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| **Position Title:** | Clinical Data Manager |
| **Department:** | Medical Sciences Organization |
| **Hiring Manager:** | Sr. Director, Biostatistics |

**Our vision is a world where science, passion, and compassion create better todays and more tomorrows.**

**Clinical Data Manager:**

The Clinical Data Manager is primarily accountable for the acquisition, transfer, cleaning, and overall quality of clinical study data. The ability to interact collaboratively, cross-functionally, and in external partnerships and oversee CROs is critical to this position. Pharmaceutical/Biotech experience and knowledge of regulatory standards (CDISC, SDTM) are required. The ability to translate clinical team objectives into operational actions maximizing the current technical platforms is a heavily leveraged skillset.

**Responsibilities:**

Reporting to the Senior Director of Biostatistics, the Clinical Data Manager provides oversight for data management aspect of the clinical trials.

* Design, review, and validate the clinical database.
* Deliver clean data for analysis and submission as part of a regulatory filing.
* Design/review case report forms (CRFs), edit checks and aggregate check specifications with the CRO.
* Oversee the development of the clinical database by the EDC/CRO vendor and manage the sponsor user acceptance testing of the clinical database.
* Work in coordination with statisticians and programmer/analysts.
* Work in coordination with clinical operations team and CROs to develop study documents .
* Primary interface with CROs for any data management related activities.
* Ensure that data management tasks remain on target according to study timelines and requirements.
* Proactively work with CROs to organize ongoing data review throughout the study to ensure timely identification and correction of errors or discrepancies.
* Routinely communicate site data concerns/issues with clinical operations team and CROs to ensure collaboration toward resolution.
* Ensures delivery of a quality locked database on time for analysis at the close of studies.

**Required background and experience:**

* 3+ years of clinical trial data management experience in the biopharma industry
* Experience with Medidata RAVE
* Experience with ePROs
* Strong understanding of clinical trial process and EDC platforms
* Experience with data programming tools and/or data viewing tools (J-review, SAS, JMP, etc.)
* Excellent communication and organizational skills, along with problem solving, conflict resolution, leadership and team-building skills.