocol compliance. As part of the topics covered during this presentation, examples of GCP non-compliance cited during FDA inspection and found on Form FDA 483s, will be reviewed.
Presenter: Craig Garmendia, PhD, MS, Investigator, U.S. Food & Drug Administration

1:50 Identifying and Resolving Key Risk Issues in Clinical Trial Agreements
CTA negotiations are often long, time-consuming and costly. As a result, many sites simply chose to not negotiate CTAs, negotiate only a few provisions, or have improperly trained contract reviewers involved. This can unnecessarily expose the site, the PI and all study personnel to serious financial risk. Mr. Rajakaruna will help identify and describe the key risk-related issues in CTAs and will then provide the attendees with suggestions of how to mitigate these risks in a proper and efficient manner. 904
Presenter: Marlon Rajakaruna, BA, MBA, LLB, CRCP, Lawyer, Kingsgate Legal

2:20 Clinical Research Response Toolkit (CRRT): Project Management Approach in Conducting Clinical Research During an Infectious Disease Outbreak
Clinical research that can provide scientifically valid results can be successfully conducted during an infectious disease outbreak. However, project management approaches for facilitating the conduct of clinical research under routine conditions must be customized to fit the rapid response needs of initiating, planning and implementing clinical research studies during a public health emergency. The project management team within Clinical Monitoring Research Program Directorate (CMRPD), Leidos Biomedical Research (LBR), Frederick National Laboratory for Cancer Research (FNLCR) collaboratively worked with all key stakeholders and subject matter experts to successfully facilitate the conduct of high-profile clinical research during the Ebola outbreak in Liberia and Democratic Republic of Congo (DRC). This presentation aims to summarize the requirements and strategy adopted to develop the Clinical Research Response Toolkit (CRRT) and to demonstrate how this framework could be customized to fit the rapid response needs for conducting clinical research during an infectious disease outbreak. Co-authors on this presentation include: Jiwan Giri, Cynthia Osborne, Kevin Newell, Eric Stavale, Jen Sandrus, and Seth Baseler. 905
Presenters: Jiwan Giri, MSPM, MSIS, PMP, Clinical Project Manager II, Leidos Biomedical Research Inc. Cynthia (CK) Osborne, BS, Clinical Project Manager IV, Leidos Biomedical Research Inc

2:50 Innovative Educational Platforms in Clinical Research Education
In the changing environment of workforce development, education and training is also evolving to remain astute to the needs of the industry. A certificate or associate degree with a concentration in clinical research can provide employers with a highly trained workforce, and a technical college offers an additional affordable option to current training.
Presenter: Michelle Forthofer, BSN, RN, Program Director, Clinical Research Cert Program, Gwinnett Technical College

PATRICIA BEERS BLOCK, MDEd, BS, BS, CCRP
LISA BENSON, BS, CRCP
QUINCY BYRDSONG, EdD, EdD, CCRP, CIP
Kathi Durdon, MA, CCRP
Amanda Galster, MPH, CCRP
Jennifer Goldfarb, MSN, RN, CCRP
Anatoly Gorkun, MD, PhD, CIPD
Donna Headlee, RN, BS, CCRP

lenore Jackson-pope, BSN, MSM, RN, CCRP
John Kessler, PharmD, BS Pharm
Wendy Lloyd, BA, LPN, CCRP
Sandhya Patel, BScN, BSc
Mike Rashti, BS
Angela Rock, MBA, CCRP
Susanna Sellmann, BSc, CCRP, MRT
Nancy Wintering, BA, MSW, LCSW, CRC, CCRP

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WE’D LIKE TO GIVE SPECIAL THANKS TO THE 2020 ANNUAL CONFERENCE PROGRAM COMMITTEE

VIRTUAL POSTER PROGRAM

Abstract Submission

• Award winners will be encouraged to give an oral presentation at a future annual conference.
• Authors of posters must be registered attendees for the conference at the time of submission in order to be considered for the poster program and competition and to have the abstract published.
• At least one author must be a SOCRA member prior to abstract submission in order to qualify for the Special Recognition Award.
• Abstract applications received after July 31 will not be included in the abstract/poster evaluation and award process, but will be accepted for the poster sessions at the Annual Conference.
• Poster sessions will be conducted as a distinct part of the virtual program.

Poster Evaluation Process

1. Abstracts are submitted and scored prior to the annual conference.
   • Abstract scores are based on the following criteria: Impact on Clinical Research, Impact on Audience, Adequacy of Findings and Conclusions, Adherence to Format, and Clarity.
2. The displayed posters are scored by the evaluation committee during the first day of the conference.
   • Poster scores are based on Flow / Layout, Impact on Clinical Research, Impact on Audience, Adequacy of Findings and Conclusions, Adherence to Format and Clarity.
3. The highest combination of the abstract score and poster score determines the finalists, up to five in each category.
4. The top 5 scores from each category will be notified on Friday September 11th and will be invited to record a brief (5 minute) presentation which will be posted on the Virtual Conference Platform for conference attendees to view.

5. The presenter with the highest aggregate score among abstract, poster, and presentation session for each of the two categories (management and clinical trials) is awarded $500 and a fee waived registration to the 2021 Annual Conference to the primary author.
6. Special recognition awards will be announced on the SOCRA virtual conference platform.

Why be a Poster Presenter?

• Peer Recognition, Exposure and Networking
• Fee Waived Registration for the 2021 Annual Conference

If you don’t see an opportunity that fits your needs, Please contact the SOCRA office by e-mailing office@socra.org.

VIRTUAL SPONSORSHIP OPPORTUNITIES

Each year, the SOCRA Annual Conference welcomes clinical research professionals from across the world to pursue our mission to promote clinical research excellence and human research participant protection through education and certification of the clinical research community. This mission could not be fulfilled without our members, authors, speakers and instructors, exhibitors, sponsors, Board of Directors, chapter leaders, and all of the millions of subjects who participate in clinical research. Work with us to find an opportunity that fits your needs and reach a targeted audience of clinical research professionals from across the U.S., Canada and the world.

ANNUAL CONFERENCE SPONSOR CATEGORIES

Exhibitor Program

Location: Virtual Experience
Meeting Dates: September 23 to September 26, 2020
Exhibit Fees: $1,200

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