Global Program Clinical Head – Cardiovascular (Early Projects and Licensing)

Job ID
REQ-10035864
Ene 29, 2025
Suiza

Resumen

The Global Program Clinical Head (GPCH) for Cardiovascular early development projects and licensing is the global clinical leader responsible for working with Research and Translational Medicine across indications and involving multiple compounds. The GPCH works to ensure early development plans and proof of concept studies are aligned with Development strategy and leads licensing evaluations for Clinical Development for the therapeutic area. The GCPH may contribute to disease area strategy

About the Role

Major accountabilities:

- Serves as the Clinical Development Representative on Biomedical Research(BR) clinical/project teams to drive transition of pre-PoC (Proof of Concept) projects to Development Decision Point (DDP)
- Supports Business Development & Licensing (BD&L) activities
- Leads the GCT, represents Clinical Development on the Global Program Team (GPT)
- Post-Transition Development Point, 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.

Minimum Requirements:

- 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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Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
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