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

The material in this syllabus was coordinated for educational use only. This syllabus is not for sale and can only be obtained through SOCRA Annual Conference Registration.

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

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REGISTRATION

Registration fees include access to all live and on-demand content including the poster and exhibit program. All sessions will be recorded and available on-demand allowing you access for up to 45 days after the conference (until November 12, 2020).

CONTINUING EDUCATION CREDITS:

SOCRA designates this educational activity for a maximum of 50+ Continuing Education Credits for SOCRA CE and Nurse CNE. SOCRA designates this live activity for a maximum of 50+ AMA PRA Category 1 Credit(s)™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

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.

CNE 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.
## SCHEDULE OF EVENTS

### MONDAY, SEPTEMBER 21, 2020
**Exhibit Hall Opens**
9:00 am ET - Learn about our sponsors and exhibitors plus new products, services, and career opportunities in the Virtual Exhibit Hall. You will also have the ability to chat live with each of these companies during booth hours or book an appointment. The exhibit hall will be open from Monday, September 21st to Saturday, September 26th.

### 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 3:20 pm - Join us for the broadcasting of the breakout sessions in all 8 educational tracks featuring live Q+A via chat box!

**Chapter Session**
4:00 pm to 5:00 pm ET - Join us for a virtual chapter session with SOCRA President Amy Jo Jenkins. Please know space is limited. Email office@socra.org if you’d like to attend.

### FRIDAY, SEPTEMBER 25, 2020
**Breakout Sessions by Educational Track**
11:00 am to 4:10 pm ET - Join us for the broadcasting of the breakout sessions in all 8 educational tracks featuring live Q+A via chat box!

**Chapter Session**
4:00 pm to 5:00 pm ET - Join us for a virtual chapter session with SOCRA President Amy Jo Jenkins. Please know space is limited. Email office@socra.org if you’d like to attend.

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

## 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 in 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 implement 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.

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Conference Information
The Virtual Annual Conference platform is a website. There is nothing to download - you can simply visit the site on any device. It is password protected. Once you have accessed the virtual platform landing page (link below), you will need to log in by entering the email address you used to register for the conference and the password “SOCRA2020”.

Virtual Platform link: https://www.onlineevent.com/socra

Navigating the Site:
It is recommended that you use the “SCHEDULE AT A GLANCE” section of the platform to find sessions and their broadcast time. This schedule provides direct links to each session. You can also locate a session by searching the session number, title or speaker in the search bar in the top right hand corner of the page.

Returning to “HOME” screen: You can always return to the home page by clicking “Society of Clinical Research Associates” in the upper left hand corner of the page.

Opening and Closing Plenary Sessions
Opening and closing plenary sessions will air on Wednesday, September 23rd and Saturday, September 26th from 11:00 am ET to 3:20 pm ET each day. You will need to “REGISTER” for these days once you have logged on to the platform. Enter the opening or closing plenary section of the site and click the “REGISTER” button prior to the start of the conference to be able to easily join the live stream and add the sessions to your calendar.

Breakout Sessions
Breakout sessions will be broadcast on Thursday, September 24th and Friday, September 25th. Navigate to these sessions using the “SCHEDULE AT A GLANCE”. While every presentation will be available for viewing on demand until November 12th, speakers will only be available during the session’s scheduled time to answer questions in the chat box. Please note: Sessions will not appear on the platform until their scheduled broadcast time.

Conference Handouts
Conference handouts can be accessed by session in the “RESOURCES” tab located just below the presentation video window within each individual session. You may choose to download and print these as you wish.

Poster Program
The poster program remains an excellent opportunity for individuals to share their research, findings and achievements with their colleagues. Under the posters section of the platform, read abstracts, view the posters, and watch videos from the finalists. Winners of the Special Recognition Award Competition will be announced on Sat, Sept. 26th during the Closing Plenary.

