SOCRA CERTIFICATION AND MEMBERSHIP

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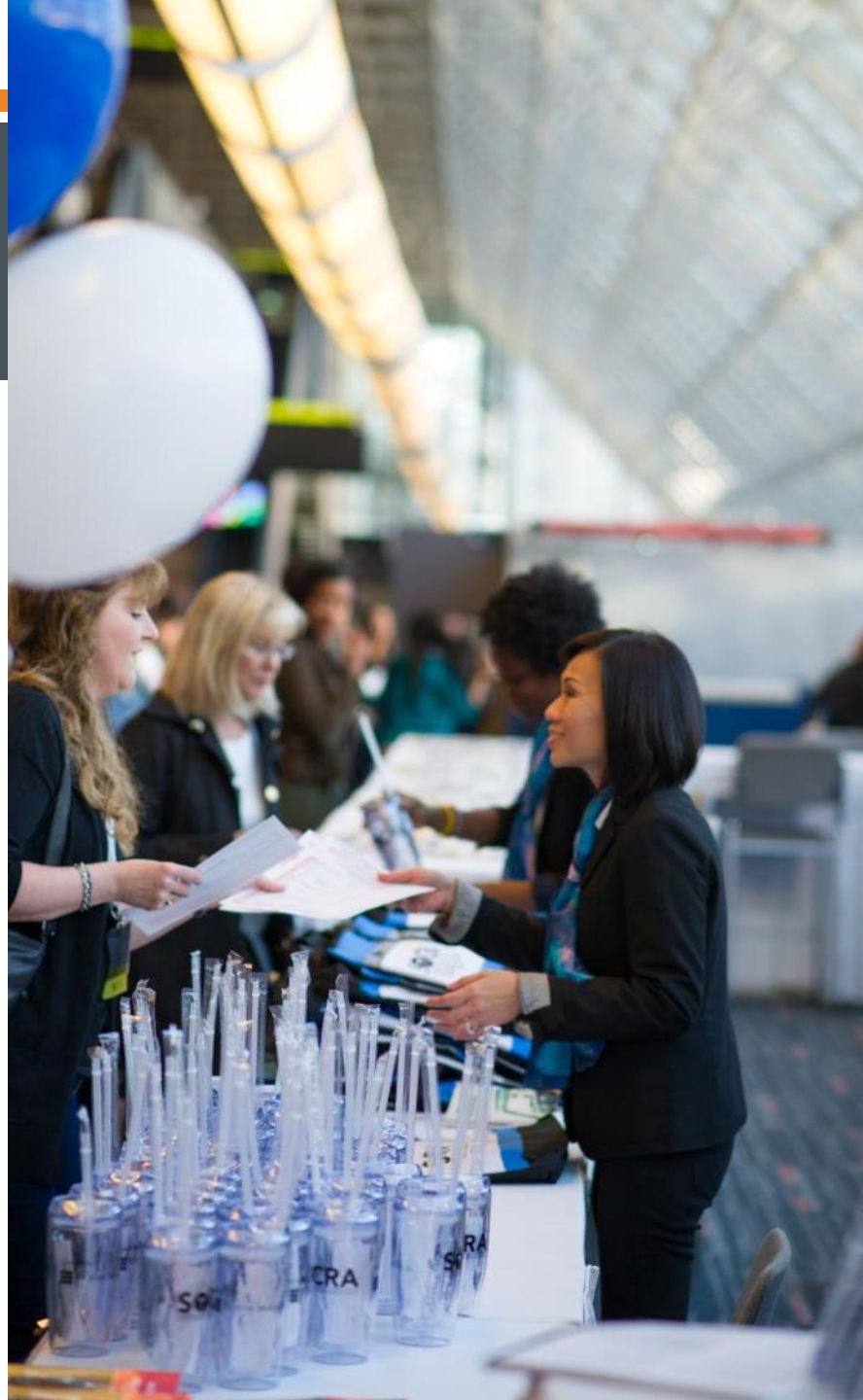
SOCRA MISSION

