NOVARTIS

Senior Study Leader

Job ID
REQ-10052819
May 21, 2025
Japan

Summary

Accountable, 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 co-leads together with the Clinical Science Lead (CSL) 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. Oversee budget and people allocation within assigned study/studies.
Contribute in promoting operational excellence through process improvement and knowledge sharing across studies. Fosters an empowered, psychologically safe organization that can navigate a matrix environment, learns, and adjusts quickly to changing conditions and business needs.

About the Role

Please noted that there are cases to make an offer Study Leader(Clinical Trial Level 4).

・Study Lead is a role in Global Study Leadership organization. SLs execute clinical trials as CTT Co-Leaders in accordance with the Global SOPs.

・Within Japan Study Leadership(Japan Community), the majority of studies are Japan initiated trials based on the Japan development strategy, and most of trials are Japan standalone trials. Development phase and therapeutic area are varied (Ph1,2,3, PMCT, Oncology/Hematology, Immunology, Cardiovascular etc).

・The CTT members for Japan communities trials are mainly composed of Japan based team members. SL also closely communicate with Global member such as COPH, GCT and GPT same as multinational trials which manages by Global Study Leadership.

Accountabilities

1.Co-Leader of the Clinical Trial Team

- Co-leads the clinical trial team with the CSL with per needed-basis oversight from the Study Director-community Lead (SD-CL) and support from the Clinical Operations Program Head (COPH), delivery of multiple medium to complex global studies and promotes learning, sharing, consistent performance, and operational excellence through an agile mindset, agile principles, and a team of teams' model
- Acts as the CTT product owner with duties and responsibilities for delivery of operational strategy 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, maximizing 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 support from the Clinical Operations Program Head (COPH), and overseeing 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
- Oversees study recruitment and responsible for activating mitigation strategies in collaboration with the SSO Clinical Project Managers (CPMs)
- Fosters a close working relationship with the Vendor Partnerships & Governance (VPG) Trial Vendor Managers (TVMs) to strengthen the relationship between the vendors and CTT to deliver on clinical study objectives
- Fosters a close working relationship with the Clinical Data Operations (CDO) Trial Data Scientist (TDS) to deliver on clinical study objectives
- Ensures proper handling of all study close out activities including but not limited to site close out, final drug accountability and audit readiness of Trial Master File documentation
- Promotes operational excellence and contributes to the development of Clinical Study Reports, reporting of clinical trial results, and internal/external publications, when appropriate
- May deputize for the Clinical Operations Program Head as a leader and spokesperson for the CTT at Novartis internal meetings
- Partners and collaborates with Portfolio Strategy & Planning (PSP)/COPH to deliver clinical studies in alignment with program strategy
- Play a key role in achieving excellence in study operations and management through process improvement in collaboration with the Study Leadership Community Lead/Host and GCO Process, Training, and Compliance (PTC)

2.CTT coaching and resource management

- Partners and collaborates with functional line leadership to ensure optimal people staffing of the study team
- Build high-performing teams and create an empowered, psychologically safe culture to foster high performance in a matrix environment
- Serves as the single point of contact as the SSO representative in the CTT for internal/external customers

3.Community participation

- Active member of a community(ies) as a citizen within the study leadership organization
- Apply and encourage new CTT mindset, values, and principles; be a catalyst for these CTT ways of working (incl agile).

Activities & Interfaces

- Facilitates CTT collaboration across the CTT to include CTT sub-teams through agile events, meetings, and workshops
- Participates and reports study progress and issues/resolution plan at the GCO sub-teams and Global Clinical Team (GCT)
- Engaged and active participant in assigned Study Leadership Community

Leadership Capabilities

- Demonstrated ability in building relationship and communication skills with experience leading diverse work teams, achieving study excellence, and engaging functional partners coupled with excellent problem-solving, negotiation, and conflict resolution skills
- Transformational and servant leadership capabilities with ability to role model agile leadership
- Proven strategic capabilities; organizational awareness; advanced planning and project management skills as well as understanding of business processes
- Establishment of successful external partnerships and collaborations
- Proven ability to coach and motivate others

KPI

- Timely, efficient, and high-quality delivery of assigned studies and study-related activities within budget and in compliance with quality standards
- Proactive, iterative operational planning with effective contingencies and embedded risk management mindset in CTT
- Ability to foster an empowered, psychologically safe CTT culture and environment where all associates thrive and are working towards their fullest potential
- Cost effective management of budget with limited unforeseen cost overruns
- Consistent application and practice of agile leadership behaviors

Education

- Bachelor’s degree in life sciences/healthcare (or clinically relevant degree) is required. Advanced degree is strongly preferred.

Languages

- Fluent English, oral and written

Experiences/Professional requirements

- 4 years 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, executing, 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 stakeholders
- Excellent communicator and presenter (oral and written); ability to communicate at all levels

- Excellent organization and prioritization
- Strong negotiation and conflict resolution skills and enterprise mindset
- Strong project management skills and demonstrated ability to meet timelines
- Proven track record in trial operations process improvement(s) in some aspects of clinical trials
- Superior strategic thinking with strong analytical and problem-solving skills
- Knowledge of appropriate therapeutic area strongly preferred

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/sites/novartis_com/files/novartis-life-handbook.pdf

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Site
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Functional Area

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Full time
Employment Type
Regular
Shift Work
No
Apply to Job

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