2015 ANNUAL REPORT

clinical research certification
peer recognition
quality education
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Dear Colleagues in Clinical Research:

This Annual Report offers an introduction to SOCRA, as well as details about the programs and services available to our members and stakeholders. Our membership includes approximately 16,000 clinical research professionals. Those members work in most areas of clinical research, and for most types of research organizations including those involved with industry, academia, and government. Our almost 11,000 SOCRA certified clinical research professionals (CCRP®) have achieved that designation by demonstrating excellence in clinical research through their work and by demonstrating their knowledge by successfully completing the SOCRA certification examination.

The SOCRA mission could not be fulfilled without our members, authors, speakers and instructors, exhibitors and advertisers, SOCRA Board of Directors, chapter leaders, and all of the millions of research subjects who participate in clinical trials. Each of these vital groups contributes to the improvement of health around our world. We thank them and we encourage them to strive for excellence in their support of the clinical research endeavor.

SOCRA members do strive for excellence in all areas of support for clinical research. SOCRA education is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

SOCRA is an approved provider of continuing nurse education by the American Nurses Credentialing Center. These accreditations benefit nurses, physicians, pharmacists and other researchers by allowing them to maintain their licenses and credentials. Continuing education credit is awarded to all of our program participants for all of our programs.

SOCRA’s certified members are dedicated to quality research and to the protection of research subjects. Our certification program for clinical research professionals (the CCRP® designation) recognizes an individual’s understanding and correct application of clinical research regulations and guidance. We are proud of this program, our volunteer certification program committee members, and the staff who support the program. Our certificants are knowledgeable regarding policies, procedures, rules, and regulations pertaining to best practices, operating procedures, and subject safety. We held 95 exams during the past year at venues throughout the US and Canada, and in Belgium.

Our certification and education programs have an enormous impact on the competency of our members as well as on their ability to perform quality research. The health improvement statistics published by our governments as well as the outcomes and publications produced by the research community are a great testimony to the performance of clinical research professionals around the globe.

We intend to continue to make a positive impact on clinical research professionalism, research subject protection, research outcomes, and ultimately, global health.

Our annual conference schedule includes Montreal, Quebec in 2016; Orlando, Florida in 2017; New Orleans, Louisiana in 2018; and San Antonio, Texas, in 2019. The Annual Conference offers a great way to become involved with SOCRA – as a speaker, poster presenter, exhibitor, or as a program participant. Please plan to attend our conferences and training programs, and please consider becoming even more involved by submitting a poster or presentation for the annual conference. Remember, this is a peer-to-peer organization that wouldn’t be successful without people like you! Our annual conference offers eight tracks (100+ speakers) with a large variety of content areas as well as an exhibit program. The poster program offers two special recognition awards for poster presenters that include a $500 award and an annual conference registration waiver. The exhibit program offers attendees an opportunity to learn about the latest trends, products and services appropriate for the research professional.

Finally, please remember that the SOCRA Board of Directors is here to represent you. I encourage you to contact any of the representatives with your questions, feedback, and suggestions on how we can best serve our valued members.

Sincerely,

Jody L. Green, PhD, CCRP
President, SOCRA

WELCOME

The SOCRA mission could not be fulfilled without our members, authors, speakers and instructors, exhibitors and advertisers, SOCRA Board of Directors and chapter leaders, and all of the millions of research subjects who participate in clinical trials.
**INTRODUCTION AND HISTORY**

**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.

**Introduction**

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**

15,900 members as of August 15, 2015

Our worldwide membership includes members from the U.S.A., Canada, Australia, Austria, Bangladesh, Belgium, Brazil, Bulgaria, Cayman Islands, Chile, China-SAR, Colombia, Costa Rica, Denmark, Egypt, France, Germany, Great Britain, Greece, India, Italy, Jamaica, Japan, Lebanon, Lithuania, Malaysia, Mexico, Netherlands, Nigeria, Peru, Philippines, Portugal, Puerto Rico, Qatar, Russia, Saudi Arabia, Scotland, Singapore, South Africa, South Korea, Spain, Switzerland, Thailand, Turkey, and UAE.
**A BRIEF HISTORY OF SOCRA**

