Global Clinical Operations - Clinical Project Manager

Job ID
REQ-10047640

Apr 07, 2025

China

Summary

临床试验研究、数据收集活动和临床操作的规划、执行和说明。
制定并批准临床协议、数据收集系统和最终报告的设计和实施科学方法。
支持新的和正在进行的临床研究和临床试验，确保有效、及时处理保密协议和临床协议。
监测协议的遵守情况并确定研究完成情况。
管理临床和监管文件，对分发至各研究中心的临床库存进行保管。
可能需要与研究中心、临床顾问、合同研究组织和其他供应商进行沟通。与国家/地区医学/临床同事、全球临床团队进行合作，对执行和交付指定研究的活动进行指导。选择、培养和评估人员，以确保职能的有效运作。

About the Role

Key responsibilities:

Study & Site Operations strategy

- Supports SSO Study Start-up Manager in the development of country/cluster/hub study execution plans and timeline commitments
- Participates in the recruitment sub-team and supports the development of innovative solutions for site and patient participation to ensure the delivery of assigned studies on time
- Proactively identifies risk and opportunities for the assigned studies within the country/cluster/hub and develops respective mitigation plans

Initiation and conduct of trials

- When requested by the SSO Feasibility Manager supports the study feasibility by providing input to the study protocol, and operational aspects of the study
- Maintains a strong knowledge of the study protocol to answer standard operational questions from CRAs, sites and Country/Cluster/Hub personnel
- Drives the conduct of the study, (tracks status, maintains relevant reporting systems, oversees forecasts, progress, and mitigation plans), to ensure all study operational aspects are on track
- Ensures recruitment targets are met and reviews enrolment at the site level including responsibility for getting approval from the STUDY LEADER on enrolling above site targets. Responsible to set up contingency plan to ensure recruitment targets are achieved in accordance with trial execution plan
- Oversees local study team activities to achieve study timelines and quality execution, (proposing and implementing corrective actions where appropriate), according to Novartis standards and relevant regulations
- Leads/chairs country/cluster/hub study team meetings, participates in global clinical trial team meetings, as required and is the single point of contact for the conduct of assigned studies
- Maintains oversight of country/cluster/hub level data management activities, including timely understanding of screen failure reasons and discontinuation rates, review of patient profiles, and proactively identifies data entry issues (on quality and timing) to mitigate queries, proactively identifies query resolution issues
- Coordinates the study handover process with CRAs and their managers to ensure proper documentation and communication, when necessary
- Tracks that all study close-out activities are performed in a timely manner, in collaboration with CRAs and key study stakeholders

Delivery of quality data and compliance to quality standards

- Conducts or coordinates training, as needed, for CRAs to support site readiness to recruit and study execution ensuring adherence to clinical data standards, prevailing legislation, GCP, Ethical Committee and SOP requirements
- Conducts or coordinates local investigator meetings as needed and ensures relevant documentation of training is archived in the Trial Master File
- Evaluates potential challenges/risks within the protocol and operational aspects of the study; assessing impacts, develops risk management plans and communicates/ escalates to global teams and SSO Hub Head Portfolio, as appropriate
- Accountable for monitoring quality and issue resolution through timely review and approval of study monitoring visit reports to ensure quality trial oversight and appropriate issue escalation
- Promotes a compliance culture advocating the adherence to highest standards and ethical integrity, ensuring human subject protection and reliability of trial results at all times
- Escalation point for issues in monitoring visit reports (MVRs) for the assigned studies. Responsible for evaluating trends identified in MVRs and communicating/escalating to global

teams, as appropriate. Communicates with CRAs and their managers to ensure issue resolution in a timely manner
- Provides feedback about the quality of monitoring activities to CRA Managers, MSOM, SSO Country Managers, FSP/BiS line managers (as propriate) and local QA (when required per Novartis SOPs)
- Supports inspection readiness and submission preparation for monitoring related activities and assists and coordinates with country Portfolio Execution and Quality Assurance for internal audits organization and HA inspections, as required, and ensures implementation of corrective actions within specified timelines
- Participates in multidisciplinary taskforces to support continuous improvement initiatives

Budget and productivity

- Monitors the status of site budget and contract negotiations as well as the collection and review of essential documents throughout study conduct
- Tracks study budget with appropriate study budget responsible in Country. Ensures timely TCF preparation and submission
- Processes invoiceable items for site level clinical study activities to allow timely payments

Essential requirements：

- A degree in scientific or health discipline required and advanced degree with clinical trial experience and/or project management, is preferable
- Fluent in both written and spoken English
- Minimum 5 years’ experience in clinical research in a role that oversees (project management) and/or with monitoring clinical trials
- Capable of leading in a matrix environment, without direct reports and working cross-border managing study in various countries
- Understanding of all aspects of clinical drug development with particular emphasis on monitoring and study execution

Desirable requirements：

- Strong project management capabilities with demonstrated ability to problem solve and mediate complex issues
- Thorough understanding of the international aspects of drug development process, including strong knowledge of international standards (GCP/ICH), health authorities (FDA/EMA), local/National Health Authorities regulations and Novartis standards

- Demonstrated negotiation and conflict resolution skills both internal and external (site relationships)
- Communicates effectively in a local/global matrixed environment

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部門
Development

部門
Innovative Medicines

国
China

勤務地
Shanghai (Shanghai)

Company / Legal Entity
CN14 (FCRS = CN014) China Novartis Institutes for BioMedical Research Co., Ltd.

Alternative Location 1
Beijing (Beijing), China

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