Global Program Clinical Head

Job ID
REQ-10012248
Jul 10, 2024
Estados Unidos

Resumen

The Global Program Clinical Head designs and provides oversight of clinical research programs. Builds relationships with key opinion leaders and applies their input to enhance study design and protocols. Serves as medical/scientific consultant to marketing or research project teams and government regulatory agencies. Establishes the criterion essential for determining the safety, efficacy, and medical utilities. Interprets results of Phase I-III investigations in preparation for new-drug or medical device application. May serve as safety expert for individual clinical projects. May be responsible for post marketing studies

About the Role

Job Description

Are you an experienced Drug Development Leader looking for an exceptional opportunity to make a global impact? Novartis is seeking a Global Program Clinical Head for In-market Brands to join our team in Switzerland. As a leader in the industry, Novartis is dedicated to discovering innovative solutions that improve patients' lives worldwide.

Responsibilities:

- Leading the GCT and representing Clinical Development on the Global Program Team (GPT)
- Leading 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, pharmaco-economic dossiers) with high quality and consistency with Integrated Development Plan (IDP) and Target Product Profile (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)
- May serve as the Clinical Development Representative on NIBR clinical/project teams to drive transition of pre-PoC (Proof of Concept) projects to Development Decision Point (DDP)
- Post-DDP, leading the development and execution of the clinical strategy. Developing an endorsed (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
- Where applicable, supporting Business Development & Licensing (BD&L) activities

Requirements:

- MD, PhD, or PharmD degree required, specialization in a subspecialty preferred
- Minimum 10 years involvement in clinical research or drug development in an industry environment spanning clinical activities in Phases I through III/IV, including submission dossiers
- Sophisticated knowledge of assigned therapeutic area preferred, 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
- Thorough knowledge of Good Clinical Practice, clinical trial design, statistics, and regulatory/clinical development process
- Strong leadership skills with the ability to effectively collaborate and influence cross-functional teams

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

EEO Statement:

The Novartis Group of Companies are Equal Opportunity Employers and take pride in maintaining a diverse environment. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, gender, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status. We are committed to building diverse teams, representative of the patients and communities we serve, and we strive to create an inclusive workplace that cultivates bold innovation through collaboration and empowers our people to unleash their full potential.

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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