

Study Leader

Job ID
REQ-10021244
Sep 05, 2024
Japan

Summary

The 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 (GOT) 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.

May 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

"Accountabilities"

Leader of the Clinical Trial Team

- Leads the clinical trial team with appropriate oversight from the Study Director-community Lead (SD-CL) and close support from the Clinical Operations Program Head (COPH), delivery of multiple global studies of standard complexity and priority and promotes learning, sharing, consistent performance, and operational excellence through an agile mindset, agile principles, and team of teams7 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, 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 trial 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 appropriate oversight from the Study Director-community Lead (SD-CL) and close 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 Program Managers (CPMs) to strengthen the relationship between the global and local teams

- 11. Oversees study recruitment and responsible for activating mitigation strategies in collaboration with the SSO Clinical Program Managers (CPMs)
- 12. Fosters a close working relationship with the VPG Vendor Program Managers (VPMs) to strengthen the relationship between the vendors and CTT to deliver on clinical study objectives
- 13. Fosters a close working relationship with the CDO Trial Data Scientist (TDS) to deliver on clinical study objectives
- 14. 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
- Contributes to the development of Clinical Study Reports, reporting of clinical trial results, and internal/external publications, when appropriate
- Partners and collaborates with PSP/COPH to deliver clinical studies in alignment with program strategy
- Play an important 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)

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 creates 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

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 an ambassador and a catalyst for the 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"

- Abilities to build 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
- 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 motivate others

"Key Performance Indicators"

- 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
- 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

"Job Dimensions"

Number of associates:

- No direct reports. Indirect: matrix management of clinical trial team

Financial responsibility:

- External budget accountability for multiple clinical studies.

"Ideal Background"

Education(minimum/desirable):

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

Languages:

- Fluent English, oral and written

Experience/Professional requirements:

- > 2 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 complexity and priority
- > 1 year of recent contribution to and accomplishment in all aspects of conducting clinical studies of standard 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 experience leading
- Experience in developing effective working relationships with internal and external stakeholders
- Good communicator and presenter (oral and written)
- Good organization and prioritization
- Negotiation and conflict resolution skills and enterprisemindset, demonstrated by ability to drive for aligned solutions for SSO and GCO/GDD
- Project management skills and demonstrated ability to meet timelines
- Strategic thinking with analytical and problem-solving skills
- Knowledge of appropriate therapeutic area preferred

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Division

Development

Business Unit

Innovative Medicines

Location

Japan

Site

Head Office (Japan) (Pharmaceuticals)

Company / Legal Entity

JP05 (FCRS = JP005) Novartis Pharma K.K.

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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