

## Soleno Therapeutics Job Description

<b>Job Title:</b> Manager, Clinical Data Management	<b>Reports To (Title):</b> Senior Director, Biostatistics	<b>Date Created:</b> 4/21/23
<b>Department:</b> Biostatistics and Programming	<b>Job Type:</b> <input checked="" type="checkbox"/> Full-time <input type="checkbox"/> Part-time <input type="checkbox"/> Contractor	

**SUMMARY OF JOB (brief description):** Soleno Therapeutics, Inc., based in Redwood City, California, is a clinical-stage biopharmaceutical company developing novel therapeutics for the treatment of rare diseases.

This Clinical Data Manager reports to Soleno's Senior Director, Biostatistics, and plays a key role in the development of data management strategies including outsourcing and oversight strategies, standards, and processes. This Manager serves as a subject matter expert related to data management activities and ensures that all data management milestones for assigned projects are delivered on time, with high quality, and in compliance with the ICH/GCP, Regulatory Authorities' regulations/guidelines, and applicable SOP.

### RESPONSIBILITIES:

- Responsible for all clinical data management owned deliverables and ensure that all data management related milestones are met.
- Operational responsibility from reviewing protocols to identify data management requirements.
- Oversee data management vendor activities including consistency, quality and timeliness of all data management deliverables in compliance with ICH/GCP guidelines, Regulatory Authorities' regulations/guidelines, and applicable SOPs.
- Author or oversee the development of all Clinical Data Management (DM) documentation including, but not limited to, DM Plan, CRF Specifications, CRF Completion Guidelines, Data Validation Specifications, Data Transfer Specifications.
- Contribute to the development and review of eCRFs and data capture across all platforms and lead the User Acceptance Testing (UAT) the EDC and all data capture platforms.
- Engage in data reviews and data cleaning activities with the study team to ensure data quality.
- Oversee data vendor through review, cleaning, auditing, validation procedures and ensure data handling compliance with regulatory requirements.
- Lead and participate in cross functional data review and report on performance and quality; review clinical data within studies and across for trend analysis.
- Create and maintain trackers, dashboards, metrics to monitor DM activities.
- Follow up on data issues to resolution.
- Overall management of DM vendor management, which includes selection, review of invoices and change orders.
- Develop processes, guidelines, data standards, and SOPs related to Data Management.
- Ensure archival and inspection readiness of all Data Management documents for trials, including legacy trials, and ensure inspection readiness for data management.
- Participate in audits and inspections.
- Perform responsibilities in compliance with SOPs, ICH/GCP guidelines in accordance with regulatory, legal and ethical standards.

## **Soleno Therapeutics Job Description**

### **QUALIFICATIONS:**

- Bachelor's degree or higher with relevant experience of at least 5 years working in data management and at least 3 years as a clinical data manager at a study/project level.
- Detail oriented with knowledge of clinical operations and clinical data flow.
- Thorough knowledge of using data management technologies.
- Familiarity with Base SAS preferred.
- Knowledge of regulations and guidelines such as ICH, GCP, privacy rules (HIPAA).
- Excellent interpersonal and communication skills.
- Strong collaborative skills and ability to work with a cross-functional team.
- Strong project management skills.

**Salary Range:** \$140,000 – 160,000

Please submit resumes to Soleno Therapeutics, Inc. at [hr@soleno.life](mailto:hr@soleno.life).