1 Duncan Drive
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Clinical Trial Manager – 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 Trial Manager (CTM) in our Cranbury NJ office. The CTM at Rafael is responsible for operational planning and oversight of all study activities and escalates issues when needed from study concept through finalization of clinical study reports. S/he will collaborate with cross functional teams to execute clinical study protocols, develop and manage clinical operational, project and study management plans while adhering to budget, scope and schedule requirements. S/he will manage and lead the day-to-day operations of assigned studies including:

- Develop the following study-specific strategy tools and processes:
    - investigator/site/country/patient recruitment plans
    - request for proposal [RFP] process
    - vendor specifications and systems set-up
    - communication plans (including site escalation)
    - ongoing data review plans
    - risk management plans
    - study timeline and budget
    - educational/training plans
    - performance and compliance metrics
- Develop, review and ensure operational excellence of study-specific forms and tools including:
    - clinical protocols and amendments
    - informed consent templates
    - site feasibility questionnaires and assessments
    - case report forms [CRFs] and CRF guidelines

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  - data / IWRS management plans
  - Investigative site binders, pharmacy brochures, and regulatory binders
  - pharmacy, laboratory, and operations manuals
  - serious adverse events [SAEs] forms
  - statistical analysis plans and data monitoring committee charters
  - clinical study reports
- Manage and lead cross-functional study teams, including vendors and CROs; liaise with other functional areas in order to accurately coordinate clinical study activities and effectively manage interactions with vendor study teams;
- Collaborate with Legal and/or clinical research organizations [CROs] to ensure timely review of the confidential disclosure agreements [CDAs] and clinical trial agreements [CTAs];
- Support selected investigative sites for IRB/IEC submissions, regulatory document collection and review, and budget and contract negotiations in collaboration with Legal and CROs;
- Manage and resolve study conduct issues (including protocol deviations, data queries, SAEs/AEs, laboratory discrepancies, and archive reconciliation activities) as applicable;
- Provide study-specific training, oversight, direction and leadership to internal staff, CRO, vendors, sites, and other contract personnel;
- Prepare and present program debriefings and regular updates of study progression to management; proactively identify and resolve issues that arise during study conduct; manage escalation of study-related issues;
- At the discretion of the function head, perform periodic site monitoring and vendor audit activities in accordance with protocol, monitoring plan, and ICH-GCP guidelines including:
  - Perform Site Qualification Visits, Site Initiation Visits, Interim Monitoring Visits, and Close-out Visits according to applicable company standard operating procedures [SOPs], regulations, and requirements of ICH-GCP;
  - Complete visit report and investigator correspondence documenting visit progress and issue identification and reconciliation;
  - Adequate follow-up with investigative sites as needed to ensure the identified study conduct issues are resolved and reconciled;
- Oversee the clinical aspects of timely data cleaning, data analysis and the availability of top line results; participate in data reviews and review of statistical analysis plans;
- Support coordination with Finance to track the financial status of studies against budget;
- Participate in and leads departmental initiatives as requested;
- Contribute to SOP development.

Requirements:

Experience: Minimum of 5 years' experience in a combination of the following:

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- Minimal of 2 years of global trial or project management experience
- Experience in the pharmaceutical/biotech or medical device industry
- Experience in oncology desirable.
- Experience with application of FDA and ICH rules, regulations and guidelines governing conduct of clinical studies, clinical protocols, investigator brochures and other materials.
- Experience with all aspects of clinical trials including on-site monitoring experience.
- Experience in management of CROs and other vendors

Education:

- A minimum of a Bachelor' s degree in a scientific discipline or equivalent RN/BSN nursing degree (other majors considered with relevant work experience); advanced degree preferred

Skills:

- ICH-GCP and FDA regulatory requirement understanding and competency.
- Strong clinical study management skills, including risk assessment and contingency planning.
- Ability to approach assigned duties in a highly organized, detailed and accurate manner.
- Ability to manage multiple priorities and work in a flexible, dynamic, and fast-paced environment.
- Willingness to travel as dictated by assigned project requirements (approximately 25%). International travel may be required.
- Ability to work cross-functionally with other departments involved in the conduct of a clinical trial including excellent oral/written communication, organizational, problem solving and conflict resolution skills.
- Ability (experience preferred) to work with cross-cultural teams including personnel from global locations as required per project with a positive attitude.
- Microsoft Project, Office, PowerPoint and Excel proficiency.

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/.