SOCRA®
FOR CLINICAL RESEARCH EXCELLENCE

32ND ANNUAL CONFERENCE

ADVANCING INNOVATION AND INTEGRITY: A TIME FOR TRANSFORMATION IN CLINICAL RESEARCH

SEPTEMBER 29 TO OCTOBER 1
MONTREAL, QUEBEC, CANADA

CONFERENCE SCHEDULE

WEDNESDAY, SEPTEMBER 27
Certification Prep + GCP Review Course

THURSDAY, SEPTEMBER 28
CCRP Certification Exam
14 Preconference Workshops

FRIDAY, SEPTEMBER 29 TO OCTOBER 1
Main Conference - Plenary Sessions, Breakout Sessions by Educational Track, Poster Program, Exhibits, Sponsors + More!

7 TRACKS, 20+ TOPIC AREAS, 80+ SESSIONS, 100+ SPEAKERS, 50+ CE

32ND ANNUAL CONFERENCE

September 29 to October 1, 2023 I Montreal, Quebec, Canada

Join 1,000 of your colleagues back in person at SOCRA's 2023 Annual Conference! For the 32nd year, SOCRA will welcome clinical research professionals from across the world. Located in Old Montreal, this three-day conference 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. The program will feature expert-led academic sessions, hands-on workshops, opportunities to network and connect, a peer-driven poster session, and an exhibit program.

OPENING SESSION PLENARY SPEAKERS

JENNIFER LI, BSC, CCRP

SOCRA President, Quality Manager, Princess Margaret Cancer Centre

JESSICA ROWE, MA, MS, CCRP, CIP

SOCRA Incoming President, Associate Director, HRPP and YCCI, Regulatory Compliance & Quality, Yale School of Medicine

ANNE E. JOHNSON, BA

Program Division Director, Bioresearch Monitoring Operations (East), Office of Regulatory Affairs, U.S. Food and Drug Administration

HEALTH CANADA

Coming soon - representative speaking on Health Canada regulations and initiatives

ANNIE ELLIS

Research Advocate, Ovarian Cancer Research Alliance

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REGISTRATION

Early Bird Registration

confirmed prior to or on August 22:

- Member Fee: $750 USD
- Non-Member Fee: $825 USD*

Standard Registration

confirmed prior to or on August 22:

- Member Fee: $800 USD
- Non-Member Fee: $875 USD*

Preconference Workshops (Optional)

- Additional: $175 USD

**Non-Member Fees include a non-refundable one-year SOCRA membership*

WHO SHOULD ATTEND?

Clinical Research Professionals Including: investigators, nurses, coordinators, monitors, auditors, associates, project managers, consultants, educators, administrators

Participant / Attendee affiliations such as: medical centers, cooperative research groups, research consortia, pharmaceutical, device and biotechnology companies, contract research organizations, independent research firms

CONFERENCE INFORMATION

VENUE AND HOTEL

Venue: Palais des Congrès de Montréal

(Montreal Convention Center)
1001 Place Jean-Paul-Riopelle
Montreal, QC H2Z 1H5

Main Conference Hotel:
Double Tree by Hilton Montreal

1255 Rue Jeanne-Mance, Montréal, QC H5B 1E5, Canada
Hotel Phone: +1 (514) 285-1450 I Reservations: (800) 361-8234 or Make Your Reservation Online
SOCRA's hotel room rate is $265 / $290 CAD (plus applicable taxes). These rates are available until Sept 1, 2023 or until the SOCRA room block is filled. You must mention SOCRA to receive the room rate.

TRAVEL

International Travel:

Canadian law requires that all persons entering Canada carry proof of citizenship and identity. A valid U.S. passport, passport card, or NEXUS card satisfies these requirements for U.S. citizens.

The Public Health Agency of Canada no longer collects COVID-19 test samples from travelers entering Canada.

Air and Ground Transportation:

Montréal is easily accessed by land, water and air. Downtown is a mere 20 minutes from the Pierre-Elliott Trudeau International Airport (YUL).

SCHEDULE OF EVENTS

Wednesday, September 27, 2023

CRP Certification Prep and GCP Review Course*
8:00 am to 4:30 pm - Course Registration and Session
**requires separate registration*

Thursday, September 28, 2023

Certification Examination*
7:30 am to 12:00 pm - Examination Registration and Session
**Requires separate registration. Registration Deadline to apply for this date is August 17, 2023*

Preconference Workshop Seminars
12:30 pm to 5:15 pm - Registration and sessions

- Preparing for the FDA Clinical Investigator Site Inspection
- IRBs and the Informed Consent Process
- Legal Issues Involving Researchers, Including Fraud and Misconduct
- The Ins and Outs of Publishing and Presenting Research Results with Pizzazz
- Clinical Research Administration, Budgeting, Contract Negotiation and Finance: A Site's Perspective
- GCP 101: A Workshop for the New Study Coordinator
- Statistics in Clinical Research: Understanding Protocols and Statistical References
- Device Research Regulatory Basics
- Project Management & Process Standardization in Clinical Trials
- Risk-Based Management - Principles and Practices for Successful Management of Clinical Research
- SOP Development and Implementation
- Investigator-Initiated Sponsored Research (IISR)
- Optimal Study Start-Up Through Protocol Assessment
- ClinicalTrials.gov Administration

MAXIMIZE YOUR ATTENDANCE

MAIN CONFERENCE

Thursday, September 28, 2023

Welcome Reception and Registration
6:00 pm to 7:00 pm - Reception and Registration for Attendees, Speakers, Exhibitors, Poster Presenters and SOCRA Board of Directors.

Friday, September 29, 2023

General Session
7:30 am to 5:00 pm - Registration
8:00 am to 8:30 am - Continental Breakfast
8:30 am to 12:15 pm - Welcome and Opening Plenary
10:00 am to 10:30 am - Morning Break
10:00 am to 5:00 pm - Exhibits and Poster Hall Open
12:00 pm to 1:15 pm - Luncheon / Exhibits and Posters
1:15 pm to 5:00 pm - Breakout Sessions
2:50 pm to 3:25 pm - Break / Exhibits & Posters

Saturday, September 30, 2023

General Session
7:30 am to 5:00 pm - Registration
8:00 am to 8:30 am - Continental Breakfast
8:30 am to 5:20 pm - Breakout Sessions
10:05 am to 10:50 am - Break / Exhibits & Posters
10:05 am to 4:00 pm - Exhibits and Poster Hall Open
12:25 pm to 1:40 pm - Luncheon / Exhibit and Posters
12:40 pm to 1:30 pm - Chapter Roundtable and Luncheon
3:15 pm to 3:45 pm - Break / Exhibits and Posters

Sunday, October 1, 2023

General Session
8:00 am to 8:30 am - Continental Breakfast
8:30 am to 8:40 am - Poster Recognition Award Presentation
8:40 am to 12:00 pm - Closing Plenary
9:50 am to 10:10 am - Morning Break
12:00 pm - Program Adjourns

CONFERENCE INFORMATION

EARNING CE

SOCRA CE

SOCRA designates this educational activity for a maximum of 50+ Continuing Education Credits for SOCRA CE. The Annual Conference offers 15 credits live (maximum). Preconference Workshops offer an additional 4 credits live (maximum). The remaining credits are available through on demand viewing of sessions through the SOCRA mobile app platform.

CNE and CME

SOCRA designates this educational activity for a maximum of 19* Continuing Education Credits for Nurse CNE and AMA PRA Category 1 Credit(s)™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

**15 credits main conference, 4 credits preconference*

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

50+ CE AVAILABLE

This one event meets the CE requirement for your SOCRA CCRP recertification!

- Main Conference - 15 credits live
- Preconference Workshops - 4 credits live
- 30+ remaining credits - On-demand viewing through the SOCRA mobile app

PROGRAM LEARNING OBJECTIVES PREVIEW

- Discuss best practices, tips and tricks for new Clinical Research Associates
- Discuss how to create effective strategies in a remote training environment
- Discuss the benefits of adopting an electronic regulatory documentation system
- Discuss the challenges of conducting multicenter clinical trials at satellite sites
- Discuss principles of leadership in clinical research
- Discuss how to revamp your workflows, including finances, regulatory, management, and training in a resource limited institution
- Discuss the regulatory requirements for ClinicalTrials.gov
- Discuss the critical leader attributes for managing and implementing workforce development
- Discuss the variety of tools and benefits in REDCap that can be utilized for the collection of research data
- Discuss resources for researching medical devices using databases maintained by US, EU, and other health authorities
- Discuss the importance of clinical trial population diversity to understanding a new therapy's benefit-risk profile, as well as practical approaches to improve the inclusiveness of clinical trials
- Discuss Education Partnership Models that lead to successful recruitment opportunities
- Discuss the successes in utilizing e-consenting, especially in community based research
- Discuss issues of paying research participants
- Discuss misconduct in clinical trials and the possible consequences of clinical research coordinator intentional misconduct
- Discuss the often overlooked issues that affect research study budgets
- Discuss the use of technology and administrative data to streamline clinical trial conduct
- Discuss monitoring best practices, new tips and tools
- Discuss the role of virtual tools in Human Ethic Committee (HEC) meetings
- Discuss fundamentals of project management in an easily comprehensive manner utilizing Project Management Institute's (PMI) terminology and best practices
- Discuss the use of The Expert Problem to generate clear communication in clinical research

AND SO MUCH MORE!

CONFERENCE INFORMATION

POSTER PROGRAM

Presenting a poster at SOCRA's Annual Conference is a noteworthy way to share expertise or accomplishment in a specific area while contributing to clinical research.

2023 Special Recognition Award Competition

Attendees interested in participating in the Poster Special Recognition Award Competition have an opportunity to compete for a $500 award and a fee waived registration to next year's 2024 SOCRA Annual Conference.

Posters may be entered in one of two categories:

- Clinical Trials: Scientific papers reporting on findings of treatment, intervention, or survey studies.
- Clinical Research Management: Critical reviews, position papers, or descriptive case reports dealing with issues associated with implementation, coordination, or management of clinical research programs.

