

Clinical Development Medical Director

Job ID REQ-10062982	
10月 06, 2025	

Ireland

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

Minimum Requirements:

•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.

Previous experience /disease area expertise in Immunology/Rheumatology

Work 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
- 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 Innovative Medicines

地点

Ireland
站点 Dublin (NOCC)
Company / Legal Entity IE02 (FCRS = IE002) Novartis Ireland Ltd
Alternative Location 1 Barcelona Gran V í a, Spain
Alternative Location 2 Basel (City), Switzerland
Alternative Location 3 London (The Westworks), United Kingdom
Functional Area Research & Development
Job Type Full time

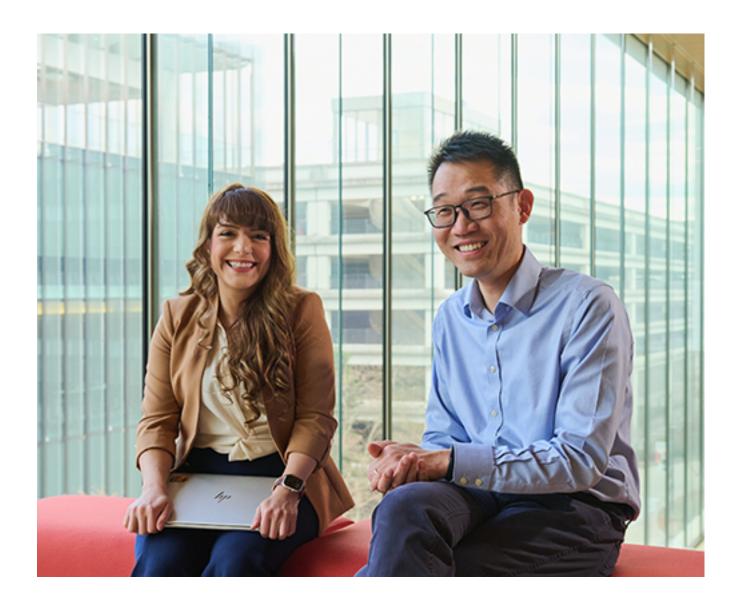
Employment Type

Regular

Shift Work No

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