

Global Clinical Operations- Study Start-Up CRA

Job ID
REQ-10032137
Dec 04, 2024
China

Summary

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 (e.g., FD, CV, GCP certificates, DSL...) 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

Commitment to Diversity and Inclusion / EEO:

Novartis is committed to building an outstanding, inclusive work environment and diverse team's representative of the patients and communities we serve.

Essential Requirements:

- A degree in scientific or health discipline, preferably with clinical operations experience (or, for United States: 4-year degree plus relevant, related healthcare experience)
- Fluent in both written and spoken English, local language as needed
- Minimum 3 years' experience in clinical operations in a monitoring / site management role

Desirable Requirements:

- Advanced 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

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?

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Accessibility and Accommodation:

Novartis is committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please tell your relevant request to our hiring managers.

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Division

Development

Business Unit

Innovative Medicines

Location

China

Site

Beijing (Beijing)

Company / Legal Entity

CN06 (FCRS = CN006) Beijing Novartis Pharma Co., Ltd

Functional Area

Research & Development

Job Type

Full time

Employment Type

Shift Work

No

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