1 Duncan Drive
Cranbury, NJ 08512 USA
Telephone: (609) 409-7050
Facsimile: (609) 409-6035

Senior Manager/ Director – Clinical Data Management

Cranbury/Newark, NJ, US

Worker Category: Active - Regular full-time

Now is an exciting time to join Rafael Pharma, a leading late stage Oncology company. Our focus is the patient: "To *Save A Life Is To Save A Universe*"

We are a company united by strong values – passion towards patients, innovation, integrity, excellence, leadership, ownership and teamwork. Our values reflect the way we strive to improve the quality of life for patients and are at the heart of our company's success and future growth.

We continue to seek passionate, dedicated, and solutions-oriented people and consistently ensure that our people develop their talent. If Rafael Pharma is to realize its vision, we need people who think innovatively and act with integrity.

We currently have an opening for, Senior Manager/ Director, Clinical Data Management at our Cranbury/Newark NJ office.

In addition to developing its lead Cancer Metabolic molecule CPI-613® (devimistat), Rafael is looking to increase its breadth through co-development, partnering and acquisitions. The Senior Manager/ Director-Clinical Data Management at Rafael will be responsible for developing and implementing departmental strategies and ensuring that the quality meets regulatory standards and requirements. The Senior Manager/ Director Clinical Data Management will be responsible for providing timely and professional ongoing management of Data Management deliverables and of clinical trial data with respect to cost, quality and timelines for assigned trials managed within Clinical Data Management. The position will report to the Vice President- Clinical Operations.

Role and Responsibilities:

- Design and Implementation of CRFs in the database and assuring that the database for each study is live in a timely manner.

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- Oversight of all clinical data management activities, database cleaning and lock activities including developing data management plans, supervising database development and reviewing and processing clinical trial data to ensure completeness, accuracy and consistency of clinical trials databases across multiple programs (Oncology experience preferred).

- Good understanding of clinical data flow.

- Proven Clinical Data Management experience (e.g. as a Lead Data Manager).

- Work with the CRO and coordinate activities for the medical review of coding data and approval of adverse events, medical history, concomitant and protocol-related medications.

- Educate study team members by preparing and distributing study related reports, resolving questions and providing clinical data management guidance.

- Lead interactions between company, IIT and IST sites and outside vendors on the collection, transmittal and transfer of study specific laboratory data.

- Participate in cross functional team meetings and communicate with all departments regarding project statuses/issues, provide ongoing feedback on data management workflows to increase efficiency and provide feedback to Clinical Operations.

- Work closely with safety, clinical operations group, biostatisticians, SAS programmers and other staff as appropriate to develop CRFs to ensure the required information is captured for statistical analysis.

- Work with biostatisticians and SAS programmers to harmonize data collection, compile and maintain SAS data standards.

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- Provide review and oversight on quality database design, validation, and deployment to ensure quality and efficiencies through data and process standardization.

- Review clinical study protocols and statistical analysis plans and ensure data quality for data analyses.

- Take a leadership role in the review and query of clinical data. This includes participation of the critical review of data-populated tables, figures, and listings as part of the database clean-up and prior to database lock.

- Assure regulatory compliance of vendors and investigational sites with company SOPs, FDA and ICH guidelines, and other applicable regulations and guidelines.

- Develop and maintain appropriate data management SOPs (associated with the data collection, handling and review processes to meet regulatory compliance and operational needs).

- Assist in addresses Regulatory Submission issues within Biometrics and with other related departments.

- Utilize appropriate CDM concepts and resources to solve moderately complex technical CDM issues.

- Lead initiatives to gather, organize, and analyze interim clinical data from various data sources, and examines issues from various perspectives.

Required Skills:

- Education: BA/BS, MS or equivalent in a scientific discipline is preferred.

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- 15+ years of progressively more challenging work experience in Clinical Data Management or Project Management.

- In-depth knowledge of regulatory regulations and ICH guidelines in drug development and approval with good experience in multiple FDA, EMA and PMDA filings.

- Good organizational and problem-solving skills, as well as the ability to evaluate resource needs.

- Thorough knowledge of Clinical Data Management procedures with good ability to develop and implement a high-quality data system and associated procedures and perform systematic data quality control management.

- Proficient at creating and communicating a clear vision among team members effectively aligning resources and activities to achieve functional area and/or organizational goals.

- The successful candidate should be a results-oriented, team player with strong interpersonal and communications skills, capable of working collaboratively with colleagues.

About Rafael Pharmaceuticals:

Rafael Pharmaceuticals, Inc. is clinical stage company and a leader in the growing field of cancer metabolism-based therapeutics. Rafael's primary objective is to develop and commercialize innovative, highly selective, well tolerated and highly effective anti-cancer agents by selectively targeting the altered metabolism in cancer cells. Rafael's first-in-class clinical lead compound, CPI-613®(devimistat), is being evaluated in multiple ongoing/completed Phase I, II, and III clinical studies. CPI-613®(devimistat) has been granted orphan drug designation for the treatment of Pancreatic Cancer, Acute Myeloid Leukemia (AML), Peripheral T-Cell Lymphoma (PTCL), Burkitt Lymphoma and Myelodysplastic Syndromes (MDS). Rafael Pharmaceuticals is an affiliate of Rafael Holdings, Inc. (NYSE AMERICAN: RFL). For more information, visit http://www.rafaelpharma.com/.