The deadline for the 2022 Special Recognition Award competition is August 13, 2023.

After this date, abstracts may be submitted but will not be eligible for the Special Recognition Award. The deadline to submit abstracts for the Poster Program and not be considered for the Special Recognition Award competition is August 21, 2023

View additional details on page 22 including Abstract Submission Details and the Poster Evaluation Process for the Award Competition.

SPONSOR + EXHIBIT

Educational environments are evolving to meet the needs of sponsors and exhibitors with enhanced features and new ways to connect. This event will be a dynamic, interactive program, with networking and collaborative opportunities. This three-day conference will connect 1,000 clinical research professionals and to inform them on the best and most up-to-date practices.

Exhibit

In the exhibit hall, Exhibitors will share information about their latest products and services, showcase their latest innovations, and connect with research collaborations, customers, and peers. SOCRA's members are clinical research professionals that work in all types of job functions in clinical research and represent varying therapeutic areas.

Sponsor

Maximize your exposure by sponsoring the event. We offer a variety of sponsorship levels and opportunities. If you don't see an opportunity that fits your needs, contact us at **office@socra.org**.

VIEW THE 2023 MEDIA KIT HERE

Plus additional details + opportunities to sponsor, exhibit, and advertise on page 24.

CONFERENCE SCHEDULE

FRIDAY, SEPTEMBER 29, 2023

9:00 am to 12:00 pm — OPENING PLENARY SESSION

LUNCH

FRIDAY, SEPTEMBER 29, 2023

TIME	TRACK 1	TRACK 2	TRACK 3	TRACK 4	TRACK 5	TRACK 6	TRACK 7
1:15 pm	Behavioral Health	Device Research	IIR	Regulatory / Legal	Responsible Conduct	Training	Project Management
2:05 pm	Behavioral Health	Device Research	IIR	Regulatory / Legal	Responsible Conduct	Training	Project Management
BREAK							
3:25 pm	GCP + Audit Preparedness	Device Research	IIR	Regulatory / Legal	Scientific	Training	Project Management
4:15 pm	GCP + Audit Preparedness	Device Research	IIR	Regulatory / Legal	Scientific	Training	Project Management

SATURDAY, SEPTEMBER 30, 2023

TIME	TRACK 1	TRACK 2	TRACK 3	TRACK 4	TRACK 5	TRACK 6
8:30	Poster	Advanced Management	Monitoring	Quality Management	Site Management	Training
9:20	Poster	Advanced Management	Monitoring	Quality Management	Site Management	Training
BREAK						
10:50	Oncology	Advanced Management	Monitoring	Quality Management	Site Management	Enrollment, Retention + IC
11:40	Health Disparities	Advanced Management	Ethics	Quality Management	Site Management	Enrollment, Retention + IC
LUNCH						
1:40	Finance + Billing	Advanced Management	Ethics	Quality Management	Study Start-Up	Enrollment, Retention + IC
2:30 pm	Finance + Billing	Advanced Management	Ethics	Quality Management	Study Start-Up	Enrollment, Retention + IC
BREAK						
3:45 pm	Finance + Billing	Pediatric Research	Ethics	Human Research Protections	Site Management	Enrollment, Retention + IC
4:35 pm	Finance + Billing	Pediatric Research	Ethics		Site Management	Enrollment, Retention + IC

SUNDAY, OCTOBER 1, 2023

8:40 am to 12:00 pm — CLOSING PLENARY SESSION

PRECONFERENCE SEMINARS

ClinicalTrials.gov Administration

Are you involved in the registration, management, and results entry of studies in the Protocol Registration and Results System (PRS)? Are you struggling with how to start and where to go for help? The workshop will review PRS Administrator responsibilities, lessons learned from moving an existing program toward a positive direction, and provide guidance for managing trials, in addition to reviewing the registration and results entry process. Best practices and helpful tips for both Administrators and users will be provided. Attendees are invited to bring their own scenarios for group discussion and should leave the workshop with skills to successfully manage trials within ClinicalTrials.gov.

Presenters: Cristina Ferrazzano Yaussy, MPH, CCRP, Research Regulatory Affairs Specialist, Dartmouth-Hitchcock Medical Center
Stacey Arnold, PhD, Results Team Subject Matter Expert, ClinicalTrials.gov, National Library of Medicine, National Institute of Health

Preparing for the FDA Clinical Investigator Site Inspection

This workshop will address Food and Drug Administration (FDA) perspectives and the regulations regarding adherence to protocol, records management, patient rights, drug / product management and record keeping, and regulatory issues related to an FDA audit. This workshop will educate the attendee in Good Clinical Practice (GCP) requirements and FDA audit expectations, in order to aid in preparation for an FDA GCP audit. This interactive workshop will provide the following: A brief introduction to the FDA; Overview of clinical research, including the Federal Regulations covering clinical research and clinical investigator obligations; Discussion on Trial Site Roles and Responsibilities; Explanation of the FDA's Bioresearch Monitoring Program, focusing on the Clinical Investigator inspection; Insight on understanding the FDA GCP inspection: Who is the FDA auditor? What makes FDA suspicious? Common FDA inspection findings at the clinical site audit; Specific examples of FDA-483 observations; FDA inspection strategy.

Presenter: Erin Krohl, MPH, MS, BS, President, EHKrohl Consulting Inc.

Investigator-Initiated Sponsored Research (IISR)

Why conduct investigator-initiated research? This workshop will discuss the regulatory obligations of an IND/IDE sponsor-investigator. Dr. Arbit and Dr. Teeple will describe the resources needed to support and the risks associated with conducting investigator-initiated clinical trials. The participants will learn how to determine if a sponsor-investigator IND or IDE is needed. There will be ample opportunity for discussion and Q&A.

Presenters: Harvey Arbit, PharmD, RAC, CCRP, President and CEO, Arbit Consulting, LLC
Wrenda Teeple, PharmD, Chief Clinical Officer and Director of Regulatory Affairs, Arbit Consulting LLC

IRBs and the Informed Consent Process

Initial and continuing ethical review by institutional review boards (IRBs), also referred to as independent ethics committees (IECs), and the informed consent process are the cornerstone for the protection of the human research subject. FDA regulations establish rules that clinical research professionals must follow during the clinical research process. The International Council on Harmonization (ICH) Good Clinical Practice (GCP) Guideline is an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects. Dr. George D'Addamio will discuss the FDA's regulatory requirements and the ICH GCP guideline's standards for IRBs and current challenges facing IRBs. Laura Holtz and Jessica Rowe will discuss and explain the elements of a quality informed consent process under FDA regulations and ICH standards and will also consider emerging challenges in obtaining informed consent. Lessons learned from experience and case studies will be presented for discussion.

Presenters: George D'Addamio, PhD, BS, MS, President, PharmConsult Inc
Laura Holtz, MS, PMP, CCRP, Clinical Research Associate, Yale School of Medicine - YCCI
Jessica Rowe, MA, MS, CIP, CCRP, Associate Director, HRPP/YCCI, RCQ, Yale School of Medicine

THURSDAY, SEPTEMBER 28, 2023

PRECONFERENCE SEMINARS

Legal Issues Involving Researchers, Including Fraud and Misconduct

Traditionally research has been the one area in medicine where, other than the regulatory process, there has been little interaction with the legal system. However, in recent years this has changed. Within the U.S. and internationally there has been an increase in civil and criminal actions against researchers. This session will provide an overview of recent problem areas, as well as insight on how to avoid them.

Presenter: Melissa Markley, JD, CISSP, Attorney / Shareholder, Hall, Render, Killian, Heath & Lyman, LLP

Clinical Research Administration, Budgeting, Contract Negotiation and Finance: A Site's Perspective

This session will discuss the elements of a clinical trial protocol, budgeting and contracting, and the impact of these elements on the conduct of a trial. The administrative and financial aspects of the trial will be covered with special emphasis on the study administration, effective budget development and management and contract negotiations. This session will be interactive with participation from attendees to include developing and negotiating the study budget.

Presenters: Bryan Soronson, MPA, FACMPE, Retired Senior Administrator, University of Maryland Department of Neurology

Lisa Benson, BS, CRCP, President, Pediatric Clinical Research Consulting, LLC

GCP 101: A Workshop for the New Study Coordinator

In an effort to enhance quality assurance at academic institutions, private practices or government-supported sites, SOCRA is offering a workshop for research personnel who are new to the field, or for those coordinators who want to refresh their understanding of GCP in the ever changing world of clinical research. This four-hour interactive workshop will include presentations, group discussion, and Q&A. The workshop will provide essential tools for coordinating and managing a research project. The material will range from understanding terminology to tackling a new project.

Presenter: Tammy Neseth, MA, CIP, CCRP, Monitor

FRIDAY, SEPTEMBER 29, 2023

OPENING PLENARY

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

Welcome and Introduction

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

Presenters: Jennifer Li, BSc, CCRP, Quality Manager, Princess Margaret Cancer Centre
Jessica Rowe, MA, MS, CCRP, CIP, Associate Director, HRPP and YCCI, Regulatory Compliance & Quality, Yale School of Medicine

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

An Update on the FDA's ORA's BIMO Program

The presentation will cover organizational developments including personnel updates, key indicators and performance measures in the OBIMO program. Ms. Johnson will also discuss upcoming projects from BIMO to benefit stakeholders. 002

Presenter: Anne Johnson, BA, Program Division Director OBIMO East, U.S. Food and Drug Administration

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

Health Canada's Clinical Trial Compliance Program

Dr. Kasian will provide an overview of Health Canada's Clinical Trial Compliance Program, including compliance trends and program updates. 003

Presenter: Alicja Kasina, MSc, BPharm, Sr Regulatory Advisor, Clinical Trial & Biologic Compliance, Health Canada

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

A Patient's Perspective on Clinical Trial Participation

Cancer survivor and research advocate, Annie Ellis will discuss factors that led to her interest in clinic trials as well as personal experiences with medical team communication and clinical trial participation. Ms. Ellis will also share perspectives gained from providing peer support and research advocacy. 004

Presenter: Annie Ellis, Research Advocate, Ovarian Cancer Research Alliance

NIGHT OUT

SAVE THE DATE:
FRIDAY, SEPTEMBER 29TH
Enjoy an evening strolling through Old Montreal! Details coming soon!

