NOVARTIS

Global Program Clinical Head - CRM

Job ID
REQ-10003153
Sep 20, 2024
Switzerland

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 withing 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

Role Requirements

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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Division
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Business Unit
Innovative Medicines
Location
Switzerland
Site
Basel (City)
Company / Legal Entity
C028 (FCRS = CH028) Novartis Pharma AG
Alternative Location 1
Ireland
Functional Area
Research & Development
Job Type
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Employment Type
Regular
Shift Work
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