NOVARTIS

Senior Study Leader

Job ID
REQ-10001236
Sep 03, 2024
USA

Summary

Responsible with per needed-basis oversight from the Study Director community Lead (SD-CL) for the execution and delivery of the GCO supported clinical studies of standard to medium complexity and priority per the Operational Execution Plan (OEP) and clinical study protocol.

The Senior Study Leader is the leader of the cross-functional clinical trial team (CTT), guides planning and management of the assigned clinical study/studies end-to-end to achieve Global Program Team (GPT), Global Clinical Team (GCT) and GCO objectives.
Accountable for proactive, iterative operational planning with effective contingencies and embedded risk management mindset in CTT. Be responsible for budget and people allocation within assigned study/studies.

Contribute in promoting operational excellence through process improvement and knowledge sharing across studies. Cultivate an empowered, psychologically safe organization that can navigate a matrix environment, learns, and adjusts quickly to changing conditions and business needs.

Your Key Responsibilities:
1. 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
2. Acts as the CTT product owner with duties and responsibilities per established ways of working
3. 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
4. Fosters an agile culture within assigned studies to achieve sprint goals and cycles, enhancing collaboration and minimizing dependencies to achieve long-term business impact
5. 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
6. Create effective CTT dynamics and achieve on performance, prioritization, and communication in close collaboration with CTT sub-team leaders
7. Proactive risk management and inspection readiness
8. 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
9. Ensures systems are maintained with up-to-date study status, risks , and issues
10. Fosters a close working relationship with SSO Clinical Project Managers (CPMS) to strengthen the relationship between the global and local teams

About the Role

• 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.

Why Novartis? Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-and-culture

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Commitment to Diversity and Inclusion: Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between $158,400-237,600/year; however, while salary ranges are effective from 1/1/24 through 12/31/24, 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.

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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.

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Employment Type
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