

Global Program Clinical Head - Neurosciences

Job ID REQ-10032147 jan 08, 2025 Suisse

Résumé

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 world-class 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

The Global Program Clinical Head (GPCH) is the global clinical leader responsible for one or more clinical programs across indications, involving one or multiple compounds.

As the leader of Global Clinical Team(s) (GCT), the GPCH is accountable for the design, implementation, and execution of a clinical development program(s) to support decision milestones, regulatory requirements, market access and owns the risk benefit-assessment for the program(s). The GCPH contributes to the disease area strategy.

Your responsibilities include, but are not limited to:

- Leading the development and execution of the clinical strategy in full development (Phase 2b and 3) and developing an endorsed Clinical Development Plan (CDP) 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
- Responsible for clinical input to support Business Development & Licensing (BD&L) activities
- Might serve as the Clinical Development Representative to drive transition of pre-PoC (Proof of Concept) projects to Transition Development Point (TDP))
- Drive creation and implementation of Clinical Development to support decision analysis and optimal resource allocation in program(s).
- Lead a cross functional team (Global Clinical Team GCT) 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 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 (6+ years for MD's) 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 (preferred)

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

Read our handbook to learn about all the ways we'll help you thrive personally and professionally: Novartis Life Handbook

Accessibility and accommodation Novartis is committed to working with and providing reasonable accommodation to all individuals. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to receive more detailed information about the essential functions of a position, please send an e-mail to diversity.inclusion_ch@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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

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

Division Development **Business Unit** Innovative Medicines **Emplacement**

Suisse

Site

Basel (City)

Company / Legal Entity

C028 (FCRS = CH028) Novartis Pharma AG

Alternative Location 1

London (The Westworks), Royaume-Uni de Grande-Bretagne et d'Irl. du Nord

Functional Area

Recherche & Développement

Job Type

Full time

Employment Type

Regular

Shift Work

Nο

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