Study Start-up Clinical Research Associate

Job ID
REQ-10064844

10月 15, 2025

Australia

摘要

#LI-Hybrid
Location: Sydney, Australia

About the Role:

The Study Start-Up CRA is accountable for site selections as well as study-specific start-up activities and deliverables of assigned sites for Phase I-IV GDD trials within the country in adherence with monitoring procedures and processes in accordance with ICH/GCP, local regulations and SOPs.

Proactive site preparation and early identification of real site needs and issues and close handover to execution CRA for all sites is key (from issue management to risk identification).

About the Role

Key Responsibilities :-

- Supports country SSU strategy in close collaboration with SSO Study Start-Up Team Lead, SSO Study Start-Up Manager, SSO Feasibility Manager as well as SSO Site Partnership Manager
- Collaborates with SSO Study Start-Up Manager, SSO Study Start-Up Team Lead and global study team to ensure Study Start-Up timelines and deliverables are met according to country commitments
- Accountable for timely start-up activities from country allocation until site greenlight at assigned sites
- Conducts site selection visits, verifies site eligibility for a specific study. Main contact for trial sites during site selection, study start-up and IRB/IEC and HA submission preparation. Ensures that milestones (KPIs) and time schedule for study start-up are met as planned. Facilitates the preparation and collection of site and country level documents
- Collects submission relevant site-specific documents for all relevant site personnel within agreed timelines. Supports SSU Manager in preparation of country-specific documents, e.g., ICF, patient facing materials, etc. Supports SSO Study Start-Up Manager and assigned sites in vendor set-up activities
- Prepare and finalize site specific documents for submission. Negotiates investigator payments as needed. Supports preparation of financial contracts between Novartis and investigational sites and investigators as needed. Updates all systems until site Green Light on an ongoing basis. Supports preparation of audits and inspections as applicable. Supports reduction of formal site-specific IRB/IEC deficiencies

- Ensures timelines, accuracy, and quality of country and site 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. Ensures sites are prepared for “Green Light” and is accountable to send the Green Light to SSU Manager for review and approval

Essential Requirements

- A degree in scientific or health discipline, preferably with clinical operations experience
- Minimum 3 years’ experience in clinical operations in a monitoring / site management role
- understanding of all aspects of clinical drug development with particular emphasis on trial set-up, execution, and monitoring
- Central/in-house monitoring or field monitoring experience is desirable.
- Strong site management capabilities with demonstrated negotiating and problem-solving skills. Understanding of the international aspects of drug development process, including strong knowledge of international standards. Strong interpersonal, negotiation and conflict resolution skills.
- Ability to travel, e.g., for site selections, if applicable. Ability to manage multiple priorities and manage time efficiently. Fast change adaptability to best partner & influencing with sites on fast changing landscape.
- Trust and rapport building is a very important skill needed. Good communication skills, ability

to influence others. Relationship management.

Commitment to Diversity and Inclusion / EEO paragraph:

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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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