

Clinical Project Manager

Job ID
REQ-10034420
Dec 19, 2024
India

Summary

This role is responsible to Lead and manage a multidisciplinary cross functional Clinical Trial Team (CTT) (medical writing, statistics, data management, monitoring partner, drug supply, regulatory, safety etc.) or support the Sr. CPM (where applicable) in the effective planning, regular re-evaluation and implementation of assigned clinical studies and/or MAP//Research Collaborations/IIT/Digital Solutions programs according to Novartis Global processes ensuring adherence to timelines, budget, quality standards and operational procedures.

About the Role

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Location – Hyderabad #LI Hybrid

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Key Responsibilities:

- Agree with colleague/customer team and Line Functions on realistic project and study timelines. Escalate to higher level in the organization if no agreement can be achieved or support the Sr. CPM (where applicable).
- Lead and manage a multidisciplinary cross functional Clinical Trial Team (CTT) (medical writing, statistics, data management, monitoring partner, drug supply, regulatory, safety etc.) or support the Sr. CPM (where applicable) in the effective planning, regular re-evaluation and implementation of assigned clinical studies and/or MAP//Research Collaborations/IIT/Digital Solutions programs according to Novartis Global processes ensuring adherence to timelines, budget, quality standards and operational procedures.
- Might be required to support or lead other projects/program, in collaboration with cross-functional teams.
- Responsible for investigators meeting organization and all internal meetings related to the clinical study execution and operational excellence.
- As applicable, directly interact with investigator sites and CRAs/CROs/vendors to ensure smooth study set up and smooth study conduct, reviewing site performance, protocol deviations, ongoing risk assessment and

timely issue resolution in alignment with Novartis global standard with local regulation requirement.

- As applicable, support compilation of study regulatory documents for submissions to competent authorities and ethics-committees in collaboration with other associated CONEXTS, Novartis line functions and CRO Partners as required.
- Also, if needed support clinical studies with all onsite/remote monitoring activities and communications with investigators, investigational sites, clinical trial team, healthcare professional and other associated internal line-functions.
- As applicable, responsible for review of all site visit related reports and quality control of monitoring activities in timely manner.

Commitment to Diversity & Inclusion: :

We are committed to building an outstanding, inclusive work environment and diverse teams representative of the patients and communities we serve.

Essential Requirements

- Approximately 8 years' of Global Clinical Operations experience with managerial experience in designing, planning, executing, reporting and publishing clinical studies (interventional and non-interventional clinical studies, early to late phase) in a pharmaceutical company or contract research organization.
- Proven ability to work independently in a complex matrix environment (including remote), including leading cross-functional team.

Desirable Requirements:

- Solid project management skills. Thorough knowledge of Good Clinical Practice, clinical study design, statistics, regulatory processes, and global clinical development process.
- Demonstrated presentation and diplomacy skills. Negotiation and conflict resolution skills. Strong customer-oriented mindset. Ability to resolve issues with minimal supervision and understand when to escalate.

Willingness to act accountably in project/study management.

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Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: <https://www.novartis.com/careers/benefits-rewards>

Division

Operations

Business Unit

Innovative Medicines

Location

India

Site

Hyderabad (Office)

Company / Legal Entity

IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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manager

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