NOVARTIS

Clinical Project Manager

Job ID
REQ-10011982
Jun 26, 2024
Brazil

Summary

The SSO Clinical Project Manager (CPM) at Novartis is responsible for the daily management, oversight and reporting of Global Drug Development (GDD) studies, ensuring compliance and acting as the main point of contact within the country/cluster/hub for these studies. The CPM coordinates with various team members and managers to execute studies efficiently, adhering to schedules, budgets, quality standards, and regulatory requirements. Additionally, the CPM may contribute to the improvement of clinical trial processes and share knowledge for operational excellence.

About the Role

Major accountabilities:

- Study & Site Operations strategy: Support the SSO Study Start-up Manager in creating study execution plans, participate in the recruitment sub-team to develop innovative solutions for site and patient participation, and proactively manage risks and opportunities for timely delivery of studies.
- Initiation and conduct of trials: Support study feasibility, contribute to the protocol and operations, maintain protocol knowledge to assist CRAs and sites, and track study progress. Ensure recruitment targets are met, oversee the local study team for timely and quality execution, lead team meetings, maintain oversight of data management, coordinate study handovers, and complete study close-out on time
- Delivery of quality data and compliance to quality standards: Support site readiness and adherence to clinical standards, legislation, and SOPs. Identifies and manages study risks, ensuring quality oversight and issue resolution through monitoring visit report reviews. Advocates for compliance and ethical integrity, serving as an escalation point for monitoring issues and providing feedback on monitoring quality. Supports inspection readiness, audit coordination, and continuous improvement initiatives.
- Budget and productivity: Monitor the status of site budget, contract negotiations, and essential document collection and review. Track the study budget with the responsible party in the country to ensure timely Trial Confirmation Forms (TCF) preparation and submission.

Key performance indicators:

- Timely submission and delivery of high-quality clinical trial documentation/data;
- Performance against study commitments at the country/cluster/hub level, including delivery of studies per defined timelines (including study close out), number of patients and quality;
- Delivery of study milestones in adherence to prevailing legislation, GCP, Ethical Committee and SOP requirements.

Minimum Requirements:

Work Experience:

- 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

Skills:

- Project Management.
- Negotiation and Conflict Resolution Skills.
- Effective communication in matrixed and regional environment.
- Clinical Trials: including strong knowledge of international standards (GCP/ICH), health authorities (FDA/EMA), local/National Health Authorities regulations
- Process Improvement.

Languages :

- English.

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together? https://www.novartis.com/about/strategy/people-and-culture

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Innovative Medicines
Location
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Site
Santo Amaro
Company / Legal Entity
BR03 (FCRS = BR003) NOVARTIS BIOCIENCIAS S.A
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Clinical Project Manager

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