Associate Director, Clinical Sciences

Job ID
REQ-10056204
Jun 26, 2025
India

Summary

Associate Director Clinical Sciences responsibilities include but are not limited to: Oversees the 6 clinical sciences resources & reports up to the Director, Clinical Sciences HYD. In addition, will have tactical responsibilities of assigned clinical research tasks related to IITs, RCs and NIS/LIS.

About the Role

Location – Hyderabad #LI Hybrid

Major Accountabilities:

Oversee the 6 clinical sciences resources & reporting to the Director, Clinical Sciences HYD.
In addition will perform clinical sciences tactical responsibilities:

- Accountable for the accuracy and timeliness of trial information in all trial databases and tracking systems. Facilitates MRC and SRC review of concepts.

- Interfaces with the disease area(s), global and US clinical team members, regulatory affairs, drug supply, data management, finance and other relevant functional areas- Preparation of trial related documentation, TMF maintenance: project files including ethics committee approvals; curricula vitae of investigators and study personnel; clinical investigators brochure; protocols; case report forms instructions; consent documents; clinical trial material shipping orders; start-up meeting attendance documentation; letters of agreement; lab reference ranges; all investigator and site correspondence; and schedules of payment.

Ensures key processes and documents are maintained/updated on time (e.g. TPSR, ICF Clinical Review, TMF)

- Ensures TPSR & Pubs Review

- Initiation of IND x-ref letter and IN & IB distribution

- Establishes charters for and support management of SC and EO

- Conducts Pre-RC alignment and Ensure EPRM and TPIAT completion for RCs (internal and external interface management)

- Responsible for the initial and subsequent drug supply across trials within a therapeutic area in collaboration with the Local Clinical Supply Manager.

- Contributes to the preparation and review of clinical program documents (PowerPoint presentations, IND annual report, regulatory documents, clinical study reports, (CSR) and submissions) and other study related documents assuring quality and consistency.

Supports the management and tracking of trial budgets including payments working closely with the appropriate partners

- Study close out execution, including financial reconciliation & creating closure letters

- Prepare for and support quarterly review meetings with TA teams

- Understands and comply with company SOPs and GCPs; contributes to continuous improvement in SOPs and local Working Practices.

- Any other clinical activities as assigned

Oversees execution of assigned clinical research activities, ensuring key processes are completed with consistency, quality and compliance

Liaison between US/MXC/HYD clinical sciences teams.

Minimum Requirements:

- Bachelor's degree in a science related field or a Registered Nursing certification or equivalent certification/licensure from an appropriately accredited institution.

Experience Required:

- Significant clinical research or research monitoring experience (comparable to 8 years) that provides the required knowledge, skills and abilities and experience mentoring or training others.
- In some cases, an equivalent combination of education, professional training, and experience that provides the required Knowledge, Skills and Abilities may be considered.

Technical Knowledge/Competencies:

- Excellent understanding and demonstrated application of FDA guidelines, Good Clinical Practices, and applicable Standard Operating Procedures.
- Ability to mentor and train other clinical associates in a positive and effective manner.
- Ability to evaluate medical research data and proficient knowledge of medical terminology.
- Effective oral and written communication skills, with the ability to communicate effectively with medical personnel.
- Strong customer focus, Excellent interpersonal skills & Strong attention to detail.
- Good computer skills: good knowledge of Microsoft Office and the ability to learn appropriate software.
- Effective presentation skills. Effective organizational and time management skills. Proven flexibility and adaptability. Excellent team player with team building skills. Ability to work independently as required
- Ability to utilize problem-solving techniques applicable to constantly changing environment

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