Medical Director, Clinical Development or

Senior Medical Director, Clinical Development

Do you want to be part of building a fully integrated biopharmaceutical company together with a team of highly skilled colleagues who are passionate about developing best-in-class therapeutics that address significant unmet medical needs? Then Ascendis Pharma is committed to support your personal development on our journey towards becoming a leading rare disease company.

Ascendis Pharma is looking to hire a passionate Medical Director, Clinical Development or Senior Medical Director, Clinical Development who will be responsible for Clinical Development activities associated with drug development. This is an exciting opportunity to join a rapidly growing, innovative company!

Position Summary

As a member of the Clinical Development team and the Project Core team, the individual in this position will perform Clinical Development activities associated with drug development. This individual will be responsible for the clinical development plan, synopsis and protocol writing and review, study monitoring, safety review, and clinical strategy supporting the project strategy including supporting and participation in regulatory interactions and submissions. This individual will be the clinical lead for a high visibility Phase 2 study and a pivotal Phase 3 program. The Director or Senior Medical Director, Clinical Development performs and coordinates all aspects of the clinical monitoring process in accordance with GCP's and global SOP's to assess the safety and efficacy of investigational products. She/he will work with Clinical Operations, Biometrics and Regulatory Affairs to conduct independent monitoring of sites to determine adherence to protocol, applying knowledge of FDA regulations to ensure regulatory compliance. She/he will assist the VP, Clinical Development, working with the VP, Clinical Operations and Clinical Trials Manager, to coordinate activities of the CRO and investigators, and perform medical monitoring.

Key Responsibilities

- Lead the clinical TransCon CNP program and oversee clinical operations activities
- Supports the CEO, CMO, and VP, Clinical Development and Project Director
- Effectively manages key opinion leaders (KOLs)/Clinical Advisory Boards
- Assists in portfolio management and commercial activities as needed
- In support of the CMO and VP, Clinical Development, oversees all clinical and clinical operations activities in support of Ascendis programs
- Maintains an up-to-date knowledge on all clinical data relevant to Ascendis programs, the competitive landscape, GCPs, and clinical trial information
- Participates in professional and industry organizations to follow clinical trends, meets with KOLs, participate in patient meetings and develops relationships to represent the interests of the company
- Recruits, monitors and completes clinical trials
- Authors study synopses and protocols
- Maintains study tracking tools and status reports
- Participates in core teams and be team lead for clinical project team meetings Maintains contact with study sites for issues, resolution, and regulatory documentation

- Assists with the development of case report forms
- Assists in the review of clinical safety reports from sites
- Assists in review of clinical trial safety data
- Represents clinical development at Ascendis in regulatory interactions regarding TransCon CNP for treatment of achondroplasia and related disorders.
- Assists in other regulatory submissions, as appropriate
- Represents Clinical Development in submission planning meetings
- Provides training and advice to Clinical Operations and potentially other functional group contributors on endocrine physiology and disorders
- May assist with the coordination of non-routine projects as applicable in support of the Clinical Development department
- Collaborates with cross functional peers to facilitate and optimize the product development and registration process
- Stays abreast of new medical information and newly issued regulatory laws and guidance as well as clinical publications, articles, and abstracts to promptly identify possible impact, competition or improvements to product programs

Knowledge, Skills and Experience

- MD degree, with specialization in pediatric endocrinology preferred. At least 5 years (Director) to 10 years (Senior Director) of industry or academic experience including scientific training at MD level or similar.
- At least 5-10 years of experience with clinical trial design and execution
- Excellent understanding of the drug development process and GCPs
- Very strong clinical/scientific background/aptitude
- Strong writing and presentation skills
- Ability to follow complex direction/processes under pressure
- Very strong organizational skills, attention to detail, and ability to meet high standards vital in a regulatory environment consistently
- Proficient in balancing multiple routine tasks simultaneously to achieve goals
- Works well under general direction and may independently determine and develop approaches to non-routine problems – a self-starter
- Open-minded and dedicated team player who thrives in a dynamic and international environment of continuous development, with attention to high quality, high ambitions and results.

Want to apply? Please send your resume to HumanResources@ascendispharma.com. Please write " Medical Director, Clinical Development or Senior Medical Director, Clinical Development" in the subject field.