NOVARTIS

Global Clinical Operations- CRA Manager

Job ID
REQ-10075519
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Китай

Сводка

Oversight of CRA performance, development and coaching of CRA to drive mindset and behavior- responsible for managing and addressing CRA performance targets per defined KPIs: delivery, productivity, and quality performance indicators, including managing site recruitment commitments, timely data entry and issue resolution.
People and resource management – ongoing assessment of allocation of CRAs to studies and sites.
Budget oversight – monitors and approves CRA travel and expense to ensure compliance to T&E policy, and to ensure local targets for travel budget are met.
Ensures CRA monitoring competency gaps are identified and resolved through targeted coaching and training curricula in collaboration with training group.
Liaise on ongoing basis with CPMs to ensure enrollment, data collection and data cleaning are executed by CRAs in a timely manner.

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

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.
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Business Unit
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Сайт
Shanghai (Shanghai)
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CN14 (FCRS = CN014) China Novartis Institutes for BioMedical Research Co., Ltd.
Alternative Location 1
Beijing (Beijing), Китай
Alternative Location 2
Guangzhou (Guangdong Province), Китай
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

Accessibility and accommodation

Novartis is committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to diversityandincl.china@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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