- 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



SOCRA HISTORY AND GROWTH

- **1991** SOCRA Founded
- **1992** First Annual Conference
- **1995** First Clinical Science Course
  First CCRP Certification Examination
- **1996** Chapter Program Began
- **1999** First Human Research Protections Program
  First Clinical Investigator Conference
- **2000** First Clinical Research Monitoring Workshop
  First Certification Preparation & Review Course
- **2002** Awarded ANA/ANCC providership for Nurse CNE
- **2003** First Site Symposium - Coordinators, Associates, Nurses
  First FDA Co-Sponsored Regulations Conference
- **2005** SOP Development and Implementation Workshop
  Salary Survey for Clinical Researchers Published
- **2006** First Device Research Conference
- **2007** Pre-Application Approval by ACCME
- **2008** Offer online Basic GCP and Research Protections at No Cost to SOCRA Members through CITI Program
- **2009** Annual Conference Workshop on Device Research
- **2010** Project / Program Management Conference
  Published Second Salary Survey
- **2011** First Online Training Courses Offered
- **2012** Completed and Published Job and Task Survey of Clinical Research Activities
  Instituted Option for Peer Review of SOCRA Source Journal Articles
- **2013** First Conducting Clinical Trials in Canada Conference
- **2014** First Pediatric Clinical Research Conference
- **2015** First Oncology Clinical Trials Conference
- **2016** Offer Risk Based Monitoring & GCP E6 (R2) for Online Education
- **2017** Computer-Based Testing Launched
- **2018** First Emergency Clinical Research Symposium
- **2019** First Clinical Research Nursing Conference
- **2020** Now offering of At-Home Testing
  Launch of Live Webinars

SOCRA MEMBERSHIP

15,200+ Members (January 2022)

Global Membership Represented in 57 Countries

- **Investigational Sites - 60%**
- **Industry - 30%**
- **IRB / Ethics Boards - 5%**
- **Other Areas of Research - 5%**

SOCRA MEMBERSHIP

SOCRA membership is available to all clinical research professionals who work with cooperative research groups, academic, government, and private institutions, pharmaceutical and biotechnology companies, device manufacturers, CROs, SMOs, independent research and development organizations, and those who are involved in the management or conduct of clinical trials.

MEMBERSHIP BENEFITS

- **High Quality Professional Education** - SOCRA membership offers discounted conference, workshop and course registrations. SOCRA education offers CNE and CME, as well as SOCRA CE credit. In addition, SOCRA members enjoy CITI program access and stimulating cost-free chapter events.
- **Member Directory** - More than 15,000 Clinical Research Professionals in your global network. Keep in touch with peers through the Member Directory and find members who specialize in your areas of interest.
- **Chapter Network** - Access to local education and networking opportunities through Chapters. All SOCRA members are automatically included in SOCRA's vast local chapter network for continuing education and numerous networking opportunities.
- **Members Stay Connected** - The SOCRA Source quarterly journal, monthly email newsletters, and periodic email alerts, keep members informed about topics related to clinical research.
- **Leadership Opportunities - Get involved in a local chapter, speak at a conference, and present a poster during the Annual Conference.**
- **CME for Physicians**: SOCRA is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.
- **CNE for Nurses**: SOCRA is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation.
- 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. Recognized programs include:
  - "CCRP" SOCRA Certified Clinical Research Professional
  - Certification Preparation & GCP Review Course
  - Clinical Site Coordinator/ Manager Workshop
  - Conducting Clinical Trials in Canada conference
  - Clinical Investigator GCP & Trials Management
  - Conference For Clinical Investigators and Key Research Staff

LEADERSHIP

- Present at a SOCRA event
- Join a Chapter / lead a Chapter
- Submit a journal article
- Apply as an Annual Conference poster presenter
- Get involved with a program / develop a program

Members who are involved can be considered for Board of Directors nomination.

EDUCATION

- All SOCRA education offers CNE and CME, as well as SOCRA CE credit.
- They currently offer 17 **live courses** across the U.S. and Canada plus 12 **online courses** you can access anytime through the website (www.socra.org).
- They are also excited for our new **live webinar series**!
- SOCRA membership offers discounted conference, workshop and course registrations.
- In addition, SOCRA members enjoy **CITI program** access.