CE Credit
To receive CE credit for your attendance, completion of conference evaluations through the virtual conference platform is required. Due to the nature of the virtual conference with sessions being available for viewing for 45 days following the conference, evaluations for CE credit, must be completed by November 11, 2020 at 11:59 PM ET. Certificates will be sent after November 12, 2020 or once you submit your “FINAL EVALUATION”.

SOCRA educational programming offers CME and CNE (Continuing Medical Education and Continuing Nurse Education). In addition to Nursing and Physician credits, CE for SOCRA courses may be used to satisfy other CE requirements, depending on your licensing board / certification body’s requirements. Please contact your licensing board or certification body to see if SOCRA CE, CNE, or CME credits apply to your licensure or certification CE requirements.

Credits offered: SOCRA designates this educational activity for 50+ Continuing Education Credits for SOCRA CE and Nurse CNE. SOCRA designates this educational activity for 50+ AMA PRA Category 1 Credit(s)™. Physicians should claim credit commensurate with the extent of their participation in the activity.

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Completing the Evaluations
To receive CE for sessions you attend, you must first view the session in its entirety. At the conclusion of the session a window will pop up asking if you would like to stay on the page you are currently on or go to next item. Click “GO TO NEXT ITEM” and you will be taken to the evaluation for that session. Complete each question on the evaluation and click “SUBMIT”. Please know all questions are required in order to submit the evaluation. When you have successfully completed an evaluation you will see “Thank you for completing the survey” appear on the page. Additionally, we ask that all attendees complete the “FINAL EVALUATION” located under the “Evaluation” section on the main landing page of the platform to provide overall feedback regarding the conference and SOCRA programming.
PROGRAM INFORMATION

Sponsor + Exhibit Program
Thank you to our Sponsors – Complion, Egnyte and Ripple Science. Learn about our sponsors’ and exhibitors’ new products, services, and career opportunities in this section of the platform. You will also have the ability to chat live with each of these companies during booth hours or book an appointment. The exhibit hall opens on Monday, September 21st.

Chapter Session
Friday, September 25, 2020 at 4:00 PM ET
The Annual Conference in its live, in-person format includes a chapter session for attendees interested in learning about how to start a chapter in their area. We have decided to host a virtual chapter session with SOCRA President Amy Jo Jenkins. Please know space is limited. Email office@socra.org to attend.

REMEMBER

Remember to use the “SCHEDULE AT A GLANCE” section of the platform to easily navigate to the live broadcast of the conference sessions.

While every presentation will be available on demand until November 12th, 2020, speakers will only be available during the scheduled session times to answer questions in the chat box.

To receive CE credit, evaluations must be completed by November 11, 2020 at 11:59 PM ET. Certificates will be mailed after November 12, 2020 or once you submit your “FINAL EVALUATION”.

Conference handouts can be accessed by session in the “RESOURCES TAB” located just below the presentation video window within each individual session.

Questions? Visit the “QUESTIONS” section of the platform to chat directly with SOCRA staff. You can also call us at 215.822.8644 or email us at office@socra.org.
# 2020 ANNUAL CONFERENCE SCHEDULE
## SEPTEMBER 23, 24, 25, AND 26, 2020 | VIRTUAL PROGRAM

### Wednesday, September 23, 2020

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**Opening Plenary - General Session**

### Thursday, September 24, 2020

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<tr>
<td>11:00-11:50</td>
<td>Behavioral Health</td>
<td>Device Research</td>
<td>Finance and Billing</td>
<td>GCP and Audit Preparedness</td>
<td>International Trials and ICH</td>
<td>Responsible Conduct of Research</td>
<td>Oncology Research</td>
<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>
<td>Responsible Conduct of Research</td>
<td>Oncology Research</td>
<td>Project Management</td>
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<td>1:40-2:30</td>
<td>Investigator Initiated Research</td>
<td>Device Research</td>
<td>Finance and Billing</td>
<td>International Trials and ICH / Canadian</td>
<td>International Trials and ICH</td>
<td>Enrollment/Retention and Informed Consent</td>
<td>Oncology Research</td>
<td>Advanced Management</td>
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<tr>
<td>2:30-3:20</td>
<td>Investigator Initiated Research</td>
<td>Device Research</td>
<td>Finance and Billing</td>
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### Friday, September 25, 2020

