Job Posting
Study Start Up Specialist

Position Overview:
The Study Start Up Specialist is responsible for supporting the study start-up phase for in-home studies.

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.

- Comply with the Quality Management System (e.g. Quality Manual, SOPs, role specific trainings).
- Participate in clinical trial tasks and study activities during the study start up period.
- Work with the Study Start Up Manager on developing study specific strategic plans according to sponsor contractual and internal timelines, milestones, and team needs.
- Assist Study Start Up Manager with activities relating to identification of suppliers, agencies, and vendors as applicable.
- Assist with and participate in sponsor kick-off meetings.
- Create, maintain/track, and obtain approval on essential study start up documents (e.g. study specific forms, physician standing orders, training procedures, PowerPoint training presentations).
- Adhere to start up timelines set forth by the Manager of Study Start Up.
- Attend and participate in internal and external calls, as well as develop agendas and circulate meeting minutes.
- Establish and maintain and deliver Sponsor/CRO, Central Lab/Supplier communication as well as actions, decisions, and issues.
- Develop and manage internal team study trainings in collaboration with Study Start Up Manager.
- Develop and implement internal process improvement initiatives as applicable.
- Point of contact for internal and external staff throughout the start-up process.

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:

- Associate Degree or equivalent experience defined as a minimum of 4 years related, combined experience in employment, education, knowledge, and skills that will enable the incumbent to perform the tasks of the role proficiently.
- Must have demonstrated a high-level of core and technical competencies as a Home Trial Coordinator (directly working in home health visits) or at least 2 years of clinical trial employment experience.
- Current knowledge of and the ability to apply ICH/GCP and all applicable regulations and guidelines.
- Client management experience desired.
- Must have demonstrated the ability to work independently and in a team environment. Must have demonstrated successful experience working with multiple or complex studies.
- Competent in application of standard business practices (SOPs, Global Regulations).
- Must be well organized, manage time accordingly and be able to manage multiple complex studies simultaneously.
- Positive and energetic attitude.
- Professional, well spoken, and articulate.
- Excellent written and verbal communication skills.
- Ability to perform other responsibilities as requested.
- Proficient computer skills including Word, Excel (Advanced), PowerPoint, Visio, and Adobe software.

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