

Global Program Clinical Head: In-market Brands

Job ID

REQ-10010858

Juil 19, 2024

Royaume-Uni de Grande-Bretagne et d'Irl. du Nord

Résumé

-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

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**

At Novartis, we believe in fostering an inclusive and diverse workforce. We are an equal opportunity employer and are committed to providing reasonable accommodations/adjustments to individuals with disabilities during the recruitment process.

If you are a motivated individual with a passion for research and a drive to compete in the global pharmaceutical industry, this is the opportunity for you. Join Novartis and be part of a team that is determined to make a difference in the lives of patients worldwide. Apply now and help us successfully implement groundbreaking therapies that will shape the future of medicine.

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>

Division
Development

Business Unit
Innovative Medicines
Emplacement
Royaume-Uni de Grande-Bretagne et d'Irl. du Nord
Site
London (The Westworks)
Company / Legal Entity
GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.
Functional Area
Recherche & Développement
Job Type
Full time
Employment Type
Regular
Shift Work
No
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Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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