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<td>11:00-11:50</td>
<td>Pediatric Research</td>
<td>Device Research</td>
<td>Risk Management</td>
<td>Research Ethics</td>
<td>International Trials and ICH / Canadian</td>
<td>Training</td>
<td>Compliance / Noncompliance</td>
<td>Advanced Management</td>
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<td>11:50-12:40</td>
<td>Pediatric Research</td>
<td>Device Research</td>
<td>Site Management</td>
<td>Research Ethics</td>
<td>International Trials and ICH / Canadian</td>
<td>Training</td>
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### Saturday, September 26, 2020

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**Closing Plenary - General Session**
OPENING PLENARY

Wednesday, September 23, 2020

Time: 11:00 am ET

SOCRA Overview

Time: 11:05

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: Amy Jo Jenkins, MS, CCRP, Executive Director, Translational Research Institute, University of Arkansas for Medical Sciences

Presenter: Quincy Byrdsong, EdD, EdD, CCRP, CIP, 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 that 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: Rachele Peterson, MS, CCRP, CRA, Director of Healthcare Provider Organization Engagement, All of Us Research Program / Vibrent 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 better complying with the 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, CCRP, CIP, Associate VP for Research Administration, WellStar Research Institute

Thursday, September 24, 2020

BREAKOUT SESSIONS

Track 1

Behavioral Health

Time: 11:00

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

Track 1

Health Disparities

Time: 11:50

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 (MODEL), 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: 1:40  Track: Investigator-Initiated Research

Challenges and Risk Management for Investigator-Initiated FDA-IND Clinical Trials

In the past decade, many functional foods or dietary bioactive components have received great attention for showing strong therapeutic effects on management of chronic diseases, such as osteoporosis and obesity. Dr. Shen will briefly review how to study dietary bioactive components (green tea polyphenols and tocotrienols) in management of osteoporosis and obesity through FDA-IND clinical trials including FDA-IND application process, communication between FDA, funding agency (federal and industry), and IRB, and follow-up IND reports. In addition, Dr. Shen will discuss the challenges, risk management, and solutions in investigator-initiated IND studies.

Presenter: Chwan-Li (Leslie) Shen, PhD, CCRP, Professor of Pathology, Texas Tech University Health Sciences Center

Time: 2:30  Track: Investigator-Initiated Research

USP for Clinical Research Areas: Implementing Standards and Developing Training for Safe-Handling and Administration of Investigational Agents

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 they 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.

Presenter: Ashley Trost, MSN-Ed, RN, Clinical Education Coordinator, Northwestern Memorial Hospital
**Track 3: Finance and Billing**

**Time: 11:00   Track: Finance and Billing**

**Front End and Back End Billing – Revenue Compliance**
Ms. Willenberg 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.

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

**Time: 11:40   Track: Finance and Billing**

**Managing 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 complex cancer clinical trials and be effective in performing them right from the beginning will be discussed.

**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**

**Navigating Industry-Sponsored Clinical Trial Budgets and Finance: Setting your site 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.

**Presenter:** Jennifer Goldfarb, MSN, RN, CCRP, Vice President, Clinical Research, The IMA Group

**Track 4: GCP and Audit Preparedness**

**Time: 11:00   Track: GCP and Audit Preparedness**

**Investigator/Investigational Site Responsibilities**
Mr. Rashti will highlight the importance of investigator and investigational site responsibilities, and relate Good Clinical Practice compliance to the successful completion of clinical studies in support of New Drug Applications. He will describe how to prepare for an audit by FDA staff, how to address deficiencies, and will share past audit experiences. Mr. Rashti will explain the site’s responsibilities and commitments. Additionally, he will explain the most common deficiencies observed during an FDA audit, how to avoid them and how to be in compliance with the GCP regulations.