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

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
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<tbody>
<tr>
<td>1991</td>
<td>SOCRA Founded (June) and Incorporated (October)</td>
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<tr>
<td>1992</td>
<td>First Annual Conference</td>
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<tr>
<td>1995</td>
<td>Clinical Science Course offered</td>
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<tr>
<td></td>
<td>First Certification Examination (CCRP)</td>
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<tr>
<td>1996</td>
<td>Chapter Program begun</td>
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<td>1999</td>
<td>Human Research Protections Program begun</td>
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<td></td>
<td>Clinical Investigator Training Course offered</td>
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<tr>
<td>2000</td>
<td>Clinical Research Monitoring Workshop developed</td>
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<tr>
<td>2001</td>
<td>Certification Preparation &amp; Review Course offered</td>
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<tr>
<td>2002</td>
<td>Awarded ANA/ANCC providership for Nurse CNE</td>
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<tr>
<td>2003</td>
<td>Japanese Language Certification examination offered</td>
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<tr>
<td></td>
<td>Site Symposium for Coordinators, Associates, Nurses offered</td>
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<tr>
<td></td>
<td>FDA Clinical Trial Regulations Conference series begun</td>
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<td></td>
<td>French Language Certification exam offered</td>
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<tr>
<td>2004</td>
<td>French Language Prep Course offered</td>
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<td>2005</td>
<td>SOP for Senior Site Managers workshop offered</td>
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<td></td>
<td>Salary Survey for Clinical Researchers Published</td>
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<td>2006</td>
<td>First annual Device Clinical Research Conference</td>
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<td>2007</td>
<td>Annual Conference workshops added on Research Law, Protocol Development, and Grant Writing</td>
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<tr>
<td>2008</td>
<td>Approved as a provider of physician CME by ACCME</td>
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<td></td>
<td>Advanced Site Management/ Finance Workshop offered</td>
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<td></td>
<td>First on line basic GCP course (through CITI program)</td>
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<td>Annual Conference workshop on Statistics in Clinical Research</td>
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<td>2009</td>
<td>Annual Conference workshop on Device Research</td>
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<td>2010</td>
<td>Awarded Accreditation with Commendation as a provider of physician CME by ACCME</td>
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<td>Chapter Chairperson Recognition Award first presented</td>
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<td></td>
<td>Project / Program Management Conference offered</td>
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<td>2011</td>
<td>Online training courses offered</td>
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<td></td>
<td>Annual Conference workshop on Project Management</td>
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<td></td>
<td>Clinical Trial Management System (CTMS) Conference offered</td>
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<tr>
<td>2012</td>
<td>Completed / published Task Analysis survey of clinical research activities</td>
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<td></td>
<td>Instituted option for Peer Review of SOCRA SOURCE journal articles</td>
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<td>2013</td>
<td>Conducting Clinical Trials in Canada Conference offered</td>
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<td></td>
<td>Social Media in Clinical Research Conference offered</td>
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<td>2014</td>
<td>Pediatric Clinical Research Conference offered</td>
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<td>2015</td>
<td>Oncology Conference Offered</td>
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<td></td>
<td>New Annual Conference Pre-Conference Workshops: Investigator Initiated Sponsored Research Optimal Study Start-up Through Protocol Assessment</td>
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**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. Our certification program offers many testing dates and locations, with 90 testing opportunities scheduled in 2015.

For all our enthusiasm, we remain realistic about the changing work environment and current economic conditions. We will continue to work towards innovative programming and technologies to benefit our members in cost effective ways.
Why Certification?

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 Certified Clinical Research Professional Certification program is intended to evaluate a CRP’s knowledge, understanding, and application of the conduct of clinical investigations involving humans in accordance with the International Conference on Harmonisation Guideline for Good Clinical Practice (E6) (ICH/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.

Currently more than 11,000 certified!

95 exam sites hosted in 2014
2,321 candidates took CCRP exam
70% passed exam*
2,431 CCRPs recertified*
* based on May 2014-May 2015 data

CCRP Examination Content

The CCRP® certification examination is organized into five major content areas.

