Global Clinical Operations- CRA Manager

Job ID
REQ-10060865

8月 29, 2025

China

摘要

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

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

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部门
Development

Business Unit
Innovative Medicines

地点
China

站点
Shanghai (Shanghai)

Company / Legal Entity
CN14 (FCRS = CN014) China Novartis Institutes for BioMedical Research Co., Ltd.

Alternative Location 1
Guangzhou (Guangdong Province), China

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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Accessibility and accommodation

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