FRIDAY, SEPTEMBER 29, 2023

BREAKOUT SESSIONS

TRACK 1: BEHAVIORAL HEALTH

1:15 to 2:00 Track: Behavioral Health

Managing, Measuring, Motivating Millennials and Personnel To Promote Accountability and Personal Satisfaction in Clinical Research Management

Clinical Research Personnel Management involves meeting objectives and milestones while maintaining a productive and motivated workforce. Ms. Wintering will discuss a leadership approach that promotes personal performance objectives that are aligned with the project objectives. The speaker has learned much from working with Millennials and Gen Z. Managing a multigenerational workforce requires adaptation and flexibility which she will share with the attendees.

There is an implicit expectation that work and interaction in the workplace will be fulfilling. The importance of learning and development in the context of enhancing skills and professional development is key to retain motivated staff. Topics to be presented will be developing cross-training, promoting self-regulation and personal accountability and strategies toward adapting the work culture that can meet and measure performance while supporting personal satisfaction with less demand for managers. 109

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

2:05 to 2:50 Track: Behavioral Health

The Power of Coaching: A Goal-Oriented, Problem-Solving Solution to Engage Participants in the Research Process

When research participants join a study, they are often asked to alter their daily routines and habits in order to adhere to study protocols and requirements. In many cases throughout the various phases of a study, subjects may encounter barriers to participation that include environmental, personal, and activity-related factors. At times, these barriers can lead to attrition.

Through the lens of an occupational therapist, Dr. McNabb will review the use of coaching as a method to support participant engagement in the research process, which includes helping participants develop and track personal goals within the context of a research study. The author will highlight the use of coaching as an opportunity to problem-solve through barriers in order to find practical solutions to help the participant reach their study-related goals and improve their overall participation in the process. 111

Presenter: Sarah McNabb, OTD, MEd, OTR/L, Senior Director of Programs, Occupational Therapist & Adjunct Faculty, Marcus Institute of Integrative Health at Jefferson Health, Thomas Jefferson University

TRACK 1:GCP + AUDIT PREPAREDNESS

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

Proper Documentation of a Clinical Trial: What are all these forms and how do I complete them?

From Case Report Forms to Adverse Event, Deviation, Screening-Enrollment, Delegation of Authority and IP Accountability Logs, there is A LOT of information to be recorded when documenting a clinical trial. Both new and experienced study team members often have many questions on 'Best Research Practice' when it comes to filling out essential forms. When the regulations are silent, IRBs, institutions, sponsors, CROs, and investigators are free to develop their own procedures and practices as long as applicable regulatory requirements are met. However, certain elements should be taken into consideration when determining how to record data with integrity (reliable, accurate, complete, consistent, trustworthy, in context). This talk will present background information on WHY the forms are needed and guidance on HOW best to complete them to comply with regulations." 113

Presenter: Laura Adkins, MAP, CCRP, CCRA, CRS, AdvCRS, Director, UAMS Office of Research Regulatory Affairs

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

Informed Consent in Clinical Research: Getting it Right!

Ms. McAvoy will introduce Informed Consent in Clinical Research starting with a brief historical overview of why informed consent is important using examples (e.g., Nuremberg Trials). The speaker will describe what the consenting process is, how to document it correctly, special considerations, plus common errors and audit findings related to the informed consent process. Research Ethics Board requirements in the form of templates and checklists will be covered, plus additional topics such as assent, alterations/waivers to consent, consent for secondary use of identifiable information, and how email plays into the informed consent process. Finally, Ms. McAvoy will provide some tips for writing patient-centered informed consent forms. 115

Presenter: Elizabeth McAvoy, MA, CCRP, Associate Director, Kingston General Health Research Institute

BREAKOUT SESSIONS

TRACK 2: DEVICE RESEARCH

Time: 1:15 to 2:50 Track: Device

Developing a Quality Management System at a Clinical Site: A Case Study

With the release of the ICH E6(R2) GCP guideline in November of 2016 and regulatory agencies' expectations of a quality management system (QMS) approach to the conduct of regulated clinical trials, many sponsors are quickly adapting such an approach. At this time, the same cannot be said of many clinical research sites. This presentation will describe a clinical site that chose to apply a QMS approach, along with the trials and tribulations it faced along the way. We will describe the actual process, including the difficulties and challenges faced. The presentation will also outline the positive outcomes experienced since applying such an approach and what future activities will be needed to ensure maintenance of the QMS approach. 209 / 211

Presenters: Marcus Stone, PhD, ACRP-CP, Director of Clinical Research, Spine Institute of Louisiana Foundation
Lee Truax-Bellows, MS, FNP, CCRA, RQAP-GCP, TIACR, President and CEO, Norwich Clinical Research Assoc., Ltd.

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

The Transition from GLP to GCP: The Benefits of Designing Pivotal Large Animal Studies to Better Reflect the Design of Future Clinical Trials in Humans

Good Laboratory Practice (GLP) studies can be more than just one of the boxes you need to check off in order to receive regulatory approval to initiate a human clinical trial with your company's new medical device. Large animal GLP studies are mainly used to support the filing of IDE/ITAs, but they can be designed to provide additional valuable information that can increase the chances of human trial success. GLP studies are traditionally designed to provide safety and efficacy data with an emphasis on safety, on the use of a medical device, but these studies can also be designed to collect information for areas such as reimbursement, clinical adoption, human factors, risk evaluation and mitigation, and transportation and storage logistics; all important factors in the successful development of any new medical device. It is all about making sure that you maximize every opportunity to collect information related to your company's new medical device. 213

Presenter: Michael Jamieson, DRSc, Advisor, Research & Innovation Partnerships, Queens University

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

Metal Hypersensitivity Reactions to Implantable Devices

This presentation will provide an overview of hypersensitivity reactions to metal, review of the evidence and findings from a recent qualitative study on the experiences of people with metal hypersensitivity. 215

Presenter: Dzifa Dordunoo, PhD, MSN, BSN, RN, Assistant Professor, University of Victoria

TRACK 3: INVESTIGATOR-INITIATED RESEARCH

1:15 to 2:00 Track: IIR

Setting Up Your IIS Program for Success – From Ideation to Dissemination

Investigator-initiated studies (IISes) are clinical investigations that are developed by physicians. A successful IIS program requires certain elements to ensure that studies are well-designed, scientifically sound, address an important knowledge gap, and provide reliable, high-quality data on which to draw conclusions and insight. The right team will work collaboratively with the physician investigator to take a concept from ideation to study startup and from data analysis to dissemination. 309

Presenter: Amy Starosciak, PhD, Director of Research Concept & Protocol Development, Miami Cancer Institute

Time: 2:05 to 2:50 Track: IIR

Why does it have to be so complicated? How a cross-functional Feasibility Review carves a pathway to study success.

In a competitive research environment, it is critical to get a study through the startup process efficiently with a strong, feasible and well-written protocol. The University of Minnesota's Clinical Research Support Center designed and implemented a structured Feasibility Review process that addresses startup challenges and efficiently helps investigators develop protocols ready for IRB submission and successful execution. The Feasibility Review is a valuable, cross-functional program providing timely expert guidance for study teams to efficiently and successfully launch and execute clinical research studies. Feasibility Review can be easily replicated, adapted, and implemented at other institutions to increase the quality and efficacy of academic research. 311

Presenter: Nicole Tosun, MS, CCRP, Senior Clinical Research Specialist, University of Minnesota

FRIDAY, SEPTEMBER 29, 2023

BREAKOUT SESSIONS

TRACK 3: INVESTIGATOR-INITIATED RESEARCH

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

Investigator-Initiated Research: From Start to Audit

Ms. Weidler will discuss the processes for investigator-initiated research protocol development and launch and discuss the perspective of a sponsor-investigator for an FDA audit. The experience of being a 100% electronic study for a 14-site NIH U-grant project will be presented. 313

Presenter: Erica Weidler, MEd, MA, CCRC, Research Associate/Assistant Professor, Phoenix Children's Hospital

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

Trials and Tribulations: Auditing and Monitoring Investigator Initiated Trials (IITs)

Investigator Initiated Trials (IITs) present unique regulatory and operational challenges and risks. Specialized skills and knowledge are required for implementing internal monitoring and auditing programs in order to achieve compliance leading to successful trial execution. This session will share monitoring and auditing programmatic plans and techniques to address the challenges of IITs as well as lessons learned and successes 315

Presenter: Wendy Portier, MSN, RN, CHRC, CHC, Consultant, Portier & Associates, LLC

Cynthia Dunn, MSN, CCRP, RN, CCRA, Clinical Research Consultant, Crescent City Research Consulting LLC

TRACK 4:REGULATORY / LEGAL

Time: 1:15 to 2:00 Track: Regulatory / Legal

Why Boilerplate Clauses in Clinical Trial Agreements Matter

CTA negotiations are often long, time-consuming, and costly. As a result, many sites simply chose to ignore the boilerplate clauses such as governing law, venue, assignment, survival, force majeure, and others. This can unnecessarily expose the site, the PI, and all study personnel to serious financial risk. This presentation will help identify and describe the key boilerplate clauses in CTAs and will then provide the attendees with suggestions of how to negotiate these clauses in a proper and efficient manner. 409

Presenter: Marlon Rajakaruna, BA, MBA, LLB, CRCP, Lawyer, Kingsgate Legal

TRACK 4:REGULATORY / LEGAL

Time: 2:05 to 2:50 Track: Regulatory / Legal

How to Assess Adverse Event Causality in a Clinical Trial

There have been numerous methodological publications for assessing causality in adverse events. The Bradford Hill Criteria is one of the most practical and easy to implement. This presentation will discuss the diverse options for assessing causality and present a pragmatic approach to this important task. 411

