**Senior Clinical Trial Lead, Clinical Research**

OnQuality Pharmaceuticals is a clinical-stage biotech company focusing on developing targeted cancer supportive therapy for intolerable side effects caused by anti-cancer medications.Our leading compound is in onco-dermatology, which is studied in a phase 2 clinical trial. We also have four assets in onco-dermatology and onco-GI scheduled to file INDs in 2022 and two others in early discovery stage. Joining us at this stage grants you the chance to make a tremendous impact on the company growth. We sincerely invite you to work together with us, to realize the vision of reshaping the landscape of cancer supportive care by solving multiple unmet medical needs, and thus to help cancer patients live better.

**Job Summary**

We are currently seeking a Project Manager, Clinical Research to join our medical team. This person will be responsible for ensuring project plans are developed and executed according to planned timelines, cost and quality. He or she will oversee the daily operation of various development programs, collaborate with colleagues in preclinical, translational, CMC, regulatory, and medical team, facilitate timely decisions to ensure alignment and deliverables. Reporting to Director of Clinical Operation, this position offers an excellent opportunity for someone who enjoys working in a fast-paced company where he or she will have the opportunities to take ownership of his or her own work, enhance his or her current abilities and have an exciting and rewarding career in drug research and development while making a positive impact to lives of cancer patients.

**Responsibilities**

* Serve as a key member of product team to contribute to the accomplishment of trials outlined by the global clinical development plan
* Oversee all aspects of project management, including scope, cost, time, quality, safety, communication, integration, risk, vendor, stakeholder, and scenario planning
* Lead the selection of vendors (as well as in the Request for Proposal (RFP) process) on a global scale, and also contribute to study site selection
* Facilitate contract and budget negotiations with clinical sites and vendors
* Oversee and manage CROs, other third-party vendors and contractors, to ensure delegated outsourced activities are delivered according to contract
* Act as point of contact for all site-related issues and procedural questions escalated from vendors
* Contribute to the development and active management of study-specific patient recruitment strategies, project and keep track of study enrollment / drug supply / related resources needs
* Oversee / collaborate with multiple study functions at CRO, including data management and EDC, IWRS, drug supply chain, biostatistics, medical and pharmacovigilance, regulatory, etc.
* Participate in developing and finalizing cross-functional activities to ensure delivery of critical clinical trial documents such as protocols, deviation lists, informed consent forms (ICFs), country and site contract / budget templates, master labels of investigational products, database specifications, drug supply and bio-sample management plans, TMF, and CSRs
* Develop study tools, guidelines and training materials, or oversight the deliverables from CRO
* Lead the trial information/results registration activities on regulatory platforms (e.g., clinicaltrials.gov), and support the publication plan of studies
* Provide relevant budget review and forecasting
* Coordinate planning and execution of investigator meetings and various trial advisory committees (e.g. Steering Committee), may be accountable for driving agenda and content for the meetings
* Provide routine updates on project status, proactively identify risks / issues, and develop and implement risk mitigation / issue resolution plan to ensure operational effectiveness

**Qualifications**

* Bachelors or Master’s degree in scientific, biological, and life sciences
* 2-3 years of project management experience in the biopharmaceutical industry
* Understanding of all aspects of drug development with experience in global clinical trial operations in multiple phases including experience with site startup and vendor management
* Knowledge and familiarity with industry standards including ICH guidelines, GCP and FDA regulations
* Performance driven with ability to work independently, with proven operational and tracking skills
* Ability to assess complex issues and identify creative, practical solutions
* Excellent organizational and priority management skills
* Exceptional interpersonal and communication skills with conflict resolution and consensus building abilities
* Highly collaborative and works well in a team environment
* Able to work effectively with colleagues from different cultures, backgrounds and geographies

**Special requirements**

* Mostly home-based
* Teleconference with colleagues overseas could take place on weekends or nights