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WELCOME

The SOCRA mission could not be fulfilled without our members, authors, speakers and instructors, exhibitors and advertisers, SOCRA’s Board of Directors, chapter leaders, and all of the millions of research subjects who make clinical trials possible.

Dear Colleague:

SOCRA has continued to offer education and certification during these very difficult times for everyone working in medicine and clinical research. We applaud our members and stakeholders as they attend to COVID-19 patients and to others who require medical care. Our members and stakeholders are also continuing to perform research activities that might solve the current crisis and many of the other maladies that affect humanity.

SOCRA necessarily cancelled in-person conferences and workshops and our CCRP (Certified Clinical Research Professional) in-person and computer based testing early this year because of safety concerns regarding the current pandemic and as a result of government restrictions on gatherings. Our certification program restarted computer based testing at selected sites in July and initiated “at home” testing in August. We are offering some of our conferences and workshops in a virtual format and are finding that our technology overcomes the separation of our faculty members and attendees and that our members are accepting of these solutions.

While in-person activities are scheduled through 2021, many of these programs are being replaced with distance learning/meeting solutions. We are striving to accomplish our mission for providing education and certification for the clinical research community. This year’s Annual Conference is also being offered virtually, which should allow interested individuals working with budgetary and travel constraints to participate in and benefit from the program. SOCRA Chapters have been sponsoring meetings and providing education by utilizing the many virtual conferencing technologies available to them. Whether virtual or in-person, SOCRA’s programs are accredited by the Accreditation Council for Continuing Medical Education (CME) and the American Nurses Credentialing Center (CNE). These accreditations benefit nurses, physicians, pharmacists and other research professionals by allowing them to maintain their licenses and credentials through continuing education.

As we navigate through the many difficulties the COVID-19 pandemic has imposed upon us, we see our instructors, members, and other stakeholders responding professionally, and with great enthusiasm for maintaining a sense of normalcy in order to return to productive areas of science and medicine. Clinical research will be utilizing many new innovations as a result of the pandemic, including telemedicine for clinical trial visits and for clinical investigator and coordinator consultations, as well as for monitoring visits, and other mechanisms that will improve processes and activities involved in the administration of clinical trials.

We thank you for your commitment to excellence in clinical research and encourage your participation in SOCRA chapter activities, education opportunities, and clinical research professional certification.

Sincerely,

Amy Jo Jenkins, MS, CCRP
President, SOCRA
2019 - 2020
INTRODUCTION

MISSION
In order to promote quality clinical research, protect the welfare of research participants, and improve global health, SOCRA’s mission is:

• To establish educational programming and provide continuing education for clinical research professionals.

• To establish an internationally recognized certification program for clinical research professionals (CCRP®).

• To foster the professional development and peer recognition of clinical research professionals.

WHO WE ARE
SOCRA is a non-profit, charitable and educational membership organization committed to providing education, certification, and networking opportunities to all persons involved in the clinical research community. SOCRA began as the premier educational organization for oncology site coordinators and has emerged as a leading educational organization for clinical researchers in all therapeutic areas, supporting industry, government and academia.

Since our incorporation in 1991, SOCRA has been through many changes, all of which were important contributors to our growth. The lack of available educational opportunities for site based coordinators and the thirst for information resulted in an organization founded by creative and forward thinking leaders. Today, the organization has realized membership growth and program expansion exceeding its expectations.

The most important factors contributing to our success over the past few years have been our membership support, educational programming and certification program. Innovation and investment of skill and knowledge have resulted in an exceptional organization with expertise and understanding in providing educational programming and member services. The quality of our programs and educators is unparalleled.

Our educational programming has been wonderfully successful as has our certification program and our noteworthy Annual Conference. We are committed to developing and providing new and innovative approaches to learning and we intend to explore new educational opportunities to maximize those opportunities for future success. This is especially important as we navigate the COVID-19 pandemic. While many of our education and certification activities have been cancelled through 2020, we have used this time to expand our online courses, launch new virtual webinars and offer at-home CCRP certification testing. Learning and adapting in this new environment has proved successful and rewarding.

WHO WE SERVE
As of January 2020, we have 16,000+ members and 12,000+ certified clinical research professionals. Our members have backgrounds in a variety of fields - nursing, pharmacy, medical technology, business administration, health record management, statistics, science, education, and more. They also work in various settings including private practice, cooperative research groups, public and private academic institutions, pharmaceutical, device, and biotechnology companies, contract research organizations (CROs), site management organizations (SMOs), independent research and development organizations, and organizations otherwise involved in the management of clinical trials.

16,000+ MEMBERS
12,000+ CCRPS
GLOBAL MEMBERSHIP REPRESENTED IN 48 COUNTRIES
Our worldwide membership includes members in the U.S.A., Canada, Argentina, Australia, Austria, Belgium, Botswana, Brazil, China-SAR, Colombia, Costa Rica, Cuba, Egypt, France, Germany, Ghana, Greece, Guatemala, Hungary, India, Italy, Japan, Kenya, Lithuania, Malaysia, Mexico, Netherlands, New Zealand, Pakistan, Panama, Peru, Philippines, Portugal, Qatar, Russia, Saudi Arabia, Singapore, South Africa, South Korea, Spain, Sweden, Switzerland, Thailand, Uganda, Ukraine, UAE, United Kingdom, West Indies.

INVESTIGATIONAL SITES
60%
INDUSTRY
30%
IRB/ETHICS BOARDS
5%
OTHER AREAS OF RESEARCH
5%
A BRIEF HISTORY

As you review this list of accomplishments you will see that our mission to develop meaningful education for our members continues to be at the forefront of our activities. SOCRA has again made important strides in offering educational opportunities.