Presenter: Gerald Klein, MD, Principal, MedSurgPI LLC

Time: 3:25 to 4:10 Track: Regulatory / Legal

The Difference is in the Details – Drug vs. Device Trials: A Regulatory Perspective

Overview of FDA regulatory requirements for INDs and IDEs is presented as a side-by-side comparison, based on the experience of working mostly with investigator-initiated clinical trials. Drug and device trials have differences. One unarguable similarity they have in common: Patients. Regulations are in place to ensure a well-controlled, properly and ethically run clinical trial, and the patients' safety. 413

Presenter: Felicia Nica, MD, MS, MBA, CCRP, RAC, Administrative Director, Clinical Research, MD Anderson Cancer Center

Time:4:15 to 5:00 Track: Regulatory / Legal

Overview of Regulatory Requirements of the ClinicalTrials.gov Registration and Results Reporting (PRS) System

The ClinicalTrials.gov Protocol Registration and Results System (PRS) database is the largest national registry of clinical trials and contains data from studies conducted across the world. Attendees will learn why, when, and how to register Clinical Trials in the PRS. Additionally, they will understand how to report the results of their studies in the system. This session is aimed at clinical research team members seeking to learn more about the importance of the regulatory requirements of the ClinicalTrials.gov system. 415

Presenter: Susan Hmwe, PhD, MS, MBBS, CCRP, Manager, Clinical Research Data Quality & Reporting, City of Hope Comprehensive Cancer Center

BREAKOUT SESSIONS

TRACK 5: RESPONSIBLE CONDUCT OF RESEARCH

Time:1:15 to 2:00 Track: Responsible Conduct

What's All The Fuss About ESG and How Does it Affect My Clinical Trial Program?

Environmental, Social, and Governance (ESG) is impacting clinical trial sites from the CRO and sponsor perspective. Sites and clinical research associates should be aware of what ESG is and how to set a strategy to use resources effectively and meet the standards ethically. 509

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

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

Being a SMART Whistleblower: Responding to Suspicious Behavior and Suspected Wrongdoing

Dr. McIntosh will discuss how decision-making strategies can help navigate situations where someone: 1) observes suspicious behavior or wrongdoing, or 2) is asked to engage in suspicious behavior or wrongdoing. These social-cognitive decision-making strategies—seeking help, managing emotions, anticipating consequences, recognizing context, and testing assumptions—support effective information gathering, professional decision-making, and whistleblowing practices. Additional considerations, such as how to identify misconduct, how strategies may differ when the wrongdoer is an authority figure, and differences between taking formal and informal action will also be discussed. 511

Presenter: Tristan McIntosh, PhD, Assistant Professor of Medicine, Washington University School of Medicine

TRACK 5: SCIENTIFIC (GENOMICS, PHARMACOKINETICS, ETC)

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

Ancillary Materials in Manufacture of Cellular Therapies.

Given the potential to resolve a large number of unmet clinical indications, there has been an increase in the number of clinical studies using stem cell therapies derived from Induced pluripotent stem cells (iPSC). iPSC are a type of pluripotent stem cell that can be generated from adult somatic cells. This talk will focus on the raw materials used in the manufacture of cellular therapies and their regulatory requirements. 513

Presenter: Anat Feldman, PhD, MBA, CCRP, Manager, Business Development, Clinical Applications, STEMCELL Technologies Canada Inc.

TRACK 5: SCIENTIFIC (GENOMICS, PHARMACOKINETICS, ETC)

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

Psychedelic Clinical Trials in Concussion and Traumatic Brain Injury Research

Ms. Grewal will provide practical insights into the current state of this emerging area of medicine and research including but not limited to international regulatory review, study design considerations, and recruitment strategies. Additionally, Ms. Grewal will review target populations and discuss how cultural competency plays an important role when working with veteran, professional athletic, and first responder communities. 515

Presenter: Jaspreet Grewal, MSc, CCRP, CEO, Knowde Group, Inc.

TRACK 6: TRAINING

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

Unconventional Applications of REDCap from New Hire Training to Administrative Support

While many institutions offer clinical research training basics for new hires, learning the nuisances of a specific protocol and the associated lexicon can be challenging. Oftentimes, staff express frustration over a lack of resources in these areas and this deficiency in knowledge can lead to preventable mistakes. Additionally, such training resources should be evolving and made readily available through internet-based access. REDCap can be harnessed to create a library of resources (and interactive activities) for new and current staff for any project in order to tackle training issues. This presentation will explore this concept and its implementation in a nontherapeutic longitudinal data collection study. 609

Presenter: Elizabeth Solinger, MS, CCRP, Senior Clinical Research Coordinator, The Ohio State University

BREAKOUT SESSIONS

TRACK 6: TRAINING

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

Site Management for Successful Clinical Trials

The research site is the first core for successfulness of any clinical trial. If the site is educated, trained and well developed, there will be a fruitful outcome for the sponsor of clinical research. This starts with the clinical research coordinator, pharmacy team and lab team supported by the clinical investigator/sub-investigators. Ms. Al-Mudaris will be addressing this points. 611

Presenter: Zena Al-Mudaris, BSc, MSc, CRA, QA Associate/CRA/Regulatory Affair Associate

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

Team Science Competencies and the Clinical Research Professional: Leveling the Playing Field

Team science principles and competencies are increasingly important for clinical research optimization and success. However, team science competencies have historically emphasized researchers and principal investigators at the exclusion of clinical research professionals. Using an existing team science framework and implementing a modified Delphi approach, a team with expertise in team science and CRP fields defined and developed a practical team science CRP specific competency rubric. Fundamental, skilled, and advanced competency levels were created with specific skills and examples for each level of professional development. 613

Presenters: Shirley Helm, MS, CCRP, Senior Adm for Network Capacity & Workforce Strategies, Virginia Commonwealth University

Jessica Fritter, MACPR, ACRP-CP, Clinical Instructor of Practice, The Ohio State University - College of Nursing

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

They Said What?! Communication for Research Professionals

This session addresses JTF core competencies in communication and teamwork. While research professionals should excel at skills such as regulatory management, participant engagement, study design, and others, one skill that they must use every day is communication—and it is vital that research professionals learn to communicate effectively.615

Presenter: Catherine Barnes, BS, CCRP, Assoc Director of Clinical Research Operations, University of North Carolina at Chapel Hill

TRACK 7: PROJECT MANAGEMENT

Time:1:15 to 2:00 Track: Project Management

Snow White the Coordinator and Seven Tiny Tips to Succeed with Managing Research Trials

Project management is a skill that is not often included in training programs. These seven tips to build success and confidence are where things start. This session will provide a great foundation for coordinators and tools for research staff to use as they navigate management of clinical research projects. 709

Presenters: Teri Crumb, MSN, RN, CCRC, Project Manager, Pediatric Nephrology Research Consortium

Margret Kamel, PhD, CCRC, Associate Director of Research Projects, Emory University

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

"Hakuna Matata" Means ... "No Trouble, No Problems" for your Project Management Training and Onboarding

Set your project manager up for success. Project management is a broad field with multiple role definitions. This session will review onboarding/training implemented at a pediatric academic institution and training utilized among various sites within a clinical research network and consortium. This session has been designed for various roles within project management and will be showcased for implementation at other institutions. 711

Presenters: Jessica Fritter, MACPR, ACRP-CP, Faculty, Clinical Instructor of Practice, The Ohio State University - College of Nursing

Corinna Bowers, BSBA, CCRC, Team Lead - Clinical Research Program Manager, Nationwide Children's Hospital

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

Tools for Successful Clinical Project Management – Sponsor Perspective

Clinical Project Management is complex and can be a source of stress or frustration for project managers or coordinators. The clinical program at Lallemand Health Solutions has less than 15 years of existence. However, by using innovative communication skills, project management tools and proactive collaboration with CRO, sites and suppliers, the program has been able to grow exponentially, gain credibility within the company and achieve company goals while maintaining the motivation of the employees. 713

Presenter: Marie-Laure Oula, MSc, Clinical Program Manager, Lallemand Health Solutions

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

From CRA to Clinical Project Manager

How to transition from being in a CRA role to a Clinical Project Management role, and what the differences are between the two roles. 715

Presenter: Allison Mossing, MS, CCRP, Clinical Project Manager, Align Technology

SATURDAY, SEPTEMBER 30, 2023

BREAKOUT SESSIONS

TRACK 1: POSTER SESSION

Saturday, September 30, 8:30 to 10:05 am

Finalists are afforded two to three minutes to present their poster, followed by a question and answer session with interested attendees and the selection committee.

