Title: Clinical Data Manager
Location: Worcester/Remote
Reports to (title): VP Clinical Operations

Overview

The clinical data manager will work closely with the clinical team and is responsible for coordination and oversight of all data management activities in support of clinical trials/programs.

Specific Responsibilities

- Work collaboratively with clinical sites and internal team members to ensure data is collected, managed and reported clearly, accurately and securely.
- Provides support and day-to-day contact with team to handle data management questions, troubleshoot, help resolve issues and mitigate risks
- Develop or oversee vendors and/or consultants in data management services, database development and eCRF design, UAT, data entry guidelines, data management plans, reports, manuals, and related operations.
- Responsible for executing or overseeing data cleaning activities, including oversight of generating and managing clinical trial data queries, coding specified clinical trial data (e.g., adverse events and concomitant medications) and data reconciliation (e.g., SAE and vendor).
- Track and report data management activities; data timelines, key deliverables and project status ensuring industry standards related to clinical data collection, processing and quality.
- Accommodate *ad hoc* data requests between clinical team members, scientists, and vendors to support data cleaning, data entry requirements and exploratory data review.
- Manage external data transfer protocols and standards to ensure deliverables adhere to industry best practices and deliver high quality output in line with agreed timelines.
- Provide input and participate in the development of clinical study documents including protocols, clinical monitoring plans and statistical analysis plans.
- Participate in the development and maintenance of Standard Operating Procedures (SOPs) and work Instructions related to data management activities and other clinical departmental activities.
- Assess system performance and make recommendations for new software, hardware, and data storage improvements.

Education & Experience

- BS Degree, preferably in statistics, science, math or computer programming
- 7+ years as a Data Manager within Data Management or Clinical organization
- Prior experience serving as a Clinical Data Manager leader for early phase oncology clinical trials, experience working as Data Management line function representative to Clinical Study Team
- Prior experience interacting with CROs, including direct oversight while coordinating day to day study data management activities

- Primary experience with CDMS process in the context of early phase clinical trials, working knowledge of SDTM/CDISC standards
- Knowledge in medical terminology, medical coding classification system (e.g., MedDRA and WHODrug Dictionaries)
- Expertise in EDC and industry standards including ICH-GCP guidelines, and CDASH/CDISC
- Overall understanding of ICH, GCP, CDISC and other applicable regulatory guidelines as they pertain to data management
- Ability to communicate technical issues to non-DM team members and collaborate with entire clinical team (CRAs, Safety, Biostatistics, etc.)
- Excellent teamwork, organizational, interpersonal, conflict resolution, and problem-solving skills