NOVARTIS

Global Clinical Operations- CRA Manager

Job ID
REQ-10075519
Apr 12, 2026
LOC_CN

About the Role

Key responsibilities:

- In collaboration with SSO Clinical Project Manager (CPM), supports recruitment strategies and site performance by ensuring high quality and compliance of monitoring activities
- Is accountable for monitoring quality, timely data entry and issue resolution
- Ensures CRA monitoring competency gaps are identified and resolved through targeted training curricula in collaboration with training group as well as by performing co-monitoring visits with training purposes
- Promotes a compliance culture advocating the adherence to highest standards and ethical integrity, ensuring human subject protection and reliability of trial results at all times
- Actively manage CRA team performance including implementation of development and performance improvement plans
- Supports implementation of Risk Based Monitoring in GCO clinical trials by coaching and training CRAs on process thinking, risk-based monitoring concept and related systems
- Is responsible for execution of annual CRA oversight visit plan to assess ongoing CRA monitoring competency, identifying issues, and developing resolution strategies
- Collaborates with CPM for monitoring trends that require targeted training and/or development of CRAs to deliver to trial and quality KPIs
- Collaborates with MSOM for country resource strategy
- Ensures adherence to clinical data standards, prevailing legislation, GCP, Ethical Committee and SOP requirements
- Supports Clinical Development Audits, site audits and inspection and ensures CAPA follow-up and implementation for CRA and site identified issues
- Manages CRA adherence/compliance to SOPs and required training curricula
- Is responsible for the hiring, training, development, and retention of a team of CRAs executing Phase I-IV Global Drug Development (GDD) trials
- Performs ongoing assessment and allocation of monitoring resources within countries to ensure balanced CRA workload for quality monitoring
- Ensures CRAs have the required level of monitoring and disease area knowledge and skills to successfully deliver to protocol requirements
- Monitors, tracks and approves CRA travel and expense to ensure compliance to T&E policy and budget

Band

Level 4

Job Description Summary

To lead Patient Safety operational processes at the Country Organization ensuring compliance with Novartis global and local procedures, national and international regulations/ standards/ guidelines for vigilance of Novartis group approved, marketed and investigational products (incl. drugs, food supplements and medical devices).

Job Description

Key responsibilities:

- Manage a team of PS Associates (such as PS Specialists, PS Senior Specialists and/or PS Managers) in line with the country PS organizational structure and PS strategy in place.
- Act as qualified delegate of the Local Qualified Person for Pharmacovigilance/ Local PV Responsible Person in Novartis Country Organization, as defined by local regulation and applicable legislation, in terms of ensuring compliance of adverse drug reactions monitoring and submission.
- Act as qualified delegate of the Country Patient Safety Head in terms of operational vigilance processes.
- Ensure robust oversight and compliance in terms of reporting/submission/distribution of safety reports/updates/information (e.g., SAE, SR, IN, SUSAR, PSUR, DSUR, changes in risk-benefit profile) to Local Health Authorities (LHA) according to regulatory requirements and Novartis procedures.
- Work in close collaboration with other local and global medical safety functions to ensure accurate evaluation of safety data.
- Interact and exchange relevant safety information with Health Authorities, other functional groups, third-party contractors, and PS associates, as applicable.
- Monitor national pharmacovigilance regulations and provide update to global PS organization.
- Set up, update, and implement local procedures to ensure compliance with PS global procedures and national requirements.
- Ensure local PS-related RMP commitments are executed and properly documented
- Provide scientific expertise during review of all Phase IV Clinical Trial and NIS protocols safety sections including Research Collaborations and if a Contract Research Organization (CRO) is conducting the trial or study, review safety relevant sections of the contract.
- Act as a key partner who provides input, during the process of establishing local programs (ex. POPs, DEAs; SM/SML, etc.): comments on proposals for vigilance language, content, and establishment of necessary controls on collection and reporting of adverse event information.
- Ensure that relevant local literature articles are screened, as appropriate.
- Supervision of management and maintenance of all relevant PS databases.
- Ensure timely preparation and submission of KPI reports on AE reporting and AE follow-up attempts including identification of root cause(s) e.g., for late reporting to HA, missed or delayed follow-up attempt, development and implementation of corrective and preventative action(s) as needed.
- Support in developing and updating training materials for pharmacovigilance and ensure training of Country Organization associates on relevant PS procedures for AE reporting, including field force and third-party contractor, if applicable.
- Ensure support for and close-out of audits, corrective action plan, investigation, and Health Authority inspections.
- Ensure selection, and recruitment of qualified PS team members and their further professional development.
- Ensure training and oversight of commissioned staff, as applicable.
- Contribute to the preparation and update of the local Pharmacovigilance System Master File as per regulation and related procedures.
- Other agreed tasks assigned by manager.

Essential requirements:

- A degree in scientific or health discipline required and advanced degree preferable (or, for United States: 4-year degree plus relevant, related healthcare experience)
- Fluent in both written and spoken English
- Minimum 7 years’ experience in clinical research - planning/executing and/or monitoring clinical trials
- Experience in project management and evidence of team leadership capabilities
- Understanding of all aspects of clinical drug development with particular emphasis on monitoring and trial execution

Desirable requirements:

- Decision making capability

- Excellent site management capabilities with demonstrated capability to problem solve and mediate complex compliance issues.
- Excellent coaching capability to best support CRA in driving right mindset and behavior
- Thorough understanding of the international aspects of drug development process, including expert knowledge of international standards (GCP/ICH), health authorities (FDA/EMA), local/National Health Authorities regulations, risk-based monitoring and Novartis standards
- Demonstrated negotiation and conflict resolution 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.
- 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

Role Requirements

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

Benefits and Rewards: Learn about all the ways we'll help you thrive personally and professionally.
Read our handbook (PDF 30 MB)

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
Apply to Job

Job ID
REQ-10075519

Global Clinical Operations- CRA Manager

Apply to Job

Source URL: *https://jobapi.novartis.com/req-10075519-global-clinical-operations-cra-manager*

List of links present in page

1. https://jobapi.novartis.com/req-10075519-global-clinical-operations-cra-manager
2. https://www.novartis.com/about/strategy/people-and-culture
3. https://www.novartis.com/sites/novartis_com/files/novartis-life-handbook.pdf
4. https://www.moseeker.com
5. https://www.moseeker.com