1991 SOCRA founded and incorporated
1992 First Annual Conference
1995 Clinical Science Course offered
1996 Chapter Program begun
1999 Human Research Protections Program offered
2000 Clinical Research Monitoring Workshop developed
2001 Certification Preparation & Review Course offered
2002 Awarded ANA/ANCC providership for Nurse CNE
2003 Japanese Language Certification examination offered
2004 French Language Prep Course offered
2005 SOP for Senior Site Managers Workshop offered
2006 First Annual Device Clinical Research Conference
2007 Annual Conference Preconference Workshops added on Research Law, Protocol Development, and Grant Writing
2008 Approved as a provider of physician CME by ACCME
2009 Annual Conference Preconference Workshop on Device Research added
2010 Awarded Accreditation with Commendation as a provider of physician CME by ACCME
2011 Online training courses offered
2012 Completed / published Task Analysis survey of clinical research activities
2013 Conducting Clinical Trials in Canada Conference offered
2014 Pediatric Clinical Research Conference offered
2015 Oncology Clinical Trials Conference offered
2016 Oncology Conference Poster Program
2017 Emergency Clinical Research Symposium offered
2019 Clinical Research Nursing Conference offered
2020 Additional online courses offered

In light of the COVID-19 pandemic, it has never been more important for SOCRA to invest in developing new and innovative approaches to education and certification. We look forward to continuing to develop our portfolio of online course offerings and live virtual webinars, while investing in new and innovative ways to assure our members are up to date and compliant in their clinical research practice. We remain committed to our mission of excellence in clinical research and look forward to bringing our community together to foster professional development and peer recognition in this unprecedented time. SOCRA looks to its members and individuals working in clinical research for new course content to support our stakeholders. Whether in-person or virtual, our education programs offer high levels of participation and great overall satisfaction. We will continue to work towards innovative programming and technologies to benefit our members in cost effective ways.

THE FUTURE

In light of the COVID-19 pandemic, it has never been more important for SOCRA to invest in developing new and innovative approaches to education and certification. We look forward to continuing to develop our portfolio of online course offerings and live virtual webinars, while investing in new and innovative ways to assure our members are up to date and compliant in their clinical research practice. We remain committed to our mission of excellence in clinical research and look forward to bringing our community together to foster professional development and peer recognition in this unprecedented time. SOCRA looks to its members and individuals working in clinical research for new course content to support our stakeholders. Whether in-person or virtual, our education programs offer high levels of participation and great overall satisfaction. We will continue to work towards innovative programming and technologies to benefit our members in cost effective ways.
EXAM VALIDATION
The exam is statistically and psychometrically validated by independent consultants. The Certification Committee evaluates the results from statistical/psychometric evaluations and updates the exam as needed. The examination pass/fail score, or “cut score,” is statistically determined by a panel of experts using the “Modified Angoff Method.” The “cut score” is validated after a review of psychometric analysis.

SCOPE
The Clinical Research Professional Certification program is intended to evaluate a CRP’s knowledge, understanding, and ability to apply regulations to the conduct of clinical investigations involving humans. Knowledge areas include: the International Council on Harmonisation Guideline for Good Clinical Practice (ICH E6 GCP), ICH Clinical Safety Data Management: Definitions and Standards for Expedited Reporting (E2A), the United States Code of Federal Regulations (CFR) Parts 11, 50, 56, 312, 812, and the ethical principles that guide clinical research consistent with the principles of the Nuremberg Code, the Belmont Report and the Declaration of Helsinki.

EXAM DESCRIPTION
The examination is made up of multiple choice questions. The questions are formulated to be straightforward and easily understood. Each test question has only one correct answer. Each question is weighted equally, and there is no penalty for an incorrect answer. Therefore, it is advantageous to answer all questions. The certification examination is offered in the English language. The CCRP Certification examination has no testing windows and the exam is offered in paper and pencil and computer based testing formats.

EXAM SCORING
The CCRP Certification Examination consists of 130 multiple choice questions. Thirty (30) of these questions are “beta test” questions and will not affect the candidate’s score (unscored). These items are not identified to the candidate. The data collected on the unscored items is used to evaluate the psychometric soundness of each CCRP test item. The number of scored items on the exam is 100. The passing score is determined by a panel of experts using the “Modified Angoff Method”.

CERTIFIED CLINICAL RESEARCH PROFESSIONAL “CCRP®” PROGRAM
SOCRA established the Certification Program for Clinical Research Professionals in order to create an internationally accepted standard of knowledge, education, and experience by which clinical research professionals will be recognized by the clinical research community. Certified individuals may use the title “Certified Clinical Research Professional” or CCRP®.
CANDIDATE ELIGIBILITY

In order to be considered for CCRP certification, the applicant must be working with GCP guidelines under IRB/IEC/REB approved (or specifically exempted) protocols. SOCRA will not consider candidates who are unable to provide the supporting documentation requested regarding their clinical research experience.

MINIMUM EXPERIENCE

2 years of full-time experience* as a Clinical Research Professional within the past five years
*equal to 3500 part-time hours

OR

1 year of full-time experience* as a Clinical Research Professional within the past two years
*equal to 1750 part-time hours

AND

Degree in "Clinical Research" from an Associate, Undergraduate or Graduate Degree Program*

OR

Undergraduate or Graduate Certificate in "Clinical Research"

Associate or Bachelor Degree in a science, health science, pharmacy or related field

*Degree and Certificate Programs must meet requirements. Visit www.socra.org/certification for more details

APPLICATION PORTFOLIO

The applicant must submit the following:

» Certification Application
» Resume / CV
» Verification of Employment Letter
» Job Description(s)
» Payment for the examination fee
» Signed Ethics Statement

If applying using a degree or certificate program for eligibility purposes, appropriate forms and documentation (including transcripts) must be included (see website for details).

PAYMENT OPTIONS

Payment in Full:
(3 years of certification, includes complimentary membership)

<table>
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<tr>
<th></th>
<th>Non-member: $450 (includes 3 years complimentary SOCRA membership)</th>
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<tbody>
<tr>
<td>Current Member:</td>
<td>$395 (includes 3 years complimentary SOCRA membership)</td>
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3 year Installment Plan

| Installment (includes a complimentary SOCRA membership upon successful completion of exam) | $100 in years 2 & 3, includes complimentary SOCRA membership | Total = $500 |
| Current Member: | $250 initial installment (includes a complimentary SOCRA membership upon successful completion of exam) | Total = $450 |

Retest Fee: $200 (paper and pencil) $275 (CBT)
Each retest within one year of your original test date = $200

MAINTAINING YOUR CERTIFICATION

The CCRP credential is awarded in three year increments. Certification of Clinical Research Professionals by SOCRA is based on a continuing process of professional experience and education. This program is intended to provide recognition and validation of the continued professional growth of the individual CCRP®. Installment certification fees, if selected, must be paid in a timely manner.

