NOVARTIS

Global Clinical Operations- CRA

Job ID
REQ-10089721
Oct 15, 2026
LOC_CN

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:

- Degree in scientific or healthcare discipline
- Fluent in both written and spoken English and country language
- 1-3 years pharmaceutical industry experience or other relevant experience
- Field monitoring experience is desirable

Desirable Requirements:

- 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

Role Requirements

Division
DIV_GD
Business Unit
Development
Location
LOC_CN
Site
Shanghai (Shanghai)
Company / Legal Entity
CN14 (FCRS = CN014) China Novartis Institutes for BioMedical Research Co., Ltd.
Alternative Location 1
LOC_CN
Functional Area
FCT_RD
Job Type
Full time
Employment Type
Regular
Shift Work
No
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