

Clinical Trial Associate

Job ID
REQ-10034025

12月 17, 2024

Singapore

摘要

Internal Role Title: Clinical Trial Associate

Location: Singapore #LI-Hybrid

About the Role:

The Clinical Trial Associate (CTA) supports SSO Study Start-Up Manager and SSO Clinical Project Manager in assigned studies during set-up and whole study lifecycle in compliance with Novartis processes, GCP/ICH and regulatory requirements.

About the Role

Key Responsibilities:-

- Supports document collection, preparation, and adaption for submission to IRB/EC and Health Authorities as applicable
- Sets-up systems, supports vendor selection, documentation processes and data entry
- Set-up and maintenance according to regulatory and Novartis requirements, document oversight and tracking, support vendor set-up as applicable
- Checks site “Green Light” completeness and ensures all documentation is in place for initial and subsequent drug release in collaboration with the local Qualified Person(s)
- Supports preparation and translation of ICF into local languages. Supports preparation of patient facing material
- Responsible for completeness of uploaded trial related documents. Supports country SSU strategy in close collaboration with SSU Team Lead and SSU Managers to ensure SSU timelines and deliverables are met according to country commitments. Ensures adherence to financial standards, prevailing legislation, health authority and requirements.
- Provides logistic support to SSU CRA, CRA, CPM, SSU Manager in all phases of the clinical trial. Implements innovative and efficient processes which are in line with Novartis strategy.

Essential Requirements:-

- Commercial or medical training (e.g., vocational qualification, bachelor ' s degree), Medical records administrator or equivalent education, preferably with experience in clinical operations
- At least 1 year of relevant working experience.
- 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 process and system understanding. Self-motivated, structured and committed way of working
- Ability to prioritize and high coordination skills. Demonstrated collaboration and communication skills

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部门

Development

Business Unit

Innovative Medicines

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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