

Senior Clinical Development Medical Director - Renal

Job ID
383772BR
Ago 30, 2024
Estados Unidos

Resumen

The 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 CDMD in the Renal TA, 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.

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
- Leading development of clinical sections of trial and program level regulatory documents
- Driving execution the assigned clinical program and/or clinical trial in partnership with global line functions, assigned Global Trial Directors (GTDs), and regional/country medical associates, where applicable
- Supporting (Senior) Global Program Clinical Head (GPCH) in ensuring overall safety of the molecule for the assigned section, and may act as a core member of the Safety Management Team (SMT), supporting overall program safety reporting in collaboration with Patient Safety colleagues
- Supporting the Clinical Development Head (CDH) by providing medical input into Clinical Development Plan (CDP), Integrated Development Plan (IDP) and Clinical Trial Protocol (CTP) reviews, and contributing to/driving development of disease clinical standards for new disease areas
- As a medical expert, supporting the (Sr.) GPCH or CDH in interactions with external and internal stakeholders and decision boards
- May work with BR (Novartis Biomedical Research/ Translational Medical Sciences) to drive transition of pre-PoC (Proof of Concept) projects to DDP (Development Decision Point) and with BD&L (Business Development & Licensing) 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 advanced knowledge and clinical training in medical/scientific area; Clinical practice experience 4 years (including residency) and board certification or eligibility in disease area preferred
- Minimum of 7 years of experience in clinical research or drug development

- Experience in an academic clinical research or industry environment spanning clinical activities in Phases I through IV required. • 2 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 in pharmaceutical industry required.
- Working knowledge of disease area is required, with proven ability to interpret, discuss and present efficacy and safety data relating to clinical trial(s) and proven ability to understand and interpret basic and clinical scientific research reports
- 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.

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