Visterra
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# Associate Director or Director, Clinical Operations

## Company

Visterra is a clinical stage biotechnology company committed to developing innovative antibody-based therapies for the treatment of patients with kidney diseases and other hard-to-treat diseases. Our proprietary technology platform enables the design and engineering of precision antibody-based product candidates that specifically bind to, and modulate, key disease targets. Applying this technology to disease targets that are not adequately addressed by traditional therapeutic approaches, 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 and a wholly owned subsidiary of Otsuka Pharmaceutical Co., Ltd. of Japan. Visterra has approximately 75 employees and is in Waltham, Massachusetts.

## Summary

The Associate Director or Director of Clinical Operations is responsible for the execution of domestic and global clinical studies. The position reports to the Executive Director, Head of Clinical Operations. This position is responsible for the operational planning, implementation and conduct of primarily early phase clinical studies. Responsibilities include managing all aspects of clinical study conduct: participate with protocol development, CRO oversight/selection, budgets, timelines, contracts, study set-up, study conduct, and reporting. This individual will need expertise in successful planning, implementation, and delivery of clinical operations strategy, plans and study execution. The right candidate will also have experience in mentoring staff to develop skills and ensure they remain professionally challenged and engaged. This is a full-time position located at Visterra's facility in Waltham, MA.

## Responsibilities

- Manage and execute global complex clinical studies.
- Manage resource planning for each clinical trial and across all assigned clinical trials.
- Proactively and independently manage vendors, including identifying risks and outlining mitigation plans.
- Manage Clinical Operations team, CROs and ancillary vendors to ensure work quality, timelines and adherence to budget.
- Set expectations within the organization to ensure the timely setup, initiation, execution and for the timely generation of data.
- Review and develop SOPs, and support the design and execution of quality management plans consistent with GCP and other applicable government and regulatory agency standards.

- Manage Clinical Operations budget forecasting and monitor the budget against actuals and apprise Management of variances.
- Mentor staff to develop skills and ensure they remain professionally challenged and engaged.

**Requirements**

- Bachelor's degree and 10 years' related clinical development experience in pharmaceutical and/or CRO industry.
- At least 6 years of experience managing a clinical operations team and CROs.
- Experience and expertise managing and executing global complex clinical studies.
- Clinical trial monitoring experience.
- Working knowledge of GXP regulations.
- Deep knowledge of and experience in ICH/GCP and the drug development process.
- Excellent time management and organizational skills, demonstrated ability to manage and prioritize a team and meet deadlines;
- Prior experience managing direct reports.
- Excellent verbal, written and presentation skills.
- The ability to travel domestically and internationally up to 30% of 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.