The presenter with the highest aggregate score among abstract, poster, and Q&A session for each of the two categories (management and clinical trials) is awarded $500 and a fee waived registration to the 2024 Annual Conference to the primary author

Special recognition awards will be announced (and awarded) at the beginning of the Sunday morning closing plenary session

Learn more about becoming a poster presenter on page 22

TRACK 1: ONCOLOGY

Time: 10:50 to 11:35 Track: Oncology

Development of a Successful Multidisciplinary Shared Resource for Cancer Research

Our institute has developed a unique and innovative shared resource that delivers integrated, curated, and annotated multi-scale data to research investigators enabling cutting-edge research to improve early detection, diagnosis, and treatment of cancer. 121

Presenter: Preeti Ahuja, PhD, PhD, MS, CCRP, PMP, Associate Director, UCLA

TRACK 1: HEALTH DISPARITIES

Time: 11:40 to 12:25 Track: Health Disparities

The Long Journey to Health Equity: A Candid Conversation about Public Health in Philadelphia

Various Philadelphia communities experienced health inequities in the absence of a global pandemic, and COVID-19 exacerbated many barriers to quality healthcare. Community leaders, researchers, healthcare workers, students and non-profits work to identify inequities and implement solutions to enhance the health of these communities. Ms. Simmons will discuss the long journey to health equity, its successes and failures along the way, and how the pandemic provided opportunities to innovate methods to improve the health of Philadelphia communities. 123

Presenter: Marsha Simmons, MPH, CCRP, Research Manager, Diabetes Research Center, Jefferson University

TRACK 1:FINANCE + BILLING

Time: 1:40 to 2:25 Track: Finance + Billing

Financial Management for Clinical Research Programs: How to effectively manage staffing assignments and costs in a highly variable environment

Successful clinical research operations and finance go hand in hand but they can be difficult to connect for many sites. This presentation will focus on ways to align your clinical research program operations- specifically how you ensure you can manage staff assignments and cover staffing costs. Ms. Goldfarb will discuss effective operational and financial management through processes, tools, and the use of the smartsheets platform. 125

Presenter: Jennifer Goldfarb, MSN, RN, CCRP, Director of Clinical Research, University of Minnesota

Time: 2:30 to 3:15 Track: Finance + Billing

Financial and Billing Compliance Plan

Tracy Popp will discuss controls that will identify and reduce financial and billing compliance errors. Development of a financial business plan for clinical research departments will be discussed.. 127

Presenter: Tracy Popp, MBA, CHRC, CRCP, CCRP, Educator, A Clover Group, LLC

Time: 3:45 to 4:30 Track: Finance + Billing

Developing Clinical Research Finance Professionals

Every organization involved in clinical research needs finance personnel who are proficient in clinical research finance. These individuals possess knowledge of clinical operations, insurance regulations, and the regulations governing the clinical research industry. This session will equip attendees with tools and resources to build an educational platform to develop these uniquely skilled finance individuals. 129

Presenter: Mary Veazie, MBA, CPA, CHC, CHRC, Clinical Research Finance Consultant, Clinical Research Consulting & Education Services, LLC

Time: 4:35 to 5:20 Track: Finance + Billing

Getting the Most Bang for Your Buck: Developing and Implementing a Financial Audit Process at an Academic Medical Center

Keeping track of your finances from study start-up to study closeout is essential. We will discuss how to build a financial process; first looking at the initial protocol and understanding payment terms, then building a system to keep track of the items and implementing an audit system to ensure financial viability. 131

Presenters: Jessica Fritter, MACPR, ACRP-CP, Faculty, Clinical Instructor of Practice, The Ohio State University - College of Nursing

Cody Harper, BS, Clinical Research Data Analyst, Nationwide Children's Hospital

BREAKOUT SESSIONS

TRACK 2: ADVANCED MANAGEMENT

Time:8:30 to 9:15 Track: Advanced Management

Clinical Trials Before, During and After the COVID-19 Pandemic

The unprecedented demand placed on health systems from the COVID-19 pandemic has forced a reassessment of the conduct and feasibility of clinical trials. Dr. Ali will discuss clinical trials before and after the deadly COVID-19 pandemic and compare existing and new challenges to the conduct of clinical trials during the COVID-19 pandemic. 217

Presenter: Sheraz Ali, PharmD, MPH, PhD Candidate, Doctoral Researcher & Academic Staff, University of Tasmania-Australia, College of Health

9:20 to 10:05 Track: Advanced Management

Resource Management and Capacity Planning for Clinical Trials

This talk will discuss resource management and capacity planning principles used in examining the workload in a research coordinator pool at an academic research center. The aim is to improve clinical research leaders' ability to make informed decisions to increase operational efficiency and ensure workloads are adequately resourced. 219

Presenter: Kesley Tyson, DHA, MS, CCRP. Director, Clinical Trials Office & Research Operations Morehouse School of Medicine

Time: 10:50 to 11:35 Track: Advanced Management

Adaptive Design Trials: Logistical Considerations for Clinical Operations

Adaptive design studies are often considered more complex to execute than traditional studies. This presentation will provide an overview of the different types of adaptive trials that are usually accepted by regulators and delves into logistical/operational challenges encountered during their implementation, including solutions to overcome such challenges. 221

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

Time: 11:40 to 12:25 Track: Advanced Management

Challenges Conducting Multi-Center Trials at Satellite Sites

This session focuses on how to mitigate common challenges such as clinical investigator oversight (and what language should be included in Standard Operating Procedures), operationalization of studies at multiple sites, and associated financial concerns. This discussion will help sites prepare for successful clinical trial implementation. 223

Presenter: Jo Ann Elrod, PhD, CCRP, Clinical Research Director, Fred Hutchinson Cancer Center

TRACK 2: ADVANCED MANAGEMENT

Time: 1:40 to 2:25 Track: Advanced Management

Feasibility Surveys - How to Make them Feasible for Your Site

Feasibility surveys represent an important tool for sites and sponsors/CRO's to collect information about each other, but best methods haven't kept up with the changing landscape of clinical research. Understanding why and how sponsors use these surveys allows sites to identify best practices for managing this step of site selection. This talk will provide background, regulatory considerations, and several actionable takeaways to consider, including T&E, tech solutions, creating standardized documents, and implementing master agreements. 225

Presenter: Betsy Wagner, BS, MPH, CRC, Director, Inteliquet, an IQVIA business

Time: 2:30 to 3:15 Track: Advanced Management

Implementing Clinical Research Onboarding and Educational Programs at an Academic Medical Center

Ms. Wentzel will provide attendees with an overview of how a large pediatric academic medical center established a formalized onboarding program as well as a clinical research competency series for clinical research professionals. 227

Presenter: Grace Wentzel, BA, CCRP, CHRC, Executive Director, Site Operations, Javara Research

TRACK 2:PEDIATRIC RESEARCH

Time: 3:45 to 4:30 Track: Pediatric Research

Research Priorities for Children and Youth

Children face different issues during distinct developmental periods. Several problems, such as obesity, mental health issues, suicide, and firearm injuries, have reached concerning levels. It is crucial to prioritize research agendas based on children's existing problems. There may be substantial challenges to developing and implementing high-quality, practice-changing research. This presentation emphasizes epidemiology, risk factors, and strategies to address these current childhood problems. These research priorities can inform future interventions and potentially improve children's and youth's lives. 229

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

BREAKOUT SESSIONS

TRACK 2:PEDIATRIC RESEARCH

Time: 4:35 to 5:20 Track: Pediatric Research

Tales of a Pediatric Clinical Research Nurse - The Lengths We Will Go to for High Quality Data

Ms. Roush will discuss ways research nurses can help decrease protocol deviations and manage expectations for all involved in the research. Helpful tips on ways to promote adherence to pediatric protocols will be provided as well as measures that nurses are willing to do to get quality data and still ensure safety and patient satisfaction. 231

Presenter: Kandice Roush, BSN, RN, CCRC, Clinical Research Nurse & Team Leader, Nationwide Children's Hospital

TRACK 3:MONITORING

Time:8:30 to 9:15 Track: Monitoring

CRA Best Practices

We will discuss best practices gained by a senior CRA with over 20 years of experience. 317

Presenter: Aaron Chan, BA, Senior CRA, GSK

Time:9:20 to 10:05 Track: Monitoring

Remote Monitoring Challenges During the Midst of a Pandemic

Ms. Mahanti will discuss how the world of clinical trial monitoring faced challenges during this the COVID-19 pandemic. We will learn to do the best with limited resources, yet maintain patient safety! 319

Presenter: Harshini Mahanti, MSc, CCRP, Clinical Research Monitor, University of Miami

Time:10:50 to 11:35 Track: Monitoring

How a CRA Can Support a Study Site Before, During, and After a Regulatory Inspection

It doesn't happen often in a CRA's career, but when it does, it can induce panic like nothing else: the phone call from your site announcing "The FDA is coming on Monday." That is exactly what happened to me one already busy day. After the initial panic (I may or may not have hyperventilated), and with the support of my company's quality department, I put together a plan to effectively prepare my site for the inspection, support the site during the inspection, and guide them in responding to the 483 after the inspection. Saying that my learning curve was steep is an understatement, but the site and I survived and even became stronger because of it. I am here now to share the steps you can take when you get that phone call to cultivate a well-prepared site, a smooth inspection, and a stellar 483 response that results in a stronger site (and makes you a stronger CRA). 321

Presenter: Wendy Upton, BA, RN, Senior CRA, PPD

TRACK 3:ETHICS IN RESEARCH

Time:11:40 to 12:25 Track: Ethics

Why Privacy is the Cornerstone of Trial Participant Trust

Rob Masson will discuss the most important issues North American sponsors need to consider when collecting personal data from EU & UK clinical trial participants. The presentation will cover the impact of the Clinical Trial Regulation, the introduction of the Clinical Trial Information System, the need for oversight of your CRO and trial partners, EU & UK representation requirements and considerations for cross-border personal data transfers. 323

Presenter: Rob Masson, Chief Executive Officer, The DPO Centre

Time:1:40 to 2:25 Track: Ethics

Human Radiation Experiments in the United States: History and Ethical Considerations

From the 1940s and into the 1970s, researchers exposed human subjects to radiation, often without the knowledge or consent of the subject. Study subject selection and the use of vulnerable populations are also ethical concerns in radiation studies. This talk will review the history of radiation experiments in the United States and the concepts of autonomy, beneficence, and justice as it applies to research subjects. 325

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

Time: 2:30 to 3:15 Track: Ethics

Eliminate Unconscious Bias Through a Better Understanding of History

This riveting and insightful presentation is designed to examine the early Indigenous inhabitants of the Americas before the arrival of European settlers. In this session, you will gain a deeper perspective concerning the injustices that occurred during that time and take a closer look at how Spain would emerge to define its role. Discover the irrefutable facts about African people and their past history that were purposely omitted as part of the process to dehumanize indigenous then African people. Develop a new “belief system” and truth about ethnic groups that created large-scale organized cities, kingdoms, and empires. Empower your leadership team with a clearer perspective, promote a more diverse workforce culture and remove undue fear and discomfort about racism. All ethnic groups will be more equipped with knowledge of inclusion after this life changing presentation. 327

