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Dear Colleagues,

SOCRA’s overall mission to promote quality clinical research, to protect the welfare of research participants, and, ultimately, to improve the health of the global population is being implemented by well informed and capable research professionals who make the work of our innovators and implementers both successful and beneficial. SOCRA’s mission facilitates the approval of new products and methods that will benefit our stakeholders in their quest for excellence in process management and product development. Included in this Annual Report you will find an overview of SOCRA activities and details regarding the programs and services offered. We constantly strive to make a positive impact on clinical research professionalism, research subject protection, research outcomes, and ultimately, global health.

All of the programs highlighted in this report offer the most up-to-date guidance related to good clinical practice and research subject protection. SOCRA’s programs not only benefit the clinical researchers who take part in them, but also benefit the associates and research participants they work with on a daily basis. As SOCRA participants share knowledge gained as a result of attending SOCRA programs, they also recognize the importance of well run clinical trials. They understand the necessity for assuring research subject informed consent and subject protections, ramifications of proper planning and budgeting, and the essence and details related to regulations and guidance as they apply domestically and internationally.

SOCRA currently offers 17 live conferences across the U.S. and Canada and 8 online courses which can be accessed from anywhere and at any time. This year, SOCRA added the Clinical Research Nursing Conference, a two-day conference addressing the unique challenges clinical research nurses face regarding the administration of clinical research and the care of patients. This program is not only applicable to those currently serving as clinical research nurses but also to those who are considering becoming involved in clinical research nursing, including nurses practicing in clinical areas. The program presented a wealth of information and will also benefit clinical research staff and managers from all educational backgrounds who are interested in advancing their understanding of the rigors of clinical research nursing. SOCRA’s programs are accredited by the Accreditation Council for Continuing Medical Education (ACCME) and the American Nurses Credentialing Center (ANCC). These accreditations benefit nurses, physicians, pharmacists and other research professionals by allowing them to maintain their licenses and credentials.

SOCRA also offers continuing education credit through its Chapter Program. SOCRA’s 59 Chapters offered 249 meetings during the last year that were attended by almost 5,000 clinical researchers. Clinical researchers are encouraged to attend these (no-cost) programs to learn more about research activities and to maintain awareness of issues and innovations affecting the research community. This Chapter Program is successful through the efforts of the chapter leaders and presenters who prepare and deliver programs of strategic importance to the research community.

We are proud of our members for the positive impact they are making towards our on-going mission to protect human research participants and to improve the health of people around our world through the enhancement of processes and products of clinical research. Our members come from diverse areas of clinical research, working in research organizations in industry, academia, community, and government. Our SOCRA Certified Clinical Research Professionals (CCRP) are eminently qualified to participate in clinical research. By successfully completing the SOCRA certification examination, CCRPs have demonstrated their knowledge of regulations and guidance. We have created more flexible and convenient ways to become certified, through computer based (anywhere / anytime) testing at more than 600 testing centers, in addition to in-person paper and pencil testing at 95 sites this year.

We invite you to join us in our mission to benefit the population through clinical research. I thank you for your interest in SOCRA and your involvement in the clinical research endeavor.

Sincerely,

Jamie Harper, MHA, CCRP
President, Society of Clinical Research Associates

Jamie Harper, MHA, CCRP
President 2018-2019

WWW.SOCRA.ORG
The Society of Clinical Research Associates (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 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 in our success over the past years have been our membership support, our educational programming and our 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 devoting a tremendous effort to developing and providing new and innovative approaches to learning. We intend to explore new educational opportunities, and to maximize those opportunities for future success.

