Senior Global Program Clinical Head, Oncology

Job ID
393918BR
Nov. 07, 2024
USA

Zusammenfassung

Onsite
Location: East Hanover, New Jersey
Job Description Summary

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Location: East Hanover, New Jersey
Hybrid
#LI-Hybrid

About the role:
As Global Program Clinical Head (GPCH), you are the clinical lead of a Oncology full development product and will lead the clinical assessment of internal Novartis Institute for Biomedical Research (NIBR) early clinical programs and external assets (Business Development & Licensing - BD&L) across Oncology (Solid Tumor) indications. 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. In addition, you will lead the development and execution of the disease area strategy.

About the Role

Your Key Responsibilities:

- 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.

The ideal location for this role is East Hanover, NJ, but remote work may be possible (there may be restrictions based on legal entity). Please note that this role would not provide relocation as a result. If the associate is remote, all home office expenses and travel/lodging to the East Hanover or corporate site for periodic live meetings will be at the employee's expense. The expectation of working hours and travel (domestic and/or international) will be defined by the hiring manager.

Video Link

- https://www.youtube.com/watch?v=ggbnzRY9z8w

Role Requirements:

Essential Requirements:

- MD with 6+ 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 Oncology
- Advanced expertise in Oncology 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

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

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Accessibility and reasonable accommodations

The Novartis Group of Companies are committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the application process, or in order to perform the essential functions of a position, please send an e-mail to tas.nacomms@novartis.com call +1 (877)395-2339 and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

https://www.novartis.com/careers/careers-research/notice-all-applicants-us-job-openings

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