CONTINUING EDUCATION (CE) REQUIREMENT

Certificants must complete 45 hours of CE during their three-year certification period. The breakdown of CE that may be claimed within each CE category follows:

| Clinical Research Operations / Regulatory | Minimum of 22 CE must be claimed (no maximum) |
| Therapeutic / Professional Area | NO minimum |
| Recertification Continuing Competence Learning Module | 1 CE may be claimed |

Total of 45 CE per 3-year certification period

Only educational hours may be claimed for CE; you may not claim CE credit for your work hours.

RECERTIFICATION / CERTIFICATION

To maintain active certification status, certificants must apply for renewal of certification every three years. Those wishing to renew their CCRP certification must successfully complete an online regulatory learning module and provide documentation of 45 hours of validated CE credit. The fee for recertification for three years is currently $350. An installment payment plan is available at $200, $100, $100 over three years for a total of $400.

TESTING

View our website for details on testing options. SOCRA currently offers the paper and pencil exam and computer-based testing (CBT), which now offers an option for at-home testing during the covid-19 pandemic.

TO APPLY VISIT WWW.SOCRA.ORG/CERTIFICATION

Applicants should thoroughly review all of the information provided in the Certification section of the website. Before submitting an application packet, applicants must review the eligibility requirements, application procedures, deadlines, and certification program policies and procedures. Candidates’ applications and documentation must support the minimum work experience required.
The Annual Conference Exhibit Program offers opportunities for attendees to connect with institutions and stay up-to-date on current products and services. The program provides opportunities to support clinical research programs and individual professional development in enhancing attendees’ effectiveness and productivity.

The Poster Program offers an opportunity for members to share their research with interested colleagues. Posters offer information for viewers to understand the methods, results, and significance of the research, and to promote conversations and networking among the research community.

In light of COVID-19, the 2020 Annual Conference will be held virtually. 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. Despite this change in plans, we are committed to our mission of excellence in clinical research and look forward to bringing our community together to foster the professional development and peer recognition of clinical research professionals. The virtual program will feature:

- Live opening and closing plenary sessions
- 8 educational tracks with on demand content and live Q+A
- Peer-driven poster program and award competition
- Sponsor and exhibit opportunities
2019 ANNUAL CONFERENCE IN REVIEW

2019 PRESIDENT’S AWARD

SOCRA presents a special recognition award annually to an individual who has given exceptional service to the society. The recipient of the 2019 President’s Award for outstanding service was Brad Pollock, PhD, MPH. Dr. Pollock exemplifies outstanding service as an active member of SOCRA’s faculty. He was a faculty member of the first Clinical Science Certificate Course in 1992. Since 1995, he has been a presenter at the Clinical Science Course which is still offered today. He is also a presenter at SOCRA’s Emergency Research Symposium. He has spoken for SOCRA 50+ times over the years.

Dr. Pollock is Professor and Chairman of the Department of Public Health Sciences, Associate Dean for Public Health Sciences, and holds the Rolkin Chair in Public Health Sciences in the School of Medicine at the University of California, Davis. He is the Co-Director of the Population Sciences and Health Disparities research program of the UC Davis Comprehensive Cancer Center.

2019 POSTER PROGRAM SPECIAL RECOGNITION AWARD

This program recognizes excellence for activities involved in clinical research in the two categories of Clinical Trials and Clinical Research Management. Posters are evaluated by a group of experts in clinical research. Recipients demonstrate ability to present their work during the Annual Conference poster program. The special recognition awards for 2019 were presented by John Petrich, MS, RPh:

CLINICAL TRIALS CATEGORY

Using a User-Centered Design Approach to Refine the Pain Squad+ Smartphone App for Adolescents with Cancer to Manage their Pain
Author: Cynthia Nguyen

CLINICAL RESEARCH MANAGEMENT CATEGORY

Where Does the Time Go? An Analysis of Task Distribution in a Centralized Research Support Unit
Author: Caroline Buse

2019 CHAPTER CHAIRPERSON RECOGNITION

SOCRA annually recognizes the chapter chairperson from the chapter granting the greatest amount of learning opportunity (SOCRA approved Continuing Education hours) to clinical research professionals.

Wendy Lloyd, BA, LPN, CCRP of the SOCRA Nashville Chapter, was honored as the 2019 recipient of the Chapter Chairperson Award.

Jamie Harper, MHA, CCRP presents the Chapter Award to Wendy Lloyd, BA, LPN, CCRP on behalf of the Nashville Chapter.
THE IMPORTANCE OF TRAINING IN THE CONDUCT OF CLINICAL TRIALS

FDA Center for Drug Evaluation and Research (CDER) audit inspection findings from fiscal year 2012 through 2019 continue to show trends in clinical investigator deficiencies in areas such as following protocol, record keeping and informed consent. SOCRA recognizes these trends and issues and offers education to clinical research professionals on Good Clinical Practice (GCP) and more. Our hope is that by participating in SOCRA programming, our members will be leaders in the clinical research profession and inspection findings will continue to improve.

EDUCATION BROUGHT TO YOU AT YOUR SITE

In addition to our numerous offerings throughout the US and Canada, SOCRA will schedule the Certification Preparation and GCP Review Course at your site for a minimum of 20 guaranteed participants. SOCRA can also customize our educational offerings to meet the needs of your research site / institution. SOCRA has held educational programs in the U.S.A., Canada, Mexico, Brazil, Japan, Belgium, Korea, and Singapore. And now many of our programs are transitioning to be offered in-person and virtually!

SOCRA PROGRAMS MEET INDUSTRY CRITERIA FOR ICH GCP INVESTIGATOR SITE PERSONNEL TRAINING

Clinical researchers who hold the SOCRA “CCRP,” Certified Clinical Research Professional designation, as well as those clinical researchers who complete specific SOCRA GCP courses (noted below), meet the minimum criteria for ICH GCP investigator site personnel training as identified by TransCelerate BioPharma member companies.