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

**Time: 11:50   Track: GCP and Audit Preparedness**

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

**Presenter:** Donna Williams, BSN, RN, CCRP, Senior Clinical Research Specialist, Hill-Rom

**Track 4: International Trials and ICH / Canadian**

**Time: 1:40   Track: International Trials**

**Clinical Trials Regulations in Canada: Moving Towards a Modernized Approach**
Dr. Legare will review the current clinical trial landscape in Canada, current regulations and how Canada is proposing to modernize its clinical trial regulatory framework.

**Presenter:** Carole Legare, MD, CCFP, Director of the Office of Clinical Trials, Therapeutic Products Directorate, Health Canada

**Time: 2:30   Track: International Trials**

**Health Canada’s Clinical Trial Compliance Program**
An overview will be provided of Health Canada’s Clinical Trial Compliance Program. Ms. Kasina and Dr. Abid will cover compliance trends, program updates, Canada’s implementation of ICH E6 (R2) and Gui-0100, as well as preparation for inspection.

**Presenters:** Alicia Kasina, PhD, MSc, Senior Regulatory Advisor, Clinical Trial & Biologic Compliance Program, Health Canada

Hocine Abid, MD, MBA, National Manager, Clinical Trial Compliance Program, Health Canada
**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?**
Professor, University of Applied Sciences and Arts, Hannover

Dr. Fortwengel will report on the current status and what into force of the regulation is currently expected for 2019. Regulations are being observed.

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

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

**South American Countries: Essential Tips to Successful COVID-19 Research Projects**
Presenter: Elizabeth Polo, MD, CCRP, CQA, General Manager, TRI CRO S.A.C.

Dr. Polo will explain why Peru, Brazil, Argentina, Colombia and Chile are countries of opportunity for COVID-19 clinical research. Essential tips for managing research projects will be discussed.

**Time: 2:30  Track: International Trials and ICH**

**Update on Clinical Trials - Regulation EU No 536/2014**
Presenter: Gerhard Fortwengel, PhD, MPH, MSc,
Professor, University of Applied Sciences and Arts, Hannover

Although the Regulation entered into force on 16 June 2014, the date of its application depends on the development of a fully functioning portal and database for clinical studies in the EU, which are confirmed by an independent audit. The Regulation will enter into force six months after the European Commission has published this confirmation. The entry into force of the regulation is currently expected for 2019.

**Track 6: Responsible Conduct of Research**

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

**Lessons Learned from Case Studies in Research Misconduct**
Presenter: Donna Kessler, PhD, Research Integrity Officer, Duke University

The research outcome will be presented. Although the Regulation entered into force on 16 June 2014, the African continent offers many good conditions for conducting clinical trials. Beside a diverse population of potential patients, many patients have not been previously exposed to any kind of pharmaceutical drugs and are defined as naïve patients. In addition, a number of diseases – 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? The research outcome will be presented.

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

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

**Responsible Conduct of Research/Research Misconduct – a Year in Review**
Presenter: Debra Parrish, JD, Partner, Parrish Law Offices

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.

**Time: 2:30  Track: Responsible Conduct of Research**

**“We Would Like to Talk to You About this Study”: How to Educate Prospective Subjects About Their “Role” as a Research Subject**
Presenter: Laura Holtz, MS, CCRP, Senior Research Manager, IU Center for Aging Research, Regenstrief Institute

Research recruitment and retention in clinical trials continues to be paramount to successful trial completion. However, many subjects do not have a clear understanding of the role of the research subject and may contribute to the lack of protocol adherence or continued enrollment. Ms. Holtz will use an ethical framework to establish a description of the research subject’s role and look at key areas to educate potential subjects to ensure understanding of expectations for research participation, including: assessing knowledge about research, addressing therapeutic misconception, and confirming alignment of goals and expectations. Case studies will be used to develop strategies and practical applications to educate potential subjects at the time of enrollment in research.

