OnCusp THERAPEUTICS
Job Descriptions

Job Description

Division:	R&D
Title:	Senior Director, Clinical Scientist
Location:	Boston, MA; New York, NY; or Remote (US Based Only)
Direct Supervisor:	VP Clinical Development

Position Summary:

The primary responsibility of the **Senior Director, Clinical Scientist** is to drive the success of the CUSP06 clinical development program, working closely with the development team leader. This individual will serve as a key scientific contributor and will be accountable for the successful implementation of the CUSP06 Clinical Development Plan (CDP). The Clinical Scientist is responsible for the clinical trial design and successful execution of the trial, including ongoing oversight and safety monitoring from a clinical and scientific perspective. The Clinical Scientist will ensure the highest standards of patient safety, data integrity, and will be responsible for high quality clinical data and output for internal and external presentations and publications as well as the CSR. Responsibilities include leading protocol writing, site engagement, and contributing to regulatory submissions, publications, and presentations. Close engagement with Medical, Clinical Operations, Regulatory, Translational and other team members will be essential.

Responsibilities:

- Serve as a scientific lead and be accountable for the clinical execution of clinical study protocols including providing clinical oversight and medical review of clinical trial data
- Respond to study questions from CROs and sites, with study medical monitor supervision where needed
- Contribute and coordinate the writing and revision of clinical documents, such as study protocols, protocol amendments, clinical study reports, investigator brochures, and other materials for regulatory submission
- In collaboration with medical writing and other functions, work on clinical study protocol(s), amendments, study manuals/plans, and other study materials
- Assists in drafting clinical scientific documents such as IND, IND amendments, investigator brochures, annual DSUR and FDA or other regulatory submissions
- In collaboration with data management contribute to case report form development and completion guidelines
- Monitor, review, and summarize safety and efficacy data in 1 or more ongoing studies.
- Represent clinical development at project team meetings internally, CRO/vendors, and partners

- Develop and manage relationships with appropriate consultants
- Contribute to the planning and design of new clinical studies, in addition to contributing to the creation and updating of CDPs in accordance with corporate objectives
- Work in close collaboration with Clinical Operations to ensure translation of the clinical protocol (and amendments) into operational deliverables, including but not limited to performing ongoing review and analysis of clinical study data and preparing/reviewing study plans (i.e., Medical Monitoring, Medical Data Review, Safety Management, etc.)
- Establish good working relationships with external scientific advisors, thought leaders, clinical investigators, and external partners
- Perform literature searches and critically review and summarize the relevant scientific, drug development, and medical literature to support new clinical trial design as well as the development of clinical and/or regulatory documents
- Support preparation of scientific material for conference presentations or publications
- Contribute to the development of SOPs and associated guidelines and templates

Qualifications:

- Ph.D. or PharmD preferred, minimum 6 years of biopharmaceutical experience working on oncology clinical studies
- BS or MS degree with 10+ years of biopharmaceutical experience working on oncology clinical studies
- Experience in small or mid-sized biotech companies
- Experience in Oncology and first-in-human Phase I studies required; Phase 3 and NDA/ BLA experience strongly preferred.
- Experience working with medical monitors, R&D functions, regulatory affairs, program management, quality assurance, thought leaders, and clinical investigators
- Excellent communication (oral and written), analytical, organizational, and project management skills
- Ability to think strategically and creatively, function independently, deliver on timelines, have strategic insights, and have a detailed knowledge of the activities, and procedures involved in clinical drug development
- Strong ability to work collaboratively in a matrix environment and to foster relationships.
- Experience with global clinical studies
- Experience with critical regulatory submissions

This is a full-time role. Benefits include annual performance-based bonus, generous paid time off, 401(k) with company match, and an employee stock ownership plan.

Equal Opportunity Employer

We are an equal opportunity employer and value diversity at our company. We do not discriminate based on

race, color, religion, national origin, gender, gender identity or expression, sexual orientation, age, marital status, veteran status, disability status, or any other legally protected status. We are committed to creating an inclusive environment for all employees