MEMBERSHIP DEMOGRAPHICS

12,000+ CCRPs and 16,000+ Members

Our worldwide membership includes members from the U.S.A., Canada, Australia, Austria, Belgium, Botswana, Brazil, Chile, China-SAR, Colombia, Cuba, Denmark, Egypt, France, Germany, Ghana, Greece, India, Israel, Italy, Jamaica, Japan, Lebanon, Lithuania, Malaysia, Mexico, Netherlands, New Zealand, North Korea, Pakistan, Panama, Peru, Philippines, Portugal, Qatar, Russia, Saudi Arabia, Serbia, Singapore, Somalia, South Africa, South Korea, Spain, Sri Lanka, Switzerland, Thailand, Ukraine, UAE, United Kingdom, West Indies.
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 (June) and incorporated (October)
1992  First Annual Conference
1995  Clinical Science Course offered
      First Certification Examination (CCRP)
1996  Chapter Program begun
1999  Human Research Protections Program begun
      Clinical Investigator Training Course 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
      Site Symposium for Coordinators, Associates, Nurses offered
      FDA Clinical Trial Regulations Conference series begun
      French Language Certification exam offered
2004  French Language Prep Course offered
2005  SOP for Senior Site Managers Workshop offered
      Salary Survey for Clinical Researchers published
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
      Advanced Site Management/ Finance Workshop offered
      First online basic GCP course (through CITI program)
      Annual Conference Preconferencece Workshop on Statistics in Clinical Research added
2009  Annual Conference Preconference Workshop on Device Research added
2010  Awarded Accreditation with Commendation as a provider of physician CME by ACCME
      Chapter Chairperson Recognition Award first presented
      Project / Program Management Conference offered
      Salary Survey for Clinical Researchers published
2011  Online training courses offered
      Annual Conference Preconference workshop on Project Management added
      Clinical Trial Management System (CTMS) Conference offered
2012  Completed / published Task Analysis survey of clinical research activities
      Instituted option for peer review of SOCRA SOURCE journal articles
2013  Conducting Clinical Trials in Canada Conference offered
      Social Media in Clinical Research Conference offered
      Salary Survey for Clinical Researchers published
2014  Pediatric Clinical Research Conference offered
2015  Oncology Clinical Trials Conference offered
      New Annual Conference Preconference Workshops: Investigator Initiated Sponsored Research
      Optimal Study Start-up Through Protocol Assessment
      CCRP NCCA Accreditation
2016  Oncology Conference Poster Program
      Additional Online training courses offered
      Emergency Clinical Research Symposium offered
2018  Clinical Research Nursing Conference offered

THE FUTURE

SOCRA promises to provide continued educational programming that will offer the most current information available to the clinical researcher. SOCRA looks to its members and individuals working in clinical research for new course content to support our stakeholders. 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.
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. Those individuals so approved may use the title “Certified Clinical Research Professional” or “CCRP®”.

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 examination contains case studies that relate to clinical research practice. The case studies are intended to evaluate a candidate’s ability to abstract data and do not require clinical experience. 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.

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.

EXAM SCORING
The CCRP Certification examination consists of 145 multiple choice questions. Five (5) 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 130. The passing score is determined by a panel of experts using the “Modified Angoff Method.”

CURRENTLY 12,000+ CERTIFIED
81 exam sites hosted in 2018
2,016 candidates took CCRP exam
73% passed exam*
3,188 CCRPs recertified*
* based on May 2017- May 2018 data
CANDIDATE ELIGIBILITY
In order to be considered for CCRP certification, the applicant must be working with GCP guidelines under IRB/EC/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*

and

Undergraduate or Graduate Certificate in "Clinical Research"

OR

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


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)
Non-member: $450
(Current Member: $395 (includes 3 years complimentary SOCRA membership))

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)
($100 in years 2 & 3 includes complimentary SOCRA membership) 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®.

MAINTENANCE OF CERTIFICATION
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 RENEWAL
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.

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 and deadlines, and certification program policies and procedures. Candidates’ applications and documentation must support the minimum work experience required.
Each year the SOCRA Annual Conference features 100+ speakers presenting in 8 scholarly tracks covering 25 different sessions/topics. All sessions offer CNE (Continuing Nurse Education) and CME (Continuing Medical Education) credit. The conference also includes robust exhibit and poster programs. It offers a great way for clinical research professionals to meet their educational goals.

EXHIBIT PROGRAM

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 Exhibit Program is open to attendees Thursday evening (during the Welcome Reception), Friday and Saturday, from 10:00 am - 4:00 pm.

POSTER PROGRAM

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.

