NOVARTIS

Study Start-up Clinical Research Associate

Job ID
REQ-10032936
Dec 12, 2024
Hungary

Summary

Fixed term - 2 years contract
Location: Budapest, Hungary.
Hybrid #hybrid

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. This is a field position and will require ability to travel to sites throughout the country.

About the Role

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

Activities & Interfaces

- Externally facing role with impact on Principal Investigators and Institution/Site business offices.
- External engagements with vendor partners to lead site issue resolution as needed.
- Partners with execution Clinical Research Associate to ensure seamless transition of site responsibility at time of site initiation

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

Education:

- A degree in scientific or health discipline, preferably with clinical operations experience

Languages:

- Fluent Hungarian and Fluent in both written and spoken English

Experience/Professional requirement:

- 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

Competencies:

- Strong site management capabilities with demonstrated negotiating and problem-solving skills
- Advanced 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

Skills & Knowledge:

- 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

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Division
Development
Business Unit
Innovative Medicines
Location
Hungary
Site
Budapest
Company / Legal Entity
HU02 (FCRS = HU002) Novartis Hungary
Functional Area
Research & Development
Job Type
Full time
Employment Type
Temporary (Fixed Term)
Shift Work
No
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