



Sr./Clinical Research Associate

Reports to: Sr. Clinical Trial Manager

Classification: Exempt

Summary:

The in-house Sr./CRA will work closely with the Clinical Operations team in assisting with protocol feasibility, country assessment(s), site identification, patient recruitment, study monitoring, case report form development and study management. This position will interface with site coordinators, field clinical staff, Clinical Research Organizations (CRO), and other company representatives.

Essential Functions and Job Responsibilities:

- Participate in planning, prioritizing, and executing all aspects of Phase 1-4 clinical trials
- Participate in problem-solving and risk mitigation strategies
- Drafts and coordinates review of protocols, informed consents, case report forms and monitoring plans
- Interfaces with individuals in other functional areas to address routine study issues
- Ability to develop tools and processes that increase measured efficiencies of the project
- Assists in CRO or vendor selection
- Participate in departmental and corporate initiatives under general supervision
- Perform co-monitoring visits to provide oversight during site qualification, site initiation, routine monitoring and close-out visits, as required
- Review reports and metrics to ensure site compliance with the protocol and regulatory requirements
- Generate and maintain reports, listings, and trackers as needed
- Manage and QC eTMF(s) for supporting study(ies)
- Manage study vendors to ensure compliance with the protocol
- Complete other responsibilities as assigned

Minimum Qualifications:

- Bachelor's degree in life sciences or equivalent experience
- Minimum 3+ years of experience in a clinical research environment
- Site monitoring experience at clinical sites is preferred
- Working knowledge of GCP, ICH and relevant CFRs is required
- Ability to work independently and manage multiple projects with minimal supervision
- Strong communication skills, both written and oral
- Demonstrated problem solving skills, a strong sense of urgency, keen attention to detail, and the ability to plan, organize and successfully execute in an environment under time and resource pressures
- Ability and willingness to travel 10 – 20% (domestic and international) as necessary
- Enjoy working in a fast-paced, small-company environment