POSITION POSTING – CLINICAL PROJECT SPECIALIST

Employee: You	**Title: Clinical Project Specialist**
Department: Clinical Development	**Reports to: VP Clinical, Regulatory & Quality**

Ripple Therapeutics is an early commercial stage, privately held company based within the MaRS Discovery District in downtown Toronto. Ripple develops innovative formulations and delivery systems for pharmaceutical applications. Our sustained local drug delivery technology is applicable across a range of drug classes and medical specialties with an initial focus on ophthalmology. The company's lead product under development in the local drug delivery technology is a dexamethasone intravitreal implant (IBE-814 IVT) for the treatment of posterior inflammatory eye diseases. Following successful interactions with FDA, IBI is presently initiating Phase II trials with the IBE-814 IVT Implant. More information on the local, drug delivery technology can be found at: https://www.rippletherapeutics.com

I: General Functions and Scope

We are looking for a highly experienced and hands-on clinical operations professional to implement and manage clinical development plans and provide clinical operations and GCP compliance expertise in support of product development. S/he will work closely with Ripple Clinical Scientists, Product Development and our CROs to develop detailed plans, and manage the project activities, resources, budget and timelines to execute projects on scope and achieve milestones. The Clinical Project Specialist will coordinate and manage the activities between the Clinical CRO, Clinical Trial Vendors, Clinical Sites and the Company's internal team. This person must thrive in a fast-paced startup environment, be nimble to work on multiple activities simultaneously, and be motivated by the opportunity to learn new technologies.

II: Specific Responsibilities

Corporate:

- Participate in establishing project plans, priorities, milestones, timelines and budgets to meet Company objectives;
- Support business development activities by preparing presentations, updates and reports to Company members, Board of Directors and Industry Partners;
- Develop and maintain relationships with strategic research, development and business partners as required for project needs.

Project Management and Development:

- Serve as the lead Sponsor Clinical Operations contact with outside organizations such as Study Sites, CROs, Central Laboratories and other contract organizations
- Work in concert with R&D for:
    - Product and trial performance data acquisition, analyses and communication;

    - Documentation development (protocols, IBs, PICFs, amendments, etc.)
    - Investigator meeting content
- Oversee the CRO contract activities including: (i) the development and execution of the project execution plan, (ii) site management and monitoring, (iii) clinical supply management, and (iv) budget
- Coordinate the site selection, initiation and activation processes in collaboration with CRO; responsible for ensuring effective communication between Sponsor, CRO and sites
- Oversee CRO execution of start-up activities and ensure communication is optimized across all stakeholders
- Coordinate planning and logistics of Investigator meetings
- Serve on core teams and provide clinical trial execution and compliance expertise
- Identify and mitigate risks during the study; Communicate and manage risks around timelines during study execution
- Oversee data collection and integrity in support of safety reviews and study reports
- Coordinate data safety reviews in collaboration with Clinical Sciences
- Oversee maintenance of CTMF, ensuring compliance and completeness of required trial documentation
- Ensure overall data quality and integrity and human subject protection by managing studies according to company standard operating procedures and regulatory requirements, including ICH GCP, CFR, EU Directive, HIPAA, as applicable
- Prepare and provide training on company clinical operations SOPs

III: Education/Knowledge and Experience

- A minimum of a Bachelor's Degree or equivalent is required, preferably in medical/scientific field
- Minimum 5 years experience in clinical research environment
- Experience in successful initiation, execution and completion of drug and/or medical device clinical trials. Experience in ophthalmology and/or combination product trials is preferred.
- Solid understanding of drug and/or medical device product development and commercialization
- Experience engaging thought-leaders in clinical trial design and execution
- Solution driven, highly collaborative and strategic thinker
- Experience managing clinical trials subject to domestic and international regulations on conducting human clinical trials
- Demonstrated ability to effectively collaborate within a functionally and geographically diverse team
- Exceptional verbal and written communication skills, ability to articulate compelling reports and presentations
- Highly organized

IV: Skills and Core Competencies

- Excellent written and verbal communication skills;
- Problem solving ability, creative and lateral thinking capability;
- Ability to work independently and also bring team activities together;

- Ability to work under pressure, within time/resource considerations to accomplish objectives;
- Team player with excellent interpersonal skills;
- Pragmatism combined with a positive, “can do” attitude;
- Strength in balancing details and big picture

V: Your Application

- Ripple Therapeutics welcomes and encourages applications from people with disabilities. Accommodations are available on request for candidates taking part in all aspects of the selection process.

- Compensation, including benefits and equity, is competitive and commensurate with experience.

- This is a great opportunity to work with engaged, committed and dedicated colleagues in an innovative and progressive environment. Please forward your application to *careers@rippletherapeutics.com* by 22 March 2021, referencing “Ripple CPS/M” in the subject line.

We thank you for your interest.