Clinical Development Medical Director (CDMD) NS

Job ID
REQ-10055877

7月 02, 2025

United Kingdom

摘要

The Clinical Development Medical Director (CDMD) is the Global clinical leader of defined and assigned program level activities and deliverables (e.g. submission activities, briefing books etc.), or clinical trial(s), under the leadership of the GPCH or Sr CDMD.

About the Role

Major accountabilities:

- Provides clinical leadership, scientific and medical strategic input for all clinical deliverables in the assigned or defined program activities as applicable. Clinical deliverables may include (sections of) individual protocols consistent with the Integrated Development Plans (IDP) and CDP, clinical data review, program specific standards, clinical components of regulatory documents/registration dossiers, and publications
- Leads development of clinical sections of trial and program level regulatory documents (e.g.,

Investigator ' s Brochures, briefing books, safety updates, submission dossiers, and responses to Health Authorities)
- Drives execution of the section of the clinical program in partnership with global line functions, assigned Clinical Trial Heads (CTHs), and regional/country medical associates if applicable
- Provides medical oversight and leadership of trials and may act as medical monitor. Provides input into final analyses and interpretation including the development of the Clinical Study Report(s) (CSRs), publications and internal/external presentations
- Supports GPCH or Sr CDMD in ensuring overall benefit/risk assessment and monitor safety of the molecule for the assigned section on an ongoing basis and may be a core member of the Safety Management Team (SMT), and supports overall program safety reporting (e.g., Periodic Safety Update Reports (PSURs), Drug Safety Update Reports (DSURs), and other safety related documents) in collaboration with Patient Safety
- May be assigned to provide medical input into IDP/CDP and CTP reviews and contributing/driving development of disease clinical standards for new disease areas.
- As a medical expert, supports the GPCH or CDH/TAH in interactions with external stakeholders (e.g., regulatory authorities, key opinion leaders, data monitoring boards, advisory boards, patient advocacy groups), internal stakeholders (e.g., CTT, Research, Translational Medicine, Global Medical Affairs, Marketing, HE&OR), and internal decision boards. As the medical/clinical lead interacts with and represents Novartis to global key opinion leaders and experts and may lead or co-chair steering committees for defined clinical trials or section of a clinical development program
- May work with Biomedical Research/Translational Medical Sciences to drive transition of pre-PoC (Proof of Concept) projects to DDP (Development Decision Point) and with BD&L (Business Development & Licensing) including target identification and due diligences together with other medical matters, as assigned by the CDH
- Ensures career development of Program reports and other clinical colleagues through active participation in the performance management and talent planning processes. Provides on-boarding, training, & mentoring support

Minimum Requirements:
Education (minimum/desirable):

- MD or equivalent medical degree required. Advanced knowledge and clinical training in a medical/scientific area (e.g., internal medicine or sub-specialty) required, with Medical Board certification preferred; Clinical practice experience $\geq$ 4 years (including residency) preferred
- Experience in Neurodegenerative or Movement Disorder diseases such as Huntington's disease, Parkinsons disease, Alzheimer's disease strongly preferred.

Languages:

- Fluent oral and written English. Solid scientific writing skills.

Experience/Professional requirement:

- $\geq$ 5 years of involvement in clinical research or global drug development in an academic or industry environment spanning clinical activities in Phases I through IV. $\geq$ 3 years of

contribution to and accomplishment in all aspects of conducting clinical trials (e.g., planning, executing, reporting and publishing) in a global/matrix environment in pharmaceutical industry. Experience in late phase clinical development preferred
- Solid and advanced scientific acumen and ability to analyze and interpret scientific literature and data
- Advanced knowledge of assigned therapeutic area
- Demonstrated ability to establish strong scientific partnership with key stakeholders
- Thorough knowledge of ICH, GCP, clinical trial design and methodology, statistical analysis methodology, and regulatory/ clinical development process
- 1 year or more of people management experience required, this may include management in a matrix environment. Global people management experience desirable

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部门
Development

Business Unit
Universal Hierarchy Node

地点
United Kingdom

站点
London (The Westworks)

Company / Legal Entity
GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.

Alternative Location 1
Basel (City), Switzerland

Alternative Location 2
Dublin (Country President Office (CPO)), Ireland

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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