SSO Study Start-Up Manager

Job ID
REQ-10048452

4月 15, 2025

Netherlands

摘要

The SSO Study Start-Up Manager is accountable for study planning, SSU activities and activation deliverables of assigned projects in compliance with Novartis processes, GCP/ICH and regulatory requirements in the country. Leads all SSU activities of assigned projects in close collaboration with SSO Feasibility Manager(s), SSO Study Start-Up Team Leads, and Clinical Research Medical Advisor as well as the global study team.

About the Role

Accountabilities:

- Collaborates with SSO Study Start-Up Team Leads, SSO Portfolio Team Leads, Clinical Project Managers, SSU CRA(s) and global study team to ensure SSU timelines and deliverables are met according to country commitments
- Accountable for timely start-up activities from country allocation until Country Greenlight and

last Site Initiation signoff in assigned projects
- Ensures that study start-up activities are conducted and completed on time, including preparation of Key Country Documents, creation and review of Informed Consent Forms, engaging Regulatory Affairs/CTA Hub for EU CTR submissions, as required
- Coordinates reportable events, milestones and notifications to IEC and Health Authorities via CTIS as applicable
- Accountable for timelines, accuracy, and quality of country TMF documents in study start-up to ensure TMF inspection readiness
- Ensures adherence to prevailing legislation, ICH/GCP, IEC, Health Authority and SOP requirements
- Implements innovative and efficient processes which are in line with Novartis strategy
- Supports study feasibility in close collaboration with Feasibility Manager(s) Clinical Research Medical Advisor as well as the global study team
- Leads site selection in collaboration with SSU CRA(s), Clinical Research Medical Advisor and Clinical Project Manager
- Serves as main contact for quality/compliance issues in SSU phase, escalating as necessary
- Responsible for "Country Regulatory Greenlight" and ensures all documentation is in place for initial and subsequent drug release.
- Oversees local SSU team activities in assigned studies to achieve start-up timelines and quality execution according to Novartis standards and local and international regulations, and proposing and implementing corrective actions where appropriate
- Leads/chairs local SSU team meetings, and participates in global study team meetings, as required
- Leads the development of country site initiation and patient enrolment plans together with SSU CRA, CPM and SSU Lead

Key performance indicators:

- Performance against study commitments at the country level (actual vs. planned patients), including set-up/delivery of trials per defined timelines and milestones (Country approval, Country Greenlight, SIV) and data quality requirements
- Delivery of study milestones in adherence to prevailing legislation, ICH/GCP, EU CTR, IEC, Health Authority and SOP requirements
- Timely submission and delivery of high-quality clinical trial documentation/data

Minimum Requirements:

- A degree in scientific or health discipline required and advanced degree with clinical trial experience and/or project management, is preferable
- Fluent in both written and spoken English, local language as needed
- Minimum 5 years 'experience in clinical operations in a role that oversees (project management) and/or with monitoring clinical trials
- Capable of leading in a matrix environment, without direct reports
- Understanding of all aspects of clinical drug development with particular emphasis on trial set-up, execution, and monitoring

Competencies:

- Strong project management capabilities with demonstrated ability to problem solve and mediate complex issues

- 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

Skills and knowledge:

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

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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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