**Presenter: Laura Holtz, MS, CCRP,**
Senior Research Manager, IU Center for Aging Research, Regenstrief Institute
PAY-TO-PLAY: The Ethics of Volunteers Paying to Participate in Clinical Trials

The FDA allows for charging for investigational products used in clinical research under certain circumstances. The federal regulations also state that participants should be informed of any additional costs that may result from participation in research. Recent “research studies” are using this guidance as a loophole to charge participants for studies that may not create generalizable knowledge. Ms. Oeser will review the ethical issues involved in recent pay-to-participate “research studies” and how these may violate the pillars of respect of persons, beneficence, and justice.715

Presenter: Annette Oeser, BS, MLAS, CCRP, Clinical/Translational Research Coordinator III, Vanderbilt University Medical Center
Friday, September 25, 2020

**Track 1: Pediatric Research**

**Time: 11:00**

**Pediatric 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.117

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

**Time: 11:50**

**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 will encourage efficiencies through electronic systems.119

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

**Time: 1:40**

**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 CRAs/minters as well.211

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

**Time: 2:30**

**Pediatric Compliance and Accountability: A ‘How To’ Guide for the Pediatric Population**

Dr. Duke Endsley will cover topics related to investigational 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.515

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

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**Track 2: Device Research**

**Time: 11:00**

**Device Best Practices in Scientific Database Searching**

The MEDDEV 2.7/1 Rev 4 (June 2016) and EU Regulation 2017/745 (2017) have placed a new or 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-life case studies that exemplify how informed changes to a search string can yield more targeted results.217

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

**Time: 11:50**

**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 investigators, proper monitoring, and UADE reporting. The relationship between the sponsor and the site will also be discussed.219

**Presenter: Sivan Yani, Clinical Research Associate, Align Technologies**

**Time: 1:40**

**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-world non-compliant informed consent scenarios. The challenges associated with each example will be highlighted and solutions will be offered. Specific recommendations regarding how monitors can help their study teams prevent unanticipated problems within the context of informed consent will be emphasized.221

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

**Time: 2:30**

**Monitoring Recognizing Mr. Hyde: Misconduct in 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.223

**Presenter: Melissa Markey, JD, CISSP, Attorney / Shareholder, Hall Render**
### Integrating Quality into Investigator-Initiated Clinical Trials
**Ms. Lane**

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 and study initiation process for IITs, and approaches to mitigate potential risks during the trial's conduct.  

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

### Establishing a Regulatory Support Program-Steps to Success
**Dr. Arbit**

Dr. Arbit will discuss the importance of regulatory support for IISR in an academic health center along with involving the necessary support functions, 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

### Challenges for Consenting when Enrolling Children in Research
**Ms. Waseem**

In this presentation, Ms. Waseem will highlight the challenges and barriers for effective and adequate consenting for pediatric research using a scenario-based format. He will demonstrate practical mechanisms for obtaining appropriate assent and consent when conducting research involving pediatric patients, so as not to cause harm to this unique population.

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

### Improvements in the Start-Up Process in an Academic Clinical Trials Office
**Ms. Wheeler**

Ms. Wheeler will discuss some innovative ways to work through study start-up, beginning with study feasibility through parallel budget/contract negotiations. Process maps, workflows, and checklists to streamline start-up and reduce work redundancy will be discussed.

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

### A Journey from Inspection Fear to ‘No Observations’
**Mr. Gajiwala**

Surprised or announced, QA or operations, everyone fears for an inspection. Mr. Gajiwala will not only provide assistance for the overall management of an inspection, but also for assuring all-time readiness within the sponsor, investigator and site staff for facing any external audit or regulatory inspection. Key snippets will include understanding the inspection process, meeting inspector expectations and discussion on some of the do’s and don’ts, handling observations and implementing CAPAs such that re-finding is avoided.

