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Position: Clinical Trial Manager, Rare Disease

Reports to: Associate Director, Clinical Operations

Location: Waltham, MA

Description: The Clinical Trial Manager is accountable for the management of one or more clinical trials including trial start-up, conduct, and close-out activities. Will lead one or more Study Management Teams.

Job Responsibilities:

- Ensure trial adherence to ICH/GCP/local regulations.
- Develop study plan(s) including key milestones and timelines.
- Ensure country and site selection meet study requirements.
- Develop and manage clinical trial budgets.
- Ensure accuracy and timeliness of vendor and site payments.
- Vendor identification and management (e.g., CROs, IVRS, Reading Centers, etc); including participating in negotiation of vendor scope of work, budgets, performance management, issue resolution, and quality assessments.
- Ensure availability of clinical/non-clinical supplies.
- Provide input for clinical regulatory documents (IB, CSR, IND updates).
- Participate in development and testing of clinical systems (laboratory, data entry, IVRS, etc).
- Ensure internal and external systems are updated in a timely manner (CTMS, clinicaltrials.gov).
- Maintain and oversee the Trial Master File.
- Author/co-author protocols in collaboration with Medical Monitor and other stakeholders.
- Identify, address, and communicate quality and compliance concerns.
- Ensure inspection readiness internally and externally.
- Provides regular study status updates and as requested.
- Communicate effectively with internal and external study personnel (investigative staff, vendors, etc).
- Provide study-specific direction, mentoring, and management to other staff as appropriate.
- Manage direct reports as assigned.
- Other duties and responsibilities as required.

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Experience and Background:

- Bachelor's Degree required.
- Experience in rare disease preferable, but not essential.
- Experience assisting in clinical trials.
- Knowledge of GCP and ICH.
- Experience developing study plans and budgets including risk mitigation strategies.
- Experience in multiple phases of research preferred.
- Applicants must be authorized to work in the U.S.
- Excellent verbal and written communication skills.
- Experience in a start-up environment preferred.
- Must be pro-active team player, flexible, and open to change.