Five Content Areas and Percent of Test Items in Each Area

- Ethical Principles / Informed Consent / Safety = 20% – 25%
- Institutional Review Board / Institutional Ethics Committee (IRB/IEC) Roles and Responsibilities = 7% – 11%
- Clinical Trial Protocol and Protocol Amendments = 4% – 8%
- Investigator Roles and Responsibilities = 28% – 32%
- Sponsor Roles and Responsibilities = 31% – 35%

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 straight-forward 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 Scoring

The CCRP certification examination consists of 135 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”. In order to achieve a passing score, candidates must correctly answer 102 of the 130 scored questions.

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 the psychometric testing analysis.
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 be able to 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
- OR
- 1 year of full-time experience as a Clinical Research Professional within the past two years
- OR
- Degree in “Clinical Research” from an Associate, Undergraduate or Graduate Degree Program*
- OR
- Undergraduate or Graduate Certificate in “Clinical Research”
- OR
- 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

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

1. Payment in Full: (3 years of certification, includes complimentary membership)
   - Non-member: $450
     (includes 3 years complimentary SOCRA membership)
   - Current Member: $395
     (includes 3 years complimentary SOCRA membership)

2. 3 year Installment Plan
   - Non-member: $300 initial installment
     (includes a complimentary SOCRA membership upon successful completion of exam)
     ($100 in years 2 & 3, includes complimentary SOCRA membership)
   - Total = $500
   - Retest Fee: $200
     Each retest within one year of your original test date = $200
   - 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

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:

- Minimum of 22 CE must be claimed (no maximum)
- 1 CE may be claimed

Therapeutic / Professional Area

Recertification Continuing Competence Learning Module

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 re-certification 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.
The Annual Conference, held in Denver, CO in 2015, features 100+ speakers presenting in 8 scholarly tracks – covering 25 different sessions/topics. The conference also includes a robust exhibit and poster program. It offers a great way for clinical research professionals to meet their educational goals.

The SOCRA Annual Conference has been enhanced and now includes fourteen pre-conference workshops, plenary sessions, break out sessions, an exhibit program, posters sessions, CNE (Continuing Nurse Education) and CME (Continuing Medical Education) Credit, and a mobile conference App, all contributing to attendance growth and positive evaluations and testimonials.

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 held on 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.
2014 ANNUAL CONFERENCE IN- REVIEW

The 23rd Annual Conference, titled Harnessing The Tides of Innovation was attended by more than 1,000 clinical research professionals.

The conference featured scholarly presentations on topics such as Site Management, Ethics, Project Management, IRB, Academic Research, Oncology Research and more!

2014 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 2014 President’s Award for outstanding service was Donna Headlee, RN, BSN, CCRP.

Ms. Headlee has a nursing background and a master’s certificate in regulatory compliance. She began her career in clinical research at the NCI as a research nurse involved in phase 1 and 2 clinical oncology trials. She was with the NCI for approx. 15 years. She then joined the FDA, CDRH and has been there for approximately 12 years, initially with the Bioresearch Monitoring Program and now currently in the Office of Device Evaluation. She has had the honor presenting at a number of workshops, developing and facilitating the SOCRA SOP Workshop, serving on the SOCRA Board of Directors, and as President, and is chair of the Certification Committee.

2014 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.

Amy Jenkins, CCRP of the SOCRA Arkansas Chapter, was honored as the 2014 recipient of the Chapter Chairperson Award for awarding 29.75 CE hours to clinical research professionals between June 1, 2013 and May 31, 2014.

Learn more about SOCRA’s Chapter program on page 19.

2014 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 2014 were presented by John Petrich, RPh:

Research Management Category

How Instituting a Formalized Pre-IRB Review Process Improves IRB Review Outcomes

Author: Melissa Bryant, RN, CIP
National Institute of Health / National Heart, Lung, and Blood Institute / Office of Clinical Affairs

Clinical Trials Category

Nonnutritive Sucking and Sucrose-Induced Analgesia Effect on Heart Rate, Oxygen Saturation, and Pain in Intubated Infants

Author: Harriet Miller, PhD, ARNP
Orlando Health, Robinson Florida Hospital

VISIT WWW.SOCRA.ORG
SOCRA EDUCATION and TRAINING

The Importance of Training in the Conduct of Clinical Trials

FDA Center for Drug Evaluation and Research (CDER) audit inspection findings from fiscal year 2007 through 2014 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 improve.

