Clinical Development Medical Director - Rheumatology

Job ID
REQ-10040285

2月 26, 2025

Ireland

摘要

As our Clinical Development Medical Director in our Immunology Development Unit you will be responsible for the scientific and clinical strategy of assigned clinical trials, scientific monitoring, and reporting of quality data.

The Clinical Development Medical Director (CDMD) is the clinical leader of defined program level activities (e.g., submission activities, briefing books etc.), or a large, complex trial, under the leadership of the (Sr.) GPCH. May lead a section of a clinical program (e.g., an indication, a new formulation, or a specific development phase)

About the Role

Job Description

The Clinical Development Medical Director (CDMD) for Rheumatology is the clinical leader of defined program level activities (e.g., submission activities, briefing books etc.), or a large, complex trial, under the leadership of the (Sr.) GPCH. May lead a section of a clinical program (e.g., an indication, a new formulation, or a specific development phase)

Your responsibilities include, but are not limited to:

- Provide clinical leadership and medical strategic input for deliverables in the assigned project/program. Deliverables may include sections of individual protocols consistent with the IDP, data review, program specific standards, clinical components of regulatory documents/registration dossiers, and publications (e.g., IBs, Brochures, briefing books, safety updates, submission dossiers, and responses to Health Authorities)
- Drive execution of the section of the program in partnership with global line functions, assigned Global Trial Directors (GTDs), and regional/country medical associates
- Oversee/conduct medical and scientific review of trial data with Clinical Scientific Expert(s). May be the Program Manager of other associates (e.g.., CSE). May function as study medical monitor
- Support SR/GPCH in ensuring overall safety of the molecule. May be a core member of the Safety Management Team (SMT), and supports program safety reporting (e.g., PSURs, DSURs, and safety related documents) in collaboration with Patient Safety
- Support the Therapeutic Area Head (TAH) by providing medical input into IDP and CTP reviews and contributing/driving development of disease clinical standards for disease areas.
- Provide support to the (Sr.) GPCH or TAH in interactions with external partners (e.g., regulatory authorities, KOLs, data monitoring boards, AD Boards, patient advocacy groups), internal partners (e.g., CTT, Research, Translational Medicine, GMA, Marketing, HE&OR), and decision boards)
- Work with NIBR (Novartis Institute of Biomedical Research)/ Translational Medical Sciences) to drive transition of pre-PoC projects to DDP and with BD&L including target identification and due diligences together with additional matters
- Ensure career development of Program reports and clinical colleagues through active participation in performance management and talent planning processes. Provide on-boarding, training, & mentoring support
- Contribute to medical/scientific training of relevant Novartis stakeholders on the disease area and compound/molecule. May serve as speaker for franchise.
- May serve on or lead global initiatives (e.g., process improvement, training, SOP development, other Clinical Development line function initiatives)

Minimal Requirements:

- MD (or equivalent medical degree) is required.
- Medical Board certification preferred. 4+ years Clinical practice experience (including residency) is preferred
- Possess advanced knowledge and clinical training in a medical/scientific area (e.g., internal

medicine or sub-specialty) is required.
- 5+ years ' experience in clinical research or drug development from the pharma/biotech industry 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
- Showcase advanced knowledge of assigned therapeutic area
- Demonstrate ability to establish strong scientific partnership with key partners
- Need thorough knowledge of GCP, trial design, statistical analysis methodology, and regulatory/ clinical development process
- Have people management experience preferred, this may include management in a matrix environment. Global people management is preferred.
- Exhibit excellent business communication and presentation skills
- Possess strong interpersonal skills
- Adept with excellent negotiation and conflict resolution skills

Why Novartis? Our purpose is to reimagine medicine to improve and extend people ' s lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-and-culture

You ' ll receive: You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook. https://www.novartis.com/careers/benefits-rewards 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.

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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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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 Provincial, Spain

Alternative Location 2
Basel (City), Switzerland

Alternative Location 3
Hyderabad (Office), India

Alternative Location 4
London (The Westworks), United Kingdom

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' representative of the patients and communities we serve.

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