SSO Study Start-up Manager

Job ID
REQ-10047436

4月 11, 2025

Australia

摘要

Internal Role Title: SSO Study Start-Up Manager

Location: Sydney, Australia #LI-Hybrid

Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.

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:

- Support country SSU strategy in collaboration with SSO Study Start-Up Team Lead, SSO Country Head Portfolio, and SSO Cluster Head Portfolio
- Ensure timely start-up activities from country allocation until Green Light (ready to initiate site milestone) in assigned projects
- Collaborate with local IRBs/IECs and Health Authorities to ensure study start-up activities are conducted and completed on time
- Prepare and finalize local submission packages for IRB/IEC, CTA Hub, and Health Authorities, including subsequent amendments
- Coordinate timely responses to deficiency letters in collaboration with local and global stakeholders
- Oversee local SSU team activities in assigned studies to achieve start-up timelines and quality execution
- Lead the development of country site initiation and patient enrolment plans together with SSU CRA, CPM, and SSU Lead

Essential Requirements:

- A degree in a scientific or health discipline is required; an 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 monitoring clinical trials.
- Capable of leading in a matrix environment without direct reports.
- Thorough understanding of the international aspects of the drug development process, including strong knowledge of international standards (GCP/ICH), health authorities (FDA/EMA), and local/National Health Authorities regulations.
- Strong project management capabilities with demonstrated ability to problem solve and mediate complex issues.
- Strong interpersonal, negotiation, and conflict resolution skills.
- Fluent in both written and spoken English; local language proficiency as needed.

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部门
Development

Business Unit
Innovative Medicines

地点
Australia

站点
New South Wales (NSW)

Company / Legal Entity
AU04 (FCRS = AU004) AU Pharma Pty Ltd

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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