

SSO Study Start-Up Team Lead

Job ID
REQ-10065154

11月 04, 2025

Netherlands

摘要

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

#LI-Hybrid

Location: Amsterdam, Netherlands

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

Key Performance Indicators

1. Performance against study commitments at the country level (actual vs. planned patients), including set-up/delivery of trials per defined timelines and milestones (IRB/IEC & HA approval, RIS, SIV) and data quality requirements

2. Delivery of study milestones in adherence to prevailing legislation, ICH/GCP, IRB/IEC, Health Authority and SOP requirements

3. Timely submission and delivery of high-quality clinical trial documentation/data

Experience/Professional requirement:

- 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

Competencies:

- Strong capability in working in a global/country matrix environment
- Proven successful leadership of teams (with or without direct reports), preferably with experience in working with international teams

Skills & Knowledge:

- Strong interpersonal, negotiation and conflict resolution skills
- Communicates effectively in a local/global matrix environment

Commitment To Diversity And Inclusion

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部门
Development

Business Unit
Universal Hierarchy Node

地点
Netherlands

站点
Amsterdam

Company / Legal Entity
NL08 (FCRS = NL008) Novartis Pharma NL

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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