Head Protocol and Clinical Program Excellence

Job ID
REQ-10039389
Feb 10, 2025
Reino Unido

Resumen

The Head Protocol & Clinical Program Excellence will provide strategic planning and operational execution support to the Head CD Program Scientific Excellence to deliver on the CD program excellence goals aligned with the overall CD strategy and vision. This role must have keen and broad clinical science insight and experience, to positively impact Novartis' protocols and CDPs, the fundamental units of Development's scientific work.
The role will oversee the operational activities of CD Central Integrated Scientific Review Committee (C-ISRC) and work closely with Head CD Program Scientific Excellence, CDHs, GPCHs, as well as cross functional partner functions as needed. This role will provide operational support to leverage latest industry trends, scientific rigor and apply best practices consistently across the CD teams to ensure delivery of high-quality clinical programs.

This role is based in the UK / London and in a hybrid working approach

About the Role

Minimum Requirements:

- Provides scientific and operational support to the Central Integrated Scientific Review Committee (C-ISRC), ensuring a thorough review of Clinical Development Plans (CDPs) and Key clinical documents (Study protocols, DMC charters, etc), to maintain high levels of quality and consistency across the therapeutic areas.
- Heads the ISRC Office and is the line function manager for the Director Protocol & Clinical Program Excellence and ISRC Leads in charge of managing ISRC activities. This includes organization of priority topics, key outcomes and actions and regulatory feedback, improvements to C-ISRC strategic advice through establishing and reporting metrics and their review process.
- Working with Head CD Program Scientific Excellence and CDHs, supports and guides GPCHs for the design, implementation, and execution of clinical development program(s) to support decision milestones, regulatory requirements and market access.
- Supports and acts as delegate to the Head CD Program Scientific Excellence Head in activities like interactions with external stakeholders (e.g., regulatory authorities, key opinion leaders, data monitoring committees, advisory boards etc.) and internal NVS stakeholders as needed.
- May serve as senior functional expert for individual clinical projects, e.g. assess results of Phase I-III investigations in preparation for new-drug application.
- Provides clinical input to evaluate products for in licensing/out licensing, participates in business development processes as needed.
- Supports in driving scenario development for Clinical Development to support decision analysis and

portfolio decisions, as needed.
- Supports and execute plans on strategic enhancement and simplification of the Novartis clinical development approach (CDP, clinical trial designs, protocol and its review) to improve speed and outcome success of clinical programs.
- Engages the GPCH and the broader CD community around clinical learnings across therapeutic areas. Supports the CD talent step-up strategy. Supports strategic directions for professional CD capability building.
- Supports the Head CD Program Scientific Excellence to build cross-function collaborations and initiatives leading to a step-wised transition to the futuristic digital clinical trial era.

Key Performance Indicators

- Seamless delivery of CD program excellence initiatives and projects.
- Seamless management of regular C-ISRC meeting; documentation of the meeting minutes and follow up of action items
- Extensive collaboration and effective partnerships with the relevant stakeholders

Education (minimum/desirable):

- MD, PhD with extensive clinical development expertise, MD/PhD required

Languages:

- Fluent oral and written English

Experience/Professional requirement:

- 10+ years pharmaceutical industry experience; with a focus on medical, clinical development, regulatory and related work. Preferred versatile talents with varied experience beyond clinical.
- People leadership experience preferred
- Broad external connections and strong bonds with KOLs.
- Outstanding verbal and written communications
- Strong evidence of strategic thinking
- Strong skills at influencing without formal authority
- Proven track record in working across a matrix organization and demonstrating expert skills in building partnerships
- Preferred but not required:
- Oncology clinical development expertise

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División

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Business Unit
Innovative Medicines
Ubicación
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Sitio
London (The Westworks)
Company / Legal Entity
GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.
Alternative Location 1
Dublin (NOCC), Irlanda
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
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