Job Posting
Manager, Clinical Operations

Position Overview:
Responsible for oversight and management for Clinical Operations staff and studies, and as directed by Director or Vice President, Clinical Operations.

Primary Responsibilities and Essential Functions:
To perform this job successfully, incumbent must be able to satisfactorily perform the essential functions of the role without or with reasonable accommodations. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

- Manages clinical operations employee resources and employee resource projections to ensure that project teams meet client expectations and contractual obligations.
- Provide guidance, mentorship, training, and supervision to departmental personnel.
- Ensures audit preparedness of Clinical Operations employees, including training records, processes, and SOP compliance.
- Responsible for onboarding and training new employees.
- Participate in the hiring and interview process for the department.
- Participate in budget and new business activities by reviewing RFPs, assessing study strategies, and attending bid defense/capabilities presentations.
- Comply with the Quality Management System (Quality Manual, SOPs) and maintains all assigned controlled documents.
- Comply with applicable Good Clinical Practice (GCP) through training, processes and early issue, identification, and correction.
- Develops and tracks objectives and key performance indicators (KPIs) relating to clinical research studies.
- Responsible for performance metrics and management for their direct reports.
- Allocates departmental resources as appropriate.
- Oversees and supports clinical research study tasks and study activities.
- Strategize to identify, develop, and implements internal quality and/or process improvement initiatives.
- When needed, directly manage project/program, or work within the department.
- Participate in, and act as key contributor to initiatives and advancement of the organization.

  Note: This list is not intended to be an exhaustive list of duties and responsibilities. There may be other duties as assigned.

Qualifications Including Education, Experience, and Skills:

- Bachelor's Degree or equivalent experience defined as a minimum of 6 years related, combined experience in education, knowledge, and skills that will enable the incumbent to perform the tasks of the role proficiently.
- A minimum of 3 years direct clinical research experience including experience in managing and completing clinical trials from pre-study activities through study completion and data summarization. Phase II or Phase III experience is required. Experience in multiple therapeutic areas or disease state/indications desirable.
- Current knowledge of and the ability to apply ICH/GCP and all applicable regulations and guidelines
- Responsibility for cross-functional clinical program management required. Client management desired
- Must have demonstrated ability to independently execute a clinical study from study start through completion. Must have demonstrated experience in planning, managing and completing multiple or complex studies or equivalent experience. Proven track record of successful studies (delivered on time, within budget, and with high quality).
- Competent in application of standard business procedures (SOPs, Global Regulations, OEC, Outsourcing)
- Management of employees, mentoring, oversight providing issue escalation and resolution, oversight of project, team management
- Proven leadership skills with the ability to establish and maintain effective working relationships with executive management and coworkers
- Well organized and able to multi-task
- Positive attitude
- Able to drive a team to work both independently and as a team
- Able to give clear and concise directives. Professional, well spoken, articulate
- Must be available to perform up to 25% of overnight travel, as required

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