Presenter: Roger Persaud, RP Consulting Solutions, LLC

SATURDAY, SEPTEMBER 30, 2023

BREAKOUT SESSIONS

TRACK 3:ETHICS IN RESEARCH

Time: 3:45 to 4:30 Track: Ethics

Applying Design Thinking to Diversity in Clinical Trials

Currently clinical trials are a linear waterfall process which is time consuming, inefficient and does not involve stakeholders from the beginning. By starting from the needs of underserved people and communities, design thinking ensures that these needs are fully understood. By using co-design, all stakeholders are involved in developing and validating new drugs and devices. The outcomes will be increased efficacy of drugs and devices at lower development costs. 329

Presenter: Daniel Steenstra, MD, Professor, OnKai Inc

Time: 4:35 to 5:20 Track: Ethics

Placebos in Clinical Research: The Science and Ethics of "Sugar Pills"

Placebo-controlled trials generate invaluable data and provide important statistics for treatment efficacy. But what are the implications of the chosen placebo – will it yield usable data or confound the results? What about studies with activities that are difficult to mask (such as aromatherapy studies)? Dr. Stevens will discuss the definitions and implications of placebos and present some historical and current case studies. 331

Presenter: Nicole Stevens, PhD, MS, BA, CCRP, CPT, CPI, CCRC, Director, Clinical Research, doTERRA International

TRACK 4: QUALITY MANAGEMENT

Time:8:30 to 9:15 Track: Quality Management

The Journey of Achieving a Quality Research Program Through Required Education and Training

This presentation will provide information about establishing a new departmental education program including a new employee orientation and robust competency program. 417

Presenter: Wendy Lloyd, BA, CCRP, LPN, Senior Clinical Research Quality Analyst-Education, Vanderbilt University Medical Center

TRACK 4: QUALITY MANAGEMENT

Time:9:20 to 10:05 Track: Quality Management

The Road from Compliance to Quality in Clinical Trials

The transformation of a clinical trials compliance program to a quality assurance program presents substantial challenges. From reorienting the stakeholders to practical issues such as title and role changes and developing new worksheets, there are many things to consider in the effort to improve oversight of studies. A successful quality assurance program offers a much more satisfying experience for the entire clinical trials team. 419

Presenter: Eileen Healy, MS, CCRP, Clinical Research Quality Assurance Coordinator, Roswell Park Comprehensive Cancer Center

Time:10:50 to 11:35 Track: Quality Management

Notes to File: Compliant Practices and Ensuring Data Integrity

This Note to File (NTF) presentation will review what an NTF is, current practices, and current problems as well as Quality System oversight. Lessons learned from audits and the use of NTFs will also be presented. 421

Presenter: Heather Pham, MS, CCRP, CHRC, Clinical Research Educator, Providence St. Joseph Health

Time:11:40 to 12:25 Track: Quality Management

Analysis of Quality Challenges in Phase I and II in Cellular and Gene Therapies

Dr. Soans will compare quality challenges seen in FDA approved cellular and gene therapies in the market to early phase development products at St. Jude. We will look at how we have responded to FDA Information requests on quality and time taken from pre-IND stages to IND submissions and what have been the limitations.. 423

Presenter: Eroica Soans, PhD, CCRA, Senior Medical Writer, St Jude Children's Research Hospital

Time:1:40 to 3:15 Track: Quality Management

A Quality Improvement Program in Human Subject Research

As research monitoring and compliance paradigms evolve, human subject research teams are challenged to ensure that quality in research maintains or exceeds expectations and standards. 425/427

Presenters: Jennifer Dolan, MS, LMT, CCRC, Specialist, Research Quality Improvement, University of Rochester

Kathleen Wessman, MPA, RN, RQAP-GCP, CCRC, Director, Research Quality Improvement, University of Rochester

Elizabeth Lyda, BS, RRT, Research Quality Improvement Specialist, University of Rochester

BREAKOUT SESSIONS

TRACK 4: HUMAN RESEARCH PROTECTIONS

Time: 3:45 to 4:30 Track: Human Research Protections

New and Innovative Research, Same Old Common Rule

Recent innovations, scientific progress, and emerging fields, including, but not limited to, artificial intelligence, big data, psychedelics, and decentralized trials, have presented new challenges for protecting the rights and welfare of human research participants. This presentation will explore ways in which the Common Rule can be applied to reviewing new trends in research involving human subjects and offer insights on the way the 46.111 review criteria could be applied to all research - new innovative, and as traditional as one gets. 429

Presenter: Marianna Azar, MA, Public Health Program Specialist, DED, Office of Human Research Protections, Health and Human Services

TRACK 5: SITE MANAGEMENT

Time: 8:30 to 9:15 Track: Site Management

How to Build a Robust Student Research Training Program

Ms. Jones will initiate a discussion that goes step by step into how to build a volunteer student research training program from recruitment, curriculum, and support to research projects. We will discuss how to set up mentorship and support for a mutually beneficial experience as a direct feed into positions at your institution and to support studies with limited financial resources. 517

Presenter: Laura Jones, BA, CCRP, IRB Principal Analyst, UC San Diego

Time: 9:20 to 10:05 Track: Site Management

What is it Really Like Switching from Paper to eRegulatory.

How does the transformation work? How long does it take? What can you do to make it most effective as a tool? What are the positives and pitfalls? In the end, is it really worth the cost and effort? 519

Presenter: Mark Sulik, PharmD, CCRP, Director of Clinical Research, Rocky Mountain Diabetes Center

Time: 10:50 to 11:35 Track: Site Management

Leading with Purpose - How to Build and Maintain a Resilient Clinical Research Team

Ms. Wentzel has been leading a multi-dimensional clinical research team for over 25 years. She will share lessons learned as well as strategies and tactics for interviewing, team-cohesiveness and, most importantly, retention. 521

Presenter: Grace Wentzel, BA, CCRP, CHRC, Executive Director, Site Operations, Javara Research

TRACK 5: SITE MANAGEMENT

Time: 11:40 to 12:25 Track: Site Management

Good Clinical Practice in an Electronic-Based Records System

Good clinical practice (GCP) is an international ethical and scientific quality standard for designing, recording, and reporting trials that involve the participation of human subjects. GCP principles help assure the safety, integrity, and quality of clinical trials by addressing elements related to the design, conduct, and reporting of clinical trials.

Electronic-Based records systems are being increasingly used in the conduct of clinical research. They enable the capability to streamline data transfer, remote enrollment capabilities, greater transparency of the trial conduct, improved research documentation, clearer audit trails and to solve the challenges of physical document storage constraints at trial sites.

From a monitoring perspective, Ms. Wright will discuss the basics of GCP in an electronic-based records system, highlight the importance of a culture of total quality, how to identify challenges, as well as offer solutions for good recordkeeping practices. Examples will be provided. 523

Presenter: Alicia Wright, MS, CCRP, Clinical Research Associate III, Vanderbilt University Medical Center

TRACK 5: STUDY START UP

Time: 1:40 to 2:25 Track: Study Start-up

Compliance in Regulatory Start Up: Tips and Tricks to Expedite Study Start Up (from a site perspective)

Everyone wants study start up to be both accurate and speedy. Ms. Gruetzmacher will go over essential areas of study start up from a site perspective, and how to quickly and accurately get trials ready for enrollment. Some of the items to be discussed include what needs to go on a 1572, which documents to ask staff for, tips and tricks gleaned from HHS emails/FAQs, delegation logs, what trainings are needed and how to document training, what is needed for an IRB submission, what should be submitted, scheduling site initiation visits, investigator meetings, and so much more. 525

Presenter: Crystal Gruetzmacher, CCRC, CHRC, Clinical Research Coordinator, Monument Health Clinical Research

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BREAKOUT SESSIONS

TRACK 5: STUDY START UP

Time: 2:30 to 3:15 Track Study Start-Up

Tips and Tricks: Improving Study Success Through Comprehensive Internal Feasibility Considerations

Feasibility considerations are fundamental for both sponsors and sites conducting clinical research. Yet, sometimes study protocol specific areas are not explored sufficiently on the front end leading to delayed study start-up, poor enrollment, and protocol noncompliance. This session will cover how to conduct thorough and consistent internal feasibility reviews including special considerations such as cybersecurity. 527

Presenters: Cynthia Dunn, MSN, CCRP, RN, CCRA, Clinical Research Consultant, Crescent City Research Consulting LLC

Wendy Portier, MSN, RN, CHRC, CHC, Consultant, Portier & Associates, LLC

TRACK 5: SITE MANAGEMENT

Time:3:45 to 4:30 Track: Study Start-Up

Building Coordinator and Clinical Investigator Work Relationships

Learning the role of the coordinator is difficult. Learning effective communication strategies in working with your site clinical investigators and research team is not typically offered in training. This session provides guidance and useful strategies for effective communication as well as the importance of documenting that communication. 529

Presenters: Margret Kamel, PhD, CCRC, Associate Director of Research Projects, Emory University

Teri Crumb, MSN, RN, CCRC, Project Manager, Pediatric Nephrology Research Consortium

Time: 4:35 to 5:20 Track: Site Management

Implementing a Workforce Development Program: Training and Retaining Entry Level Talent to Address the Critical Shortage of Clinical Research Personnel

The supply of clinical research personnel is not keeping up with the growing demand, across the industry, but especially at academic health centers. Ms. O'Malley will briefly discuss the factors and barriers that have contributed to the critical shortage of experienced research personnel and describe an innovative model to address the need. The presentation will describe the difficult but surmountable journey to create a sustainable program to train and retain entry level clinical research personnel and create a diverse workforce. 531

Presenter: Kathleen O'Malley, BSN, RN, CCRP, Director of Education and Training, Jefferson Clinical Research Institute, Thomas Jefferson Univ

TRACK 6: TRAINING

Time: 8:30 to 9:15 Track: Training

Get Out of a Mess: Managing and Preventing Difficult Situations

It may happen that you inherit an assignment (project or trial site, etc.) which is handed over to you not in the best shape. To run a business up to high standards you must fix a backlog of the existing problems to make it work as required. It might be overwhelming. "How do I start? What should I do? Is there any guidance?" - these might be the questions running through your head. But don't panic! In this talk, we'll share our experience in handling complex situations, explaining priorities and chain of actions to achieve a desired outcome. Practical examples of difficult management situations and solutions will be provided. 617