SOCRA has held educational programs in the U.S.A., Canada, Mexico, Brazil, Japan, and Singapore.

SOCRA OFFERS CME and CNE

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

CME for Physicians:
The Society of Clinical Research Associates is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

SOCRA OFFERS CME and CNE

SOCRA OFFERS CME and CNE

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 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.

ONLINE Training Programs

SOCRA offers online learning in addition to the already robust array 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.

SOCRA’s online courses provide any-time access to training and education for on-the-go clinical research professionals.

Current offerings include:
- 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 CRPs
Clinical Investigator GCP & Trials Management Conference
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.

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.

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.

Clinical Research Monitoring and GCP Workshop
For Monitors, Site Coordinators, and Auditors

This interactive workshop, for site monitors, managers or auditors with 0–5 years of experience, will review GCP and clinical research monitoring best practices.

The Clinical Research Monitoring workshop has been a huge success since its implementation in 2000.

The program is offered two to three times annually and is designed with ALL research professionals in mind. This workshop addresses the roles and responsibilities of a Clinical Research Associate / Monitor/ Auditor, and is also a great course for Research Study Coordinators who want to improve their understanding of the responsibilities and interactions with Clinical Research Monitors.

The goal is accomplished through lecture and practical application facilitated by clinical research professionals with a combined industry experience of more than 50 years. Information is presented and discussed regarding monitoring of clinical trials according to FDA Regulations and International Conference on Harmonisation (ICH) guidelines, as well as practical procedures and issues related to site / sponsor / CRO relationships.
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.

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.

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.

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

Enhanced Business 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 per year.

The topic of financial practices and business processes continues to be a challenge for clinical research sites.

The goal is 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.

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

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

Jim Simmer, MBA, RN
Performance Research
Ponte Vedra, FL
Program Co-Chairperson

Andrew Snyder, MBA, FACMPE, PMP
HealthEast HeartCare Clinic
St. Paul, MN
Program Co-Chairperson
Oncology Clinical Trials Conference
For Research Professionals

SOCRA’s newest educational program on oncology clinical research assists Research Professionals in improving their skills and understanding of the responsibilities of conducting oncology clinical trials.

The Oncology Clinical Trials Conference is a two day program that will assist research professionals in improving their skills and their understanding of the responsibilities of conducting oncology clinical research. This program focuses on discussing trends in oncology clinical research. It aims to identify how these trends are influencing oncology trials. The program also spends time discussing the Investigator’s responsibilities for conducting safe, ethical, and successful research.

Information will be presented through lecture and practical application covering the administration of oncology clinical trials according to 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.

Clinical Research Professional Certification Preparation and GCP Review Course

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

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.

The program, which can be brought to your institution, was offered at 10 venues in 2014. 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.
MEMBER RESOURCES AND BENEFITS

SOCRA offers a variety of resources to aid members in reaching their professional goals through education and networking.

QUARTERLY JOURNAL
SOCRA’s quarterly publication, the SOCRA SOURCE, Journal for Clinical Research Excellence, is a journal offering 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 selected articles. The journal contains a section advising the reader of planned educational programming, and scheduled certification examination sites, dates and times. The journal contains a section devoted to products and services available to the clinical research professional or their organization as well as career opportunities for clinical research professionals.

WEBSITE
SOCRA’s home page can be found at www.SOCRA.org. The site offers a presentation of all of our 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 the offerings of the society. A current listing of all of our certification examination sites may be found there.

NEWSLETTERS AND EMAIL UPDATES
To aid members in staying current in changes in the industry, SOCRA periodically sends updates and alerts.

LINKEDIN, TWITTER AND FACEBOOK
Stay connected with SOCRA by connecting with us on LinkedIn, Twitter (@SOCRAnow) and Facebook (socra.org).

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.

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 health care 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 Program (CITI). SOCRA has joined The Collaborative Institutional Training Program (CITI) to offer SOCRA members free entry-level basic courses in Human Subjects Research Protections, Good Clinical Practice (GCP), Health Information Privacy and Security (HIPPS), 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
Quality Improvement Through Standard Operating Procedures (SOPs)

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

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

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.

