

Global Program Clinical Head, Gene Therapies and Rare Disease (MD, PhD)

Job ID

REQ-10046020

Mar 28, 2025

USA

Summary

Novartis is seeking a Global Program Clinical Head (GPCH) for Gene Therapies and Rare Disease early development projects. The GPCH works to ensure early development plans and proof of concept studies are aligned with the Development strategy and leads licensing evaluations for Clinical Development for Gene therapies across various indications. As an integrative leader, the GPCH is accountable to lead decision milestones, regulatory requirements and market access for those early compounds in collaboration with relevant other functions.

About the Role

About the role:

Your Key Responsibilities:

- Serves as the Clinical Development Representative on Biomedical Research (BR) clinical/project teams to drive transition of pre-PoC (Proof of Concept) projects to Development Decision Point (DDP)
- Supports Business Development & Licensing (BD&L) activities
- Leads the GCT, represents Clinical Development on the Global Program Team (GPT)
- Post-Transition Development Point, leads the development and execution of the clinical strategy. Develops an endorsed Integrated Development Plan (IDP) in line with the Target Product Profile (TPP) which is designed for successful global regulatory approval/market access for one or multiple treatment indications and/or multiple programs
- Leads the creation of clinical components of key documents (e.g., Clinical Trial Protocols (CTPs), Investigator's Brochures, Clinical Study Reports (CSRs), regulatory documents including maintenance of product licenses, registration dossiers, value dossiers, pharmacoeconomic dossiers) with high quality and consistency with IDP and TPP. Supports registration, market access, commercialization, and maintenance of product licenses (e.g., Core Data Sheet, Periodic Safety Update Report, clinical benefit-risk assessment for license renewals) for the compound(s)
- Together with Preclinical Safety, Translational Medicine and Patient Safety, ensures continuous evaluation of drug safety profile, including safety monitoring of clinical studies and signal detection from post-marketing surveillance. Serves as a core member of the Safety Management Team (SMT)
- As the medical expert, leads interactions with external stakeholders (e.g., regulatory authorities, key opinion leaders, data monitoring committees, advisory boards, patient advocacy groups), internal stakeholders (e.g., Research, Translational Medicine, Global Medical Affairs (GMA), Marketing, Health Economics & Outcomes Research), and internal decision boards.

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.

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

Role Requirements:

Essential Requirements:

- MD or PhD with advanced clinical training/knowledge in medical/scientific area aligned with TA required and 6+ years' experience in clinical research or drug development in an industry environment spanning clinical activities in Phases I-III/IV, including submission dossiers.
- Advanced knowledge of assigned therapeutic area, with the capability to innovate in clinical development study designs that provide relevant evidence to decision-makers, and to interpret, discuss and present clinical trial or section program level data.
- Demonstrated leadership and management skills with a documented track record of delivering high quality projects/submissions/trials in a global/matrix environment (including remote) in pharmaceutical or biotech industry.
- Thorough knowledge of Good Clinical Practice, clinical trial design, statistics, and regulatory/clinical development process.
- Experience with submissions and health authorities.
- Demonstrated ability to establish strong scientific partnership with key stakeholders.

Essential Preferred:

- Medical Board certification preferred for MD or equivalent; Clinical practice experience ≥ 10 years (including residency) preferred for MD or equivalent PhD with 10 years
- Neurology, Neuromuscular or Neurodevelopmental Disorders, Genetics, Pediatrics or Neuroscience background is strongly preferred

Novartis Compensation and Benefit Summary:

The pay range for this position at commencement of employment is expected to be between: \$261,100 and \$484,900/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: <https://www.novartis.com/about/strategy/people-and-culture>

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:

<https://talentnetwork.novartis.com/network>

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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Division

Development
Business Unit
Innovative Medicines
Location
USA
State
New Jersey
Site
East Hanover
Company / Legal Entity
U014 (FCRS = US014) Novartis Pharmaceuticals Corporation
Alternative Location 1
Bannockburn, Illinois, USA
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
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