Presenters: Fiona Kearney, MSc, Senior Director, Study Finance Lead, PPD, part of ThermoFisher Scientific

Anatoly Gorkun, MD, PhD, Chartered MCIPD, Associate Director Global Project Management, PPD, part of ThermoFisher Scientific

Time: 9:20 to 10:05 Track: Training

Creating & Implementing a Study Management Training Program: You don't know what you don't know

Setting your study up for success starts with training. Training study staff has been a burden for institutions, large or small, and finding the best mechanisms for training can be overwhelming. This session will review the development of a clinical research onboarding program that encompasses everything from negotiating study budgets and managing the study to ensuring compliance. The program is applicable to the individual or a group and includes elements for all learning styles. This will be presented in a way that will be generalizable to other institutions. 619

Presenters: Megan Robb, BA, Senior Training & Compliance Coordinator, Nationwide Children's Hospital

Christine Baker, BA, CCRP, Team Leader-Regulatory Affairs, Nationwide Children's Hospital

BREAKOUT SESSIONS

TRACK 6: ENROLLMENT / RETENTION + INFORMED CONSENT

Time: 10:50 to 11:35 Track: Enrollment/Retention + Informed Consent

Implementation of a Consent Tracker

Tracking enrollment and specific information through a consent tracker is a foundational tool used in clinical research. Creating a consent tracker will help monitor the integrity and validity of a successful study. The creation and implementation of a consent tracker will ensure compliance during a comprehensive consent process. 621

Presenter: Christine Baker, BA, CCRP, Team Leader-Regulatory Affairs, Nationwide Children's Hospital

Time: 11:40 to 12:25 Track: Enrollment/Retention + Informed Consent

Proven Methods to Boost Enrollment with Efficient Digital Recruitment

Many researchers relying on panels and databases are struggling with poor enrollment. Implemented properly, digital recruitment can reach granular audiences and increase awareness and enrollment.
Rebecca will share years of firsthand experience and research—from working with NIH and enterprises, showing attendees how to avoid common mistakes and efficiently improving their recruitment and retention. 623

Presenter: Rebecca Doss, VP of Strategy, Rekrewt

Time: 1:40 to 2:25 Track: Enrollment/Retention + Informed Consent

What's E-Consenting Got To Do With It?

Ms. Kline will demonstrate how screen failure data can turn into screening success. Topics discussed are how analyzing screen failure data can lead to understanding a patient population to make the consenting process more clear and efficient, finding trends to help other sites, and improving the overall teamwork with a collaborative approach. 625

Presenter: Peyton Kline, MHA, CCRP, Data Management Director, The Medical University of South Carolina

Time: 2:30 to 3:15 Track: Enrollment/Retention + Informed Consent

Thinking Outside of the Box: Current Ethical Topics in Human Subjects Research

Patients tend to ask questions about things they do not understand and it is our job to be prepared for those questions. Patients sign consent forms when they feel confident enough to do so and they gain confidence from seeing recruiters with confidence. Confidence is also paired with comfort. Always emphasize your confidentiality section and what exactly you are collecting or doing with a patient's data. 627

Presenter: Casey Jackson, MS, CCRP, Research Quality Manager, Office of Research and Scholarship University of Maryland, Baltimore School of Nursing

TRACK 6: ENROLLMENT/RETENTION & INFORMED CONSENT

Time: 3:45 to 4:30 Track: Enrollment/Retention + Informed Consent

The Fundamentals of the PreScreening Process

Ms. Royse will discuss subject recruitment strategies and a step-by-step process that includes the creation and maintenance of a patient database, weekly prescreening logs and preparing for your first subject screening. Tips for being organized in this approach and potential challenges will also be shared. 629

Presenter: Martha Royse, BSN, MSN, RN, APRN, FNP, CCRP, Owner, Optimal Trial Screening, LLC

Time: 4:35 to 5:20 Track: Enrollment/Retention + Informed Consent

Enrollment and Retention in a Large Multisite Study - The "Incredible" Superpowers You Need

During this presentation, pressures and challenges associated with enrollment and retention will be discussed. We know that coordinators are superhuman and need "incredible" superpowers to address challenges encountered. The various approaches, and the associated "incredible" superpowers employed to address each will be discussed - Flexibility = super-elasticity; endurance for the long haul = super-strength; protective, robust QA and training mechanisms = force fields; infrastructure for quick adaptability in response to barriers = super speed; frequent analysis and reflection to take lessons learned into the future = clairvoyance; and quality communication across time and space ensuring comprehensive informed consent and forming invisible bonds among all study relationships (within site teams, between site and sponsor and site to subject) = invisibility. 631

Presenters: Samantha Sharpe, MD, CCRC, Clinical Research Program Coordinator, Nationwide Children's Hospital
Corinna Bowers, BSBA, CCRC, Team Lead - Clinical Research Program Manager, Nationwide Children's Hospital

CLOSING PLENARY

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

Clinical Research – A New Call to Action

Recent public health concerns, court rulings, and international trade and commerce discussions have made clinical research more visible than ever before. As a result, the clinical trial enterprise is rethinking everything from trial design to technology to enrollment to finance. However, has the reimagining of the clinical trial enterprise resulted in improved public health? This talk will look at the future of clinical research and the concrete steps that must be taken in order for clinical research to have the powerful impact it was always intended to have. 901

Presenter: Quincy Byrdsong, EdD, CCRP, CIP, Vice Provost for Health Affairs, Lipscomb University

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

Generations in the Workplace: Now and Looking Forward

The current American workplace includes five generations. i.e., Traditionalists, Boomers, Gen Xers, Gen Y and Gen Z with a sixth to join in the foreseeable future, i.e., Gen Alpha. This presentation will include an update on the interactions of the current generations, including diverse perspectives on each's impact on the workplace and views on each other, as well as a look ahead to the introduction to the next generation to arrive. 903

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

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

Leading a Successful Research Program: Perspectives on Success and Innovation

"Leading a successful research program is the same as running a business. Both depend on innovation, collaboration, and reputation for success, yet few young investigators are prepared to lead research teams as they launch independent careers."1 Yet, often hidden from manuscript publications, university press releases, and media interviews are experienced research professionals. Hard-working clinical research professionals rise to leadership roles every day to ensure successful and high-quality patient engagement, site management, and data collection. In this talk, three seasoned industry professionals will describe strategies for convening effective research teams, building collaborative relationships with research sites, and embracing passion to drive a legacy for the clinical research profession.

1. Una E. Makris, MD, MSc1 Leadership Lessons: Building and Leading a High-Performing Clinical Research Team. J Am Geriatr Soc. 2018 July ; 66(7): 1258–1261. 904

Presenters: Bradley Hightower, BA, CCRC, CEO, Hightower Clinical
Danielle Mitchell, BS, Owner and CEO, Black Women in Clinical Research
Laura Holtz, MS, PMP, CCRP, Clinical Research Associate, Yale School of Medicine - YCCI

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

Incorporating Lessons Learned from the Pandemic into your Everyday Informed Consenting Process

While guidance documents issued by the FDA and many IRBs during the pandemic were intended to remain in effect only for the duration of the COVID-19 public health emergency, the flexibility and technological advances adopted by many sponsors and research sites could enhance and facilitate the consenting process for participants and staff beyond the pandemic. We will reflect on our experiences during the past three years as we were conducting research studies throughout the pandemic. We will discuss how to incorporate lessons and techniques learned during that time that meet regulatory requirements and that improve consenting during adverse conditions. 906

Presenters: Lisa Harewood, CCRP, Clinical Trials Regulatory Specialist II, Hope Clinic of Emory Vaccine Center
Ellie Butler, MS, JM, CCRP, Clinical Trials Regulatory Specialist, Emory University

POSTER PROGRAM

SOCRA's Annual Conference Poster Program is an opportunity for individuals to share their research, findings and achievements with their colleagues. SOCRA offers dedicated times for poster presenters to present and discuss their posters with the diverse group of attendees. Presenting a poster at SOCRA's Annual Conference is a noteworthy way to share expertise or accomplishment in a specific area while contributing to clinical research. Please consider participating in this great event and becoming an integral part of SOCRA's Annual Conference.

POSTER PROGRAM GUIDELINES

Abstracts of approximately 500 words are requested for identification, evaluation, and publishing of poster presentations. There are two categories of submission:

- Clinical Trials: Scientific papers reporting on findings of treatment, intervention, or survey studies.
- Clinical Research Management: Critical reviews, position papers, or descriptive case reports dealing with issues associated with implementation, coordination, or management of clinical research programs.

2023 SPECIAL RECOGNITION AWARD COMPETITION

Papers to be considered for a special recognition award will be accepted through July 21. Submissions will be subject to blinded review by a panel of experts in clinical research. The author of the poster receiving the highest score in each of the above categories will receive a $500.00 award and a fee waived registration to the 2024 annual conference.

ABSTRACT SUBMISSION

- If the submission is a research project, the first sentence must state the purposes or specific objectives of the study. Methods should describe the study design, subjects, and evaluative procedures. Clear documentation of statistical methodology should accompany the methods/results section. A summary of the results must be stated in the abstract to support the final conclusions. Please do not include statements about providing further data or conclusions at the time that the abstract is presented.
- If the submission is an overview or a theoretical position paper, state the purpose and methodology, if appropriate. The body of the abstract should include the main points that are to be made as well as the conclusion(s).
- Abstracts of posters are limited to 500 words in length, (not including figures, tables, or graphs) and must be presented on a single page/poster. Poster boards are limited in size to four feet high by eight feet wide (4'x8').
- Abstracts must present new data. The author must certify that no prior copyright or ownership applies to the abstract or poster.
- Once an abstract is accepted, it may not be revised prior to publication. Updated material may be presented in the poster or during the presentation.
- 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 postmarked after July 21 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 program.

