

Study Start-up CRA -Hungary(home-based)

Job ID
REQ-10010299
Juli 15, 2024
Ungarn

Zusammenfassung

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
- 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 timelines, accuracy, and quality of country and site TMF documents in study start-up and make sure that 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 Study Start-Up Manager in preparation of country-specific documents and vendor set-up activities
- Supports preparation of financial contracts between Novartis and sites and investigators as needed and negotiates investigator payments as needed
- Supports preparation of audits and inspections as applicable
- Supports reduction of formal site-specific IRB/IEC deficiencies
- 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

Minimum Requirements:

Work Experience:

- Minimum 3 years' experience in clinical operations in a monitoring / site management role
- Advanced understanding of all aspects of clinical drug development including strong knowledge of international standards (GCP/ICH), health authorities (FDA/EMA) and local/National Health Authorities regulations, with particular emphasis on trial set-up, execution, and monitoring
- Central/in-house monitoring or field monitoring experience is desirable

Skills:

- Strong site management capabilities with demonstrated negotiating and problem-solving skills
- Strong interpersonal and conflict resolutions skills
- Ability to travel, e.g., for site selections(up to 30% of working time)
- Ability to manage multiple priorities and manage time efficiently
- Good communication skills, ability to influence others & Relationship management
- Fluent Hungarian and English (written and spoken)

Why Novartis:

Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: [https://www.novartis.com/about/strategy/people and culture](https://www.novartis.com/about/strategy/people-and-culture)

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

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If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here:

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Abteilung

Development

Business Unit

Innovative Medicines

Ort

Ungarn

Website

Budapest

Company / Legal Entity

HU02 (FCRS = HU002) Novartis Hungary

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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