

Sr. Global Program Clinical Head

Job ID REQ-10046333

3月 29, 2025

USA

摘要

The Senior Global Program Clinical Head (GPCH) is the global clinical leader responsible for one or more clinical programs across indications, involving one or multiple compounds. As the leader of Global Clinical Team(s) (GCT), the Sr GPCH is accountable for the design, implementation, and execution of a clinical development program(s) to support decision milestones, regulatory requirements, market access, and owns the risk benefit-assessment for the program(s). The Sr. GCPH contributes to the disease area strategy and is accountable specifically for the clinical development strategy.

About the Role

Job Description

Are you prepared to embrace a distinctive opportunity as the Sr Global Program Clinical Head - Immunology at Novartis?

As the overseer of Global Clinical Team(s) (GCT), you will have a vital role in creating, implementing, and carrying out clinical development programs. Your contributions will aid in crucial decision-making, meeting regulatory standards, and ensuring market accessibility, while also allowing you to contribute to the overall strategy in the field of immunology. Join our exceptional team and make a substantial difference in this specialized area.

Your responsibilities will include, but are not limited to:

- The Sr Global Program Clinical Head (GPCH) is the global clinical leader responsible for one or more clinical programs across indications, involving one or multiple compounds. As the leader of Global Clinical Team(s) (GCT), the Sr GPCH is accountable for the design, implementation, and execution of a clinical development program(s) to support decision milestones, regulatory requirements, market access, and owns the risk benefit-assessment for the program(s). The GCPH contributes to the disease area strategy and is accountable specifically for the clinical development strategy.
 - Your responsibilities as Sr GPCH will include the following:
- Leading the GCT and representing Clinical Development on the Global Program Team (GPT)
- May serve as the Clinical Development Representative on Novartis Institute for Biomedical Research (NIBR) Translational Medicine/project teams to drive progress of early projects to Transition Decision Point (TDP), including developing the Clinical Development Plan (CDP)
- Post-TDP, leading the execution of the CDP and contributing to the Integrated Development Plan (IDP) generated by multiple line functions, 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
- Leading the creation of clinical components of key documents (e.g., Clinical Trial Protocols, Investigator Brochures, Clinical Study Reports, regulatory documents including maintenance of product licenses, registration dossiers, value dossiers, pharmacoeconomic dossiers) with high quality and consistent with the CDP, IDP, and TPP. Supporting 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 Patient Safety, ensuring continuous evaluation of the drug safety profile, including safety monitoring of clinical studies and signal detection from post-marketing surveillance; serving as a core member of the Safety Management Team
- As the medical expert, leading interactions with external stakeholders (e.g., regulatory authorities, key opinion leaders, data monitoring committees, advisory boards, patient advocacy groups), internal stakeholders (e.g., NIBR Research, Translational Medicine, Medical Affairs, Commercial, Portfolio & Strategy, Health Economics & Outcomes Research), and internal decision boards

To be successful in this role, you should meet the following minimum requirements:

- MD or equivalent (preferred), PhD, or PharmD degree required, with equivalent experience also considered. Specialization in a subspecialty may be needed.
- Board certified in Immunological Specialty Area with 6 years (MD or equivalent) or equivalent experience, 10 years (PhD or PharmD) or equivalent experience of involvement in clinical research or drug development in an industry environment spanning clinical activities in Phases I through III/IV, including submission dossiers.

- Strong Global team leadership skills and a capacity to work effectively and manage reports across time zones, while based out of our US headquarters in East Hanover, NJ or Basel, Switzerland
- Advanced knowledge of assigned therapeutic area required, with the capability to innovate in clinical development study designs
- 5 years of people management experience required
- Thorough knowledge of Good Clinical Practice, clinical trial design, statistics, and regulatory/clinical development process
- Experience with submissions and health authorities required

Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between: \$261,100/year to \$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: 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

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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 <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 Massachusetts

站点 Cambridge (USA)

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

Functional Area Research & Development

Job Type Full time Employment Type Regular

Shift Work No

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