Clinical Development Medical Director- Haematology(CDMD)

Job ID
REQ-10061371

9月 10, 2025

Ireland

摘要

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

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 Activities:

- 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
- 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

Key Performance Indicators:

- Timely delivery of high quality IDP/CDP sections, CTPs, and other clinical deliverables aligned with IDP/CDP and TPP and endorsed by review committees and internal boards, with acceptance by key external and internal stakeholders
- Applies effective clinical research methodology, including trial design/analyses, efficacy endpoints, safety assessments, and risk management across disease area and development phases
- Strong evidence of quality medical and scientific review of trial data; support TA through high quality IDP and protocol reviews; timely development of quality disease/program clinical

standards, publications, internal/external presentations, and other CD deliverables
- Strong evidence of quality contributions to and acceptance of clinical sections of regulatory documents, Investigators ' Brochures, briefing books, safety updates, and submission dossiers by key external and internal stakeholders
- Well managed, effective, and engaged clinical teams; demonstrated ability to deputize for GPCH/Sr CDMD at GCT, as well as other venues as needed
- Clearly demonstrates Novartis Values and Behaviors

Education:

- 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 ≥ 4 years (including residency) preferred

Experience:

- ≥ 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. ≥ 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
- People management experience required, this may include management in a matrix environment. Global people management experience
- desirable
- Experience with operating and delivering in a complex global matrix environment. and excellent team player
- Excellent communication skills, written and oral
- Excellent interpersonal skills
- Excellent negotiation and conflict resolution skills

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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

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
Innovative Medicines

地点
Ireland

站点
Dublin (NOCC)

Company / Legal Entity
IE02 (FCRS = IE002) Novartis Ireland Ltd

Alternative Location 1
London (The Westworks), United Kingdom

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

Apply to Job

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

Job ID
REQ-10061371

Clinical Development Medical Director- Haematology(CDMD)

Apply to Job

Source URL:
https://www.novartis.com.cn/careers/career-search/job/details/req-10061371-clinical-development-medical-director-haematologycdmd

List of links present in page

1. https://www.novartis.com/about/strategy/people-and-culture
2. https://talentnetwork.novartis.com/network
3. https://www.novartis.com/careers/benefits-rewards
4. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Dublin-NOCC/Clinical-Development-Medical-Director--Haematology-CDMD-REQ-10061371-1
5. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Dublin-NOCC/Clinical-Development-Medical-Director--Haematology-CDMD-REQ-10061371-1