- SOCRA “CCRP” Certification Preparation & GCP Review Course
- Clinical Site Coordinator/ Manager Workshop GCP for Coordinators, Research Associates, Study Nurses, Site Managers
- Conducting Clinical Trials in Canada
- Clinical Investigator GCP & Trials Management Conference for Clinical Investigators and Key Research Staff

SOCRA OFFERS CME AND CNE CREDIT FOR ALL PROGRAMS

In addition to offering the highest quality training programs for clinical research professionals, SOCRA is a provider of CME and CNE (Continuing Medical Education and Continuing Nurse Education).

ONLINE TRAINING PROGRAMS

SOCRA offers online learning in addition to its diverse complement of live educational opportunities. The programs are offered as self-paced on-demand presentations. A quiz following the presentation summarizes the topic and evaluates the participant's understanding of the material.

- Part 1: Informed Consent for Research: Operationalizing the Process
- Part II: Informed Consent for Research: The Importance of Quality for Understanding and Decision-making
- A Primer on Clinical Research
- Sponsor Responsibilities
- Institutional Review Boards (IRB)
- What You Should Know Before the FDA Arrives
- ICH E6 (R2): From the Site’s Perspective
- IND / IDE Assistance
- Risk Based Monitoring from a Site Perspective
- cGMP for Investigational New Drugs (IND) in Phase I Clinical Trials
- Where to Start & How to Create a Protocol Draft (Bedside Nursing)
- How to get from Clinical Inquiry to Conducting Nursing Research (Bedside Nursing)
CLINICAL INVESTIGATOR GCP & TRIALS MANAGEMENT PROGRAM
FOR CLINICAL INVESTIGATORS AND KEY RESEARCH STAFF

This course, for clinical investigators and key research staff, will review GCP, research finance and budgeting, and legal responsibilities of the clinical investigative site. This program creates opportunity for dialogue among clinical investigators, key research staff and program faculty. The intent of which is to enhance the participants’ ability to perform quality clinical research according to existing regulations and guidelines. This program is designed to address all of the functions of the research site related to the Good Clinical Practices as delineated by the U.S. Code of Federal Regulations and the guidelines supported by the ICH Guidelines. TransCelerate BioPharma: This ICH E6 GCP Investigator Site Training meets the Minimum Criteria for ICH GCP Investigator Site Personnel Training identified by TransCelerate BioPharma as necessary to enable mutual recognition of GCP training among trial sponsors.

Marie Falvo, BA, CCRP
Senior Manager, Clinical Quality Assurance, Boston Scientific Co-Chairperson

Gretchen Gall
Clinical Operations Manager and Clinical Operations Bidder, IQVIA Biotech Co-Chairperson

Carole Sampson-Landers, MD
Retired, Former Director, Global Clinical Development, Bayer HealthCare Pharmaceuticals Co-Chairperson

The purpose of this workshop is to assist Clinical Investigators and key research staff in improving their skills and understanding of the responsibilities of the clinical research site.

CLINICAL RESEARCH MONITORING AND GCP WORKSHOP
FOR MONITORS, SITE COORDINATORS, AND AUDITORS

Clinical Research Monitoring is an evolving practice. This interactive workshop, for site monitors, managers or auditors with 0-5 years of experience, will review GCP and clinical research monitoring best practices. Lecture and practical application are facilitated by clinical research professionals with a combined industry experience of more than 40 years. Information is presented and discussed regarding monitoring of clinical trials according to FDA Regulations and International Conference on Harmonisation (ICH) guidelines. Presenters share practical procedures and issues related to site / sponsor / CRO relationships.

James Simmer, BSN, MBA
President, Research Answers Co-Chairperson

Gretchen Gall
Clinical Operations Manager and Clinical Operations Bidder, IQVIA Biotech Co-Chairperson

This workshop addresses the roles and responsibilities of a Clinical Research Associate / Monitor / Auditor. This is also a great course for Research Study Coordinators who want to improve their understanding of the responsibilities and interactions with Clinical Research Monitors.

NOW OFFERED VIRTUALLY!

NOW OFFERED VIRTUALLY!
EDUCATIONAL OPPORTUNITIES

2019-2020

CLINICAL SITE COORDINATOR/ MANAGER WORKSHOP

GCP FOR SITE COORDINATORS, RESEARCH ASSOCIATES, STUDY NURSES & SITE MANAGERS

This workshop for site coordinators, research associates, and study nurses with 0-5 years experience, reviews the responsibilities at the clinical research site. This program is designed to address all of the functions of the research site related to the administration of clinical trials according to Good Clinical Practices as defined by the U.S. Code of Federal Regulations and the guidelines issued by the International Conference on Harmonisation (ICH Guidelines), as well as practical procedures and site / sponsor / CRO relationships. The goal is accomplished through lecture and practical application facilitated by clinical research professionals with a combined industry experience of more than 30 years. This workshop is offered four times annually.

TransCelerate BioPharma: This ICH E6 GCP Investigator Site Training meets the Minimum Criteria for ICH GCP Investigator Site Personnel Training identified by TransCelerate BioPharma as necessary to enable mutual recognition of GCP training among trial sponsors.

Helen Darwin, BSc, CCRP
President, Darwin Site Management Services
Program Committee and Faculty

Jacqueline Busheikin, CCRP
President, Jana Research Corp.
Program Committee and Faculty

ADVANCED SITE MANAGEMENT: FINANCE AND PRODUCTIVITY WORKSHOP

ENHANCED BUSINESS PRACTICES FOR CLINICAL RESEARCH PROGRAMS

This workshop for site managers and research associates reviews billing, budgeting, profitability, and business best practices for clinical research programs. The purpose of this workshop is to assist Site Managers, Site Coordinators and Research Associates in improving their skills and their understanding of the practical financial and business tasks related to clinical research. This workshop focuses on providing tools and techniques that the participants can immediately utilize to benefit their clinical research programs. This program is offered three times annually. Program objectives are accomplished through lecture, case study, practical application and hands-on experimentation facilitated by experienced clinical research professionals.

Information and practical application recommendations are discussed regarding all of the functions of the research site related to finance, productivity, budgeting, billing, and executive reporting.

Jim Simmer, BSN, MBA
President, Research Answers Program Co-Chairperson

Andrew Snyder, MBA, FACMPE, PMP
Director, Clinical Trials, HealthEast Care System, Program Co-Chairperson

Now offered virtually!

