



Company: Lungpacer Medical USA Inc.

Address: 260 Sierra Drive, Suite 116
Exton, PA 19341

Position: Clinical Data Manager

Lungpacer Medical USA Inc., a subsidiary of Lungpacer Medical Inc. - a British Columbia Corporation, is developing a novel therapeutic solution for preserving the integrity and strength of the diaphragm muscle in critically ill patients who require mechanical ventilation, is seeking to hire experienced and highly motivated contract Clinical Data Manager.

As a member of the Clinical Team, the individual in this position is responsible for providing oversight regarding all aspects of data management duties.

Responsibilities

- Direct oversight of all EDC design build and sponsor User Acceptance Testing (UAT) processes conducted by the CRO.
- Lead the efforts in establishing a Data Management Plan.
- Oversee the CRO regarding case report form (CRF) design, data edit checks and aggregate check specifications.
- Assist with all aspects of Soft and Hard Database Locks & Analysis, including coordination with the study PM, statistician and CRAs.
- Serve as the primary Sponsor contact person for day to day data management activities, as well as, the primary contact person for communication and discussion of topics related to data management timelines and deliverables.
- Provide database and data management activities status reports; contribute to the overall project planning, progress tracking and reporting.
- Conduct training on electronic data capture (EDC) system, dataflow and quality control processes to internal clinical trial personnel, as needed.
- Assist in the review of Data Management related scope of work, work orders and amendments.
- Prepare data status slides for senior management as needed for board or investigator meetings.
- Participate in study meetings as applicable (i.e., project kick off meeting, investigators meeting, and regular project management team meetings).
- Provide support to internal audits and regulatory inspections, regarding Data Management duties.
- Manage the process of database modifications, due to protocol amendments or study needs with the CRO.
- Review the CRO Data Quality Review Plan (DQRP). Coordinate with CRO programmers to complete the programming and validation of the listings and summary tables as specified in the DQRP.
- Review data, issue and resolve queries, as well as assist CRAs with resolving queries, as needed.



- Manage and coordinate data activities for all clinical trials to deliver data for analysis and submission as part of a regulatory filing.
- Provide listings as needed in preparation for Safety Committee Meetings.
- Proactively work with the CRO to organize on-going data review throughout the study to ensure timely identification and correction of errors or discrepancies.
- Oversee CRO regarding final data management documentation archival activities.

Qualifications & Required Skills

- A Bachelors' or Advanced degree in health sciences, physical/biological, or chemistry fields.
- At least 7 years of experience in Medical Device clinical trial data management with demonstrated knowledge, experience and ability to perform to meet high quality standards and high level of customer satisfaction
- Knowledge of industry and regulatory standards (CDISC, SDTM) with an ability to translate clinical team objectives into operational actions.
- In-depth understanding of clinical trial data management concepts, processes and procedures, relevant issues related to or impacting clinical data management, as well as medical device clinical trial regulations, industry guidance, conventions and standards.
- Strong leadership in clinical data management activities and a desire to excel in leading data management projects.
- Strong communication skills and ability to work efficiently with a variety of people.

The primary location of work will be at our facility in Exton, PA. The position may require some travel.

Qualified candidates may send a letter of interest and resumé to hr@lungpacer.com by September 30, 2019. Please quote Clinical Data Manager in your e-mail subject box.

We thank all interested applicants. However, only those under consideration will be contacted. No Phone Calls, please.