

Global Clinical Operations- Study Start-Up Team Lead

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REQ-10083038
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Китай
Available in: English

Сводка

The SSO Study Start-Up Team Lead is accountable for the governance and oversight of a study start-up team in a standalone country or OPC (operating country). The SSO Study Start-Up Team Lead is supporting the country/OPC SSU strategy and prioritization in close collaboration with SSU/OPC Head and Country/OPC LT to deliver operational excellence of the GDD portfolio in compliance with Novartis processes, ICH/GCP and regulatory requirements.

About the Role

Key responsibilities:

Study Start-Up Strategy

- Supports Study & Site Operations Country Leadership Team to identify innovative practices to optimize country operations and operational excellence, especially in terms of study start-up activities to increase performance, productivity, and business impact
- Seeks and evaluates external knowledge and best practices to enhance overall operational excellence of country trial operations
- Supports country SSU strategy in close collaboration with SSU/OPC Head and Portfolio Head/Portfolio Team Lead(s)
- Responsible for timely start-up activities from country allocation until site Green Light (ready-to-initiate-sites)
- Ensures close collaboration with local IRBs/IECs and Health Authorities, as applicable

Allocation, initiation and conduct of trials

- Collaborates with Head Portfolio, SSO Portfolio Team Leads and global study team (Clinical Operations Program Head, Trial Lead) to ensure SSU timelines and deliverables are met according to country commitments
- Accountable for timelines, accuracy, and quality of TMF documents, including study start-up and ongoing TMF maintenance to ensure TMF inspection readiness
- Ensures adherence to financial standards, prevailing legislation, ICH/GCP, IRB/IEC, Health Authority and SOP requirements
- Implements innovative and efficient processes which are in line with Novartis strategy

People and resource management

- Hiring, training, development, and retention of Study Start-Up associates
- Resource management and reporting of Study Start-Up associates
- Ensures associates have the required level of skills to successfully set-up and execute studies with high quality and according to business objectives
- Manages and oversees productivity targets per defined objectives, and serves as an escalation point for Study Start-Up functions

Essential requirements:

- A degree in scientific or health discipline required
- Fluent in both written and spoken English
- Fluent in both written and spoken country language
- Minimum 5 years' experience in clinical operations and planning
- Proven leadership capabilities and experience (with or without direct line management responsibilities).
- Understanding of all aspects of clinical drug development with particular emphasis on trial set-up, execution, and monitoring
- Thorough understanding of the international aspects of drug development process, including strong knowledge of international standards (GCP/ICH), health authorities (FDA/EMA), local/national Health Authorities regulations and Novartis standards
- Strong capability in working in a global/country matrix environment

Desirable requirements:

- Proven successful leadership of teams (with or without direct reports), preferably with experience in working with international teams
- Strong interpersonal, negotiation and conflict resolution skills Communicates effectively in a local/global matrixed environment

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Development
Business Unit
Development
Место
Китай
Сайт
Beijing (Beijing)
Company / Legal Entity

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

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