Beth Jorgenson, BSN, MBA, CCRC
Clinical Trials Program Manager, HealthEast Care System

The topic of financial practices and business processes continues to be a challenge for clinical research sites. Learn strategies and best practices to meet those challenges.

NOW OFFERED VIRTUALLY!
ONCOLOGY CLINICAL TRIALS CONFERENCE
FOR RESEARCH PROFESSIONALS ASSURING RESEARCH REGULATORY COMPLIANCE
ASSURING TRIAL INTEGRITY AND RESEARCH SUBJECT/PATIENT WELL-BEING

Oncology clinical research professionals will consider and discuss various mechanisms to assure integrity and validity of oncology research planning and administration. Discussions will focus on investigator and site adherence to regulations and investigational staff awareness of subject/patient safety and will focus on the subject’s clinical trial experience. Participants will consider correlative science, response evaluation, and immunotherapy.

This program will focus on discussing trends in oncology clinical trials. It aims to identify how these trends are influencing oncology trials. Information will be presented through lecture and practical application covering the administration of oncology clinic trials according to the regulation, guidance, policy and procedure.

The Oncology Conference offers a Poster Program for individuals working in clinical research in the oncology setting to share their work and findings with the research community. Posters address themes specific to best practices in clinical research within the oncology setting, including: Process Improvement and Quality in Oncology Clinical Research, Patient as Partner: Patient Oriented Research, Recruitment Methods and Strategies, and Hot Topics in Oncology Clinical Research.

NOW OFFERED VIRTUALLY!

CLINICAL RESEARCH PROFESSIONAL CERTIFICATION PREPARATION AND GCP REVIEW COURSE

The purpose of this workshop is to assist the participant in preparing for the CCRP certification examination and to review GCP regulations, policies, and procedures appropriate to the clinical research environment.

The program, which can be brought to your institution, reviews basic concepts of GCP compliance; drug and device development; the conduct of clinical trials; regulatory guidelines regarding IRB oversight and human research protections; ethical issues in clinical research; Good Clinical Practice and audits, misconduct and fraud. Attendees participate in a case study that stresses abstracting information and completing case report forms and other records.

TransCelerate BioPharma: This ICH E6 GCP Investigator Site Training meets the Minimum Criteria for ICH GCP Investigator Site Personnel Training identified by TransCelerate BioPharma as necessary to enable mutual recognition of GCP training among trial sponsors.

This one-day course will aid participants in preparing for the CCRP® Certification Exam through review of FDA regulations and ICH Good Clinical Practice (GCP) guidelines.
QUALITY IMPROVEMENT THROUGH STANDARD OPERATING PROCEDURES (SOPS)

This workshop will consider fundamental concepts for the development and implementation of effective SOPs.

This two-day workshop reviews important concepts and current issues in the development and implementation of effective SOPs for the investigational site. This workshop, offered once per year, is facilitated by clinical research professionals with experience and expertise in SOP development and implementation.

Participants will discuss basic principles and current challenges regarding development, writing, and implementation of SOPs. The importance of strategies for addressing the approval process, development of a training program, and tracking of training and implementation results will also be discussed. This workshop consists of lectures, discussions, and interactive group exercises.

Standard Operating Procedures (SOPs) are effective tools to assist in the conduct of high quality clinical trials.

Donna Headlee, RN, BSN, CCRP
Program Chairperson

EMERGENCY CLINICAL RESEARCH SYMPOSIUM

Conducting research in the emergency setting presents unique challenges to clinical research professionals. At the annual Emergency Clinical Research Symposium, information will be presented and discussed regarding the development, approval and administration of emergency clinical trials according to regulation and guidance.

After completion of the course, participants will understand the current regulations related to emergency research, as well as the current challenges facing researchers working in this setting. Attendees will also discuss practical considerations and possible solutions when conducting research in emergency settings.

Lisa Benson, BS, CCRP, CRCP
Senior Vice President Clinical Site Network, Institute for Advanced Clinical Trials for Children Program Co-Chairperson

This program will address hot topics such as the “challenges of informed consent”, “funding potential for emergency research” and “design considerations for emergency clinical research”

Susan Devine, CCRP, CRCP
Consultant Program Co-Chairperson

CLINICAL RESEARCH NURSING CONFERENCE

The Clinical Research Nursing Conference is a new and exciting offering that addresses the unique challenges clinical research nurses face regarding the administration of clinical research and the care for patients. The goal of this conference will be accomplished through lecture and practical application facilitated by clinical research professionals with extensive experience in nursing, education, and clinical research administration and management. Information will be presented and discussed regarding the American Nurses Association (ANA) scope and standards of practice for clinical research nurses.

This conference presents the opportunity to highlight the role that nurses play in clinical research, to celebrate this role, and to empower nurses to become leaders in the field of clinical research.

Jennifer Goldfarb, MSN, RN, CCRP
VP of Clinical Research, The IMA Group Program Chairperson
FDA CLINICAL TRIAL REQUIREMENTS, REGULATIONS, COMPLIANCE AND GCP CONFERENCE

This two-day conference, jointly sponsored with the U.S. FDA, shares information regarding clinical research regulations and GCP guidelines, and discusses methods to aid the research professional in their practice. This conference is designed to enhance the participant’s understanding of the mission, responsibilities, and authority of the FDA and to encourage interaction with FDA representatives. Hear directly from FDA representatives, as they share information with the regulatory community to facilitate the understanding of regulations, guidelines and practices, and to suggest methods and opportunities to enhance research professionals’ product development understanding. This conference highlights the following areas:

» FDA Regional BIMO Offices Roles, Structure and Responsibilities
» Modernizing FDA’s Clinical Trials / BIMO Programs
» FDA’s Expectations for a Clinical Trial
» Medical Device Aspects of Clinical Research
» FDA Center for Biologics’ Regulation of Research
» Adverse Event Reporting – Science, Regulation, Error and Safety
» Ethical Issues in Subject Enrollment
» Keeping Informed and Working Together

» FDA Conduct of Clinical Investigator Inspections
» Investigator Initiated Research
» Meetings with the FDA - Why, When and How
» Part 11 Compliance - Electronic Signatures
» IRB Regulations and FDA Inspections
» Informed Consent Regulations
» The Inspection is Over - What Happens Next? Possible FDA Compliance Actions

CONDUCTING CLINICAL TRIALS IN CANADA CONFERENCE
A UNIQUELY CANADIAN PERSPECTIVE FOR ALL CLINICAL RESEARCH PROFESSIONALS

Answering requests from Canadian members, SOCRA offers a program on conducting clinical trials in Canada. This program features sessions on Health Canada’s regulations for pharmaceutical and medical device clinical studies. Speakers address current trends in clinical research and identify how these trends influence clinical development now and into the future. Speakers review ethical challenges for research in the Canadian regulatory environment; key elements in preparing for a Health Canada inspection and potential corrective and remedial actions for audit inspection findings. In addition, the program reviews critical analysis and risk management strategies to mitigate cultural challenges presented by multinational trials.

