



Clinical Trial Manager

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 Clinical Trial Manager who will report to the Director, Clinical Operations based in Palo Alto. This is an exciting opportunity to join a rapidly growing, innovative company!

Position Summary

This individual will be responsible for managing global studies and for conduct of occasional single center studies. This individual will also have other responsibilities, including protocol writing and review, study monitoring, and assistance with routine regulatory interactions and submissions. The Clinical Trial Manager performs and coordinates all aspects of the job description in our Clinical Development Department in accordance with GCPs and global SOPs to develop investigational products. .

Key Responsibilities

- Manage study-related vendors and serve as the primary point of contact for contracted CROs, study staff and contract labs; identify potential risks and resolving issues with CROs; establish vendor management plans and reviewing quality metrics
- Provide input into and/or developing study related materials such as Clinical Monitoring Plans, Data Management Plans, eCRF forms and completion guidelines, protocols, patient informed consent drafts, site instructions for specimen collections, and study drug order forms
- Review monitoring reports, protocol deviations and data listings for sponsored studies to ensure reliable quality data are delivered; coordinate with CROs on site selection, IRB submissions, site initiation and close-out planning
- Communicate directly with study site staff and investigators to support the relationship between the sponsor and site; track patient recruitment and progress to study timelines; support safety reporting and IRB submissions; maintain and report metrics for clinical site performance
- Perform and/or oversee site monitoring visits for clinical trials as needed up to 20% travel
- Recruits, monitors and completes smaller, single site clinical trials
- In support of the VP, Clinical development, authors study synopses and protocols as needed
- Maintains study tracking tools and status reports
- Participates in clinical team meetings
- Participates in core project team meetings as appropriate
- Maintains contact with study sites for issues, resolution, and regulatory documentation
- Assists with the development of case report forms
- Assists in regulatory submissions, as appropriate
- May assist with the coordination of non-routine projects as applicable in support of the Clinical Development department
- Collaborate with cross functional peers to facilitate and optimize the product development and registration process

Knowledge, Skills and Experience

- Bachelor's degree in any field; Nursing, Pharmacology, Pharmaceutical Sciences or equivalent a plus
- Global phase 3 study experience preferred
- 5 years Clinical Operations experience
- Excellent understanding of the drug development process and GCP
- Able to write SOPs
- Very strong clinical/scientific background/aptitude
- Strong writing, communication 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
- Able to travel up to 20% including international travel

Want to apply? Please send your resume to US_jobs@ascendispharma.com. Please write "Clinical Trial Manager job description" in the subject field.