U NOVARTIS

Global Program Clinical Head Neuroscience (MD, PHD)

Job ID REQ-10032148 Mar 03, 2025 USA

About the Role

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 (preferred)

You'll receive:

Competitive salary, annual bonus, pension scheme, share scheme, health insurance, 25 days annual leave, flexible working arrangements, subsidized dining facilities, employee recognition scheme and learning and development opportunities as well.

Why Novartis?

769 million lives were touched by Novartis medicines in 2020, and while we're proud of this, we know there is so much more we could do to help improve and extend people's lives.

We believe new insights, perspectives and ground-breaking solutions can be found at the intersection of medical science and digital innovation. That a diverse, equitable and inclusive environment inspires new ways of working.

We believe our potential can thrive and grow in an unbossed culture underpinned by integrity, curiosity and flexibility. And we can reinvent what's possible, when we collaborate with courage to aggressively and ambitiously tackle the world's toughest medical challenges. Because the greatest risk in life, is the risk of never trying!

Imagine what you could do here at Novartis!

Role Requirements

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>

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: <u>https://www.novartis.com/careers/benefits-rewards</u>

Division Development **Business Unit** Innovative Medicines Location USA Site East Hanover Company / Legal Entity U014 (FCRS = US014) Novartis Pharmaceuticals Corporation Alternative Location 1 USA **Functional Area Research & Development** Job Type Full time **Employment Type** Regular Shift Work No Apply to Job

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