**Presenter:** Priyand Gajiwala, MPHarm, CCRP, QA Analyst KKG Science Inc.

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### Regulatory Inspections of Research Sites: What to Expect, What to Do & What Not to Do!
**Ms. Tungol**

The primary reason the FDA performs inspections is to support its mission to protect the public by ensuring the safety and efficacy of drugs, biologics, and medical devices. Faced with an impending audit or inspection, how do you prepare? This session will provide an overview of what to expect and how to prepare for an audit or inspection. This course will prepare you and your site for expectations from the FDA and provide concrete steps you can take to prepare before, during and after the inspection.

**Presenter:** Joyce Tungol, BS, CCRP, Clinical Research Associate, Duke University

### Regulatory Aspects of Clinical Research – A Lesson in History
**Ms. Selfe**

Dr. Selfe will briefly introduce various reporting standards, then focus on those most relevant to randomized trials, the Consolidated Standards of Reporting Trials (CONSORT) statement, as well as the Template for Intervention Description and Replication (TIDieR) guide. Using these guidelines, authors can ensure they maintain good reporting practices (“GRPs”) and readers can evaluate the rigor of the study design, identify potential sources of bias, and determine if the research is replicable in their population of interest (other researchers) and/or generalizable to their patients (clinicians). The TB Trials Experience in the United States, Africa, and South America

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

### The TB Trials Experience in the United States, Africa, and South America
**Ms. Wright**

Recruitment and retention is an essential part of any successful research project. Potential challenges and ways they have been addressed effectively will be presented based on more than eleven years of experience in tuberculosis 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
BREAKOUT SESSIONS

**Track 5: International Trials and ICH / Canadian**

**Time: 11:00**

**Conducting Clinical Trials According to Regulatory Guidelines**

In the demanding world of clinical research, it is imperative that researchers know and adhere to the rules in order to conduct clinical trials successfully. Ms. Marzinotti aims to help researchers learn how to fulfill their responsibilities by putting GCP E6(R2) into practice. Research teams will discover secrets to keeping investigators on track throughout the study. 517

**Presenter:** Velma Marzinotto, BScN, RN, CCRP, Independent Consultant

**Time: 11:50**

**Investigational Testing Authorizations for Medical Devices in Canada**

Ms. Desrosiers will focus on regulatory requirements for Investigational Testing Authorizations (ITA) by Health Canada. Ms. Desrosiers will also present an overview of the Medical Devices Regulations pertaining to Investigational Testing and provide information on policies and procedures required for new and revised ITAs. 519

**Presenter:** Marie-Pierre Desrosiers, MSc, Scientific Evaluator, Health Canada

**Track 5: Quality Management**

**Time: 1:40**

**Importance of Quality in Research: A Review of Quality Tools and Ideas for Incorporation**

Ms. Tudor will discuss the importance of quality in a research program and describe the various quality management tools: FOCUS, PDSA, LEAN, and Six Sigma along with the data analysis tools which can be used within each methodology. Ways each methodology and/or tools can be used within a research program will be explained. 521

**Presenter:** Heather Tudor, MBA, CCRP, RHIA, Assistant Professor, Eastern Kentucky University

**Time: 2:30**

**We are on the Same Team: A Collaborative Quality Assurance Approach**

Ms. Fors will consider the role of a quality assurance program within an academic medical center including the use of a team approach to foster growth in the clinical research process and community. She will discuss the development of a meaningful and efficient audit process, evaluation of audit metrics, and implementation of quality improvement initiatives. 523

**Presenter:** Elizabeth Fors, BA, CCRP, Director, Quality Assurance Program, University of Kansas Medical Center

**Time: 3:20**

**Developing an Internal Quality Assurance Program: A University’s Experience**

Ms. Longpre will provide an overview on the creation and development of a new QA program. How it was implemented, along with the challenges and pitfalls, will be discussed. Most common findings that led to training and education for the clinical research teams, will be highlighted. 525

