Clinical Research Associate I (Jr)

Job ID
REQ-10051177

5月 06, 2025

Brazil

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

Major accountabilities:

- Conducts continuous site monitoring activities (onsite and remote) and manages assigned study sites, conducting phase I-IV protocols. 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.
- Performs Site Initiation Visit and Site Closeout activities per SOPs and applicable regulations.
- Frontline liaison between Novartis and sites to ensure successful collaboration, meeting Novartis expectation on milestone and deliverables with true ownership mindset.
- 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
- 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.
- 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.
- 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.

Key performance indicators:

- Next level of site collaboration measured by patient density at site, achievements of commitments and targets and deliver customer satisfaction results.
- Meets study milestones.
- Ensures the delivery of high-quality data according to agreed timelines with adherence to prevailing legislation, GCP, Ethical Committee and SOP requirements.
- Quality and timeliness of updating the Novartis systems, monitoring reports, and communication efforts as defined by global KPIs and KQIs

Minimum Requirements:
Work Experience:

- Degree in scientific or healthcare discipline
- Field monitoring experience
- Operations Management and Execution.
- Up to 2 years pharmaceutical industry experience or other relevant experience
- Collaborating across boundaries.

Skills:

- Clinical Monitoring/Research/Trials.
- Fast change adaptability.
- Collaboration.
- Data Integrity.
- Decision Making Skills.
- Ability to travel.
- Good communication skills
- Ability to manage sites independently

- Time management and organization capabilities

Languages :

- English (Written and Spoken).

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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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