NOVARTIS

Global Clinical Operations-Senior Study Leader

Job ID
REQ-10091297

十月 30, 2026

China

摘要

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

Key Responsibilities：

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-Team Lead (SD-TL) 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
- Document prepared by: M. Ruffin
- Date of issue: 21 Feb 2025
- 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)

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

Team/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).

Essential Requirements:

- Bachelor ' s degree in life sciences/healthcare (or clinically relevant degree) is required. Advanced degree is strongly preferred.
- Fluent English, oral and written
- $\geq$ 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
- $\geq$ 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

Desirable Requirements:

- 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: Learn about all the ways we 'll help you thrive personally and professionally. Read our handbook (PDF 30 MB)

部门
Development

Business Unit
Development

地点
China

站点
Shanghai (Shanghai)

Company / Legal Entity
CN14 (FCRS = CN014) China Novartis Institutes for BioMedical Research Co., Ltd.

Alternative Location 1
Beijing (Beijing), China

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work

No

var kPlayer = KalturaPlayer55802022 || KalturaPlayer; var config = { targetId: "kalturaplayer6ae4737f38c4b563184329", provider: { widgetId: "10m7rm1pm", partnerId: "2076321", uiConfId: "55802022" }, playback: { autoplay: false, autopause: false, muted: false, loop: false }, sources: { options: {}, startTime: 0 }, disableUserCache: "true", plugins: {}, sources: { options: {}, startTime: 0 }, ui: { showCCButton: false, settings: { showQualityMenu: true, showSpeedMenu: false }, components: { fullscreen: { disableDoubleClick: false } }, uiComponents: [{ presets: ['Playback', 'Live'], area: 'BottomBarRightControls', replaceComponent: 'Fullscreen', get: kPlayer.ui.components.Remove }] } }; // Check and add plugins only if they exist if (kPlayer.plugins["download"]) { config.plugins.download = { disable: true }; } if (kPlayer.plugins["transcript"]) { config.plugins["playkit-js-transcript"] = { position: "right", // Default: bottom;('left', 'right', 'top', 'bottom') to enable transcript. expandMode: "over", // Default: alongside;('alongside', 'hidden', 'over') expandOnFirstPlay: false, showTime: true, downloadDisabled: false, printDisabled: false, disable: true }; } if (kPlayer.plugins["preventSeek"]) { config.plugins.preventSeek = { preventSeekForward: false, preventSeek: false }; } config.plugins.floating = { disable: true }; if (kPlayer.plugins["navigation"]) { config.plugins.navigation = { position: "right", expandMode: "over", expandOnFirstPlay: false, visible: false }; } if (kPlayer.plugins["hotspots"]) { config.plugins['playkit-js-hotspots'] = { disable: true }; } if (kPlayer.plugins["moderation"]) { config.plugins['playkit-js-moderation'] = { disable: true }; } if (kPlayer.plugins["info"]) { config.plugins['playkit-js-info'] = { disable: true }; } if (kPlayer.plugins["share"]) { config.plugins.share = { disable: true }; } config.ui.uiComponents = []; if (kPlayer.plugins["googleAnalytics"]) { config.plugins.googleTagManager = {}; config.plugins.googleTagManager.customEventsTracking = {}; config.plugins.googleTagManager.containerId = 'GTM-57RJQ5'; config.plugins.googleTagManager.customEventsTracking.custom = []; config.plugins.googleTagManager.customEventsTracking = { preset: { coreEvents: true, UIEvents: false, playlistEvents: false, castEvents: false } }; }

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