NOVARTIS

Clinical Development Medical Director - Immunology

Job ID
REQ-10008803
Juli 10, 2024
Schweiz

Summary

As the Clinical Development Medical Director (CDMD) Immunology you will lead clinical teams dedicated to autoimmune rheumatic disease development programs in indications of lupus, including both systemic lupus erythematosus and lupus nephritis, through all study phases from inception/design to database lock and read-out. Core responsibilities include planning and management of the assigned clinical projects(s) from an end-to-end clinical development perspective. Together with your team, you will drive execution of the clinical development plan. You will harness the strengths of a diverse team and create a collaborative and inclusive work environment You are eager to empower your team members, in a complex matrix environment and adjust quickly to business needs.

About the Role

Major accountabilities:

- Providing clinical leadership and strategic medical input for all clinical deliverables in the assigned project or section of a clinical program
- Lead development of clinical sections of trial and program level regulatory documents
- Drive execution of the program and/or clinical trial in partnership with global line functions, assigned Global Trial Directors, and regional/country medical associates
- Support the Global Program Clinical Head in ensuring overall safety of the molecule for the assigned section, and may act as a core member of the Safety Management Team, supporting overall program safety reporting in collaboration with Patient Safety colleagues
- Support the Clinical Development Head by providing medical input into the Clinical Development Plan, Integrated Development Plan and Clinical Trial Protocol reviews. and contributing to development of disease clinical standards for new disease areas
- As a medical specialist, supporting the GPCH or CDH in interactions with external and internal partners and decision boards
- May work with Novartis 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 other medical matters, as needed

Key performance indicators:

- Timely, efficient and quality execution of trials and trial related activities within assigned clinical program(s) within budget, and in compliance with quality standards
- Appropriate funding and resourcing for assigned clinical program(s)

- Adherence to Novartis policy and guidelines and external regulations

Minimum Requirements:

- MD or equivalent medical degree is required, in addition to a proven track record of clinical experience in and scientific contributions to your field of expertise
- Training or working experience in one or more of the following: 1) rheumatology or clinical immunology; 2) lupus clinical trials (systemic lupus erythematous and/or lupus nephritis; 3) B cell-depleting biologics
- 3+ years minimum in clinical research or drug development in immunology/inflammation
- Working knowledge in the area of Immunology and Inflammation with ability to interpret, discuss and present efficacy (clinical, biomarker) and safety data relating to clinical trials
- Understanding of GCP, clinical trial design, statistics, and regulatory and clinical development processes.
- Availability of, and readiness to leverage scientific and clinical networks to establish scientific partnerships with key collaborators
- Ability to confidently lead independent data monitoring committees and phase 2b/3 advisory boards

Skills:

- Budget Management
- Clinical Research
- Clinical Trials
- Coaching
- Cross-Functional Teams
- Lifesciences
- People Management
- Risk Management
- Risk Monitoring

Languages :

- English.

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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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
Standort
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Site
Basel (City)
Company / Legal Entity
C028 (FCRS = CH028) Novartis Pharma AG
Alternative Location 1
Dublin (Novartis Corporate Center (NOCC)), Irland
Alternative Location 2
London (The Westworks), Vereinigtes Königreich
Alternative Location 3
Madrid Delegación, Spanien
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
Apply to Job

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EEO Statement :

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