Harnessing Social Media to Advance Clinical Research

SOCRA offers a program once per year on social media's capabilities and benefits with regard to clinical research.

Featuring presenters on topics of social media for recruitment, data collection, as well as legal and ethical issues encountered using social media in clinical research.

Clinical Trial Management System (CTMS) Conference

The purpose of this program is to assist clinical research site administrators, managers, system users, investigators, nurses, other researchers and financial personnel in evaluating Clinical Trial Management System (CTMS) capabilities and benefits.

Participants will learn basic technical terms and concepts related to CTMS. The program will teach individuals how to evaluate their organization in order to determine their CTMS requirements and to begin implementation. Revenue management, financial reporting and budgeting will also be discussed.
FDA Clinical Trial Requirements, Regulations, Compliance and GCP conference

SOCRA is pleased to offer this conference, jointly sponsored in 2014 with the U.S. FDA Los Angeles, Detroit and Florida Districts, and in 2015 with the San Francisco, Cincinnati and New England Districts.

This two-day conference, jointly sponsored with the U.S. FDA, shares information regarding clinical research regulations and GCP guidelines and discuss 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.

FDA representatives share information with the regulated community to facilitate the understanding of regulations, guidelines and practices, and to suggest methods and opportunities to enhance the research professional’s product development understanding. This conference highlights the following areas:

- FDA District Offices Role, Structure and Responsibilities
- Modernizing FDA’s Clinical Trials / BIMO Programs
- FDA’s Expectations for a Pharmaceutical 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

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 also address current trends in clinical research and identify how these trends are influence clinical development now and into the future, as well as 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, in addition to discussing the objective, process, and final report of the ISCT (Initiative to Streamline Clinical Trials).

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.
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.

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.

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, 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

Protecting Human Research Participants

Legal, Ethical, and Practical Considerations

This two-day conference for Clinical Research Professionals reviews the activities and role of the FDA as they affect record keeping, investigator responsibilities, IRB management issues, audits, the informed consent process, and administrative activities falling under FDA regulations. The presenters discuss 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.

This conference is designed to aid the Clinical Research Professional’s understanding of the legal, ethical, and practical considerations of human subjects research.

The program focuses on the relationships among clinical trial staff, investigators, IRBs and the FDA. The conference highlights five areas that present challenges to sponsors and investigational sites: safety reporting, data monitoring, communication, education, and the informed consent process. The program features a case study on human safety protection considerations during clinical research study recruitment and enrollment endeavors.
Device Research & Regulatory Conference

The Premier Conference for Device Professionals
(Plus optional Pre-Conference 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 BASICS
The optional Pre-Conference 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.

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.

Pediatric Clinical Trials Conference

SOCRA's newest educational program on pediatric clinical research was a great success. Offered for the first time in February 2014, the two day program reviews regulatory, financial, and ethical components of conducting clinical trials in the pediatric population.

Kathi Durdon,
MA, CCRP
CNY Biotech Accelerator Faculty

Lisa Benson,
BS, CCRP, CRCP
Connecticut Children’s Medical Center Program Chairperson

Susan Devine, CCRP
Royal Vitória Regional Health Centre Research Manager

The conference featured information and discussion regarding the administration of clinical trials according to FDA Regulations and International Conference on Harmonisation (ICH) regarding vulnerable populations.

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

Drug Development and 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 continually 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 1 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 2 is the Medical / Scientific Module consisting of sessions pertaining to: Ethical Issues in Clinical Trials, Anatomy and Physiology, Cell Biology, Genetics, Clinical Laboratory Analysis, Epidemiology, and Research Statistics.

Faculty from esteemed institutions lead this program.
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 2014, SOCRA chapters held 196 meetings throughout the U.S.A., Canada, Brazil, and Saudi Arabia. These meetings offered 238 CE to over 3,900 attendees. SOCRA’s chapter program continues to grow, with over 55 chapters actively engaging their local clinical research community.

