NOVARTIS

Senior Clinical Development Medical Director - Renal

Job ID
383772BR
Aug 30, 2024
USA

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.

Role Requirements

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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Division
Development
Business Unit
Innovative Medicines
Location
USA
Site
East Hanover
Company / Legal Entity
U014 (FCRS = US014) Novartis Pharmaceuticals Corporation
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
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