Study Start-Up Clinical Research Associate (SSU CRA)

Job ID
REQ-10053938

6月 09, 2025

Brazil

摘要

Site relationship management role to ensure sustainable trial start-up at Site.
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

Major accountabilities:

- 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

Key performance indicators:

- Performance against study commitments at the site level (actual vs. planned patients), including set-up/delivery of trials per defined timelines and milestones (IRB/IEC & HA approval, RIS, SIV) and data quality requirements
- Delivery of study milestones in adherence to prevailing legislation, ICH/GCP, IRB/IEC, Health Authority and SOP requirements
- Actively share insights with relevant internal stakeholder to drive site and account development
- Partners with execution Clinical Research Associate to ensure seamless transition of site responsibility

Ideal Background:

- 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
- 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

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部门
Development

Business Unit
Innovative Medicines

地点
Brazil

站点
Santo Amaro

Company / Legal Entity
BR03 (FCRS = BR003) NOVARTIS BIOCIENCIAS S.A

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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