Global Program Clinical Head - Dermatology

Job ID
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USA

Sommario

The 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 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.

About the Role

Are you prepared to embrace a distinctive opportunity as the Global Program Clinical Head - Dermatology 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 dermatology. Join our exceptional team and make a substantial difference in this specialized area.

Your responsibilities will include, but are not limited to:

- The 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 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 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 Dermatologist 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

At Novartis, we value our employees and strive to provide exceptional benefits and rewards. 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

We are committed to building an outstanding, inclusive work environment and diverse teams that are representative of the patients and communities we serve.

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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