CRA Senior

Job ID
REQ-10061195

9月 18, 2025

Brazil

摘要

-Planning, execution, and interpretation of clinical trials research, data collection activities and clinical operations. May interact with investigational sites, clinical consultants, Contract Research Organizations & other vendors. Collaborates with Country medical/clinical colleagues, global clinical teams and directs activities to execute and deliver the assigned studies. Monitors patient data and study-related information related to clinical study sites and clinical trial participation. Ensures the investigator adheres to research protocols, regulatory requirements and good clinical practices and provides input into data validation plan. Provides timely and accurate monitoring of patient data and study-related information from source documents, research records, and site visits where applicable. May monitor study sites and audit facility selection.

About the Role

Major accountabilities:

- 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
- 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 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

Key performance indicators:

- Deliver customer satisfaction results for internal & external customers -Delivery of Clinical Trials to quality standards, agreed timelines, number of patients, costs and quality -Adherence to Novartis policy and guidelines and external regulations

Minimum Requirements:
Work Experience:

- Minimum 5 years pharmaceutical industry experience in all aspects of monitoring and site management

- Operations Management and Execution.
- Collaborating across boundaries.
- Project Management.
- People Leadership.

Skills:

- Fast change adaptability to best partner & influencing with sites on fast changing landscape
- Trust and rapport building is a very important skill needed
- 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
- 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

Languages :

- English.

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
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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