

Clinical Research Medical Advisor - Israel

Job ID
REQ-10019659
Sep 03, 2024
Israel

Zusammenfassung

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

About the Role

- 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.
- KPI
- Meets Country/Cluster specific clinical trial operations Key Performance Index (KPI) targets, particularly those related to trial feasibility and recruitment.
- Drives investigator site performance by providing high quality support to Investigators/Clinical trial site staff for Development and Biomedical Research studies, leading to a superior customer experience.
- Prepares high quality Country clinical trial documents according to agreed timelines especially for IRB/EC/Regulatory Authorities, and Investigator queries as needed.
- Timely management of local safety issues.
- Quality of scientific/clinical/medical input to Country, and Global teams.

Education:

- Scientific degree M.D., Ph.D., or Pharm.D. (M.D. highly desirable)
- Subspecialty training desirable

Languages:

- Speaks and writes English
- Speaks and writes Hebrew

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.

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>

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Abteilung

Development

Business Unit

Innovative Medicines

Ort

Israel

Website

Israel

Company / Legal Entity

IL04 (FCRS = IL004) Novartis Israel

Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
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