NOVARTIS

SSO Clinical Project Manager (Remote)

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REQ-10077604
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США

Сводка

The Study & Site Operations (SSO) Clinical Project Manager (CPM) is accountable for the day-to-day planning, executing and reporting, (from first site initiation visit to and including study site close-out), of assigned Global Drug Development (GDD) studies in compliance with Novartis processes and regulatory requirements.

The CPM is the single point of contact and study team lead within the country/cluster/hub for the assigned studies. The CPM is responsible for assuring aligned communication with Trial Lead and other CTT members, locally with Clinical Research Associates (CRAs), CRA Managers, and other key associates on the execution and progress of their studies. The CPM collaborates with the SSO Country Manager, SSO Country Head, SSO Feasibility Manager, SSO Study Start-up Manager and SSO Site Partnership Manager in the planning, execution, and delivery of their assigned studies. This role is accountable for execution and reporting of assigned GDD studies in end to end (E2E) product line Clinical Operations Program Head/Study Lead/ CPM – Clinical Research Associate (CRA). The SSO CPM be assigned partially to participate in the review process of Site Monitoring Plans across the Portfolio.

About the Role

Key Responsibilities:

- **Study & Site Operations strategy:** Supports SSO Study Start-up Managers 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:** 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 and site 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.
- **Portfolio Delivery**: Ensures recruitment targets are met and reviews enrollment 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, 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.
- **Delivery of quality data and Patient Engagement** 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.
- **Ensure 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 and Hub Head Portfolio, as appropriate.
- **Performance indicator management:** 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.
- **Study Team coordination**: Provides feedback about the quality of monitoring activities to CRA Managers, MSOM, SSO Country Managers, FSP/BiS line managers (as appropriate) 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

This position can be based remotely anywhere in the U.S. (there may be some restrictions based on legal entity). Please note that this role would not provide relocation as a result. The expectation of working hours and travel (domestic and/or international) will be defined by the hiring manager.

Essential Requirements:

- A minimum of a bachelor's degree in scientific or health discipline
- Fluent in both written and spoken English
- Minimum 5 years' experience in clinical research overseeing (project management) and/or monitoring clinical trials
- Capable of leading in a matrix environment, without direct reports and working cross-borders managing global studies in various countries
- Understanding of all aspects of clinical drug development with particular emphasis on monitoring and study execution
- 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 internally and externally (site relationships)
- Communicates effectively in a local/global matrixed environment

Preferred Requirements:

- An advanced degree with clinical trial experience and/or project management is preferable

The salary for this position is expected to range between $145,600 and $270,400 USD per year.

The final salary offered is determined based on factors like, but not limited to, relevant skills and experience, and upon joining Novartis will be reviewed periodically. Novartis may change the published salary range based on company and market factors.

Your compensation will include a performance-based cash incentive and, depending on the level of the role, eligibility to be considered for annual equity awards.

US-based eligible employees will receive a comprehensive benefits package that includes health, life and disability benefits, a 401(k) with company contribution and match, and a variety of other benefits. In addition, employees are eligible for a generous time off package including vacation, personal days, holidays and other leaves.

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

Benefits and Rewards: Learn about all the ways we'll help you thrive personally and professionally.
Read our handbook (PDF 30 MB)

EEO Statement:

The Novartis Group of Companies are Equal Opportunity Employers. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, sex, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status.

Accessibility & Reasonable Accommodations

The Novartis Group of Companies are committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the application process, or to perform the essential functions of a position, please send an e-mail to us.reasonableaccommodations@novartis.com or call +1(877)395-2339 and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

Дивизион
Development
Business Unit
Development
Место
США
Состояние
Remote, US
Сайт
Remote Position (USA)
Company / Legal Entity
U014 (FCRS = US014) Novartis Pharmaceuticals Corporation
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No

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