Global Clinical Operations - SSO Study Start-Up Country Head

Job ID
REQ-10059038

8月 05, 2025

China

摘要

The SSO Study Start-Up Country Head is accountable for the governance and oversight of the study start-up team in a standalone country. The SSO Study Start-Up Country Head is accountable for the country SSU strategy and prioritization in close collaboration with SSO Country/Cluster Head Portfolio and SSO Country Head 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

- Collaborates with 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
- Defines and continuously optimizes country SSU strategy in close collaboration with SSO Country Head and SSO Country/Cluster Head Portfolio
- Accountable for timely start-up activities from country allocation until 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 SSO Country/Cluster Head Portfolio, SSO Portfolio Team Leads and global study team 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
- 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

People and resource management

- Hiring, training, development, and retention of Study Start-Up team

- Resource management and reporting of Study Start-Up Team
- 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 university degree in scientific or health discipline required
- Fluent in both written and spoken English
- Fluent in both written and spoken country language
- Minimum 8 years ' experience in clinical operations and planning
- Minimum 4 years ' experience in people management and team leadership
- Excellent 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

Desirable requirements:

- Strong capability in working in a global/country matrix environment

- Proven successful leadership of teams, 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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部门
Development

Business Unit
Innovative Medicines

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

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Accessibility and accommodation

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