CLINICAL TRIAL MANAGER

COMPANY OVERVIEW: Oncternal Therapeutics is a clinical-stage oncology company developing a diverse pipeline of treatments for cancers with critical unmet medical need. Oncternal focuses drug development on promising yet untapped biological pathways implicated in cancer progression.

The pipeline includes cirmtuzumab, a monoclonal antibody that inhibits the ROR1 receptor, that is in Phase 1/2 studies of mantle cell lymphoma, CLL and breast cancer; TK-216, a small-molecule that inhibits ETS-family oncoproteins, that is in a Phase 1 /2 study of Ewing sarcoma; and a CAR-T therapy that targets ROR1 currently in preclinical development as a potential treatment for hematologic cancers and solid tumors

SUMMARY OF POSITION: The successful candidate will have the skills necessary to thrive in a dynamic and growing company environment, as he/she assists Clinical Research staff in the conduct of clinical trial activities in accordance with Standard Operating Procedures and all applicable regulations governing the conduct of clinical trials. Particularly important skills include flexibility; logical thinking; ability to prioritize day-to-day and critical tasks; willingness to adapt quickly to changing business conditions and learn new skills; interpersonal and team building skills.

ESSENTIAL DUTIES AND RESPONSIBILITIES:

- Responsible for the implementation of clinical trial activities as defined by the Study Management Team. Works closely with investigative site personnel, CROs, and other study vendors under the direction of the Head of Clinical Operations;
- Partners with and manages CROs and vendors to conduct Oncternal clinical trials;
- Manages defined aspects of clinical trials at Oncternal to ensure trials are completed on time, within budget and in compliance with SOPs, FDA regulations and ICH/GCP guidelines;
- Performs the activities associated with the implementation and monitoring of clinical trials such as development of study plans and materials;
- Assists with the projection and management of both clinical and non-clinical supplies;
- Works with Medical Monitor and study lead to select investigative sites, trains investigators and investigative site staff, prepares materials for investigator meetings;
- Generates and maintains study timelines. Identifies and communicates trial issues that will impact budget, resources and/or timelines;
- May participate in oversight monitoring activities, as needed;
- Reviews and critiques electronic CRFs for accuracy and completeness. Oversees data discrepancy management and training as needed;
- Provides or assists with training internal and external CRAs, CRO team members, and investigative site staff;
- Responsible for review of vendor invoices for accuracy compared to work known to be performed by the vendor, under the guidance of Head of Clinical Operations;

- Ensures that supportive study documents are completed (e.g., scopes of work, work orders, IXRS specification documents, specific IXRS scripts, non-clinical supply materials);
- May aid in the development of technical specifications for vendors (e.g. scope of work);
- Contributes to wider organizational goals and/or activities as assigned;

NON-ESSENTIAL DUTIES AND RESPONSIBILITIES:

- Other duties as assigned

EDUCATION/EXPERIENCE/KNOWLEDGE/SKILLS/ABILITIES:

- BS/BA in Life Science or related discipline
- Clinical Research certification preferred, but not required.
- 5 to 6 years industry experience in drug development, including prior independent site monitoring experience;
- Previous on-site monitoring experience is required;
- Experience creating and/or reviewing monitoring reports and monitoring visit letters is required;
- Experience creating and/or monitoring reports and montoring visit letters required;
- Phase III Oncology or Hematology experience preferred;
- CRO and vendor Management experience preferred;
- Knowledge and understanding of FDA and ICH Guidelines, Good Clinical Practices (GCP), medical terminology, and clinical trials;
- Proficiency with MSOffice (Outlook, Word, Excel, PowerPoint), and with filing (archiving) systems;
- Must be self-motivated and be able to follow directions precisely, prioritize and manage a large volume of work, and show attention to detail;
- Strong interpersonal skills and professional attitude are essential as this individual interacts with many people of varying levels of responsibility for clinical studies and business performance.
- Excellent verbal and written communication skills. Must be able to write clearly and summarize information effectively;
- Adaptable, flexible, independent and resourceful with ability to roll up sleeves and multi-task in order to thrive and lead in smaller and growing company environments
- Self-starter who works with a sense of urgency and functions as a strong team player effectively working with other disciplines
- Small biotech company experience preferred
- Travel up to 15% may be required

Oncternal Therapeutics offers competitive compensation and benefits including Medical, Dental, Vision, Life and Disability, 401(k), Paid time off, Flexible Schedule, Remote Work for most positions, and Bonus Pay.

Oncternal Therapeutics is proud to be an Equal Opportunity Employer. All qualified applicants will receive consideration for employment without regard to race, color, religion, sex, sexual

orientation, gender identity, national origin, or protected veteran status and will not be discriminated against on the basis of disability or any other protected status.