Visterra
275 Second Avenue, 4th Floor · Waltham, MA 02451
Tel: 617-498-1070
www.visterrainc.com

Clinical Trial Manger

Company

Visterra is a clinical stage biotechnology company committed to developing innovative biologic therapies (monoclonal antibodies and therapeutic muteins) for the treatment of kidney diseases, with an immuno-nephrology focus in drug development. Our proprietary technology platform enables the design and engineering of precision antibody or protein-based drug candidates to modulate key disease targets. We are developing a robust pipeline of novel therapies for patients with unmet needs.

Visterra is a wholly owned subsidiary of Otsuka America, Inc., which is a U.S. holding company subsidiary of Otsuka Pharmaceutical Co., Ltd. of Japan. Visterra has approximately 90 employees, and is located in Waltham, Massachusetts.

Summary

Visterra is seeking a Clinical Trial Manager to join our dynamic team. The Clinical Trial Manager is a key member of the clinical operations team and supports the execution and management of clinical trial(s). The Clinical Trial Manager reports to the Director, Clinical Operations. The ideal candidate should have B.S. degree in science or healthcare and a minimum of five years of clinical research experience; ideally in early phase development.

Responsibilities

- Leading tasks as assigned by manager with decisiveness and strong judgment.
- Working with internal cross-functional study execution team and external CROs/vendors to ensure timelines are understood.
- Identifying any potential risks and escalating to manager with mitigation solutions.
- Leading document finalization process with both internal and external stakeholders to ensure all comments/feedback are incorporated and ensure proper grammar and formatting.
- Developing clinical study documents including ICF, study plans, and pharmacy manual.
- Ensuring that all clinical data is managed and completed in a timely manner. Developing tracking tools and reports as appropriate to distribute to the study team.
- Preparing and overseeing of TMF and internal files.
- May participate in regulatory audits and inspections as appropriate.
- Hosting internal study meetings, including the development of agenda and minutes.
- May be required to mentor and/or train junior team members.

Requirements

- Science or healthcare bachelor's degree required.
- At least 5 years of clinical research experience at a pharmaceutical/biotech or CRO.
- Strong knowledge and understanding of GCP/ICH Guidelines and relevant CFRs for conducting clinical trials.
- Effective communication (written and verbal), adaptability and self-motivation.
- Ability to balance changing priorities.
- Strong interpersonal, organizational, and multi-tasking skills.
- Excellent attention to detail and problem-solving skills.
- Ability to work effectively work in a team setting.
- Computer proficiency, including Microsoft Office applications. Experience with EDC and CTMS systems a plus.
- Ability and willingness to travel, usually less than 15% of the time.

Visterra provides equal employment opportunities to all employees and applicants for employment and prohibits discrimination and harassment of any type without regard to race, color, religion, age, sex, national origin, disability status, genetics, protected veteran status, sexual orientation, gender identity or expression, or any other characteristic protected by federal, state or local laws.

For consideration, please submit a cover letter and resume to careers@visterrainc.com.