

Clinical Research Associate (CRA)

Job Title(s): Clinical Research Associate, Clinical Research Associate I

Department: Clinical Operations

Organization Type: Contract Research Organization (CRO)-based

Status/Salary: Exempt and Salaried (Range \$58,000–\$89,000)



SUMMARY OF ROLE The Clinical Research Associate is responsible for assigned aspects of clinical monitoring and site management in accordance with applicable Standard Operating Procedures (SOPs) and the International Conference on Harmonisation's (ICH) guidelines for Good Clinical Practice (GCP). Site visits are conducted to assess protocol and regulatory compliance, data reliability, and the proper care and treatment of test subjects. The Clinical Research Associate represents the organization in a professional and collegial manner.



ESSENTIAL DUTIES

- Ensure compliance with standard protocol and regulatory and ICH GCP obligations in assigned aspects of clinical site monitoring, such as site initiation, routine monitoring, maintenance of study files, study close out, and retrieval of study materials
- Complete on-site and remote monitoring activities in compliance with the Clinical Monitoring Plan, including source document verification, as required
- Ensure the integrity of data and that the study is conducted in compliance with approved protocol, GCP, applicable regulations, and internal SOPs
- Perform key risk assessment and management responsibilities throughout the project, including key risk indicator and site health analysis, site process evaluation, and project escalation
- Participate in audit preparation and follow-up activities, as needed
- Verify the protection of study participants by informed consent procedures and protocol requirements that follow appropriate regulations
- Verify proper management and accountability of Investigational Product
- Write and submit reports of investigational site findings and update applicable tracking systems, as required; escalate observed deficiencies and issues as appropriate
- Manage essential documents as required by local regulations and ICH GCP before, during, and after a clinical study; assist with resolution of investigational site/data queries



KNOWLEDGE, SKILLS and ABILITIES

- General knowledge of regulatory requirements & GCP
- Ability to multi-task and deal with shifting priorities
- High proficiency with full Microsoft applications
- Strong spoken and written communication skills; fluency in English
- Strong interpersonal, collaborative, and time management abilities
- Excellent organizational skills; accurate and detail-oriented



EDUCATION and EXPERIENCE

- Bachelor's degree in a life science-related field, a registered nurse (RN) certification, or equivalent
- 2 years' experience in a clinical trials research environment required
- Valid driver's license required



TRAVEL and PHYSICAL REQUIREMENTS

- Travel can range from 60% to 85%

CAREER PATHWAYS

Foundational role that leads to many others within CRO industry, including:

- ▶ Clinical research associate 2 ▶ senior/principal clinical research associate
- ▶ Clinical trial/team lead/manager (CTM); project management
- ▶ Quality control/quality analytics (QC/QA)
- ▶ Data analytics, data management, safety