TransCelerate BioPharma: This ICH E6 GCP training meets the minimum criteria for ICH GCP Investigator and Site Personnel Training identified by TransCelerate BioPharma as necessary to enable mutual recognition of GCP training among trial sponsors.
CLINICAL RESEARCH PROJECT/PROGRAM MANAGEMENT CONFERENCE

This conference considers project management and risk management principles, budget development / financial management and global considerations for clinical research programs. Clinical trial project and program management incorporate a broad range of skill sets in order to plan, administer, track, evaluate and report activities and budgets involved in the health care product development process. The goal of this program is to introduce, affirm and enhance the participant’s understanding of the project management endeavor.

Nancy Wintering, LCSW, CRC, CCRP
Assistant Director of Research, Thomas Jefferson University Program Chairperson

Topics include:

» Developing an Infrastructure
» Introduction to PMI (Project Management Institute) Principles of Initiation, Planning, Execution, Monitoring, Controlling, Mapping, Risk Management and Closing
» Charts, Planning and Tracking Tools
» Organizational Tools and Techniques
» Organizational Dynamics in Project Management
» Global Regulatory Considerations Affecting the Project Plan
» Creating a Study Budget and Managing Finances

‘HOT TOPICS’ AND PRACTICAL CONSIDERATIONS FOR PROTECTING HUMAN RESEARCH PARTICIPANTS CONFERENCE

LEGAL, ETHICAL, AND PRACTICAL CONSIDERATIONS

SOCRA is proud to announce this conference on Protecting Human Research Participants. The conference is designed to aid the clinical research professional’s understanding of current ‘Hot Topics’ as well as the practical considerations in human subjects research.

The attendee will understand and be able to convey the responsibilities of these very important functions and the complementary role of the clinical researcher as a fundamental contributor to successful clinical research and the protection of research subjects.

The program will focus on the relationships among clinical trial staff, investigators, IRBs, the FDA, CROs and sponsors. The conference will highlight areas that present challenges to sponsors and investigational sites: writing informed consent documents, the informed consent process, use of genomic data, future use of stored biospecimens, communication, education, and research fraud.

Wendy Lloyd, BA, CCRP, LPN, CIP
Senior Clinical Research Quality Analyst, Vanderbilt Medical Center Program Chairperson

This program will broaden the participants’ knowledge of the regulatory framework, project management art and science, planning and accounting, and their attitude and aptitude for achieving successful clinical trials.
DEVICE RESEARCH & REGULATORY CONFERENCE
THE PREMIER CONFERENCE FOR DEVICE PROFESSIONALS
(Plus optional Preconference 1/2 day workshop)
This conference reviews fundamental concepts and current issues relating to DEVICE research compliance, research development, and clinical investigation for Device Research in the current regulatory environment. An optional half-day program on Device Basics for participants new to device research precedes the main conference. Presenters discuss fundamental concepts and issues relating to compliance, human subject protection, research development and clinical investigation in the current regulatory environment. Speakers from academia, government (FDA) and industry share their knowledge and expertise.

DEVICE HALF DAY WORKSHOP: DEVICE RESEARCH BASICS
The optional preconference workshop, designed for those new to research or for those who would like to have a refresher on the device clinical research regulations and guidelines, offers a comprehensive overview for those interested in device clinical research and serves as a building block for the more advanced general session.

DEVICE RESEARCH: GENERAL SESSION
This 2-day advanced conference includes experts involved in the research and development of safe and effective medical devices. Topics include: 510(k) Program Update, Device Total Product Life Cycle (TPLC) Case Study from FDA experts, Conducting Device Trials in Ascending Markets, IVD trials, IRB Roles and Responsibilities, ISO 14155, as well as presentations from innovation, communication and human factors experts.

CLINICAL RESEARCH / CLINICAL SCIENCE COURSE +
FOR CLINICAL RESEARCH PROFESSIONALS
The Clinical Science Course was first offered in 1995, as SOCRA’s flagship educational program. Since its inception, it has been revised and enhanced to meet the constantly changing needs of our members. This program is divided into 2 modules; a regulatory/procedural module and a medical/scientific module, to maximize its value to course attendees. Attendees may elect to attend one (either) or both modules.

Module I is the Regulatory / Procedural Module consisting of sessions pertaining to: Drug Development Process, Clinical Pharmacology, Adverse Event Reporting, Budgeting, Good Clinical Practice, ICH Guidelines, Informed Consent, Preparing for a GCP Audit, Regulatory Affairs and IRBs, IND/NDA, Research Ethics, and Source Documentation and Administration.

Module II is the Medical / Scientific Module consisting of sessions pertaining to: Ethical Issues in Clinical Trials, Anatomy and Physiology, Cell Biology, Genetics, Clinical Laboratory Science, Epidemiology, and Research Statistics. Faculty from esteemed institutions lead this program.

SOCRA’s Pediatric Conference provides attendees with information, tools, and real life examples to help participants navigate the evolving landscape of pediatric research.