SOCRA EDUCATIONAL OPPORTUNITIES

Live Workshops and Conferences

- Clinical Science Course
- Site Management
- Clinical Research Monitoring
- Clinical Investigator & Key Staff
- Site Finance and Budgeting
- SOP Development
- Project / Program Management
- Certification Prep & GCP Review
- Clinical Research Nursing
- Annual Conference
- Device Research Regulations
- FDA Clinical Trial Requirements
- Emergency Clinical Research
- Human Research Protections & Legal Issues
- Clinical Trial Management Systems (CTMS)
- Conducting Clinical Research in Canada
- Pediatric Clinical Research
- Oncology Clinical Research
- Clinical Research Nursing

15th Annual SOCRA Medical Device Conference

April 28-29, 2022 – Main Program
April 27, 2022 – Optional Pre-conference Half-day Device Basics Workshop
Embassy Suites by Hilton Savannah, Savannah, GA
AGENDA

Main Program

Day 1 Presentations:

Keynote: Direct Sponsor Involvement in Clinical Trial Recruitment and Other Trial Activities
The Ethics and Regulations of Medical Device Research: Treating a Patient or Experimenting on a Research Subject?
Medical Device Event Reporting
Lessons Learned: De Novo Classification Pathway
FDA's Digital Health Centers of Excellence Program (DHCoE) – Overview of Resources
Speaker Panel

Day 2 Presentations:

Keynote: Improving Regulatory Processes through Collaboration
Utilization of Real World Evidence in Cardiac Lead Post-Approval Studies
Product Development Process Informs Clinical Trial Design
Medical Device Industry Trends – 2022 and Beyond
Cultural Considerations in Global Clinical Trials Management
Speaker Panel

SOCRA EDUCATIONAL OPPORTUNITIES

Online Educational Programs

- Part I + II: Informed Consent for Research
- A Primer on Clinical Research
- Sponsor Responsibilities
- Institutional Review Boards (IRB)
- IND/IDE Assistance
- cGMP for INDs in Phase I Trials
- Preparation for FDA Inspections
- Risk Based Monitoring
- GCP E6 (R2) Updates
- Bedside Nursing: Want to Write a Research Protocol? What to Consider, Where to Start & How to Create a Protocol Draft
- Bedside Nursing: The Journey from Point A to Point B: How to get from Clinical Inquiry to Conducting Nursing Research

Free for Members

SOCRA EDUCATION OFFERS CME AND CNE

SOCRA is an Accredited Provider of:

Continuing Medical Education (CME) by ACCME

Continuing Nurse Education (CNE) by ANCC

CERTIFICATION

12,000 CCRPs (as of January 2022)

SOCRA established the Certified Clinical Research Professional 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.

SOCRA developed the program to evaluate a CRP's knowledge, understanding, and application of the conduct of clinical investigations involving humans in accordance with the International Conference for Harmonisation Guideline for Good Clinical Practice E6(R2) (ICH/GCP), ICH Clinical Safety Data Management: Definitions and Standards for Expedited Reporting (E2A), the United States Code of Federal Regulations (CFR) 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 CONTENT AREAS

Major Content Area	Brief Description	Approximate % of Exam
Research Study Start-Up	Regulatory Requirements of IRB/IEC, sponsors and investigators related duties/task related to study start up	40
Research Study Implementation	Regulatory Requirements of IRB/IEC, sponsors and investigators related duties/task related to conduct of the study	45
Research Study Closure	Regulatory Requirements of IRB/IEC, sponsors and investigators related duties/task related to study close out and record maintenance	15

The applicant must work under Good Clinical Practice (GCP) guidelines, and with IRB/IEC/REB-approved (or Specifically exempted) protocols. Documented experience must fall within one of the three following categories:

Eligibility Categories

1. 2 year of full-time experience* as a Clinical Research Professional within the past five years
   **equal to 3500 part-time hours*
2. 1 year of full-time experience* as a Clinical Research Professional within the past two years
   **equal to 1750 part-time hours*
   \+ Degree in "Clinical Research" from an Associate, Undergraduate or Graduate Degree Program*
3. 1 year of full-time experience* as a Clinical Research Professional within the past two years
   **equal to 1750 part-time hours*
   \+ Undergraduate or Graduate Certificate in "Clinical Research"
   \+ Associate or Bachelor Degree in a science, health science, pharmacy or related field

EXAM ELIGIBILITY

EXAM FLEXIBILITY

Evolving to meet the changing needs of the clinical research professional

Paper and Pencil

- SOCRA hosts in person exams in paper and pencil format
- SOCRA makes it easy to bring the CCRP exam to your location for your personnel

