Manager, Clinical Data Management

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 Manager, Clinical Data Management to join our team. This is an exciting opportunity to join a rapidly growing, innovative company!

Position Summary

The Manager, Clinical Data Management, will be responsible for overseeing all data management activities for assigned projects in accordance with ICH/Good Clinical Practices (GCP), GDCMP and other relevant procedures and guidelines. This position will be based in Palo Alto and will report directly to the Associate Director, Data Management.

Key Responsibilities

- Serve as primary data management representative on cross-function project teams and ensure effective communication exchange
- Manage, collaborate, and act as the primary point of contact with CROs to ensure that study deliverables and timelines are met for outsourced studies
- Monitor Data Management processes and CRO performance
- Lead eCRF design and lead activities with external vendors developing and validating systems/applications for clinical trial data collection (e.g. EDC, ePRO/eCOA) to ensure quality and timely deployment
- Conduct trainings for appropriate users of data collection systems (e.g. EDC)
- Generate and/or review/approve study documents (e.g. Data Management Plans, data transfer specifications, SAE and/or external data reconciliation plans, coding conventions, study protocols)
- Ensure the quality of clinical data to meets standards for regulatory submissions. Generate and/or implement the Data Review Plan (DRP) defining and documenting the data quality review strategy for each clinical trial in collaboration with cross-functional team, enabling the quality review of patient data supporting regulatory filings, publications and other high-profile business activities
- Work with CROs to generate and/or distributes data management metrics, data listings and status reports
- Contribute to the ongoing development, review, and revisions of data management Standard Operating Procedures (SOPs) and standard DM templates
- May supervise direct reports in the future

Knowledge, Skills and Experience

- B.S. /B.A. in a science or technical discipline degree with 6 years Clinical data management experiences, or M.S. degree with 4 years Clinical data management experiences

- 3+ years of experiences as study lead data manager
- Familiar with clinical trial life cycle, proficient in clinical data collection, cleaning and locking for Phase I-IV clinical trials in a pharmaceutical industry/CRO
- Working knowledge of ICH/Good Clinical Practices (GCP), Good Clinical Data Management Practices (GCDMP), and related regulatory requirements. CCDM is preferred but not required
- Working knowledge of CDISC CDASH/SDTM standards, medical terminology, and medical coding dictionaries
- Working knowledge of different EDC platforms and data collection systems (e.g. IRT, ePRO, etc.)
- Prior experience supporting a BLA or NDA filing preferred
- Experience managing CRO vendors
- Ability to manage multiple initiatives and shifting priorities within a small company environment
- Excellent interpersonal skills with the ability to work independently and collaboratively in a dynamic team environment
- Prior people management experience preferred but not required

Want to apply? Please send your resume to HumanResources@ascendispharma.com. Please write "Manager, Clinical Data Management" in the subject field.