NOVARTIS

# Senior Clinical Development Medical Director - Cardio | Renal | Metabolism

Job ID
REQ-10007757
Jul 01, 2024
Estados Unidos

## Resumen

The Senior Clinical Development Medical Director (Sr. CDMD) is the clinical leader of a section of a clinical program (e.g., an indication, a new formulation, or a specific development phase), or a large, complex trial, under the leadership of the (Sr.) GPCH.

## About the Role

**Major accountabilities:**

- Provides clinical leadership and strategic guidance for all clinical deliverables in the assigned section of a clinical program or programs. Clinical deliverables may include the clinical development strategy for assigned program section(s), clinical sections of individual protocols consistent with the Integrated Development Plans (IDP), clinical data review, program specific standards, clinical components of regulatory documents/registration dossiers, and publications
- Leads development of clinical sections of trial and program level regulatory documents (e.g., Investigator's Brochures, briefing books, safety updates, submission dossiers, and responses to Health Authorities)
- Drives execution of the section of the clinical program in partnership with global line functions, assigned study leads (SLs), and regional/country medical associates
- Ensures ongoing medical and scientific review of clinical trial data
- Supports (Sr.) GPCH in ensuring overall safety of the molecule for the assigned section, may be a core member of the Safety Management Team (SMT), and supports overall program safety reporting (e.g., Periodic Safety Update Reports (PSURs), Drug Safety Update Reports (DSURs), and other safety related documents) in collaboration with Patient Safety
- Leads the Global Clinical Team (GCT), if there is a separate GCT for the assigned program section. Represents the section when needed in Global Program Team (GPT) meetings, and as the section spokesperson in internal and external meetings/boards, as needed
- Supports the Clinical Development Head (CDH) by providing medical input into IDP and CTP reviews and contributing/driving development of disease clinical standards for new disease areas. May take on other TA responsibilities as directed by the CDH
- As a medical expert, supports the (Sr.) GPCH or CDH in interactions with external stakeholders (e.g., regulatory authorities, key opinion leaders, data monitoring boards, advisory boards, patient advocacy groups), internal stakeholders (e.g., CTT, Research, Translational Medicine, Global Medical Affairs, Marketing, HE&OR), and internal decision boards
- May work with NIBR (Novartis Institute of Biomedical Research)/ Translational Medical Sciences) to drive

transition of pre-PoC (Proof of Concept) projects to DDP (Development Decision Point) and with BD&L (Business Development & Licensing) including target identification and due diligences together with other medical matters, as needed
- Ensures career development of Function and Program reports and other clinical colleagues through active participation in the performance management and talent planning processes. Provides on-boarding, training, & mentoring support
- Contributes to medical/scientific training of relevant Novartis stakeholders on the disease area and compound/molecule. May serve as speaker for franchise medical/scientific training
- May serve on or lead global initiatives (e.g., process improvement, training, SOP development, other Clinical Development line function initiatives)
- Specific responsibilities related to the clinical program in CRM include:
- Serving as the lead medical for a pivotal registration trial (CV outcomes study)
- Leading the clinical work related to an NDA submission
- Coach and support junior clinical team members through the submission phase

**Minimum Requirements:**

- MD or equivalent medical degree required. Advanced knowledge and clinical training in a medical/scientific area (e.g., internal medicine or sub-specialty) required, with Medical Board certification preferred; Clinical practice experience ≥ 4 years (including residency) preferred
- Fluent oral and written English
- ≥ 7 years of involvement in clinical research or drug development in an academic or industry environment spanning clinical activities in Phases I ~ IV
- ≥ 4 years of contribution to and accomplishment in all aspects of conducting clinical trials (e.g., planning, executing, reporting and publishing) in a global/matrix environment in pharmaceutical industry
- NDA submission experience with major health authorities (FDA and EMA)
- Advanced knowledge of assigned therapeutic area
- Demonstrated ability to establish strong scientific partnership with key stakeholders
- Thorough knowledge of GCP, clinical trial design, statistical analysis methodology, and regulatory/clinical development process
- Excellent communication skills, written and oral
- Strong interpersonal skills
- Excellent negotiation and conflict resolution skills

**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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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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