

Clinical Development Medical Director

Job ID
REQ-10006550
Aug 26, 2024
United Kingdom

Summary

In Global Health, we focus our expertise on delivering life-enhancing medicines and improving access to healthcare for underserved populations. Novartis has one of the broadest and most innovative Global Health R&D portfolios in industry, with at least 9 different programs in various stages of maturity against Malaria and Neglected Tropical Diseases.

About the Role

As our Clinical Development Medical Director, 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)

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)

At Novartis, we are committed to fostering an inclusive and diverse work environment. We believe that diversity drives innovation and creativity, and we strive to create a culture where everyone feels valued and respected. As an equal opportunity employer, we welcome applicants from all backgrounds and experiences. We also offer reasonable accommodations and adjustments for applicants with disabilities to ensure a fair and accessible recruitment process.

Requirements:

MD (or equivalent medical degree) 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

Expertise and experience in anti-infective drug development (desirable)

- 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

Commitment to Diversity & Inclusion:

Novartis embraces diversity, equal opportunity and inclusion. We are committed to building diverse teams, representative of the patients and communities we serve, and we strive to create an inclusion workplace that cultivates bold innovation through collaboration, and empowers our people to unleash their full potential.

Novartis is an equal opportunities employer and welcomes applications from all suitably qualified persons.

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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<https://talentnetwork.novartis.com/network>

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

Division

Development

Business Unit

Innovative Medicines

Location

United Kingdom

Site

London (The Westworks)

Company / Legal Entity

GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.

Alternative Location 1

Basel (City), Switzerland

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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