This conference highlights the following areas:
» Unique Challenges of Conducting Clinical Trials in a Pediatric Setting
» Regulatory Considerations in the Pediatric Population
» Challenges Faced in Recruitment, Enrollment, and Retention
» Development of Pediatric Research Studies
» Budgeting and Contracting
» Project Planning and Management
» Monitoring, Auditing and Compliance
» Study Closeout

Kathi Durdon, MA, CCRP
Executive Director, Central New York Biotech Accelerator Faculty

Lisa Benson, BS, CCRP, CRCP
Senior Vice President Clinical Site Network, Institute for Advanced Clinical Trials for Children Program Co-Chairperson

Susan Devine, CCRP
Consultant Program Co-Chairperson
MEMBER RESOURCES + BENEFITS

SOCRA is an international organization with a mission for excellence through research subject protection, improving global health, education, information exchange, and certification for clinical research professionals. SOCRA membership is available to all clinical research professionals and others who are interested in clinical research. SOCRA members work in all fields of research. A common bond exists among those involved in clinical research. They deal with protocols, the informed consent process, health care ethics, regulatory issues, and GCP (Good Clinical Practice). With changes occurring daily in the healthcare field, we must all stay abreast of the latest developments.

QUARTERLY JOURNAL
SOCRA’s quarterly publication, the SOCRA SOURCE, Journal for Clinical Research Excellence, offers scientific and technical information in the form of academic and instructional articles of interest to the clinical research professional. Articles consist of items submitted by interested members as well as specifically developed articles intended to meet a need expressed by the membership. A peer review process has been developed for submitted articles. The journal contains a section advising the reader of planned educational programming, and scheduled certification examination sites, dates and times.

PROFESSIONAL EDUCATION
SOCRA membership offers discounted conference, workshop, and course registrations. All SOCRA education offers CNE and CME, as well as SOCRA CE credit. We currently offer 17 live courses across the U.S. and Canada plus 12 online courses you can access anytime through our website. Also, in light of covid-19, many of our in-person programs are now offered virtually through a recently launched webinar series.

MEMBERS STAY IN THE KNOW
To aid members in staying current, SOCRA periodically sends updates and alerts of changes in the industry, as well as new and relevant educational offerings. Plus, visit our website (www.socra.org) for educational programming, locations, and links to hotels and meeting facilities, as well as local chapter information, certification information, and meeting announcements. Stay connected across social media platforms by following us on LinkedIn (SOCRA), Twitter (@SOCRAnow), Facebook (facebook.com/socra.org), and YouTube (youtube.com/SOCRA).

MEMBERSHIP DIRECTORY
Our online Membership Directory may be found under the Membership heading of the website. The online directory was first launched in early 2007 and has provided quick access for member-to-member communication. With this directory, you have more than 16,000 clinical research professionals in your global network.

CHAPTER PROGRAM
SOCRA members are automatically included in SOCRA’s vast local chapter network for continuing education and numerous networking opportunities. SOCRA’s chapter program was developed to help support continuing education at the local level. Local chapters support peer-to-peer education and foster a community for clinical research, continuing education and networking at no-cost.

CAREER RESOURCES
Our Careers and Services section offers our members a view of career opportunities in clinical research available through employers and recruiters associated with the pharmaceutical and healthcare industries. It includes opportunities in government, academia, and industry related to all therapeutic areas.

LEADERSHIP OPPORTUNITIES
As a membership organization, we encourage you to get involved in a variety of ways - join a local chapter, submit a journal article to the SOCRA Source, or become a speaker or poster presenter at the Annual Conference. There are also leadership opportunities through our Board of Directors.

CITI PROGRAM
SOCRA offers no-cost Basic GCP and Research Protections online Education through the Collaborative Institutional Training Initiative (CITI). SOCRA has joined CITI to offer SOCRA members free entry-level basic courses in Human Subjects Research Protections, Good Clinical Practice (GCP), Health Information Privacy and Security (HIPS), Animal Care and Use (ACU), and Responsible Conduct of Research (RCR).

RECOGNITION BY TRANSCELERATE BIOPHARMA
Clinical researchers who hold the SOCRA CCRP®, Certified Clinical Research Professional designation, as well as those clinical researchers who complete specific SOCRA GCP courses (noted below), meet the minimum criteria for ICH GCP Investigator Site Personnel Training as identified by TransCelerate BioPharma member companies.

- Certification Preparation & GCP Review Course
- Clinical Site Coordinator/ Manager Workshop
- Conducting Clinical Trials in Canada
- Clinical Investigator GCP & Trials Management Conference
- Certified Clinical Research Professional (CCRP®)

APPLY FOR MEMBERSHIP
Apply, renew, and update your membership all on our website. Visit www.socra.org/membership. Membership fees: $75 USD/ year.
SOCRA’s chapter program was developed to help support continuing education at the local level. Local chapters support peer-to-peer education and foster a community for clinical research, continuing education and networking. SOCRA’s chapter model also allows clinical research professionals to acquire no-cost continuing education credit.

Interested SOCRA members wishing to administer educational programming at the local level may organize a chapter and plan clinical research education. Those interested may contact the SOCRA office for information and to discuss their educational programming.

A chapter’s membership consists of current SOCRA members who are located within a non-exclusive geographic area defined by the chapter. Therefore, the chapter’s “active” membership consists of those who are interested in developing and participating in the local chapter activities.

In 2019, SOCRA chapters held 271 meetings throughout the U.S.A., Canada, Saudi Arabia, and Belgium. These meetings offered 322 credit hours to almost 5,000 learners. SOCRA’s chapter program continues to grow, with over 63 chapters actively engaging their local clinical research community.

SOCRA recognizes that chapter education programs, coupled with SOCRA programming, help our members achieve personal and professional growth through continuing education. This award recognizes a SOCRA volunteer chapter chairperson for excellence in their commitment to this goal through the coordination of education for local clinical research professionals. This award recognizes the representative of the chapter granting the greatest amount of learning opportunities for the period between June 1 and May 31 annually. See page 9 for details regarding the 2019 recipient.

SOCRA encourages the development of local chapters to provide a cost free forum under which members can learn, exchange information, grow professionally, and acquire CE for SOCRA CCRP® recertification.
SOCRA’S LEADERSHIP IS COMPRISED OF AN ALL VOLUNTEER, 15 MEMBER BOARD OF DIRECTORS.

Our volunteer leaders are clinical research professionals from all areas of clinical research, including academia, government and industry and with experience in a wide range of therapeutic areas.

