NOVARTIS

Global Program Clinical Head - Oncology

Job ID
REQ-10041717
Feb 27, 2025
Regno Unito

Sommario

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 Biomedical Research (BR) 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.

Role Requirements:

- **Essential Requirements**:
- MD, PharmD, PHD degree 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

Desirable Requirements:

- MD license is highly preferred and desirable.

This is a hybrid role, based at The Westworks in London

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Development
Business Unit
Innovative Medicines
Posizione
Regno Unito
Sito
London (The Westworks)
Company / Legal Entity
GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.
Alternative Location 1
Basel (City), Svizzera
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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2. https://www.novartis.com/careers/benefits-rewards
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