THE 2019 ANNUAL CONFERENCE

The 2019 Annual Conference is scheduled for San Antonio, Texas and includes 14 preconference workshops and more than 110 regulatory, technical and scientific presentations, as well as poster sessions, exhibits, social events, a welcome reception, and an opportunity to participate in committee and planning meetings.
SOCRA presents a special recognition award annually to an individual who has given exceptional service to the society. The recipient of the 2018 President’s Award for outstanding service was Lisa Benson, BS, CCRP. Ms. Benson exemplifies outstanding service as an active member of SOCRA’s faculty. Ms. Benson is currently a co-chair and speaker for both the Emergency Clinical Research Symposium and the Pediatric Clinical Trials Conference. She is also a speaker at the Clinical Research Project Management Course. She has also been a Preconference Workshop speaker at SOCRA’s Annual Conference since 2010 and since 2005 has spoken during the main portion of the Annual Conference. Ms. Benson is also a past Board Member (2007-2009) and has been a SOCRA member and SOCRA certified since 1998. Ms. Benson is the Senior Vice President of Research Operations, Quality and Education at the Institute for Advance Clinical Trials for Children. Her focus is on external infrastructure development and working to establish best practices and common tools for pediatric clinical trials. In this role she leads educational programs and works to ensure engagement of patients, parents, children or all ages, and research staff in the Institute’s activities.

**2018 POSTER PROGRAM SPECIAL RECOGNITION AWARD**

This program recognizes excellence in activities involved in clinical research in the two categories of Clinical Trials and Clinical Research Management. The posters are evaluated by a group of experts in clinical research. The recipients demonstrate ability to present their work during the Annual Conference poster program.

The special recognition awards for 2018 were presented by John Petrich, MS, RPh:

**CLINICAL TRIALS CATEGORY**

**Virtual Reality to Reduce Procedural Pain During IV Insertion in Children at the Emergency Department: A Feasibility Pilot Study**

Author: Cynthia Nguyen

**CLINICAL RESEARCH MANAGEMENT CATEGORY**

**How to be a Principal Investigator: Developing and Implementing of a Practical Training Program**

Author: Rachel Kingsford, CCRP

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.

Carrie Chiaro, MPH, CCRP of the SOCRA Arkansas Chapter, was honored as the 2018 recipient of the Chapter Chairperson Award. The Arkansas Chapter has won the award for seven consecutive years!
THE IMPORTANCE OF TRAINING IN THE CONDUCT OF CLINICAL TRIALS

The FDA Center for Drug Evaluation and Research (CDER) audit inspection findings 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's programming, our members will be leaders in the clinical research profession and that inspection findings will 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.

SOCRA OFFERS CME AND CNE

TransCelerate BioPharma Inc. was launched in 2012 as a non-profit organization with a mission to collaborate across the biopharmaceutical research and development community to identify, prioritize, design and facilitate the implementation of solutions to drive efficient, effective and high-quality delivery of new medicines, improving the health of people around the world. The following courses meet 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:

- Clinical Investigator GCP & Trials Management Program for Clinical Investigators and Key Research Staff
- Conducting Clinical Trials in Canada Conference: A Uniquely Canadian Perspective For all Clinical Research Professionals
- Clinical Research Professional Certification Preparation and GCP Review Course
- Clinical Site Coordinator / Manager and GCP Workshop: GCP for Coordinators and Research Associates, Study Nurses, and Site Managers

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.

Current offerings include:
- Informed Consent - It Really is a Process
- Risk Based Monitoring from a Site Perspective
- GMP for Investigational New Drugs (IND) in Phase I Clinical Trials
- What You Should Know Before the FDA Arrives
- IND / IDE Assistance in an Academic Health Center - Why Provide IND/IDE Assistance?
- Regulatory Updates for Clinical Research Professionals
- 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

Marie Falvo, BA, CCRP
Principal Clinical Quality Specialist, Boston Scientific

Carole Sampson-Landers, MD
Director, Global Clinical Development, Bayer HealthCare Pharmaceuticals

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.

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

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

James Simmer, BSN, MBA
President, Research Answers

Gretchen Gall
Clinical Operations Manager, Novella Clinical

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.

This program is offered three times annually and is designed with all research professionals in mind.

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 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.
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.

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.

Clinical research site management is a critical part to every clinical trial. SOCRA is pleased to offer this workshop to assist Site Coordinators, Research Associates, and Study Nurses in improving their skill and their understanding of the responsibilities of the clinical research site.