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Chief of Staff
Office of the Chancellor
University of Arkansas for Medical Sciences
Little Rock, AR, USA

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Tina Willbee, BS, CCRP
Project Manager, Project Management, Center of Excellence
Covance
Princeton, NJ, USA

Donna Williams BPS, RN, CCRP
Project Senior Clinical Research Specialist, Hill-Rom
Cazenovia, NY, USA

DIRECTORS ELECT

Jennifer L. Bryant, MPA, CCRP
Clinical Trial Manager
Infectious Diseases, Vaccines Clinical Research Service, ICON
Rockville, MD, USA

Alyssa K. Gateman, MPH, CCRP
Associate Director, Quality Assurance, Yale Center for Clinical Investigation, Yale University
New Haven, CT, USA

Jessica L. Rowe, MA, MS, CCRP
Human Research Protection Program Manager, Emig Research Center, WellSpan Health
York, PA, USA
Our management team has many years of experience working in healthcare, clinical research and the pharmaceutical industry. Our office provides accounting and financial management, membership records and dues management, meeting management and development, publications development and production, web site management, educational programming assistance, certification support and support for marketing and promotion activities.

The SOCRA management and administrative team has combined experience of more than 75 years in non-profit and association management with an additional 25 years working in healthcare, clinical research and the pharmaceutical industry.
EXECUTIVE DIRECTOR'S REPORT

The Society of Clinical Research Associates continues to encourage clinical research excellence among our members and stakeholders. We thank you for your interest in clinical research and in SOCRA.

Erich Lukas, MBA
Executive Director

Dear Members and Stakeholders:

Our Board of Directors, program organizers, presenters, chapter leaders, and staff members are working to meet your needs in the areas of clinical research education, certification, and professional development. Our mission is to promote quality clinical research to protect the welfare of research participants and improve global health. In this time of a global pandemic and accelerated effort to find solutions to perform clinical research on a number of vaccines and therapies to combat COVID-19, the work of our members and stakeholders have become a worldwide “center of attention” as they strive so diligently to find cures and ways to control the virus. Even as the current efforts are absolutely important, research in all other areas of medicine continues and SOCRA programming to enhance the knowledge and skills of clinical researchers also continues.

Everyone reading this message has benefited from clinical trials, whether we have been treated with a drug, a medical device, a vaccine, or any other means of medical support. We want to believe that the research was administered in a scientific manner, that researchers cared appropriately for those who participated as clinical research subjects, and that the research outcomes proved that the products or procedures were safe and effective.

As clinical research professionals, we must always be highly aware of the significance of our work and our contribution to the health and well-being of the population. The most insignificant aspects of our activities supporting clinical research contribute directly to the decisions that will follow regarding the acceptability of a product for the market place. The work we are doing has the possibility of benefiting ourselves, people close to us, and the greater general population. We should adhere to published regulations and guidance and rely on our own integrity to assure that everything we do is ethically and scientifically appropriate.

In striving for clinical research excellence, SOCRA conferences encourage discussion and conversation relating to all aspects of clinical research. Faculty members are industry experts who work diligently to develop significant and appropriate goals and learning objectives that are the foundations for our conferences. Attendees have the opportunity to comment on a number of criteria that continually help to improve the content and delivery of our programs. They also recommend new topics for future programming, develop new programs, and volunteer as speakers for future programming. Their participation strengthens our content and adds to the professional development for our members.

To assure that our conferences and programs are developed and conducted at the highest levels of professionalism, they are accredited for CNE (Continuing Nursing Education) by the ANCC (American Nurses Credentialing Center); for CME (Continuing Medical Education) for physicians by the ACCME (Accreditation Council for Continuing Medical Education); and our certification program CCRP® (Certified Clinical Research Professional®), is accredited by the NCCA (National Commission for Certifying Agencies). With 16,000+ members and 12,000+ CCRP® certified members, we hold to the highest standards for clinical research professional development.

The SOCRA Chapter Program included almost 5,000 attendees during the last year (59 chapters and 243 meetings). Chapters are organized by volunteer leaders and volunteer presenters and their programs are offered at no cost to attendees. Chapter programs are open to anyone interested in a topic, and continuing education certificates are available to SOCRA member attendees.

We appreciate that you share in our quest for clinical research excellence and hope that you are taking advantage of our programming.

Thank you for your support!

Erich F. Lukas, MBA
Executive Director
Society of Clinical Research Associates
CALENDAR OF EVENTS

OCTOBER 2020
10.12 to 10.15  Clinical Research Project / Management Virtual Conference
10.15 and 10.16  Clinical Research Professional Certification Preparation and GCP Virtual Review Course
10.21 to 10.23  Finance and Productivity: Advanced Site Management Virtual Workshop
10.27 to 10.29  Clinical Site Coordinator / Manager Virtual Workshop

NOVEMBER 2020
11.17 to 11.19  FDA Clinical Trial Requirements, Regulations, Compliance + GCP Virtual Conference

DECEMBER 2020
12.1 to 12.4  Clinical Research Monitoring and GCP Virtual Workshop
12.7 to 12.10  Advanced Concepts for Clinical Investigators and Key Research Staff: GCP & Clinical Trials Management Virtual Conference

JANUARY 2021
1.21 and 1.22  Clinical Research Professional Certification Preparation and GCP Virtual Review Course
1.26 to 1.28  Clinical Site Coordinator / Manager Virtual Workshop

FEBRUARY 2021
2.8 to 2.11  Clinical Research Monitoring and GCP Virtual Workshop
2.22 to 2.24  Finance and Productivity: Advanced Site Management Virtual Workshop

MARCH 2021
3.1 to 3.4  Pediatric Clinical Trials Virtual Conference
3.8 to 3.11  Clinical Research Project / Management Virtual Conference
3.17 and 3.18  FDA Clinical Trial Requirements, Regulations, Compliance + GCP Conference  I  Newport Beach, CA
3.22 to 3.26  Oncology Clinical Trials Virtual Conference

APRIL 2021
4.28 to 4.30  2021 Annual Device Research + Regulator Conference  I  Savannah, GA

MAY 2021
5.6 and 5.7  Clinical Research Nursing Conference  I  Newport Beach, CA
5.12 and 5.13  FDA Clinical Trial Requirements, Regulations, Compliance + GCP Conference  I  San Antonio, TX