

Global Program Clinical Head

Job ID
REQ-10012248
Juli 10, 2024
USA

Summary

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>

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Division

Development

Business Unit

Innovative Medicines

Standort

USA

Site

East Hanover

Company / Legal Entity

U014 (FCRS = US014) Novartis Pharmaceuticals Corporation

Alternative Location 1

Hyderabad (Office), Indien

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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EEO Statement :

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Major Accountabilities ~ Steigern Sie Ihr wettbewerbsfähiges Umsatzwachstum ~ Identifizierung und Priorisierung von Kunden mit hohem Potenzial durch Datenanalyse (HCPs und Stakeholder), die Verschreibungsentscheidungen beeinflussen ~ Steigern Sie die Vertriebsleistung durch die geschickte Orchestrierung positiver Kundenerlebnisse ~ Engagieren und Beziehungen aufbauen ~ Führen Sie wertorientierte Gespräche (persönlich und virtuell), um kritische Kundenherausforderungen, Entscheidungstreiber, Schwachstellen und Chancen zu verstehen ~ Personalisieren und orchestrieren Sie Customer Engagement Journeys für HCPs,

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