## **U** NOVARTIS

## Global Program Clinical Head (Early GPCH NS)

Job ID REQ-10055963

7月 01, 2025

United Kingdom

## 摘要

As Global Program Clinical Head (GPCH), you are the clinical lead for Neuroscience, leading clinical development and contributing to overall strategy in collaboration with other functions, to ensure the development and implementation of the Clinical Development plan. You will lead a cross-functional team of specialists and align early development plans with the overall strategy, oversee licensing evaluations, and develop and execute the disease area strategy.

About the Role

Your Key Responsibilities:

- Responsible for clinical input to support Business Development & Licensing (BD&L) activities.
- The GPCH works to ensure early development plans and proof of concept studies are aligned with Development strategy.

- 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

Role Requirements:

Essential Requirements:

- 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

**Desired Requirements:** 

• MD or equivalent, MD or MD/PhD in Neurology, Experience in Cell & Gene, Rare or Neuromuscular, Neurodegenerative diseases, Neuroinflammation of interest

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>

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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>

部门 Development

Business Unit Universal Hierarchy Node

地点 United Kingdom

站点 London (The Westworks)

Company / Legal Entity GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.

Alternative Location 1 Basel (City), Switzerland

Functional Area Research & Development

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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