Global Program Clinical Head - CVM - Lipids

Job ID
REQ-10037342

1月 30, 2025

Switzerland

摘要

The Global Program Clinical Head (GPCH) in CVM - Lipids 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 GCPH may contribute to disease area strategy

About the Role

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.

Minimum requirements:

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

* Final job title (Senior GPCH, Level 7 / GPCH, Level 7) and associated responsibilities will be commensurate with the successful candidates' level of expertise

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部门
Development

Business Unit
Innovative Medicines

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Switzerland

站点
Basel (City)

Company / Legal Entity
C028 (FCRS = CH028) Novartis Pharma AG

Alternative Location 1
Dublin (NOCC), Ireland

Alternative Location 2
London (The Westworks), United Kingdom

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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