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.
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.

This program will assist clinical research professionals in improving their skills and understanding of the responsibilities of conducting oncology clinical trials.

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, was offered at 12 venues in 2018. Faculty review 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.

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.

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”.

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.
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.

Jacqueline Busheikin, RN, CCRP
President, Jana Research Corp.
Program Chairperson

This conference offers a uniquely Canadian perspective and will assist all clinical research professionals in improving their skills and their understanding of the responsibilities of conducting clinical research in Canada.
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.

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 from Start Up to Close Out
- Contract Development for Good Outcomes
- Planning for the Unexpected
- Managing Multisite Projects & Projects Related to INDs and IDEs
- Global Regulatory Considerations Affecting the Project Plan
- Creating a Study Budget and Managing Finances from Start Up to Close Out
- Contract Development for Good Outcomes
- Planning for the Unexpected
- Managing Multisite Projects & Projects Related to INDs and IDEs

‘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 bio-specimens, communication, education, and research fraud.

The program will study, explain and discuss how ICH GCP and the Code of Federal Regulations guide and direct investigator responsibilities, IRB management issues, audits, the informed consent process, and administrative activities.

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.

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**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 guidances, offers a comprehensive overview for those interested in device clinical research and serves as a building block for the more advanced general session.

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**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.

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**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.

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**SOCRA’s Pediatric Conference**

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

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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

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**Lisa Benson, BS, CCRP, CRCP**
Senior Vice President, Clinical Operations, Quality & Education Institute for Advanced Clinical Trials for Children Co-Chairperson

**Kathi Durdon, MA, CCRP**
Executive Director, CNY Biotech Accelerator, SUNY Upstate Medical University Faculty

**Susan Devine, CCRP**
Consultant Program Co-Chairperson

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WWW.SOCRA.ORG
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. 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.

**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.

**CERTIFICATION PROGRAM REFERENCE MANUAL**

This compilation of selected sections of the U.S. Code of Federal Regulations (CFR) also includes the ICH (International Conference on Harmonisation) Guidelines for Good Clinical Practice (E6), the Declaration of Helsinki, the Belmont Report, the Nuremberg Code, and selected Health Canada documents. The reference manual is included in the certification application fee and is also available for purchase through the SOCRA office.

**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®)

**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.

**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. The journal also contains a section devoted to products and services available to the clinical research professionals as well as career opportunities.

**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 8 online courses you can access anytime through our website.

**NEWSLETTERS AND EMAIL UPDATES**

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.

**SOCRA WEBSITE, LINKEDIN, TWITTER, FACEBOOK AND YOUTUBE**

Visit our website (www.socra.org) for educational programming, locations, and links to hotels and meeting facilities, as well as local chapter information and meeting announcements. The site keeps our members up-to-date regarding SOCRA offerings including a current listing of all of our certification examination sites. Plus, 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.

**APPLICATION 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 allows clinical research professionals to acquire no-cost continuing education credit.

Interested members of SOCRA wishing to administer educational programming at the local level may organize a local 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 local chapter. Therefore, the chapter’s “active” membership consists of those who are interested in developing and participating in the local chapter activities.

In 2018, SOCRA chapters held 248 meetings throughout the U.S.A., Canada, Saudi Arabia, and Belgium. These meetings offered 289 credit hours to almost 5,000 learners. SOCRA’s chapter program continues to grow, with over 59 chapters actively engaging their local clinical research community.

**CHAPTER CHAIRPERSON SPECIAL RECOGNITION AWARD**

SOCRA recognizes that chapter education programs, coupled with SOCRA programming, help our members to 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 2018 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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Jamie Harper, MHA, CCRP
Director of Clinical Research
Illinois Cancer Care
Peoria, IL, USA

President Elect
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Executive Director, Translational Research Institute, Instructor
Little Rock, AR, USA

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Gregory Staios, MSc, CCRP
Manager, Research Quality & Privacy, Applied Health Research Centre, St. Michael’s Hospital, Toronto, ON, Canada

Donna Williams, BPS, RN, CCRP
Project Administrative Officer of Clinical Trials, SUNY Cancer Center, Upstate Medical Center, Syracuse, NY, USA

DIRECTORS ELECT
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 exceptional experience in non-profit and association management.
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.

