(Associate) Clinical Development Medical Director

Job ID
REQ-10062151

9月 15, 2025

USA

摘要

Accountable for all country clinical/medical aspects associated with programs/trials by providing clinical strategic and tactical leadership
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 line 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

- Provides Clinical Development and indication expertise specific to Country, and together with the clinical trial operations team, drives the execution of clinical trials with high quality and within planned time- lines:
- 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.
- 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 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 pro- grams/trials to ensure successful trial implementation, which includes:
- Provides robust indication, compound, and protocol training:
- 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.
- Gathers, informs, and acts on insights from clinical trial Investigators/site staff, Medical Experts, patients, and payers, with internal Stakeholders at the Country 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 and pro- vides general scientific/clinical/medical support for safety issues:
- 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.).

Role Requirements

Education & Experience

- MD/DO or equivalent, with training in cardiology preferred.

- Knowledge and clinical training in siRNA desirable

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 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.

- Demonstrates an understanding of Regulatory requirements and internal policies, procedures, and guidelines pertaining to clinical trials.
- 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.

Novartis Compensation and Benefit Summary:

The salary for this position is expected to range between $236,400 - $439,600 per year.

The final salary offered is determined based on factors like, but not limited to, relevant skills and experience, and upon joining Novartis will be reviewed periodically. Novartis may change the published salary range based on company and market factors.

Your compensation will include a performance-based cash incentive and, depending on the level of the role, eligibility to be considered for annual equity awards.

US-based eligible employees will receive a comprehensive benefits package that includes health, life and disability benefits, a 401(k) with company contribution and match, and a variety of other benefits. In addition, employees are eligible for a generous time off package including vacation, personal days, holidays and other leaves.

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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

Benefits and Rewards: Read our handbook to learn about all the ways we ' ll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

EEO Statement:

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Accessibility & Reasonable Accommodations

The Novartis Group of Companies are 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 application process, or to perform the essential functions of a position, please send an e-mail to us.reasonableaccommodations@novartis.com or call +1(877)395-2339 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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状态
New Jersey

站点
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Functional Area

Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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