1 Duncan Drive
Cranbury, NJ 08512 USA
Telephone: (609) 409-7050
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Clinical Research Associate – Clinical Operations
Cranbury, NJ
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. 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.

We currently have an opening for a Clinical Research Associate (CRA) in our Cranbury NJ office. The CRA at Rafael will support the execution of global and/or local oncology phase 1-3 clinical studies, programs or franchises in adherence to Good Clinical Practices (GCPs), appropriate Standard Operating Procedures (SOPs), Food and Drug Administration (FDA) regulations/EU Directive, and International Conference on Harmonization (ICH) guidelines.

Role and Responsibilities:

- Supports the clinical trial managers and leadership in the planning, execution and reporting of clinical trials, ensuring alignment of activities with study timelines, budgets, SOPs, GCP and applicable regulatory guidelines
- Performs assigned duties including investigative site recruitment/feasibility; essential document collection and review; ICF review; study document/plan development and review; maintenance and close-out of site management activities in accordance with the protocol; standard operating procedures (SOPs); ICH/GCP guidelines and all applicable regulatory requirements
- Assists in review and approval of monitoring reports
- May conduct co-monitoring, booster or oversight visits at investigational sites
- Assists with the preparation and finalization of investigators contracts, budgets and payments
- Obtain, review (to ensure completeness, accuracy, and regulatory compliance), and process essential regulatory, administrative documents, and Informed Consent Forms (ICFs) for study start-up, study maintenance, and study close-out

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- Supports investigational product shipments as needed and ensures that supplies are adequate/appropriate for assigned studies and sites
- Interacts with other functional areas and key stakeholders, including Clinical Development, Data Management, Finance, Regulatory, Quality Assurance, Safety, Clinical Supply (Investigational Product) and clinical vendors (e.g., central laboratory, CROs), as needed, to support clinical trial activities
- Supports the Clinical Trial Manager in start-up and management and oversight of vendors including the review of specifications, charters and plans
- Ongoing interaction with clinical operations team members and Investigator site staff to obtain and relay key study issues, status updates and other study information to the clinical trial team and leadership team
- Participates in development and improvement of department processes, best practices, and tools and templates related to clinical trial management and operations
- Participates in the review and development of CRFs and CRF guidelines
- Performs in-house review of CRF data for completeness and accuracy, and resolves data management/query issues with study sites and vendors as needed
- Reviews data to identify protocol deviations and risks to subject safety/data integrity
- Gains an in-depth understanding of the study protocol and related procedures
- Participates and provides inputs on site selection and site qualification activities
- Interacts with the clinical study sites to resolve data queries and/or data entry errors, and obtain additional information on potential safety events
- Trains and assists site coordinators, investigators, CRO (as applicable) in trial execution, serves as a resource to site coordinators, investigators and other staff members regarding investigational products and protocols; monitor and track progress and obstacles
- Communicates and documents communication with Investigators and site staff on issues related to protocol conduct, recruitment, retention, protocol deviations, regulatory documentation, site audits/inspections, and overall site performance
- Manages and maintains information and documentation in Trial Master File (eTMF) and various other systems per study timelines
- Contributes to, supports, and/or leads site audit/inspection preparation activities as needed
- Performs other work-related duties as assigned or required

Required Skills/Competencies:

- Minimum of Bachelor's degree or RN
- 5+ years of relevant and progressive experience with clinical trials
- Experience in all stages of drug development/pharma (study start-up, maintenance, database lock etc.) and strong understanding of clinical trial processes, protocols and medical terminology
- Oncology (Solid Tumor & Hematology) experience preferred

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- Ability to work as part of a team, multi-task and meet internal and regulatory deadlines
- Prior experience in management and monitoring of CRO and investigative sites, preferred
- Experience with patient recruitment, non-compliance, safety, document management, investigational product, IP accountability
- Strong written and verbal communication and computer literacy (e.g., Microsoft Word, Excel, PowerPoint, Outlook); strong experience utilizing CTMS, EDC, TMS and related software
- Knowledge of ICH GCP, IRB/IEC and local regulatory authority drug research & development regulations
- Motivated to work in a fast-paced, high accountability environment
- Travel potentially up to 30%

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/.