Clinical Trials Overview Position Description

This hands-on intensive training is designed for professionals seeking to develop expertise in managing and overseeing clinical trials. The program focuses on practical applications and decision-making processes critical to the success of clinical trials and is ideal for professionals with direct involvement in trial operations.

Topics will include an introduction to clinical trials and the regulatory framework, the fundamentals of clinical trial design, sponsorship, and protocols, as well as strategies for managing contracts, budgets, and financial assessments. Participants will also explore patient recruitment and retention strategies, data management and quality assurance practices, and case studies highlighting common challenges and lessons learned. Within these topics, we will address key considerations such as ethical guidelines, regulatory compliance, and effective communication across stakeholders.

This 12-hour training program is delivered over six 2-hour online cohort sessions. Speakers will lead discussions using pre-developed materials, presenting key concepts, sharing real-world examples, and guiding participants through case studies or other targeted activities.

Minimum Instructor Criteria

- Relevant Experience: Minimum of 10 years of hands-on experience managing, running, or overseeing clinical trials. Candidates must be no more than two levels removed from direct trial operations, ensuring a strong connection to the practical aspects of clinical trials. Study coordinators, compliance professionals, and those specializing in contracts or budgeting related to clinical trials are highly encouraged to apply.
- Speaking Expertise: Previous speaking experience is required, with a preference for those experienced in virtual and/or workshop-style courses.
- Practical Insights: Ability to share real-world examples and actionable insights based on direct involvement in clinical trial operations.
- Professional Support: A letter of support from the nominee's supervisor is required.
- Collaboration: Willingness to collaborate with other instructors, as the program typically includes multiple speakers working together to deliver a cohesive and engaging cohort experience.

- Passion for Mentorship: A demonstrated passion for educating and mentoring individuals in the clinical trials field, with a focus on fostering practical skills and understanding.

Additional Instructor Experience

- Clinical Trials Operations
- Regulatory Guidelines and Compliance (including Human Subject Compliance/IRB)
- Study Design and Protocol Development
- Budget Development
- Contract/Agreement Negotiation
- Study Start-up
- Patient Recruitment and Retention
- Data Management and Study Monitoring
- Study Closeout and Regulatory Submissions, including Clinical Trial Registration

Time Commitment

Instructors are rotated and assigned to cohorts at the beginning of each year, typically instructors are assigned to a minimum of one cohort. When serving as an instructor of a cohort, plan to commit the following:

- Instruction time during the live online meeting.
- 4-7 hours preparing for the meeting (i.e., plan with other instructor, practice meeting logistics, improve instructional design to personalize your meeting).
- 0.5 hours facilitating discussions in Connect.

This is a three-year appointment, renewed upon mutually by the SRAI Education and Professional Development Committee.