SSO Associate Clinical Project Manager

Job ID
REQ-10031371
nov 26, 2024
Japon

Résumé

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About the Role

Major Accountabilities
Study & Site Operations strategy
• Supports SSO Study Start-up Manager in the development of country 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 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 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 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 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 Country 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

Education:

• A degree in scientific or health discipline required and advanced degree with clinical trial experience and/or project management, is preferable

Languages:

• Fluent in both written and spoken English

Experience/Professional requirement:

• Minimum 3 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

Competencies:

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

Skills & Knowledge:

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

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Accessibility and Accommodation:

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