**SOCRA encourages the development of local chapters to provide a cost free forum under which members can learn, exchange information, grow professionally in clinical research, acquire CE for SOCRA CCRP® recertification, and build strong foundations for successful clinical research outcomes.**

**Chapter Chairperson Special Recognition**

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 to local clinical research professionals. This award also 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 2014 recipient.
SOCRA BOARD OF DIRECTORS
2014-2015

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.
Directors

Quincy J. Byrdsong, EdD, CIM, CIP, CCRP
Associate VP for Health Sciences
Strategic Initiatives & Engagement
Virginia Commonwealth University
Richmond, VA USA

Maribelle Guloy, MSHS, CCRP
Clinical Trials Director
Clinical Trials and Research Associates, Inc.
Montebello, CA USA

Jamie Harper, MHA, CCRP
Director of Clinical Research
Illinois CancerCare
Peoria, IL USA

Angela Rock, MBA, CCRP
Senior Manager, Clinical Research Associate Group
BIOTRONIK
Lake Oswego, OR USA

Susanna K. Sellmann, BSc, MRT, CCRP
Quality Assurance, Cancer Clinical Research Unit, Princess Margaret Cancer Centre
Toronto, ON CANADA

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Senior Director, Project Management, Covance
Princeton, NJ USA

Mariah Tackett, MSPH, CCRP
Clinical Director, Global Operations
St. Jude Medical Inc - Implantable Electronic Systems Division
Sylmar, CA USA

Lenore Jackson-Pope, RN, BSN, MSM, CCRP
Manager, Medical & Research Ed Massachusetts/ NH Chapter of The Alzheimer’s Association
Watertown, MA USA

John M. Furlong, RN, CCRP
Senior Field Clinical Research Associate
St. Jude Medical Inc
Sylmar, CA USA

Ruben Q. Rodarte, MBA, MS, CCRP
Program Director, ACAP Health Consulting
Richardson, TX USA

Directors Elect

Lori A. Wood, RN, BSN, CCRP, CPHN
Trauma Clinical Research Nurse Coordinator, Trauma Services, Scottsdale Healthcare Research Institute
Scottsdale, AZ USA

Sandhya Patel, BScN
Director, Research Quality Assurance, Centre for Addiction & Mental Health
Toronto, ON, Canada

Patricia Beers Block, BS, BS, CCRP
Adjunct Assistant Professor, Rutgers, The State University of New Jersey
Newark, NJ USA
The SOCRA management and administrative team has combined experience of more than 125 years in non-profit and association management.

Our management team additionally has 25 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 committee support and support for marketing and promotion activities.
The Society of Clinical Research Associates continues to pursue our mission to have positive clinical research outcomes and to protect the welfare of research participants. Our worldwide membership includes members from the U.S.A., Canada, Australia, Austria, Bangladesh, Belgium, Brazil, Bulgaria, Cayman Islands, Chile, China–SAR, Colombia, Denmark, Egypt, France, Germany, Greece, Hong Kong, Hungary, India, Italy, Jamaica, Japan, Jordan, Lebanon, Lithuania, Malaysia, Mexico, Netherlands, Nigeria, Peru, Philippines, Qatar, Russia, Saudi Arabia, Scotland, Singapore, South Africa, South Korea, Spain, Switzerland, Taiwan, Thailand, Turkey, UAE, and United Kingdom. We are presently holding educational programs in the U.S.A. and Canada, while our on–line courses are available everywhere.

Our mission is addressed through education and certification of clinical research professionals. Our programming is intended to increase the sense of community among clinical researchers while offering opportunity for collaboration and professional growth. We strive to have our members be successful in their research activities, and that they are aware of and pursue the assurance that research subjects are fully informed and properly cared for at all times.

SOCRA stakeholders include our 16,000 members and 11,000 certificants (Certified Clinical Research Professionals, CCRP®). Additionally, we include research subjects and patients; academia, government, and industry; and all who are associated in the development of products and services for the betterment of health care, as our extended family of stakeholders. We hope to positively impact all of our stakeholders through a culture of excellence in clinical research. Our emphasis on Good Clinical (Research) Practices, quality research outcomes, and safety for the research subject, has surely contributed to a more professional and productive research environment.

The designation “Certified Clinical Research Professional (CCRP®)” is available to researchers working under Good Clinical Practice (GCP) regulations and international guidance pertaining to clinical research, who meet certain eligibility requirements that are stipulated in the certification section of this annual report.

