# **U** NOVARTIS

## **Global Program Clinical Head**

Job ID REQ-10046531 Apr 04, 2025 Switzerland

### Summary

With over 60 years history in neuroscience, Novartis brought landmark therapies to patients with Multiple Sclerosis, Alzheimer's disease, Parkinson's Disease, Epilepsy, Depression and Migraine. We have a worldclass pipeline in neuro-inflammation, neurodegeneration, psychiatric and neuromuscular diseases. Our holistic R&D approach includes cutting edge molecules, comprehensive approaches to technology, biomarker and digital therapeutics to propose better solutions for patients worldwide.

### About the Role

As Global Program Clinical Head (GPCH), you are the clinical lead of Neuroscience, full development product. As a key member of the Global Program Team, you will contribute to the overall strategy in collaboration with relevant other functions such as Regulatory Affairs, Market Access and others. You will develop and ensuring the implementation of the Clinical Development plan and leading a cross functional team of specialists such as Medical Directors, Trial Directors, Safety Leaders, Biostatisticians and Regulatory Directors. The GPCH works to ensure early development plans and proof of concept studies are aligned with Development for the therapeutic area. In addition, you will lead the development and execution of the disease area strategy.

## What you'll be doing:

- Responsible for clinical input to support Business Development & Licensing (BD&L) activities
- Serve as the Clinical Development Representative to drive transition of pre-PoC (Proof of Concept) projects to Development Decision Point (DDP)
- Contribute to Integrated Development Plan (IDP) in line with the Target Product Profile (TPP) which is designed for successful global regulatory approval/market access for one or more treatment indications

and/or multiple programs.

- Drive creation and implementation of Clinical Development to support decision analysis and optimal resource allocation in program(s).
- Lead a cross functional team through the creation of clinical components of key documents (e.g., Clinical Trial Protocols, Investigator's Brochures, Clinical Study Reports, regulatory documents including maintenance of product licenses, registration dossiers, value dossiers, pharmacoeconomic dossiers) with high quality and consistency.
- As the medical expert, lead interactions with external stakeholders (e.g., regulatory authorities, key opinion leaders, data monitoring committees, advisory boards, patient advocacy groups), internal stakeholders (e.g., Research, Translational Medicine, Global Medical Affairs, Marketing, Health Economics & Outcomes Research), and internal decision boards
- Together with Patient Safety, ensure continuous evaluation of drug safety profile, including safety monitoring of clinical studies and signal detection from post-marketing surveillance.
- Support 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)
- Plan and implement publication and clinical communication strategy in coordination with Global Medical Affairs and Medical Writing, and provide input into key external presentations

## What you'll bring to the role:

- MD, or PH. D degree with 10+ years' experience in clinical research or drug development in an industry environment spanning clinical activities in Phases I-III/IV, including submission dossiers.
- A passion for Neuroscience
- Advanced expertise in Neuroscience with ability to innovate in clinical development study designs, provide relevant evidence to decision-makers and to interpret, discuss and present clinical trial or section program level data
- Detailed knowledge of Good Clinical Practice, clinical trial design, statistics, and regulatory/clinical development process
- Demonstrated ability to establish strong scientific partnership with key stakeholders
- Demonstrated leadership and management skills with a documented track record of delivering high quality projects/submissions/trials in a global/matrix environment (including remote) in pharmaceutical or biotech industry

## Desirable:

• MD or equivalent, MD or MD/PhD in Neurology, Experience in Cell&Gene, Rare or Neuromuscular diseases, Neuroinflammation of interest (preferred).

## This is a hybrid role and it can be based in Basel, London or Barcelona.

**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? <u>https://www.novartis.com/about/strategy/people-and-culture</u>

**Benefits and Rewards:** Read our handbook to learn about all the ways we'll help you thrive personally and professionally: <u>https://www.novartis.com/careers/benefits-rewards</u>

**Commitment to Diversity & Inclusion:** 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, colour, 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.

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Division Development **Business Unit Innovative Medicines** Location Switzerland Site Basel (City) Company / Legal Entity C028 (FCRS = CH028) Novartis Pharma AG Alternative Location 1 Barcelona Gran Vía, Spain Alternative Location 2 London (The Westworks), United Kingdom **Functional Area Research & Development** Job Type Full time **Employment Type** Regular Shift Work No Apply to Job

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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### **Global Program Clinical Head**

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#### List of links present in page

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