Job Title: Sr. CRA

Reports to: CPM or Associate Director/Director, Clinical Operations

Responsibilities:

- Independently manages the study start up activities for multi-center, US and/or global based studies.
- Responsible for the clinical site training and sites adherence to protocol, all applicable GCP/ICH guidelines, regulations statutes and SOPs.
- Independently creates project specific documents and tools e.g., Monitoring Guidelines, Meeting materials/study manuals, tracking spreadsheets/databases, training tools/materials, etc.
- Mentor and coach junior staff new to Clinical Research; CTAs
- Assists with the development of new studies, including protocol writing, informed consent development, CRFs, monitoring conventions, tracking forms, and other study related documents
- Authors or participates in the review and finalization of project specific plans (e.g. Clinical Monitoring Plan, Data Management Plan, TMF Plan, Vendor Management Plan)
- Perform site monitoring visits (feasibility, SIV, IMV, Close-Out) and site management activities to assess the sites ability to effectively and continuously conduct the trial per the protocol, GCP, and regulatory requirements.
- Support CPMs and cross-functional representatives as required in relationship management tasks (e.g. contracts, sample management, supplies, IP forecasting, etc.) and evaluating CRO performance
- Conduct co-monitoring activities to assure accurate and quality data from sites monitored by CRO
- Lead or participate in vendor management activities (e.g. Central Laboratory, IxRS, and PRO)

Other duties and assignments as required for the overall success of studies. Duties may change based on the current status of clinical programs and current company needs.

Skills:

Excellent verbal and written communication skills. Excellent organizational, record retention, time management, decision making, customer service, and interpersonal skills. Good command of written and spoken English language
Experience managing large clinical studies and working with CROs
Ability to travel domestically as required (up to 35%)

Education:

BS/BA, RN, or equivalent with at least 5 years clinical trial monitoring / clinical trial management and vendor management experience in accordance with CFR, GCP and ICH Guidelines, proficiency with Microsoft Office (Excel, Word, PPT, etc.)