POSITION DESCRIPTION

Position **Associate Director/Director, Clinical Operations (Part-Time)**

Company **Iconic Therapeutics**

Location **San Francisco, CA**

Website **www.iconictherapeutics.com**

COMPANY BACKGROUND

Iconic Therapeutics, Inc., is a biopharmaceutical company built on scientific insight and expertise in tissue factor (TF) biology. We're pioneering a new class of TF therapeutics that target diseases in which this protein is overexpressed, pursuing promising opportunities in ophthalmology and oncology, including wet age-related macular degeneration (AMD) and certain solid tumors.

Tissue Factor is a protein that plays a key role in inflammation and pathologic angiogenesis (the formation of abnormal new blood vessels), yet prior attempts to address this target have been hampered by inability to separate target engagement/inhibition from interference with normal blood coagulation. We have addressed the problem of safely targeting TF to disrupt those pathways and modify the underlying cause of the disease, and in doing so, we've created a pipeline of two pre-clinical programs based on our TF platform, one in ophthalmology and one in oncology. The ophthalmology program is a potential disease-modifying therapy for wet AMD. Our oncology program in preclinical development for solid tumors has shown excellent activity in difficult to treat xenografts and PDX models

ROLE: ASSOCIATE DIRECTOR / DIRECTOR, CLINICAL OPERATIONS

The individual in this position is responsible for the management of Clinical Operations in alignment with Iconic Therapeutics goals. Focusing on managerial efficiency and high-quality deliverables, this person will oversee operational aspects of one or more clinical programs including project timelines, budgets, resource allocation, and management of Contract Research Organizations (CRO) and other clinical vendors.

The AD/Director will be responsible for execution of clinical studies in full compliance with company SOPs, Good Clinical Practices (GCP), and the International Council for Harmonization (ICH), and other applicable regulatory guidelines.

The AD/Director has primary responsibility for coordinating with the Chief Medical Officer (CMO) to oversee external vendors and manage study operations, logistics and reporting. This responsibility includes appropriate fiscal oversite and accountability of vendors (CRO, Labs, etc.) The AD/Director will ensure appropriate escalation of issues to the CMO and VP of Alliance and Program Management as appropriate.

The AD/Director will contribute to creating a positive, collaborative team environment with an eye toward innovation and operational excellence.

The Associate Director / Director of Clinical Operations reports directly to the VP of Operations and Programs with dotted line responsibilities to the CMO.

KEY RESPONSIBILITIES

- Provide leadership, strategic planning, and effective management of the Clinical Operations.
- Ensure regulatory compliance and adherence to GCP/ICH guidelines and regulations.
- Facilitate and participate in the selection and management of clinical outsourcing vendors.
- Collaborate with functional heads to assure integration of company, project and functional goals, towards achieving project milestones on schedule and within budget.
- Provide strategic input on the management and resourcing of future clinical trials.
- Assist in the development and tracking of project finances and staffing with direct responsibility for adherence to project timelines and budgets; must be able to anticipate deviations and inform management with proposed mitigation strategies.
- Protocol and Investigator Brochure drafting, preparation of various clinical trial related manuals, training, documentation.
- Directly responsible for managing CO and other Clinical Operations vendors
- Work directly with sites and KOLs.
- Coordinate data management – including eCRF preparation, and database management / output, either internally or with CRO partner
- Use data management software as required to review clinical data and associated metrics, and address data quality issues directly with CROs and sites as needed.
- Assist with national regulatory and IRB/Ethics Committee submissions and responses to questions as required.

- Review and contribute to Clinical Study Reports, INDs, NDAs, and other clinical and regulatory documents.
- Represent the company as needed at professional meetings, and present clinical operations materials and provide training at such events as needed.
- Provide ongoing assessment and feedback on departmental policies and procedures toward increased efficiency and quality of deliverables; may contribute to the development of SOPs and other procedural documents.
- Develop and/or facilitate the creation of metrics and reports as needed in conjunction with vendors, other clinical operations personnel, and Iconic functional leads; summarize and present these data as required.
- Assist in clinical compliance activities and facilitate responses to auditors and satisfactory resolution of clinical quality issues.
- Travel up to 25% depending on departmental needs *

(* Travel requirements will be determined in alignment with all appropriate COVID-19 regulations)

PROFESSIONAL EXPERIENCE/QUALIFICATIONS

- Prior experience in leading early development phase I - II clinical studies
- Experience with ophthalmology development
- Experience managing CRO's, timelines and budgets.
- Experience working with sites and KOLs.
- Experience participating in and preferably leading cross functional teams such as preclinical and CMC teams.
- Broad understanding of preclinical requirements for relevant regulatory guidelines
- Excellent leadership and organizational skills, written and verbal communication skills, and interpersonal skills are required.
- Ability to work in a fast-paced environment, to multitask and manage multiple projects.
- Function independently with minimal guidance
- Demonstrated consistent achievement of team delivery against commitments and goals.
- Strategic thinker and problem-solver capable of identifying risks and risk mitigation strategies "Out of the box" thinker, to take on calculated risks, and champion new ideas and approaches.

EDUCATION

A Bachelor of Science degree in a relevant life science discipline with at least 7 years' relevant industry experience, including prior experience in a project leader role. Level of position may be adjusted based on level of competency and years of experience.

COMPENSATION

An attractive compensation package commensurate with this role will be provided. The position will be a part-time position initially.