POSTER EVALUATION PROCESS

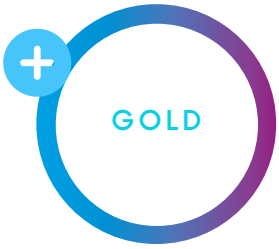
- Abstracts are submitted and scored prior to the annual conference. Abstract scores are based on the following criteria; Impact on Clinical Research, Impact on Audience, Originality, Adequacy of Findings and Conclusions, Adherence to Format, and Clarity
- The displayed posters are scored by the evaluation committee during the first day (Friday) 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
- The highest combination of the abstract score and poster score determines the finalists, up to five in each category
- The finalists are notified on Friday evening of conference and invited to a question and answer Poster Session that is scheduled on Saturday from (8:30 am – 10:00 am)
- Finalists gather in the Exhibit/Poster area on Saturday morning to present a brief review of their poster (image projected on screen)
- Finalists are afforded two to three minutes to present their poster, followed by a question and answer session with interested attendees and the selection committee. Up to two original authors of the poster may present
- Presentation scores are based on Effectiveness of Delivery, Impact on Clinical Research, Impact on Audience, Adequacy of Findings and Conclusions, Delivery, and Adherence to Format
- The presenter with the highest aggregate score among abstract, poster, and Q&A session for each of the two categories (management and clinical trials) is awarded $500 and a fee waived registration to the 2024 Annual Conference to the primary author
- Special recognition awards will be announced (and awarded) at the Sunday morning closing plenary session

SPONSOR + EXHIBIT

SPONSOR CATEGORIES

$10,000

- Four registrations
- Featured ad on mobile app
- Verbal announcement at the beginning of the opening plenary
- Individual recognition on SOCRA social media and email blast (4 posts)
- Premium placement on event signage
- Acknowledgement in the conference program book, mobile app, and SOCRA website
- List of participants (no contact information)
- Full page ad in SOCRA Source

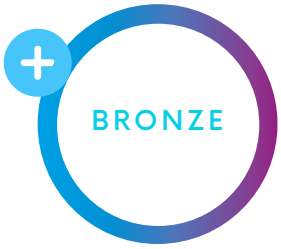


$7,000

- Three registrations
- Featured ad on mobile app
- Verbal announcement at the beginning of the opening plenary
- Individual recognition on SOCRA social media and email blast (2 posts)
- Premium placement on event signage
- Acknowledgement in the conference program book, mobile app, and SOCRA website
- List of participants (no contact information)
- Full page ad in SOCRA Source

$5,000

- Two registrations
- Featured ad on mobile app
- Verbal announcement at the beginning of the opening plenary
- Recognition on SOCRA social media and email blast (1 group post)
- Acknowledgement in the conference program book, mobile app, and SOCRA website
- List of participants (no contact information)
- Half page ad in SOCRA Source



$3,000

- One registration
- Verbal announcement at the beginning of the opening plenary
- Recognition on SOCRA social media and email blast (1 group post)
- Acknowledgement in the conference program book, mobile app, and SOCRA website
- List of participants (no contact information)

ADDITIONAL SPONSORSHIP OPPORTUNITIES

Welcome Reception
Co-Sponsored Contribution: $5,000
Full sponsorship Contribution: $15,000

Mobile App Banner
Contribution: $2,500

Lanyards
Contribution: $5,000

Tote Bags
Contribution: $5,000

Travel Mugs or Water Bottles
Contribution: $5,000

Meals / Refreshment Breaks
Break contribution: $5,000
Breakfast contribution: $10,000
Lunch contribution: $15,000

Charging Station
Contribution: $3,000 per station (may be co-sponsored)

Conference WIFI
Contribution: $5,000 (may be co-sponsored)

Program Speaker / Track
Speaker contribution: $3,000
Track contribution: $5,000

EXHIBIT

Exhibit Event Dates: Thursday, September 28, 2023 – Saturday, September 30, 2023

Exhibit Hours:
Thursday: 6:00 pm to 7:00 pm (During Welcome Reception)
Friday: 10:00 am to 5:00 pm
Saturday: 10:00 am to 4:00 pm

Exhibit Fees: $2,200*

*Includes one fee waived registration, lead retrieval, and access to all conference sessions.

Two additional staff may register at $450/each. Add on Huddle Space for $500/day

Deadline: Registration must be confirmed by August 15 in order to be listed in the program materials

ADVERTISING

ANNUAL CONFERENCE PROGRAM BOOK

PROGRAM BOOK AD

Published: Annually
Deadline: August 15
Distribution: 1,000+ Annual Conference Attendees

Cost:
Full Page (color): S1000
Full Page (B+W): S700
Half Page (color): S700
Half Page (B+W): S500

Submit an ad to the program book **here.**

ADDITIONAL POSTING OPTIONS

SOCIAL MEDIA POST

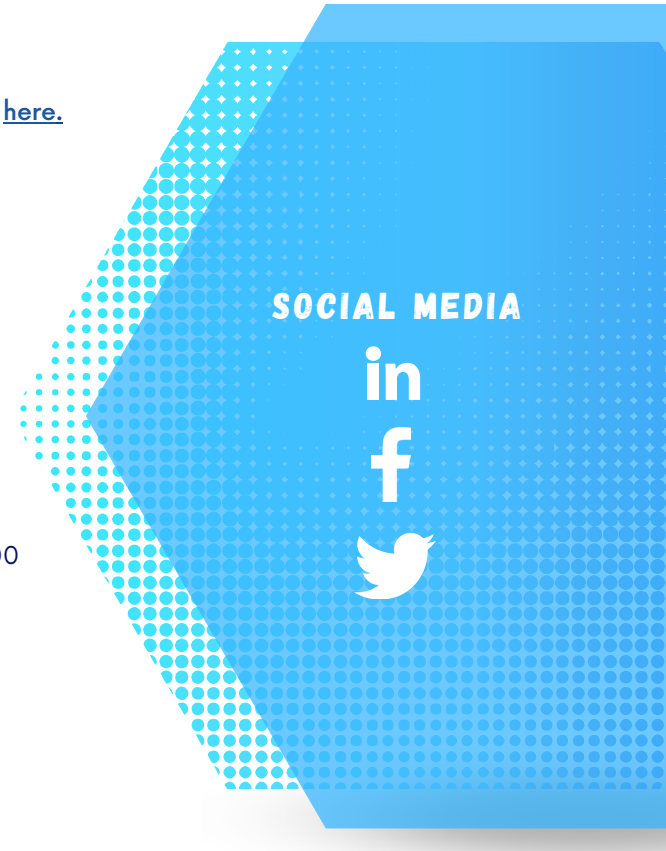
Distribution: Combined social media page following of 37,000+ clinical research professionals

Post a single social media ad on a specific platform (S500) or post a social media post across all platforms (S1000)
Social media pages are updated daily

EMAIL BLAST AD

Distribution: SOCRA email list, 50,000+ clinical research professionals

Single ad to email blast - S1,500
SOCRA email blasts go out biweekly (twice a month)
*Package pricing available.
Please contact ads@socra.org



ANNUAL CONFERENCE PROGRAM BOOK DISTRIBUTION

1,000+
attendees
100+
speakers
7
educational tracks

SOCIAL MEDIA FOLLOWERS

LINKEDIN
30,000 +
followers
FACEBOOK
6,400+
followers
TWITTER
1,500+
followers

EMAIL BLAST ANALYITCS

50,000
subscribers
32%
open rate
3%
click rate

2023 EVENTS CALENDAR

APRIL

04/21	CLINICAL RESEARCH PROFESSIONAL CERTIFICATION PREPARATION AND GCP REVIEW COURSE I MILWAUKEE, WI
04/26 TO 04/28	ANNUAL DEVICE RESEARCH & REGULATORY CONFERENCE I SCOTTSDALE, AZ
04/27 TO 04/28	SITE COORDINATOR / MANAGER + GCP WORKSHOP I SCOTTSDALE, AZ

MAY

05/04 TO 05/05	CLINICAL RESEARCH PROFESSIONAL CERTIFICATION PREP AND GCP REVIEW COURSE I VIRTUAL
05/09 TO 05/12	CLINICAL RESEARCH PROJECT/PROGRAM MANAGEMENT CONFERENCE I VIRTUAL
05/16 TO 05/19	CLINICAL RESEARCH MONITORING AND GCP WORKSHOP I VIRTUAL

JUNE

06/07 TO 06/09	QUALITY MANAGEMENT CONFERENCE I VIRTUAL
06/13 TO 06/15	FDA CLINICAL TRIAL REQUIREMENTS, REGULATIONS, COMPLIANCE AND GCP CONFERENCE I VIRTUAL
06/15/23	CLINICAL RESEARCH PROFESSIONAL CERTIFICATION PREP AND GCP REVIEW COURSE I MIAMI, FL
06/20 TO 06/21	CLINICAL RESEARCH PROFESSIONAL CERTIFICATION PREP AND GCP REVIEW COURSE I VIRTUAL
06/22 TO 06/23	HOT TOPICS AND PRACTICAL CONSIDERATIONS FOR PROTECTING HUMAN RESEARCH PARTICIPANTS CONFERENCE I ORLANDO, FL

JULY

07/12 TO 07/14	CLINICAL SITE COORDINATOR / MANAGER AND GCP WORKSHOP I VIRTUAL
07/20 TO 07/21	CONDUCTING CLINICAL TRIALS IN CANADA I TORONTO, ON, CANADA
07/27 TO 07/28	CLINICAL RESEARCH PROFESSIONAL CERTIFICATION PREP AND GCP REVIEW COURSE I VIRTUAL

SEPTEMBER

09/27	CLINICAL RESEARCH PROFESSIONAL CERTIFICATION PREP AND GCP REVIEW COURSE I MONTREAL, QC, CANADA
09/29 TO 10/01	SOCRA 2023 ANNUAL CONFERENCE I MONREAL, QC, CANADA