SSO Study Start-Up Manager

Job ID
REQ-10050814

5月 01, 2025

Saudi Arabia

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 a standalone country, OPC (operating country) or satellite country. Leads all SSU activities of assigned projects in close collaboration with SSO Feasibility Manager and SSO Site Partnership Manager as well as the global study team. In satellite countries acts as primary back-up and deputy of the country manager.

About the Role

Major accountabilities:

- Supports country SSU strategy in close collaboration with SSO Study Start-Up Team Lead, SSO Country Head Portfolio / SSO Cluster Head Portfolio
- 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 timely start-up activities from country allocation until Green Light (ready to initiate site millstone) in assigned projects
- Ensures close collaboration with local IRBs/IECs and Health Authorities, as applicable
- Ensures that study start-up activities are conducted and completed on time, including preparation of IRB/IEC submission packages, review of Informed Consent Forms, engaging Regulatory Affairs/CTA Hub for Health Authorities submissions, as required
- Prepares and finalizes local submission package for submission to IRB/IEC, CTA Hub as well as Health Authorities as applicable (including subsequent amendments, IBs, DSURs, CSRs)
- Coordinates timely response to deficiency letters in close collaboration with local and global stakeholders
- Coordinates reportable events and notifications to IRB/IEC and Health Authorities as applicable
- Accountable for timelines, accuracy, and quality of country TMF documents in study start-up 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
- Supports study feasibility in close collaboration with Feasibility Manager and Site Partnership Manager as well as the global study team.
- Supports site selection in collaboration with Portfolio Team Lead and Clinical Project Manager if already assigned
- Oversees local vendor selection and performance as needed. Serves as main contact for quality/compliance issues in SSU phase, escalating as necessary
- Ensures sites are prepared for "Green Light" and ensures all documentation is in place for initial and subsequent drug release. Responsible for review and sign off of the site "Green Light"
- Oversees local SSU team activities in assigned studies to achieve start-up timelines and quality execution, (proposing and implementing corrective actions where appropriate), according to Novartis standards and local and international regulations
- Leads/chairs local SSU team meetings in assigned studies, 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:

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, Green Light, 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

Minimum Requirements:
Work Experience:

- A degree in scientific or health discipline required and advanced degree with clinical trial experience and/or project management, is preferable

- 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
- 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 (SFDA) regulations and Novartis standards

Skills:

- Clinical Monitoring.
- Clinical Research.
- Clinical Trial Protocol.
- Clinical Trials.
- Decision Making Skills.
- Drug Development.
- Health Sciences.
- Lifesciences.
- Regulatory Compliance.
- Strong interpersonal, negotiation and conflict resolution skills
- Communicates effectively in a local/global matrixed environment

Languages :

- Fluent in both written and spoken English, local language as needed

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部门
Development

Business Unit
Innovative Medicines

地点
Saudi Arabia

站点
Riyadh

Company / Legal Entity
SA01 (FCRS = SA001) Novartis Saudi Arabia Ltd

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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