

Global Program Clinical Head - Cardiovascular

Job ID
REQ-10074754
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Великобритания

Сводка

The Global Program Clinical Head (GPCH) in CV is the global clinical leader responsible for one or more clinical programs across indications, involving one or multiple compounds. The GPCH owns the risk benefit assessment for the program(s), and as the leader of Global Clinical Team(s) (GCT) is accountable for the design, implementation, and execution of a clinical development program(s) to support decision milestones, regulatory requirements and market access. The GPCH may contribute to disease area strategy

About the Role

Ll#hybrid

This hybrid_role will be based in London, United Kingdom or Barcelona, Spain

Major accountabilities:

- Leads the GCT, represents Clinical Development on the Global Program Team (GPT)
- May serve as the Clinical Development Representative on Biomedical Research clinical/project teams to drive transition of pre-PoC (Proof of Concept) projects to Development Decision Point (DDP)
- May support Business Development & Licensing (BD&L) activities Post-DDP, leads the development and execution of the clinical strategy.
- Develops an endorsed 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 multiple treatment indications and/or multiple programs
- Leads the creation of clinical components of key documents (e.g., Clinical Trial Protocols (CTPs), Investigator's Brochures, Clinical Study Reports (CSRs), regulatory documents including maintenance of product licenses, registration dossiers, value dossiers, pharmacoeconomic dossiers) with high quality and consistency with IDP and TPP.
- Supports 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)
- Together with Patient Safety, ensures continuous evaluation of drug safety profile, including safety monitoring of clinical studies and signal detection from post-marketing surveillance. Serves as a core member of the Safety Management Team (SMT)
- As the medical expert, leads 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 (GMA), Marketing, Health Economics & Outcomes Research), and internal decision boards.

What you'll bring to the role:

- MD or equivalent (preferred) PhD, or PharmD degree required
- 6 years professional experience with (MD or equivalent) OR 10 years (PhD or PharmD) of involvement in clinical research or drug development in an industry environment spanning clinical activities in Phases I through III/IV, including submission dossiers required
- Cardiovascular disease expertise
- Advanced knowledge of assigned therapeutic area required, with the capability to innovate in clinical development study designs that provide relevant evidence to decision-makers, and to interpret, discuss and present clinical trial or section program level data
- Thorough knowledge of Good Clinical Practice, clinical trial design, statistics, and regulatory/clinical development process required
- Experience with submissions and health authorities required
- 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

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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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Дивизион
Development
Business Unit

Development
Место
Великобритания
Сайт
London (The Westworks)
Company / Legal Entity
GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.
Alternative Location 1
Barcelona Gran Via, Испания
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No

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