Clinical Development Medical Director - Immunology (All levels)

Job ID
REQ-10033326
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Sommario

As our Associate/Senior 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 Assoc/Senior 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

Please submit your application to join our Clinical Development Medical Director (Associate/Senior) Talent Pool.

Clinical Development Medical Director* (Associate/Senior) **80-100%

The (Associate/ Senior) Clinical Development Medical Director (CDMD) is responsible for leading the strategic planning and management of the assigned clinical program(s) from an end-to-end clinical development perspective. As (Associate / Senior) CDMD, you will have oversight of the clinical development for the assigned programs and drive execution of the clinical development plan. In addition, you will enable an empowered organization, which can navigate in a matrix environment and adjust quickly to business needs.

Your responsibilities will include:

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)

What you'll bring to the role:

• MD or equivalent medical degree is required*** in addition to advanced knowledge and clinical training in medical/scientific area; Clinical practice experience ≥ 4 years (including residency) preferred
• Fluent oral and written English
• Minimum requirement of years of experience in clinical research or drug development will be commensurate with level: Assoc. CDMD ≥ 3 years, CDMD ≥ 5 years, Snr CDMD ≥ 7 years
• Working knowledge of one of the above listed disease areas is desirable, with proven ability to interpret, discuss and present efficacy & safety data relating to clinical trial(s)
• Demonstrated ability to establish effective scientific partnerships with key stakeholders
• Working knowledge of GCP, clinical trial design, statistics, and regulatory and clinical development processes
• Previous global people management experience is preferred, though this may include management in a matrix environment.

* Final job title (Associate Clinical Development Medical Director, Level 5/ Clinical Development Medical Director, Level 6 / Senior Clinical Medical Development Director, Level 6) and associated responsibilities will be commensurate with the successful candidates' level of expertise.

**Some restrictions to flexible working models may apply and will be discussed at interview if applicable

*** For PharmD & PhD qualified applicants, please refer to our posting for **Clinical Development Director**

Accessibility and accommodation Novartis is committed to working with and providing reasonable accommodation to all individuals. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to receive more detailed information about the essential functions of a position, please send an e-mail to diversity.inclusion_ch@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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

Divisione
Development
Business Unit
Innovative Medicines
Posizione
Svizzera
Sito
Basel (City)
Company / Legal Entity
C028 (FCRS = CH028) Novartis Pharma AG
Alternative Location 1
Barcelona Gran Vía, Spagna
Alternative Location 2
Dublin (NOCC), Irlanda
Alternative Location 3
London (The Westworks), Regno Unito
Alternative Location 4
Madrid Delegación, Spagna
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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