U NOVARTIS

Associate Clinical Development Medical Director, In Brand Markets (M.D.)

Job ID REQ-10049287

4月 17, 2025

USA

摘要

Onsite #LI-Onsite East Hanover, New Jersey

About the role:

As our Associate Clinical Development Medical Director, Gene Therapy, you will be the clinical leader of defined program level activities such as submission activities, briefing books or sophisticated trials, under the leadership of the Global Program Clinical Head. You may lead a section of a clinical program, an indication, new formulation, or specific development phase. The Associate Clinical Development Medical Director is a key role that oversees scientific and medical aspects of clinical trials, including safety, data monitoring, and quality reporting. Depending on trial complexity, they may also handle sections of the program's medical strategy.

About the Role

Your Key Responsibilities:

- Provide clinical leadership and medical strategic input for all clinical results in the assigned project or section of a clinical program. Clinical deliverables may include clinical and scientific sections of individual protocols consistent with the Integrated Development Plans, clinical data review, program standards, clinical components of regulatory documents/registration dossiers, and publications
- Lead 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)
- Drive execution of the section of the clinical program in partnership with line functions, assigned Global Trial Director, and regional/country medical associates
- Coordinate/conduct ongoing medical and scientific review of clinical trial data with Clinical Scientific Expert
- May be the Program Manager of other associates Support GPCH in ensuring safety of the molecule for the assigned section, may be a core member of the Safety Management Team, and support overall program safety reporting (e.g., Periodic Safety Update Reports, Drug Safety Update Reports and other safety related documents) in collaboration with Patient Safety
- Work with the Clinical Development Head providing medical input into the Development Plan and Clinical Trial Protocol reviews and driving development of disease clinical standards for new disease areas.
- Support the GPCH or CDH in interactions with external partners (authorities, opinion leaders, data monitoring boards, advisory boards, patient advocacy groups), internal partners (CTT, Research, Translational Medicine, Global Medical Affairs, Marketing, Health Economics & Outcome Research), and decision boards
- Work with NIBR (Novartis Institute of Biomedical Research)/Translational Medical Sciences to drive transition of pre-PoC projects to DDP and with Business Development & Licensing

Video Link https://www.youtube.com/watch?v=ggbnzRY9z8w

The ideal location for this role is the East Hanover site but remote work may be possible (there may be some restrictions based on legal entity). Please note that this role would not provide relocation as a result. If associate is remote, all home office expenses and any travel/lodging to East Hanover for periodic live meetings will be at the employee 's expense. The expectation of working hours and travel (domestic and/or international) will be defined by the hiring manager. This position will require 10% travel.

Role Requirements: Essential Requirements:

- MD or equivalent medical degree required. Extensive knowledge and clinical training in a medical/scientific area required, with Medical Board Certification preferred.
- 3+ years of direct involvement in clinical research or drug development in an academic or industry environment or equivalent, spanning clinical activities preferably in Phases I through

IV. Having contributed to and accomplished in all aspects of conducting clinical trials in a global/matrix environment in pharmaceutical industry or equivalent

• 2+ 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

Desired Requirements:

- 4+ years Clinical practice experience (including residency) preferred
- Detailed knowledge of GCP, clinical trial design, statistical analysis methodology, and regulatory/ clinical development process
- People management experience preferred; this may include management in a matrix environment. People management experience desirable
- Excellent negotiation, conflict resolution and communication skills (written and oral).

Novartis Compensation and Benefit Summary:

The pay range for this position at commencement of employment is expected to be between: \$204,400 and \$379,600/year; however, while salary ranges are effective from 1/1/25 through 12/31/25, fluctuations in the job market may necessitate adjustments to pay ranges during this period. Further, final pay determinations will depend on various factors, including, but not limited to geographical location, experience level, knowledge, skills, and abilities. The total compensation package for this position may also include other elements, including a sign-on bonus, restricted stock units, and discretionary awards in addition to a full range of medical, financial, and/or other benefits (including 401(k) eligibility and various paid time off benefits, such as vacation, sick time, and parental leave), dependent on the position offered. Details of participation in these benefit plans will be provided if an employee receives an offer of employment. If hired, employee will be in an "at-will position" and the Company reserves the right to modify base salary (as well as any other discretionary payment or compensation program) at any time, including for reasons related to individual performance, Company or individual department/team performance, and market factors.

Why Novartis:

Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: <u>https://www.novartis.com/about/strategy/people-and-culture</u>

You'll receive:

You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook.

https://www.novartis.com/careers/benefits-rewards

Accessibility and 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 in order to perform the essential functions of a position, please send an e-mail to tas.nacomms@novartis.com 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.

Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay connected to learn more about Novartis and our career opportunities, join the Novartis Network here: <u>https://talentnetwork.novartis.com/network</u>

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? <u>https://www.novartis.com/about/strategy/people-and-culture</u>

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: <u>https://www.novartis.com/careers/benefits-rewards</u>

EEO Statement:

The Novartis Group of Companies are Equal Opportunity Employers. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, sex, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status.

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 <u>us.reasonableaccommodations@novartis.com</u> 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.

部门 Development

Business Unit Innovative Medicines

地点 USA

状态 New Jersey

站点 East Hanover

Company / Legal Entity U014 (FCRS = US014) Novartis Pharmaceuticals Corporation

Functional Area Research & Development

Job Type Full time

Employment Type Regular

Shift Work No

Apply to Job



Job ID REQ-10049287

Associate Clinical Development Medical Director, In Brand Markets (M.D.)

Apply to Job

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