NOVARTIS

Senior Study Leader

Job ID
REQ-10042265
Mar 05, 2025
USA

Summary

Oversees all operational aspects of clinical trials end-to-end including the planning, execution, and interpretation of clinical trials research, data collection activities and clinical operations. Complete oversight of budget and resource allocation within assigned trial. Drives operational excellence through process improvement and knowledge sharing across trials within program/franchise. Enables an empowered organization that can navigate in a matrix environment and adjust quickly to business needs. Point of escalation for resolution of trial management operational issues within assigned trial.

About the Role

Key Responsibilities:

- Leads the clinical trial team with per needed-basis oversight from the Study Director-community Lead (SD-CL) and delivery of multiple medium to complex global studies and promotes learning, sharing, consistent performance, and operational excellence through an agile attitude, agile principles, and a team of teams' model
- Acts as the CTT product owner with duties and responsibilities per established ways of working
- Guides planning and decision making at the study level and delivers assigned clinical study/studies per the Operational Execution Plan (OEP) and clinical study protocol
- Fosters an agile culture within assigned studies to achieve sprint goals and cycles, enhancing collaboration and minimizing dependencies to achieve long-term business impact
- In collaboration with regulatory writing and clinical development, promotes operational excellence in the development of global clinical study protocol(s), by translating the approved study concept sheet(s) into efficient, high quality, executable clinical protocols, and study-related documents
- Create effective CTT dynamics and achieve on performance, prioritization, and communication in close collaboration with CTT sub-team leaders
- Proactive risk management and inspection readiness
- Responsible for developing clinical study timelines with per needed-basis oversight from the Study Director-community Lead (SD-CL) and being responsible for assigned study budgets
- Ensures systems are maintained with up-to-date study status, risks , and issues
- Fosters a close working relationship with SSO Clinical Project Managers (CPMS) to strengthen the relationship between the global and local teams

Key performance indicators:

- Excellence in execution and implementation of clinical operations strategy -Timely, efficient and quality execution of assigned trial and trial related activities within budget, and in compliance with quality standards.

- Proactive operational planning with effective contingency and risk mitigation plans.
- Cost effective management of budget and resources with limited unforeseen cost overruns.

Essential Requirements:

- Bachelors degree in Life Sciences/healthcare (or clinically relevant degree) is required. Advanced degree strongly preferred.
- 4+ yrs of recent involvement in clinical research or drug development in an academic or industry environment spanning clinical activities in Phases I through IV of standard to high complexity and priority
- 3+ years of recent contribution to and accomplishment in all aspects of conducting clinical studies of standard to high complexity and priority (e.g., planning, driving, reporting and publishing) in a global/matrix environment in pharmaceutical industry or a contract research organization, including expert knowledge of international standards (GCP/ICH), health authorities (FDA/EMA), local/National Health Authorities regulations and Novartis standards
- Experience in managing people globally in a complex matrix environment preferred
- Management of virtual teams. Proven ability and strong experience leading teams and building capabilities
- Experience in developing effective working relationships with internal and external partners.

The pay range for this position at commencement of employment is expected to be between $145,600 and $270,400 /year; however, while salary ranges are effective from 1/1/25 through 12/31/2025, fluctuations in the job market may necessitate adjustments to pay ranges during this period. Further, final pay determinations will depend on various factors, including, but not limited to geographical location, experience level, knowledge, skills and abilities. The total compensation package for this position may also include other elements, including a sign-on bonus, restricted stock units, and discretionary awards in addition to a full range of medical, financial, and/or other benefits (including 401(k) eligibility and various paid time off benefits, such as vacation, sick time, and parental leave), dependent on the position offered. Details of participation in these benefit plans will be provided if an employee receives an offer of employment. If hired, employee will be in an “at-will position” and the Company reserves the right to modify base salary (as well as any other discretionary payment or compensation program) at any time, including for reasons related to individual performance, Company or individual department/team performance, and market factors.

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

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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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EEO Statement:

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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.

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REQ-10042265

Senior Study Leader

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List of links present in page

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2. https://talentnetwork.novartis.com/network
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