NOVARTIS

Study Start-up Clinical Research Associate -Poland (Home based)

Job ID
REQ-10022262
Sep 16, 2024
Pologne

Résumé

Site relationship management role to ensure sustainable trial start-up at Site.
The Study Start-Up Clinical Research Associate (SSU 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
- 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

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)

Languages:

- • Fluent in both written and spoken English and Polish

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
- 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
- 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

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
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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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