Job Posting
Project Manager

Position Overview:
The Project Manager is responsible for oversight and management of in- home study visits.

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.

Essential Functions:

- Oversee and participate in clinical tasks and study activities.
- Ensure effective project plans are in place and operational for each trial and work proactively with the assigned team to set priorities in accordance with applicable project plans, company standard operational procedures (SOPs), ICH/GCP guidelines and regulatory requirements.
- Manage the activities relating to the identification, contracting, training, and management of in-home nursing agencies and their providers.
- Oversee inventory sourcing, tracking/coordination, and management of shipments.
- Establish and maintain Sponsor/CRO, Central Lab, and Agency communication.
- Organize and lead Sponsor/CRO, Central Lab, and Agency teleconferences.
- Develop and implement internal process improvement initiatives.
- Serve as the point of contact for Sponsor or Sites for any questions, issues, and escalations.
- Proactively manage project level operational aspects and deliverables including management of trial timeline, budget, resources and vendors.
- Ensure potential study risks and potential risk mitigating solutions are escalated to the attention of the VP, Clinical Operations when appropriate.
- Comply with the Quality Management System (Quality Manual, SOPs).
- Track objectives and key performance indicators (KPIs) relating to the Home Trial services.
- Provide guidance, mentorship, and direct management for Home Trial Coordinators that may be assigned to your project.

  Note: This 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 2 years of 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. Global experience strongly preferred. 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 a high level of core and technical competencies of a Sr. CRA or equivalent and demonstrated potential for leadership.
- 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.
- Well organized and able to multi-task.
- Positive and energetic 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.
- Extensive experience with Service Provider identification and training (as appropriate).
- Extensive experience with Country Coordinator training (as appropriate).
- Demonstrates leadership.

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