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 an experienced Medical Director, Clinical Development to join our team. This is an exciting opportunity to join a rapidly growing, innovative company!

Position Summary

As a member of the Clinical Development team and at the direction of the line manager, the individual in this position will perform Clinical Development activities associated with drug development. This individual will be responsible for protocol writing and review, study monitoring, safety review, serving as a Medical Monitor, and assistance with routine regulatory interactions and submissions. This individual will be the clinical lead for a high visibility pivotal Phase 3 program. Furthermore, the individual will be responsible for contributing to regulatory strategy and solving complex drug development problems from time to time. The Director, Clinical Development performs and coordinates all aspects of the clinical monitoring process in our Clinical Development program in accordance with GCP's and global SOP's to assess the safety and efficacy of investigational products, either directly or in conjunction with a designee. She/he will work with Clinical Operations to conduct independent monitoring of sites to determine adherence to protocol, applying knowledge of FDA regulations to ensure regulatory compliance, either directly or in conjunction with a designee. She/he will assist the VP, Clinical Development, working with the Director and VP, Clinical Operations and Clinical Trials Manager, to coordinate activities of the CRO and investigators, and perform medical monitoring.

Key Responsibilities

- Lead the TransCon PTH pediatric program, with assistance of the VP, Clinical Development
- Assist the VP, Clinical Development with the TransCon PTH adult program
- Supports the SVP, and VP, Clinical Development
- Effectively manages key opinion leaders (KOLs)/Clinical Advisory Boards
- Assists in portfolio management and commercial activities as needed
- In support of the SVP & VP, Clinical Development, oversees all clinical and clinical operations activities in support of TransCon PTH 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, 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 clinical 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 Ascendis in regulatory interactions regarding TransCon PTH for treatment of pediatric hypoparathyroidism
- 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 metabolic bone disease and pediatric endocrinology preferred. At least 5 years of industry or academic experience.
- At least some experience with hypoparathyroidism clinical trial design and execution preferred
- Experience with the use of PTH by pump in patients with HP preferred
- 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

Want to apply? Please send your resume to US_jobs@ascendispharma.com. Please write “Medical Director, Clinical Development” in the subject field.