Clinical Development Medical Director

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Résumé

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

About the Role

Major accountabilities:

- Provide clinical leadership and medical strategic input for deliverables in the assigned project/program. Deliverables may include sections of individual protocols consistent with the clinical development plan (CDP), data review, program specific standards, clinical components of regulatory documents/registration dossiers, and publications (e.g., investigator 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, and regional/country medical associates
- Oversee/conduct medical and scientific review of trial data with Clinical Scientific Expert (CSE). May be the Program Manager of other associates (e.g.., CSE). May function as study medical monitor
- Support GPCH in ensuring overall safety of the molecule. May be a core member of the Safety Management Team, and supports program safety reporting (e.g., PSURs, DSURs, and safety related documents) in collaboration with Patient Safety
- Support the Clinical Development Head by providing medical input into CDP and clinical trial package reviews and contributing/driving development of disease clinical standards for disease areas
- Provide support to the GPCH or CDH in interactions with external partners (e.g., regulatory authorities, key opinion leaders, data monitoring boards, advisory boards, patient advocacy groups), internal partners (e.g., clinical trial team, Medical Affairs, Commercial, Health Economics & Outcomes Research), and decision boards)
- Work with BR (Novartis Biomedical Research)/Translational Medicine) to drive transition of early development projects to Transition Decision Point and with Business Development, including target identification and due diligences
- 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 Global Clinical team

Minimum Requirements:

- MD (or equivalent medical degree) required. Training in Rheumatology preferred
- 4+ years Clinical practice experience (including residency) preferred
- Possess advanced knowledge and clinical training in a medical/scientific area (Rheumatology) required
- 5+ years of experience in clinical research or drug development from the pharmaceutical/biotechnology industry, preferably 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/matrixed environment
- Showcase advanced knowledge of assigned therapeutic area
- Demonstrate ability to establish strong scientific partnership with key partners
- Need thorough knowledge of Good Clinical Practice, clinical trial design, statistical analysis methodology, and regulatory/clinical development processes
- People management experience preferred, especially at the global level (this may include management in a matrixed environment)

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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