



## **Position: Project Manager**

### **Job Description**

The Project Manager (PM) leads the project team in development strategy design process and its execution for a clinical trial, optimizing metrics including risk, cost, quality, and time tradeoffs consistent with a sponsor's objectives. Monitors the project development process and ensures that key requirements and milestones are identified and met. Serves as the point-of-contact for cross-functional communication and tracking.

### **Responsibilities include:**

- Develops a broad knowledge of drug/device development trends.
- Leads project team in designing and executing development plan for a project.
- Leads project team in developing common mission, goals, commitment, and standards of behavior.
- Collaborates with sponsors to ensure that all relevant scientific issues and opportunities are addressed in project plan.
- Assures that the conduct of assigned clinical research studies are completed in accordance with relevant corporate SOPs, FDA and local regulations, and GCP/ICH guidance documents.
- Manages resource constraints, risks, and conflicts, which could impact the project timeline, quality, or budget. Develops and implements plans to minimize their impact.
- Manages cross functional groups to ensure effective communication, and on-time, on-budget completion of contracted tasks.
- Coordinates the management of all financial aspects of the clinical trial with other project team members, including budget expenditures and change orders.
- Reviews original budget tracker for compliance with scope of work and then maintaining the budget tracker on a monthly basis.
- Participates in proposal development and in investigator and sales presentations.
- Documents project team's activities accurately through minutes, plans, and recommendations.
- Manages the project team to complete all contracted tasks, including activities associated with third-party vendors and internal functional groups.

### **Education and Experience:**

- Medical degree and three years of experience in the management of clinical projects or equivalent education and experience.
- Demonstrated ability to manage budgets and personnel.
- Demonstrated ability to work successfully in a team environment requiring matrix management.
- Demonstrated ability to evaluate and critique scientific reports and literature relative to drug and device development.
- Knowledgeable of FDA regulations and requirements governing the conduct of clinical trials including GCP and ICH.
- Demonstrated ability to make effective presentations in public settings.
- Demonstrated ability to interact with clients on sensitive issues and handle concerns appropriately.
- Experience with team building and conflict resolution desirable.



- Good command of English language and communication skills..
- Demonstrated computer skills including MS Office and Internet usage.

**Reporting Requirements:**

The Project Manager reports directly to the General Manager.