Chapter education programs are designed to allow our certified members (CCRP®) to accrue required continuing education for re–certification at no cost. SOCRA members receive attendance certificates while others are welcome to attend.

SOCRA has developed a culture through which we have implemented policies and procedures and a value system that elicit integrity from all who are involved in our leadership and from faculty and staff involved in our education and certification programs. Our members and stakeholders can trust that content is valid, professionally developed, and delivered with utmost care and attention.

As an accredited provider of continuing nurse education (CNE) and continuing education for physicians (CME), SOCRA holds to the highest standards for identification of needs, determination of educational objectives, selection and presentation of content, and for the selection of education delivery methods. As a result of our programming, the greater reward granted to our Board, faculty, staff and members is knowing that activities in research are addressed by competent and disciplined clinical research professionals.

Thank you for your interest in SOCRA.
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<thead>
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<th>Year</th>
<th>Month</th>
<th>Date</th>
<th>Location</th>
<th>Event</th>
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<tr>
<td>2015</td>
<td>October</td>
<td>8 and 9</td>
<td>Philadelphia, PA</td>
<td>Clinical Research Monitoring and GCP</td>
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<td></td>
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<td>19 to 23</td>
<td>Scottsdale, AZ</td>
<td>Drug Development and Clinical Science Course Regulatory/Procedural AND Scientific/Medical</td>
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<td>22 and 23</td>
<td>Scottsdale, AZ</td>
<td>Clinical Research Project / Program Management</td>
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<td>November</td>
<td>4 and 5</td>
<td>Boston, MA</td>
<td>FDA Clinical Trial Requirements</td>
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<td>12 and 13</td>
<td>Lake Buena</td>
<td>Clinical Site Coordinator / Manager - GCP</td>
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<td>December</td>
<td>3 and 4</td>
<td>Kansas City, KS</td>
<td>Certification Preparation and Review Course</td>
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<td>10 and 11</td>
<td>Las Vegas, NV</td>
<td>Advanced Site Finance and Productivity</td>
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<td>2016</td>
<td>January</td>
<td>15</td>
<td>Hackensack, NJ</td>
<td>Clinical Research Professional Certification Prep and GCP Review Course</td>
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<td>21 and 22</td>
<td>San Diego, CA</td>
<td>Clinical Site Coordinator / Manager - GCP</td>
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<td>February</td>
<td>11 and 12</td>
<td>Lake Buena Vista, FL</td>
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<td>Lake Buena Vista, FL</td>
<td>Quality Improvement through Standard Operating Procedures (SOPs)</td>
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<td>Lake Buena Vista, FL</td>
<td>Certification Preparation and Review Course</td>
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<td>25 and 26</td>
<td>New Orleans, LA</td>
<td>Pediatric Clinical Trials Conference</td>
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<td>March</td>
<td>9 and 10</td>
<td>San Diego, CA</td>
<td>FDA Clinical Trial Requirements</td>
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<td>14 to 18</td>
<td>Philadelphia, PA</td>
<td>Drug Development &amp; Clinical Science Course</td>
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<td>31 and April 1</td>
<td>Miami, FL</td>
<td>Oncology Research Conference</td>
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<td>April</td>
<td>7 and 8</td>
<td>Chicago, IL</td>
<td>Drug Conference</td>
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<td>Jersey City, NJ</td>
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<td>28 and 29</td>
<td>Toronto, CA</td>
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<td>May</td>
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<td>June</td>
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<td>San Francisco, CA</td>
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<td>July</td>
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<td>Denver, CO</td>
<td>Harnessing Social Media to Advance Clinical Research</td>
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<td>San Francisco, CA</td>
<td>Drug Development &amp; Clinical Science Course</td>
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<td>September</td>
<td>29 to October 2</td>
<td>Montreal, QC Canada</td>
<td>Annual Conference (and preconference workshops)</td>
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<td>October</td>
<td>13 and 14</td>
<td>Chicago, IL</td>
<td>Clinical Research Program/Project Management</td>
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<td>24 to 28</td>
<td>Chapel Hill, NC</td>
<td>Drug Development &amp; Clinical Science Course</td>
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