Everyone reading this message has benefitted 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.

We must, as clinical research professionals, 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 a good possibility of benefitting 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 our striving for clinical research excellence, our SOCRA conferences encourage discussion and conversation relating to all aspects of clinical research. Our faculty members are industry experts who work diligently to develop significant and appropriate goals and learning objectives that are the foundations for our conferences.

Our 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.

Our chapter program included almost 5,000 attendees during the last year (59 chapters and 248 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
<table>
<thead>
<tr>
<th>Month</th>
<th>Event</th>
<th>Location</th>
<th>Dates</th>
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<tbody>
<tr>
<td>October</td>
<td>Clinical Research Professional Certification Preparatory and GCP Review Course</td>
<td>Hackensack, NJ</td>
<td>11</td>
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<tr>
<td></td>
<td>Clinical Research / Clinical Science Course</td>
<td>San Diego, CA</td>
<td>14 to 18</td>
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<tr>
<td></td>
<td>Clinical Research Monitoring and GCP Workshop</td>
<td>San Diego, CA</td>
<td>17 and 18</td>
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<tr>
<td></td>
<td>Clinical Research Project / Program Management</td>
<td>Honolulu, HI</td>
<td>24 and 25</td>
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<tr>
<td>November</td>
<td>Advanced Site Management: Finance and Productivity Workshop</td>
<td>Miami Beach, FL</td>
<td>7 and 8</td>
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<td></td>
<td>Clinical Site Coordinator/ Manager and GCP Workshop</td>
<td>Philadelphia, PA</td>
<td>13 and 14</td>
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<tr>
<td></td>
<td>FDA Clinical Trial Requirements Regulations, Compliance and GCP Conference</td>
<td>Las Vegas, NV</td>
<td>5 and 6</td>
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2020

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<th>Month</th>
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<tr>
<td>January</td>
<td>Clinical Site Coordinator/ Manager and GCP Workshop</td>
<td>Memphis, TN</td>
<td>23 and 24</td>
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<td></td>
<td>Quality Improvement through Standard Operating Procedures (SOPs) Workshop</td>
<td>St. Pete Beach, FL</td>
<td>13 and 14</td>
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<td></td>
<td>Pediatric Clinical Research Conference</td>
<td>St. Pete Beach, FL</td>
<td>27 and 28</td>
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<tr>
<td>March</td>
<td>Oncology Clinical Trials Conference</td>
<td>Savannah, GA</td>
<td>4 to 6</td>
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<tr>
<td></td>
<td>Clinical Research / Clinical Science Course</td>
<td>Charleston, SC</td>
<td>16 to 20</td>
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<td></td>
<td>Clinical Research Project / Program Management</td>
<td>Charleston, SC</td>
<td>19 and 20</td>
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<td></td>
<td>FDA Clinical Trial Requirements Regulations, Compliance and GCP Conference</td>
<td>San Francisco, CA</td>
<td>25 and 26</td>
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<td>April</td>
<td>Clinical Site Coordinator/ Manager and GCP Workshop</td>
<td>Portland, OR</td>
<td>2 and 3</td>
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<td></td>
<td>14th Annual Device Research and Regulatory Conference</td>
<td>Boston, MA</td>
<td>22 to 24</td>
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<td>‘Hot Topics’ and Practical Considerations for Protecting Human Research Participants Conference</td>
<td>New Orleans, LA</td>
<td>30 and 5/1</td>
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<tr>
<td>November</td>
<td>Clinical Site Coordinator/ Manager and GCP Workshop</td>
<td>New Orleans, LA</td>
<td>12 and 13</td>
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<td></td>
<td>FDA Clinical Trial Requirements Regulations, Compliance and GCP Conference</td>
<td>Orlando, FL</td>
<td>18 and 19</td>
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<td></td>
<td>Clinical Investigator GCP &amp; Trials Management Program</td>
<td>Scottsdale, AZ</td>
<td>3 and 4</td>
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<tr>
<td>December</td>
<td>Clinical Research / Clinical Science Course</td>
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www.SOCRA.org