**Presenter:** Linda Longpre, CCRP, QA & Regulatory Compliance Specialist, University of Calgary

**Track 6: Training**

**Time: 11:00**

**Creating the Workplace in which We Want to Work: Professionalism in the Workplace**

Professionalism is a key component of a dynamic and thriving workplace, a truly defining element of a productive workplace culture. As the clinical research arena becomes more generationally-diverse, the standards of professionalism are becoming less consistent. Ms. van der Schalie will discuss the changing concepts of professionalism in the workplace, how it is judged, and how to optimize professionalism in the workplace to benefit individuals and organizations. 619

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

**Time: 11:50**

**A Difficult One in a Team: How Do We Work and Manage?**

You may happen to work with a colleague or a direct report who is difficult to please. They may have a special opinion and never want to compromise or they may think they are always right and everyone else is wrong. They want to do things their own way and poor you if you obey. Being snappy and arguing can be their norm, at the same time they still can perform very well. Dr. Gorkun will share approaches and methods to manage difficult employees, including corrective and preventive measures, supported by real-life examples. 619

**Presenters:** Anatoly Gorkun, MD, PhD, Chartered MCIPD, Senior Clinical Manager, PPD UK

Hugh Devine, IMIS, Senior Director of Clinical Operations, PPD UK

**Time: 2:30**

**From Corporate Healthcare to Site Ownership**

With 25+ years of consulting experience and executive leadership, Mr. Whitt will share his experiences and lessons learned after leaving a senior level position at a large CRO to purchase a small medical research clinic. 623

**Presenter:** Scott Whitt, MA, Owner and General Manager, Triad Clinical Trials

**Time: 3:20**

**Training Game Plan: Ensuring Successful Project Team Member Transitions Through Training**

Ms. Rugloski will provide tips and examples for creating and implementing a Project Team Member Transition/Training strategy to ensure effective and efficient project team member transitions. The session will end with an activity comprised of an interactive mind-mapping (“brainstorming”) exercise with audience participation. 625

**Presenter:** Carolyn Rugloski, MSc, CCRP, Senior Consultant, Lead Project Manager, FCI Consultants
**Track 7 - Enrollment/Retention**

**Time: 11:50**

**Track: Enrollment/Retention**

**Informed Consent**

**Efficiently Enrolling the “Correct” Patient to a Study**

Screening patients for studies can be a staggering process when most study coordinators are running multiple trials over multiple disease indications. Pulling out the eligibility criteria and simplifying the procedures help not only the coordinators, but also patients as enrolling in studies can be overwhelming. By simplifying this process you can have patients enrolled quicker and treated sooner; despite institutional scheduling barriers. 719

*Presenter: Katie Lyon, MS, CCRP, Clinical Team Lead, Cancer Insight LLC.*

**Time: 1:40**

**Track: Enrollment/Retention**

**Informed Consent**

**A Tale of Two Studies**

As a clinical research manager in the University of Maryland until 2019, Dr. Saleh managed two seemingly unrelated studies but the planning made the concurrent execution advantageous. Looking at the inclusion criteria, he was able to leverage the different criteria to achieve the goal of the 400 subjects for the first study and 120 for the latter during the same period. Knowing that patients may have overlapping criteria, Dr. Saleh encouraged his team to be open-minded during enrollment and was able to recruit participants from each study that were eligible for the other and saved much time searching for new participants in new venues. Dr. Saleh will share lessons learned from these studies. 721

*Presenter: Ahmed Saleh, PhD, MSc, MS, CCRP, Senior Clinical Project Manager, BD*

**Time: 2:30**

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

**Strategies to Enhance Informed Consent Understanding**

Consent is more than a signature on a form. Despite meeting legal requisites, the question of patients’ genuine comprehension remains a pertinent ethical issue. Various interventions have been developed to supplement the traditional paper-based approach of the Informed Consent Form, in order to address the paucity in participant knowledge and to enhance their decision-making process. Dr. Shi seeks to showcase and evaluate patient response to strategies using multimedia, print media and direct interaction. The effectiveness of informed consent interventions will be determined through standardized measures such as the QuIC (Quality of Informed Consent) questionnaire, as well as alternative customized measures. 722

