NOVARTIS

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 andmanagement 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, iterativeoperational 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 knowledgesharing across studies. Fosters an empowered, psychologically safe organization that can navigate amatrix 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-communityLead (SD-CL) and close support from the Clinical Operations Program Head (COPH),delivery of multiple global studies of standard complexity and priority and promoteslearning, sharing, consistent performance, and operational excellence through an agilemindset, agile principles, and team of teams7 model
- Acts as the CTT product owner with duties and responsibilities per established ways ofworking
- Guides planning and decision making at the study level and delivers assigned clinicalstudy/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 businessimpact
- In collaboration with regulatory writing and clinical development, promotes operationalexcellence in the development of global clinical trial protocol(s), by translating the approvedstudy concept sheet(s) into efficient, high quality, executable clinical protocols, and study-related documents
- Create effective CTT dynamics and achieve on performance, prioritization, andcommunication in close collaboration with CTT sub-team leaders
- Proactive risk management and inspection readiness
- Responsible for developing clinical study timelines with appropriate oversight from theStudy Di rector-com m u n ity Lead (SD-CL) and close support from the Clinical OperationsProgram 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) tostrengthen the relationship between the global and local teams

- 11.Oversees study recruitment and responsible for activating mitigation strategies incollaboration with the SSO Clinical Program Managers (CPMs)
- 12. Fosters a close working relationship with the VPG Vendor Program Managers (VPMs) tostrengthen the relationship between the vendors and CTT to deliver on clinical studyobjectives
- 13. Fosters a close working relationship with the CDO Trial Data Scientist (TDS) to deliver onclinical study objectives
- 14. Ensures proper handling of all study close out activities including but not limited to siteclose 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 withprogram strategy
- Play an important role in achieving excellence in study operations and managementthrough process improvement in collaboration with the Study Leadership CommunityLead/Host and GCO Process, Training, and Compliance (PTC)

CTT coaching and resource management

- Partners and collaborates with functional line leadership to ensure optimal people staffingof the study team
- Build high-performing teams and creates an empowered, psychologically safe culture tofoster high performance in a matrix environment
- Serves as the single point of contact as the SSO representative in the CTT forinternal/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 acatalyst for the CTT ways of working (incl agile)

"Activities & Interfaces"

- Facilitates CTT collaboration across the CTT to include CTT sub-teams through agileevents, meetings, and workshops
- Participates and reports study progress and issues/resolution plan at the GCO sub-teamsand 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 diversework teams, achieving study excellence, and engaging functional partners coupled withexcellent problem-solving, negotiation, and conflict resolution skills
- Transformational and servant leadership capabilities
- Proven strategic capabilities, organizational awareness, advanced planning, and projectmanagement 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 activitieswithin budget

and in compliance with quality standards
- Proactive, iterative operational planning with effective contingencies and embedded riskmanagement mindset in CTT
- Empowered, psychologically safe CTT culture and environment where all associates thriveand 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 clinicallyrelevant degree) is strongly preferred. Advanced degree ispreferred.

Languages:

- Fluent English, oral and written

Experience/Professionalrequirements:

- > 2 years of recent involvement in clinical research ordrug development in an academic or industryenvironment spanning clinical activities in Phases Ithrough IV of standard complexity and priority
- > 1 year of recent contribution to and accomplishmentin all aspects of conducting clinical studies of standardcomplexity and priority (e.g., planning, executing,reporting and publishing) in a global/matrix environmentin pharmaceutical industry or a contract researchorganization, including expert knowledge of internationalstandards (GCP/ICH), health authorities (FDA/EMA),local/National Health Authorities regulations andNovartis standards
- Experience in managing people globally in a complexmatrix environment preferred
- Management of virtual teams. Proven ability andexperience leading
- Experience in developing effective working relationshipswith 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 alignedsolutions for SSO and GCO/GDD
- Project management skills and demonstrated ability tomeet timelines
- Strategic thinking with analytical and problem-solvingskills
- Knowledge of appropriate therapeutic area preferred

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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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