

Global Program Clinical Head - CRM

Job ID
REQ-10003153

9月 20, 2024

Switzerland

摘要

The Global Program Clinical Head (GPCH) 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

The role reports into the Clinical Development Head.

Your responsibilities will include: •

- Leads the GCT, represents Clinical Development on the Global Program Team (GPT)
- May serve as the Clinical Development Representative on NIBR 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-Development Decision 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 (required) PhD (preferred)
- 5 years professional experience as MD and a minimum of 10 years of experience with clinical drug development in an industry environment spanning clinical activities in Phases I through III/IV and experience with leading submission dossiers (required)
- Ideally a Board certified Nephrologist OR extensive (> 5 years) experience in clinical development within the Nephrology Therapeutic area
- 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
- 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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部门

Development

Business Unit

Innovative Medicines

地点

Switzerland

站点

Basel (City)

Company / Legal Entity

C028 (FCRS = CH028) Novartis Pharma AG

Alternative Location 1

Dublin (Novartis Corporate Center (NOCC)), Ireland

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work
No

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