Computer Based Testing

- Now offered at Prometric Testing Centers or via At Home Testing
- Offers the convenience of anytime, anywhere CCRP certification exam testing
- Test when you want and where you want at home or any of over 600 exam locations (including internationally)

Host an Exam at Your Site (15 minimum attendees):
https://www.socra.org/certification/ccrp-certification-exam/host-an-exam-at-your-site/

CERTIFICATION COST

CCRP® Exam Fees:

Current Members: $395* Non-Members: $450*

Computer Based Testing (Testing Center or Home Proctoring): additional $115 (North America - USA, Canada, Mexico), Additional $175 countries outside North America

Retest fee within one year of original test date: Paper & pencil $200*, CBT $275*

Payment Options:

Option 1: Payment in Full *

Current Members: $395 Non - Members: $450

Option 2: Three Year Installment Plan

Current Members: $250 initial payment / $100 in years 2 & 3 (Total $450) *

Non - Members: $300 initial payment / $100 in years 2 & 3 (Total $500)**

*Includes three years complimentary SOCRA membership upon successful completion of the exam.

**Includes complimentary SOCRA membership upon successful completion of the exam.

SOCRA Certification period is 3 years

Installment payment structure created to help assist with payments.

RECERTIFICATION

- The **SOCRA CCRP Recertification Program** is dedicated to proving recognition and validation of the professional growth of the individual CCRP to the healthcare community
- Certification period is **3 years**
- Certificants must have completed 45 hours (45 credits) of CE during their certification period. A minimum of 22 CE must be related to Clinical Research regulations, policy, etc. The remaining CE may relate to your Therapeutic or Professional Area.

SOCRA offers members numerous opportunities for no-cost continuing education

ANNUAL CONFERENCE

September 16 - 18, 2022

Future Annual Conference Dates:

Montreal, QC | Sept. 29 - Oct. 1, 2023

Las Vegas, NV | September 26 - 29, 2024

Chicago, IL | September 25 - 28, 2025

100+ Speakers, 8 Tracks, 14 Preconference Workshops

SOCRA: Quality Education | Peer Recognition | Professional Certification

SOCRA CHAPTERS

Local, No Cost CE Opportunities

The purpose of the SOCRA chapter program is to provide a cost free forum under which members can learn, exchange information, grow professionally in clinical research, acquire CE for SOCRA CCRP re-certification, and build strong foundations for successful clinical research outcomes.
SOCRA currently has over 50 active chapters through out the world holding local meetings for local members.

- All Volunteer
- No Dues, Recordkeeping, or Fees

Start a chapter near you!

NYS SOCRA CHAPTER

- You don't need to be a SOCRA member to attend Chapter events
- Chapter programs currently are virtual – we are going back to in-person at the Welch Allyn Lodge, October 14
- Seeking speakers for Spring Virtual Program & Oct. 14 program
- Attendees can gain SOCRA Certification (SOCRA members) or a General Certificate of Attendance (you can't receive credit for recorded sessions)
- I maintain a listserv to send out event announcements, share job postings – if you'd like to receive announcements or have a job you would like posted: durdonk@upstate.edu

INNOVATION THROUGH LAW:
IMPORTANCE OF EARLY STAGE RESEARCH
THURSDAY, JULY 21, 2022, 2:00 – 3:30 P.M. EST

The **Innovation Law Center** (ILC) provides legal research, education, and information useful to assessing the commercialization prospects for new technology. The research is also useful when bringing new technologies from an early stage to investment ready. When it comes to commercializing new technology, knowing what you don't know is half the battle. The ILC provides entrepreneurs and companies research important to identifying potential challenges and devise effective strategies to successfully bring that technology to market. Research includes prior art searches, market and competitor analysis, and regulatory landscapes. The ILC has helped hundreds of companies and institutions make their technology vision become a commercial reality.

Register in advance for this meeting:
https://upstate.zoom.us/meeting/register/tJwrd-GurDwpHNEGrxBdN1_bO2z2HBMEDz29

The Society of Clinical Research Associates (SOCRA - www.SOCRA.org) accepts documentation of candidate participation in continuing education programs for re-certification if the program is applicable to clinical research regulations, operations or management, or to the candidate's clinical research therapeutic area.
This program will provide 1.5 hours of continuing education hours.
When registering, note Certificate of Attendance Need (General or SOCRA).

The Society of Clinical Research Associates

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CONTACT

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