Clinical Development Director (MS/MG)

Job ID
REQ-10057573

7月 18, 2025

United Kingdom

摘要

The Clinical Development Director (CDD) Neuroscience and Gene Therapy, is the clinical/scientific and clinical development expert and provides leadership and support to clinical development deliverables and activities within a defined global clinical development program and/or global clinical trial (e.g. clinical development plan, clinical trial protocol), under the leadership of the GPCH.

About the Role

Major accountabilities:

- Supports and if assigned leads delivery of all assigned clinical deliverables in the assigned section of a clinical program. Clinical deliverables may include the clinical development strategy for assigned program section(s), clinical sections of individual protocols consistent with the Integrated Development Plans (IDP), clinical data review and program specific standards, clinical components of regulatory documents/registration dossiers, and

publications
- Provides input into final analyses and interpretation including the development of the Clinical Study Report(s) (CSRs), publications and internal/external presentations.
- 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)
- Oversees/conducts ongoing clinical and scientific review of clinical trial data with medical monitor, Clinical Scientific Expert(s) with appropriate oversight from Medical Lead. Work in close collaboration with the data management and statistics teams to ensure proper data quality and analysis of clinical trial results.
- Inspection Readiness and interaction with QA - risk assessments, audit preparation, mock interviews, storyboard and presentation prep; Author and/or review abstracts, presentations and manuscripts for accuracy of clinical data and content
- Provides support to Sr CDMD and/or GPCH in monitoring and safety data and signals the molecule for the assigned section of the clinical trial, may be a 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 the medical monitor, CDMD and Patient Safety
- As a clinical development expert, may support the GPCH or CDH 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
- 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
- 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
- Contributes to medical/scientific training of relevant Novartis stakeholders on the disease area and compound/molecule. May serve as speaker for franchise medical/scientific training
- May serve on or lead global initiatives (e.g., process improvement, training, SOP development, other Clinical Development line function initiatives)
- May be assigned to lead clinical trial(s) as Clinical Scientific Lead and provide leadership and guidance for all clinical aspects of a clinical trial in close collaboration with the assigned medical monitor and/or CDMD.

Minimum Requirements:
Education
(minimum/desirable): **Advanced degree in life sciences/healthcare (or clinically relevant degree) is required. PharmD, or PhD strongly preferred**

Neurology, Experience in Cell & Gene, Rare or Neuromuscular diseases, Neuroinflammation, Neurodegenerative or Movement Disorder diseases; Experience in RMS, PMS, or MG preferred.

Experience/Professional requirement:

- ≥ 7 years of involvement in clinical research or drug development in an academic or industry environment spanning clinical activities in Phases I through IV. ≥ 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
- Advanced knowledge of assigned therapeutic area
- demonstrated ability to establish strong scientific partnership with key stakeholders
- Thorough knowledge of GCP, clinical trial design and methodology, statistical analysis methodology, and regulatory/clinical development process
- >=1 year of People management experience preferred this may include management in a matrix environment. Global people management experience desirable
- Excellent communication skills, written and oral
- Excellent interpersonal skills
- Excellent negotiation and conflict resolution skills

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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
Dublin (Country President Office (CPO)), Ireland

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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