Clinical Trial Manager

ABOUT THE COMPANY

QurAlis is a clinical-stage biotechnology company developing breakthrough precision medicines for amyotrophic lateral sclerosis (ALS) and other neurodegenerative diseases with genetically validated targets.

QurAlis is trailblazing the path to conquering amyotrophic lateral sclerosis (ALS) and other neurodegenerative diseases with genetically validated targets with next-generation precision medicines. QurAlis' proprietary platforms and unique biomarkers enable the design and development of drugs that act directly on disease-causing genetic alterations. Founded by an internationally recognized team of neurodegenerative biologists from Harvard Medical School and Harvard University, QurAlis is advancing a deep pipeline of antisense oligonucleotides and small molecule programs including addressing sub-forms of ALS that account for the majority of ALS patients.

Summary of Position:

QurAlis is seeking a highly motivated, experienced Clinical Trial Manager to support our clinical trial efforts.

Primary Job Responsibilities:

- Responsible for operational execution of global/regional Phase I-IV studies. Manage trial deliverables as well as CRO and vendor relationship and performance to ensure that clinical studies are completed in accordance with contract specifications and management's expectations of time, cost and quality
- Ensure oversight of clinical trials including the selection of investigational sites, adherence to pertinent regulations through review of monitoring reports, QA-GCP audit reports and communications with study/ site personnel
- Develop project objectives, plans, and timelines with particular focus on assumptions, and interdependencies
- Maintain control on established scope, budget, and timelines
- In collaboration with the CRO/vendor oversee operational study level feasibility, recruitment strategies and the delivery of the approved study protocol
- Review selected study clinical documents (protocol, operational plans, monitoring plans, monitoring visit reports, etc.) based on SOP, ICH/GCP guidelines and with patient centric view

- Responsible for overall risk management of study to assure timely delivery to quality, budget and time. Escalate issues to stakeholders as appropriate and ensures successful implementation
- Establish and maintain effective communication and collaboration with functional area peers to meet program objectives, proactively identify study risks and support achievement of goals
- Support inspection readiness activities. Participate as appropriate in internal and external audits. Facilitate internal audit/corrective and preventative action (CAPA) management and contributes to the resolution of CAPA
- Support interactions with the FDA, EMA and other regulatory authorities
- In collaboration with data management, facilitate ongoing data review in preparation for interim, final analyses and review of CSR
- Plan and conduct study related meetings
- Other duties as assigned

Minimum Qualifications Required:

- BA/BS in life sciences or equivalent;
- At least 4 -5 years of clinical operations experience including at least two (2) years having effectively led a study/studies project from inception to completion coupled with demonstrated ability to hold team members accountable
- Global experience of drug development ideally obtained in a biotech/pharma setting
- Working knowledge of Good Clinical Practices (GCP), EU Clinical Trials Directive / Regulation and expectations for MHRA GCP Inspections
- Awareness of FDA regulations and guidelines with respect to clinical trials, and applicable international regulatory requirements
- Prior interactions with the FDA, EMA and/or other authorities, a plus
- Knowledge and understanding of clinical development processes, including ICH guidelines
- Ability to effectively manage interactions with investigators ensuring cooperation for achieving program goals
- Ability to resolve problems and lead projects of diverse scope, analyze data and exercise sound judgment along with the ability to recommend business alternatives to senior management
- Ability to work independently and collaboratively in cross-functional teams
- Strong work ethic and professional attitude
- Detail oriented
- Strong organizational skills, work ethic, and high-level motivation
- Capacity to be highly productive in a dynamic and fast-paced work environment
- Excellent oral, written and interpersonal communication skills
- Knowledge of clinical operations, project management tools and processes

- Proficient MS Office skills including data review analysis tools
- Ability to travel up to 20% including possible international travel
- Authorized to work legally in the United States

Please send resume with cover letter to anna.beck@quralis.com.

QurAlis is committed to equal employment opportunity and non-discrimination for all employees and qualified applicants without regard to a person's race, color, gender, age, religion, national origin, ancestry, disability, veteran status, genetic information, sexual orientation or any characteristic protected under applicable law. QurAlis will make reasonable accommodations for qualified individuals with known disabilities, in accordance with applicable law.