

Job Posting Manager, Study Start-up

Position Overview:

The Manager, Study Start-up is responsible for oversight and management of start-up for home trial studies. They understand study start-up function and processes and how the function integrates with other clinical operations functions.

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:

Managerial Responsibilities

- Comply with the Quality Management System (Quality Manual, SOPs).
- Track objectives and key performance indicators (KPIs) relating to study start-up activities within Home Trial Visit Services.
- Line management of staff within the study start-up functional area.

Project Responsibilities

- Oversee and participate in clinical tasks and study activities during the study start-up period.
- Assist with creation, review, and maintenance of essential study start-up documents, (Ex: study-specific forms, physician standing orders, training procedures, PowerPoint training presentations).
- Develop and /or approve the study specific strategic plan for study initiation for each trial according to sponsor contractual and internal timelines, milestones and team needs.
- Facilitate communication with Clinical Operations team during start-up phase and closely monitor activities to ensure the study start-up objectives are met.
- Capture and report study start-up performance metrics. Work with the contracts team on generation and execution of vendor contracts.
- Develop and manage internal team study trainings.
- Establish and maintain sponsor/CRO, central lab, and agency communication.
- Organize and lead sponsor/CRO, central lab, and agency teleconferences during study start-up.
- Develop and implement internal process improvements initiatives.
- Point of contact for Sponsor or sites for any questions, issues, and escalations during study start-up.

Non-essential Functions:

- Key contributor and participant 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 in Scientific, Life Science, Healthcare disciplines or related fields or equivalent defined as a minimum of 6 years related, combined experience in employment, education, knowledge, and skills that will enable the incumbent to proficiently perform the duties of the role.
- Minimum 2 years clinical research industry experience.
- Experience in full-cycle study start-up: planning, managing, and completing multiple or complex clinical trials from pre-study activities through study completion and data summarization is required. Global experience strongly desired.
- Experience in multiple therapeutic areas of diseases state/indications desired.
- Recent experience creating current knowledge of and ability to apply ICH/GCP and applicable regulations and guidelines.
- Experience working cross-functionally and with clinical program management strongly desired.
- 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.
- Highly organized with the ability to multi-task and produce deliverables on time, within budget, and inclusive of high quality.
- Able to create and sustain positive working relationships with stakeholders.

Firma is an Equal Opportunity Employer. Firma does not discriminate on the basis of race, religion, color, sex, gender identity, sexual orientation, age, non-disqualifying physical or mental disability, national origin, veteran status, or any other basis covered by appropriate law. All employment is decided on the basis of qualifications, merit, and business need.