In-House Clinical Research Associate

CLINICAL Research Professionals

Job Title(s): Remote Site Manager, In-house Clinical Research Associate, Central Monitoring Associate
Department: Clinical Operations
Organization Type: Contract Research Organization (CRO)-based
Status/Salary: Exempt and Salaried (Range $42,000–$65,000)

SUMMARY OF ROLE The In-house Clinical Research Associate is responsible for the assigned aspects of clinical monitoring and site management that can be accomplished remotely in accordance with applicable Standard Operating Procedures (SOPs) and the International Conference on Harmonisation's (ICH) guidelines for Good Clinical Practice (GCP).

ESSENTIAL DUTIES

- Liaise with management staff to ensure compliance with standard protocol and regulatory and ICH GCP obligations in assigned aspects of clinical site monitoring
- Collect documents, review data points/findings from electronic data capture (EDC) and file review
- Review and appropriately escalate site key risk/performance/quality indicators; provide trial status reports to project management, as required
- Write, follow, and resolve clinical queries and issues
- Assist with investigator recruitment activities utilizing phone scripts, questionnaires, study site materials, and other tools for evaluating investigative sites
- Document site management contacts according to the monitoring plan
- Assist in ensuring audit ready files; contribute to company, client, and federal/local regulatory requirements/audit responses, as needed

KNOWLEDGE, SKILLS and ABILITIES

- General knowledge of regulatory requirements & GCP
- Ability to multi-task and deal with shifting priorities
- Data evaluation skills
- 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; highly accurate and detail-oriented

EDUCATION and EXPERIENCE

- Bachelor's degree in a life science-related field, a registered nurse (RN) certification, or equivalent
- 1+ year of experience in clinical research trial environment preferred

TRAVEL and PHYSICAL REQUIREMENTS

- Travel can range from 0 to 10%

CAREER PATHWAYS

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

- Clinical research associate pathway
- Data management
- Site start-up

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