Clinical Research Medical Advisor (CRMA) - Israel

Job ID
REQ-10046593

Apr 08, 2025

Israel

Summary

Accountable for all country clinical/medical aspects associated with Development and prioritized Research programs/trials by providing clinical strategic and tactical leadership as the Country Clinical Development representative. May work across several countries.

- Gathers, informs, and acts on clinical/medical/scientific insights for clinical trial concept sheets/protocols, Informed Consent Forms (ICFs) and other relevant clinical documents to optimize clinical trial implementation.
- Drives the identification and involvement of qualified investigators with greatest recruitment potential, identifies clinical recruitment hurdles and drives clinical recruitment activities to overcome these hurdles.
- Accountable for adherence to safety standards and clinical data quality in the country by providing general clinical/medical support for trial related safety findings.
- In close collaboration with other country functions (e.g., clinical trial operations, Medical Affairs and Patient Engagement) actively contributes to successful allocation, fast clinical trial start-up, timely recruitment, early identification of potential delays, and development and implementation of mitigation plans.

About the Role

From Strategy to Functional Excellence

Provides Clinical Development and indication expertise specific to Country/Cluster, and together with the clinical trial operations team, drives the execution of clinical trials with high quality and within planned timelines:

- Validates study designs, is accountable for, and makes the final decision on the clinical/medical trial and program feasibility of implementing a clinical trial protocol based on medical/clinical practice and analysis of the competitive environment in the country.

- Actively contributes to scientific/clinical/medical aspects of the start-up phase to ensure fast clinical trial site start-up.
- Provides clinical/medical expertise to clinical trial operations team members and clinical trial sites for Institutional Review Boards (IRB)/ Ethics Committee (EC) interactions.
- Decides on site/Country-specific scientific/clinical/medical content of the Informed Consent Form (ICF) as needed and ensures appropriateness of patient suitable language.
- Provides scientific/clinical/medical expertise during interactions with Country/Cluster external Experts (e.g., Regulatory Authorities, Medical Experts, Advisory Boards, Patient Advocacy Groups, etc.).
- Develops clinical/medical trial plans taking the broader ecosystem into account for assigned programs/trials to ensure successful trial implementation, which includes:
    - Pro-actively identifying early on clinical challenges to recruitment or clinical data quality and drives development of clinical/medical mitigation plans.
    - Building disease area expertise, especially for new/rare indications.
- Provides robust indication, compound, and protocol training:
    - To the clinical operations team in the country, especially to the Clinical Research Associates, and other country line functions as needed.
    - Externally as needed in the Country/Cluster at Investigator ' s Meetings or scientific venues to support recruitment and trial awareness.
- Leverages innovation in clinical trial planning and decides on clinical/medical recruitment strategy and implementation based upon physician interviews, analysis of competitive trials, and patient engagement.
- As the scientific/clinical/medical expert, supports and partners with internal Stakeholders (e.g., Clinical Trial Team, Regulatory Affairs, Medical Information, Medical Affairs, Marketing, Patient Access, HE&OR, clinical trial operations, etc.), and internal decision boards as needed regarding clinical trials.
- Gathers, informs, and acts on insights from clinical trial Investigators/site staff, Medical Experts, patients, and payers, with internal Stakeholders at the Country/Cluster level with the goal to optimize clinical trial implementation.
- Supports planning, implementation, and follow-up of scientific/clinical/medical components of Regulatory Authority inspections and internal audits.
- Reviews and resolves Country trial-related scientific/clinical/medical issues/questions. If necessary, initiates the discussion with the Global Clinical Development team.
- Accountable for adherence to safety standards, clinical data quality for the Country/Cluster and provides general scientific/clinical/medical support for safety issues:

    - Provides clinical/medical expertise to support pharmacovigilance activities.
    - May be involved in reviewing the clinical/medical aspects of clinical trial Serious Adverse Events (SAEs) occurring in the Country and supports the patient safety team, and Global as needed to ensure high quality of clinical/medical information.
    - Follows-up with the Investigator for additional clinical/medical information or clarifications for AEs and SAEs and provides clinical/medical expertise for safety amendments, Investigator Notifications (INs), Urgent Safety Measures (USM), etc. as needed.
- Supports the Global Clinical Development team as needed to address/clarify clinical/medical Protocol Deviations through follow-up with clinical trial sites.
- May support innovative study designs by identifying and conducting quality assessments of Country datasets (e.g., Registries, Electronic Health Records, Payer data, Real World Data, etc.).
- Drives all clinical/medical activities in adherence to GCP (Good Clinical Practices), and in line with ICH (International Conference on Harmonization) and Country regulations.
- Provides scientific/clinical/medical input to the overall Product strategy at the Country level with an optimized cross-functional Country team.
- May represent Clinical Development at internal and external meetings.

- Provides a superior customer experience for Investigators/site study teams, significantly impacting the external visibility and reputation of Novartis

Details of Technical

Competency

Skills:

- Ability to manage a study from the scientific/medical/clinical perspective, and a demonstrated capability to problem solve and mediate complex scientific/clinical/medical/operational issues.
- Ability to lead effectively by communicating well, motivating a cross-functional team, and handling and delegating responsibilities.
- Agility to move quickly across different therapeutic areas and indications.
- Demonstrated problem-solving skills and comfort with complexity.
- Ability to prepare and deliver high quality presentations.

Experience:

- Ideally, 3 years of clinical development experience in the pharmaceutical industry or clinical practice.
- Sound understanding of the overall clinical development process, and ICH/GCP principles.

Protocol Execution:

- Demonstrates a knowledge of how to adequately review and read a protocol to understand specifics of study design and answer questions regarding the trial.

- Applies a detailed understanding of the drug in question to provide medical context as it relates to disease processes, populations, and standards of care.
- Ability to assess the feasibility of implementing the protocol based on Country/Cluster medical practice and sound understanding of the overall Clinical Development Plan.
- Demonstrates a high level of understanding of the protocol to train others, including site personnel.
- Demonstrates an understanding of the protocol to evaluate compliance on the part of the Investigator/site staff/study participant and any patient safety issues.

Regulatory & Compliance:

- Demonstrates an understanding of Regulatory requirements and internal policies, procedures, and guidelines pertaining to clinical trials.
- Applies knowledge of Regulatory/industry requirements to work in a Country regulated environment.
- Demonstrates current knowledge of relevant Country regulations and compliance requirements and communicates to Global teams as required.
- Demonstrates knowledge of applicable SOPs, policies, procedures, and guidance documents.
- Expertise to represent the company as safety expert for clinical trials to external Regulatory and compliance bodies such as Regulatory Authorities, Health Boards, and REB/EC.

Safety Monitoring:

- Provides clinical, medical, and scientific expertise to facilitate the safe use of product(s) in clinical trials.
- Applies safety expertise to answer clinical trial site safety questions and provides required information to Country/Global where appropriate.
- Applies clinical/medical expertise to provide prompt review and follow-up on all SAEs and other safety documents relevant for clinical trial sites.

Education:

- Scientific degree M.D., Ph.D., or Pharm.D. (M.D. highly desirable,
- > 40 % of CRMA FTEs in a country if possible)
- Subspecialty training desirable

Languages:

- Speaks and writes English
- Speaks Hebrew

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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 all individuals. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to receive more detailed information about the essential functions of a position, please send an e-mail to diversity.inclusionch@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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Development

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勤務地
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Company / Legal Entity
IL04 (FCRS = IL004) Novartis Israel

Functional Area
Research & Development

職種
Full time

雇用形態
Regular

Shift Work
No

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