SSO Study Start-up Manager

Job ID
REQ-10062660

12月 16, 2025

Singapore

摘要

#LI-Hybrid
Location: Singapore

About the Role:

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

Key Responsibilities:-

- Supports country SSU strategy in close collaboration with SSO team. Collaborates with SSO Country or 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 in assigned projects.
- Ensures close collaboration with local external stakeholders. Ensures that study start-up activities are conducted and completed on time
- Prepares and finalizes local submission package for submission relevant health authority. Coordinates timely response to deficiency letters in close collaboration with local and global stakeholders.
- Coordinates reportable events and notifications to external health authority. Accountable for timelines, accuracy, and quality of country TMF documents in study start-up.
- Implements innovative and efficient processes which are in line with Novartis strategy. Supports study feasibility in close collaboration with relevant teams
- Leads site selection in collaboration with relevant teams if already assigned. In satellite countries 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 according to company and country standards. Leads or 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.

Essential Requirements:-

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

Commitment to Diversity and Inclusion / EEO paragraph:

Novartis is committed to building an outstanding, inclusive work environment and diverse teams

representative of the patients and communities we serve.

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients ' lives. Ready to create a brighter future together? https://www.novartis.com/about/strategy/people-and-culture

Benefits and Rewards: Read our handbook to learn about all the ways we ' ll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

部门
Development

Business Unit
Development

地点
Singapore

站点
Mapletree Business City (MBC)

Company / Legal Entity
SG04 (FCRS = SG004) Novartis Singapore Pte Ltd

Functional Area
Research & Development

Job Type
Full time

Employment Type

Regular

Shift Work
No

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