

Senior Clinical Development Director - Renal

Job ID
REQ-10016919
Aug 13, 2024
USA

Summary

The Sr Clinical Development Director (CDD) in the Cardio Renal & Metabolic (CRM) Development Unit is responsible for leading the strategic planning and management of the assigned clinical program(s) from an end-to-end clinical development perspective. As a Senior CDD, you will have oversight of the clinical development for the assigned programs and drive the 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 input for all clinical deliverables in the assigned project or section of a clinical program. Clinical deliverables may include clinical sections of individual protocols or sub studies consistent with the Integrated Development Plans (IDP), clinical data review, program specific standards, clinical components of regulatory documents/registration dossiers, and publications
- Leading development of clinical sections of trial and program level regulatory documents
- Driving execution of the section of the clinical program in partnership with global line functions, assigned Global Trial Directors (GTDs), and regional/country medical associates, if applicable
- Overseeing/conducting ongoing medical and scientific review of clinical trial data with Clinical Scientific Expert(s) with appropriate oversight from Medical Lead
- Supporting (Sr.) GPCH in ensuring overall safety of the molecule for the assigned section and may be a core member of the Safety Management Team, supporting overall program safety reporting in collaboration with Patient Safety
- As a clinical expert, supporting the (Sr.) GPCH or CDH in interactions with external and internal stakeholders and decision boards
- Contributing to scientific training of relevant Novartis stakeholders on the disease area and compound/molecule. May serve as speaker for franchise medical/scientific training and may be the Program Manager of other associates

Minimum Requirements

- Advanced degree in life sciences / healthcare (or clinically relevant degree) is required. PharmD or PhD is strongly preferred***

- Fluent oral and written English
- Minimum 7 years experience in clinical research or drug development
- Working knowledge of the assigned disease area is desired with proven ability to interpret, discuss and present efficacy and safety data relating to clinical trial(s) or program level
- Demonstrated ability to establish effective working relationship with key investigators
- Working knowledge of GCP, clinical trial design, statistics, and regulatory and clinical development processes
- Strong communication skills with the ability to work in a cross functional and global organization

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TEst Hello

Division

Global Drug Development

Business Unit

Innovative Medicines

Standort

USA

State

New Jersey

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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