Clinical Development Medical Director - Immunology, Rheumatology

Job ID
REQ-10010088
Juil 09, 2024
Etats-Unis

Résumé

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

Your key responsibilities:

- 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

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:

- *- Rheumatology or clinical immunology*
- *- Lupus clinical trial experience (systemic lupus erythematosus and/or lupus nephritis)*
- *- 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 expertly lead independent data monitoring committees and phase 2b/3 advisory boards

Desirable:

- Clinical practice experience 4+years (including residency in rheumatology or clinical immunology)
- Previous global people management experience in clinical trial settings is preferred, though this may include management in a matrix environment.

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