

## SSO Study Start-up Manager

Job ID  
REQ-10061217

9月 08, 2025

Australia

### 摘要

#LI-Hybrid  
Location: Australia

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.

### 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

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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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