

# Associate Clinical Development Director (VHB)

Job ID REQ-10057574

7月 10, 2025

**United Kingdom** 

## 摘要

Location: London, United Kingdom or Dublin, Ireland

## Role Purpose:

The Associate Clinical Development Director (Assoc. CDD) in Neurosciences provides input to development of protocols for assigned global clinical trials, scientific monitoring, and reporting of quality data. May be assigned to provide support to development of the clinical and scientific strategy of assigned sections of a clinical development program, depending on the size and complexity

## About the Role

Major accountabilities:

 Provides input to the development of clinical development strategy, and contributes to development of trial related documents (e.g., CTPs, informed consent form, case report forms, data monitoring committee charters, data analysis plan, reports, publications) for assigned clinical trial(s) consistent with Clinical Development Plan (CDP); develops materials for trial-related advisory boards, data monitoring committees, investigator meetings, and protocol training meetings for Novartis local clinical development teams

- Provides clinical and scientific input and contributes to clinical sections of trial and program level regulatory documents (e.g., Investigator's Brochures, Health Authority briefing books, safety updates, submission dossiers, and responses to Health Authorities)
- In collaboration with appropriate Clinical Trial Team (CTT) members:
  - a)Ensures clinical development oversight and support of trials as needed
  - b)Conducts ongoing scientific review of clinical trial data with Clinical Scientific Expert(s) with appropriate oversight from Medical Lead/CDMD/CSL
  - c)Manages patient safety reports on trial data to safety and clinical boards (e.g., Safety Management Team (SMT), GCT, GPT) with appropriate oversight from Medical Lead/CDMD/CSL in collaboration with patient safety
  - d)Provides input into final analyses and interpretation including the development of the Clinical Study Report(s) (CSRs), publications and internal/external presentations, with appropriate oversight from Medical Lead/CDMD/CSL
- Contributes to 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
- Evidence of quality clinical and scientific strategic input as well as timely delivery of highquality CTPs and other clinical deliverables
- Applies effective clinical research methodology, including trial design/analyses, efficacy endpoints, safety assessments, and risk management across disease area and development phases
- Supports TA through high quality contributions to CDP and protocol reviews
- Supports timely development of quality disease/program clinical standards, publications, and internal/external presentations
- Evidence of quality contributions to clinical sections of regulatory documents,
   Investigator 's Brochures, briefing books, safety updates and submission dossiers
- Clearly demonstrates Novartis Values and Behaviors

#### 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, Neurodegeneration, Experience in MS or related (strongly preferred)

Languages: Fluent oral and written English

Experience/Professional requirement:

• • 3 years of involvement in clinical research or drug development in an academic or industry

- environment spanning clinical activities in Phases I through IV. 2 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
- Working knowledge of the assigned disease area is desired with proven ability to interpret, discuss and present efficacy and safety data relating to clinical trial(s) or program level
- Demonstrated ability to establish effective working relationship with stakeholders
- Working knowledge of ICH, GCP, clinical trial design and methodology, statistics, and regulatory and clinical development processes
- Strong communication skills, written and oral
- Strong interpersonal skills
- · Strong negotiation and conflict resolution skills
- People management preferred

### Commitment to Diversity & Inclusion:

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

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

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? <a href="https://www.novartis.com/about/strategy/people-and-culture">https://www.novartis.com/about/strategy/people-and-culture</a>

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



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