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

**Track 8 - Advanced Management**

**Time: 11:00**

**Track: Advanced Management**

**Practical Aspects of Conducting Gene Therapy Trials**

With the growth in gene therapy, there is a need for clinical sites to understand their regulatory requirements and operational issues. Dr. Hovinga will review the regulatory and compliance elements to the conduct of gene therapy trials including the differential role of IRBs and IBCs and ways to address frequent patient concerns from those considering participation in a gene therapy studies. 817

*Presenter: Collin Hovinga, PharmD, MS, FCCP, Senior Vice President, Clinical & Scientific Development, Institute for Advanced Clinical Trials for Children*

**Time: 11:50**

**Track: Advanced Management**

**Maintaining the Blind in Clinical Trials**

Conducting blinded clinical trials is something we are so accustomed to doing that we rarely give it a second thought. Then one day, out of the blue, you receive an email that someone believes that they can identify the treatment allocation of patients in a trial you thought was not at risk for unblinding. This session will review points to consider when setting up studies to ensure the blind is adequately maintained starting from the protocol through database lock. 819

*Presenter: Gayle Flynn, BA, ALM, Director Life Sciences, Cognizant*

**Time: 1:40**

**Track: Advanced Management**

**Prevention = Safety: No Tears Approach to Research Compliance**

The value of implementing preventive quality assurance measures is essential to ensuring research compliance. For a research team to be successful, it is vital they proactively identify risks and implement measures to ensure patient safety and the integrity of the research. This proactive approach provides opportunities for coaching, mentoring, and training in a supportive non-punitive way. Preventive measures can provide confidence within the research team, preventing the crisis mode mentality that often precedes an audit or inspection. 821

*Presenter: Angie Price, MSN, CCRC, Project Director, Clinical Site Network, Institute for Advanced Clinical Trials for Children*

**Time: 2:30**

**Track: Advanced Management**

**A Case Study on International Collaboration Between Cuba’s Molecular Immunology Center and Roswell Park Comprehensive Cancer Center**

The ongoing collaboration between Roswell Park Comprehensive Cancer Center (Buffalo, NY) and Center of Molecular Immunology (Havana, Cuba) highlights the importance of international collaborations in the biotechnology field. Ms. Evans highlights the shared mission of the collaboration along with opportunities and challenges that have been faced along the way. She will discuss the development of this collaboration from the Center of Molecular Immunology investigations through the opening of a phase 1 clinical trial in the United States at Roswell Park with therapies developed in Cuba. 823

*Presenter: Rachel Evans, MS, CCRP, Clinical Research Coordinator, Roswell Park Comprehensive Cancer Center*

**Time: 3:20**

**Track: Advanced Management**

**Managing Data Management: Lessons from a Large CMS Demonstration Project**

Ms. O’Kelly Phillips will discuss how data collection and management were structured in a large CMS demonstration project involving multiple data sources, including direct input from 40 partnered nursing facilities. Lessons learned throughout the project with attention to best practices for approaching managing projects with complex data structure in investigator-initiated grants and trials will be highlighted. 825

*Presenter: Erin O’Kelly Phillips, MPH, CCRP, Research Manager, Regenstrief Institute*
11:00
**Awards Ceremony**
Presentation of the Chapter Award and the Special Recognition Poster Program Award.
**Presenter: Quincy Byrdsong, EdD, CCRP, CIP, Associate VP for Research Administration, WellStar Research Institute**
**Presenter: John Petrich, 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.
**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**

1:40
**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.
**Presenter: Marlon Rajakaruna, BA, MBA, LLB, CRCP, Lawyer, Kingsgate Legal**

2:25
**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 Beth Baseler.
**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.**

2:55
**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**
We’d like to give special thanks to the

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Save the Date

2021 Annual Conference
Denver, CO
September 24 - 26
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