NOVARTIS

Global Clinical Operations- Portfolio Team Lead

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REQ-10074904
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Китай

Сводка

The SSO Portfolio Team Lead is responsible for the Clinical Project Managers (CPMs), SSO Feasibility Managers and SSO Site Partnership Managers and their study specific activities, including the hiring, training, development, and assignment to ensure adequate and timely portfolio execution. The SSO Portfolio Team Lead assures that CPMs coordinate their activities across all CRAs working on the same trials/projects in collaboration with the CRA Managers/FSP line managers.
The SSO Portfolio Team Lead is responsible for CPMs, SSO Feasibility Managers and SSO Site Partnership Managers compliance of study management activities and for the delivery of study milestones, in close collaboration with the CRA Mangers/ FSP line managers and aligned with Global and local medical strategy, in the country/OPC country structure. The Portfolio Team Lead is responsible for overall portfolio execution related performance (KPIs), ensuring the study milestone deliverables, in accordance with GCP, ICH, SOP's, and local regulations.

About the Role

Key responsibilities:

Portfolio Execution strategy

- Collaborates with Country Head, Country/Cluster Portfolio Head and CRA Managers/FSP line managers to implement country innovative practices and patient engagement tactics (as appropriate) to advance clinical trial planning, execution and quality in line with Portfolio Execution country/OPC country leadership
- Identifies and leads innovative solutions to further advance the Project Management in GDD portfolio, in collaboration with Study & Site Operations country/OPC country leadership
- Supports the Country/Cluster Portfolio Head in implementation of the global strategy within the country/OPC country structure (incl. escalation & risk mitigation, as well as study allocation to CPMs)
- Supports the SSO Site Partnership Managers in the preparation and implementation of Key Account specific partnership strategy to ensure early engagement and timely delivery on the Novartis portfolio

Allocation, initiation and conduct of trials

- Develops opportunities in collaboration with SSO Feasibility Manager, SSO Site Partnership Manager, Country/Cluster Portfolio Head and relevant medical/clinical functions to build a competitive advantage for GDD trials within the country/OPC country, ensuring alignment with the local medical standard of care, local business drivers and site relationship management
- Ensures that SSO Feasibility Managers provide comprehensive proposals and timelines for country allocation, including early identification of risk and opportunities for the clinical program/trial
- Operationally supports allocation of new trials in collaboration with Study & Site Operations Country/OPC country leadership, during trial feasibility/allocation
- Ensures Country study site selection, activation, enrolment, data flow and timeline commitments are delivered and reported per established study milestones and Country commitments
- Collaborates with the SSO Site Partnership Manager and relevant medical/clinical functions to enhance Novartis relationship with clinical sites, to ensure optimal site relationship management and delivery on study commitments

Delivery of quality data and compliance to quality standards

- Collaborates with Clinical Research Associate (CRA) Manager to ensure that monitoring trends that require targeted training and/or development are escalated.
- Coordinates between the Clinical Research Associate (CRA) Manager, CPM and SSO Site Partnership Manager to ensure that site issues, data flow and commitment deviations are addressed and escalated.
- Ensures adherence to clinical data standards, prevailing legislation, GCP, Ethical Committee and SOP requirements
- Promotes a compliance culture advocating the adherence to highest standards and ethical integrity, ensuring human subject protection and reliability of trial results at all times
- Manages CPM, SSO Feasibility Manager and SSO Site Partnership Manager adherence/compliance to SOPs and required training curricula
- Ensures any competency gaps are identified and resolved through targeted training curricula in collaboration with the training and Portfolio Execution Excellence group
- Supports CPO/site audits and inspections (as appropriate) related to CAPA follow-up and implementation of study level identified issues

Management of people and resources management

- Is responsible for the hiring, training, development, and retention of a team of Clinical Project Managers (CPMs), SSO Feasibility Managers and SSO Site Partnership Managers to ensure study milestones are delivered for the Innovative Medicines Phase I-IV Global Drug Development (GDD) trials
- Together with the country/cluster Portfolio Head performs ongoing assessment and allocation of CPMs, SSO Feasibility Manager and SSO Site Partnership Manager resources within Country/OPC Country/Hub to ensure balanced workload
- Ensures CPMs and SSO Feasibility Managers have the required level of project management and therapeutic area knowledge and skills to successfully deliver study and protocol requirements
- Is responsible for managing and addressing CPM performance targets per defined key trial milestones (including country/OPC country trial commitment), and serves as an escalation of study issue resolution in collaboration with the CRA Managers and their CRAs

Budget and productivity

- Ensures country study budgets (Trial Commitment Forms, TCFs) are managed per established study key performance indicators and study objectives

Essential requirements:

- A degree in scientific or health discipline required and advanced degree with experience in project management, is preferable
- Fluent in both written and spoken English
- Minimum 8 years' experience in clinical research and/or project management and evidence of team management and leadership capabilities; 4 years of people management experience
- Understanding of all aspects of clinical drug development with particular emphasis on monitoring and trial execution

Desirable requirements:

- Excellent project management capabilities with demonstrated capability to problem solving and mediate complex compliance issues
- Thorough understanding of the international aspects of drug development process, including expert knowledge of international standards (GCP/ICH), health authorities (FDA/EMA), local/National Health Authorities regulations and Novartis standards
- Demonstrated negotiation and conflict resolution skills both internal and external (site relationships)
- Communicate effectively in a local/global matrixed environment

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)

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Business Unit
Development
Место
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Shanghai (Shanghai)
Company / Legal Entity
CN14 (FCRS = CN014) China Novartis Institutes for BioMedical Research Co., Ltd.
Alternative Location 1
Beijing (Beijing), Китай
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No

Accessibility and accommodation

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