(Senior) Clinical Research Associate

Job ID
REQ-10058428

7月 23, 2025

China

摘要

Site relationship management role to ensure sustainable trial execution at Site. Performs on-site and remote monitoring activities related to initiation, conduct and timely completion of 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 performance management (recruitment & quality) and early identification of real site needs and issues as the single best point of contact (internally & externally) for all sites. (from issue management to risk identification).

About the Role

Key responsibilities:

- Frontline liaison between Novartis and sites to ensure successful collaboration, meeting Novartis expectation on milestone and deliverables with true ownership mindset
- Manages assigned study sites, conducting phase I-IV protocols according to the Monitoring

Plan and Novartis procedures
- Performs Site Initiation Visit, ensures site personnel is fully trained on all trial related aspects. Performs continuous training for amendments and new site personnel as required. Re-trains site personnel as appropriate
- Conducts continuous site monitoring activities (onsite and remote). Implements site management activities to ensure compliance with protocol, ICH/GCP, global and local regulation including Health Authorities, IRB/EC, data privacy requirements, global and local processes as applicable. Documentation according to GDP and Novartis standards.
- Identifies deficiencies in site processes and monitor site processes performed outside the site, works in close collaboration with site on risks mitigation and process improvements
- Promotes a compliance culture advocating adherence to highest standards and ethical integrity, ensuring human subject protection and reliability of trial results at all times
- Identify deficiencies in site process, work in close collaboration with site on risk mitigation
- Establish a strong partnership and true collaboration with the site, to increase patient density and decrease issues at site.
- Early engagement with site on patient inventory and patient flow in advance of SIV in close collaboration with global and local study team
- Performs Site Closeout activities per SOPs and applicable regulations to ensure that site is aware of any follow up activity and archiving requirements
- Attends onboarding-, disease indication and project specific training and general CRA training as required
- Proactively collaborates with the SSO Clinical Project Manager (CPM) and CRA Manager as well as MSL, CRMA and medical advisor to ensure optimal recruitment, site development and data quality
- Ensures that relevant site insights are shared with internal stakeholders such as site partnership manager, medical advisor, MSL and CRMA etc. to improve one Novartis approach to sites
- Participates in audit organization and inspection readiness activities for monitoring and site related activities as required and ensures implementation of corrective actions within specified timelines
- Collaborates with internal stakeholders and site personnel to manage data query resolution process and to ensure timely and accurate data entry
- Ensures the site Investigator Folder is up to date. Responsible for collecting essential documents from site and accountable to keep sTMF(s) up to date

Essential requirements：

- 2+ years pharmaceutical industry experience or other relevant experience
- Central/in-house monitoring or field monitoring experience is desirable
- Decision capability
- Excellent time management and organization capabilities, including ability to prioritize and multi-task
- Risk based mindset (from issue management to risk identification) supported by Novartis systems
- Early adopter and open mindset across borders to support one study approach
- Good knowledge of drug development process specifically clinical trial/research
- Clinical and therapeutic knowledge
- Knowledge of international standards (GCP/ICH, FDA, EMA)
- Understanding the purpose of the CRA (Patient Safety; Data Integrity; PI oversight; GCP/ICH & Protocol Compliance)

- Ability to travel domestically (and possibly internationally) as needed to study sites and for training and meetings.
- A minimum of 50% overnight travel may be required

Desirable requirements：

- 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
- Excellent communicator and presenter (oral and written)
- Ability to manage sites independently; Proven ability to work independently with minimal supervision
- Good analytical thinking
- Ability to anticipate potential issues and take appropriate actions with or without supervision
- Digital & tech capabilities, including computer skills (Microsoft platforms)

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? https://www.novartis.com/about/strategy/people-and-culture

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部门
Development

Business Unit
Innovative Medicines

地点
China

站点
Guangzhou (Guangdong Province)

Company / Legal Entity
CN14 (FCRS = CN014) China Novartis Institutes for BioMedical Research Co., Ltd.

Alternative Location 1
Chengdu (Sichuan Province), China

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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Accessibility and accommodation

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