

Clinical Development Director (Neuroscience)

Job ID REQ-10060331

10月 02, 2025

United Kingdom

摘要

LOCATION: London or Dublin or Basel ROLE TYPE: Hybrid Working, #LI-Hybrid

The Clinical Development Director (CDD) 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
- May be the Program Manager of other associates (e.g., CSE)
- 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 onboarding, 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.

Education (minimum/desirable):

- Advanced degree in life sciences/healthcare (or clinically relevant degree) is required.
 PharmD, or PhD strongly preferred
- Background or experience in Neuroscience, Neurodegeneration, Neuromuscular, Gene Therapy, Rare diseases, Neuroinflammation or similar required.

· Languages: Fluent oral and written English

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

Commitment to Diversity and Inclusion:

Novartis is committed to building an outstanding, inclusive work environment and diverse teams representative of the patients and communities we serve.

#LI-hybrid

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

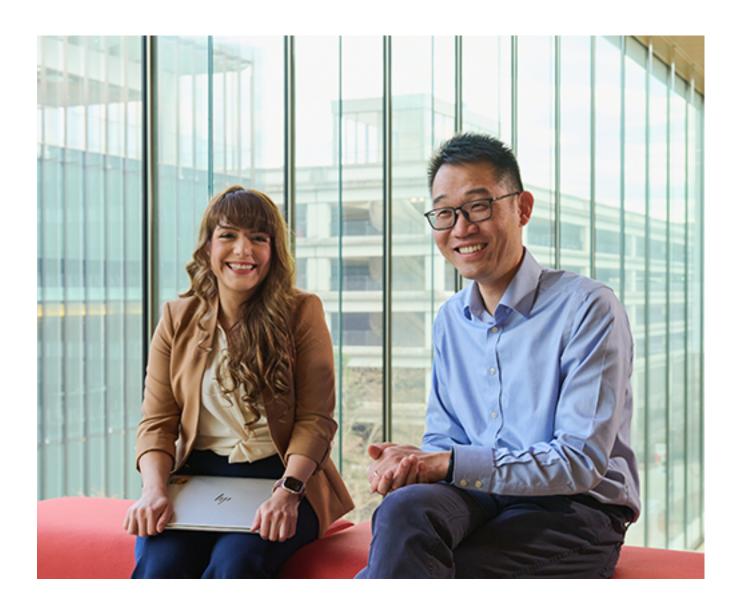
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Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

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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