Head, 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. Our most advanced program is in Phase 2 clinical development.

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 50 employees and is located in Waltham, Massachusetts.

Summary:

The Head of Clinical Operations is responsible for leading and driving clinical trial operations for Visterra' current and future programs. This role will oversee the Clinical Operations team to ensure all assigned operational trial deliverables across programs are completed according to timelines, budget, operational procedures, quality standards, SOPs and business guidelines. This individual will need expertise in successful planning, implementation, and delivery of clinical operations strategy, plans and study execution. The Head of Clinical Operations will also be responsible for managing and supporting vendor/ CRO relationships and activities including negotiations and performance evaluations. Reports directly to the CMO.

Key duties and responsibilities:

- Primary leadership role for overall clinical operations strategy development and execution across multiple clinical trials
- Provide strategic and tactical input into clinical development strategy and timelines
- Lead and develop the Clinical Operations Team
- Ensures all clinical trials are executed per key metrics (timelines, budget, operational and quality standards (ICH/GCP/ SOPs and procedures);
- Set department goals and objectives which align with broader company goals
- Establish and maintain strategic partnerships with CROs and key vendors and work to resolve
- performance issues
- Managing integration activities with parent company
- Supports the development, management and tracking of trial budget(s) working closely with the appropriate partners. Accountable for accuracy and timeliness of trial information in all trial databases and tracking systems.
- Coordinates management and meetings of the members of our data safety monitoring boards (DSMB) and clinical event committees (CEC).

- Accountable for facilitating Clinical Agreements through Clinical and Legal Review.
- Accountable for ensuring thorough reviews of study documents for accuracy and quality content. Drafts sample process instructions, in accordance to standard operating procedures (SOPs) and good clinical practice guidelines (GCPs) as needed.
- Assists/oversees medical writer(s) in overseeing the process and timelines of writing, and tracking protocols, consent forms, and amendments to ensure adherence to regulations, company SOPs and processes, and consistency across clinical trials. Develops study specific documents such as pharmacy and operational manuals as needed.
- Contributes to Global clinical/ regulatory submissions (FDA, EMA, Canadian and other countries), IRB / EC submissions.
- Drive the creation of clinical operations SOPs, systems and processes
- Oversee the clinical operation aspects of cross functional work processes (legal, QA, CMC, regulatory, IT, med affairs, translational, finance)
- Serve as a leadership role model within the company and with external stakeholders

Experience and Qualifications

- 12+years of clinical operations management experience in a pharmaceutical or clinical research organization (CRO) setting; including management of a CRO.
- 3+ years in a leadership role
- Global clinical trial experience preferred; with ability to oversee multiple trials
- Requires a BS in the health or life sciences or equivalent,
- Strong leadership and collaborative interpersonal skills.
- Possess strong critical thinking and problem-solving skills
- Proven ability to interact, train, and build strong relationships with CROs, vendors
- Excellent computer skills (Microsoft Office Suite, Project, Word, Excel, PowerPoint, Outlook; Electronic Data Capture Systems).
- Very knowledgeable of Good Clinical Practice and ICH guidelines as it relates to running clinical trials
- Experience working independently and in a team environment, being flexible and adapting in a changing environment

Management responsibilities: Management of clinical staff and external vendors.

Travel: Ability to travel up to 30% travel

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.