

Job Description: Clinical Operations Manager

About us

RQ Bio is a UK-based virology company developing long-acting monoclonal antibodies (LAABs) against seasonal influenza to provide immediate, powerful and long-lasting protection against severe viral disease. We are advancing our lead influenza programme towards clinical development and are looking for an experienced Clinical Operations Manager to help deliver our first-in-human studies and support later-stage development.

About the role

The Clinical Operations Manager will take hands-on ownership of the operational delivery of RQ Bio's clinical studies, from start-up through execution and close-out. Working with the cross-functional development team, CROs and specialist vendors, you will deliver studies to agreed timelines, budgets and quality standards, maintaining effective sponsor oversight, patient safety, data integrity and inspection readiness.

Reporting to the Head of Clinical Operations, this is a highly visible role in a small, fast-moving biotech, with the opportunity to shape how RQ Bio delivers clinical development as our lead programme advances into the clinic and towards pivotal clinical trials.

Role profile

- Own the operational planning and delivery of assigned clinical studies, including timelines, milestones, budgets, resources, risks and key deliverables.
- Lead RQ Bio's day-to-day sponsor oversight of CROs and specialist vendors, holding partners accountable for quality, timelines, budget and contractual commitments and escalating issues where required.
- Responsible for the development and management of clinical trial documents including (but not limited to) protocols, study amendments and manuals, project plans and oversight records as required.
- Oversee study start-up, country and site activation, enrolment, study conduct, database-lock readiness, close-out and delivery of final study outputs.
- Keep clinical trial documentation and the trial master file (TMF) complete, accurate and inspection-ready, including study plans, oversight records and key decisions.
- Identify and resolve study risks and issues, bringing clear recommendations to governance forums and escalating decisions where needed.
- Ensure studies are conducted in accordance with the protocol, GCP, ICH E6(R3), applicable regulatory requirements, RQ Bio procedures and agreed quality standards.
- Work cross-functionally with Clinical Development, Regulatory, Medical Writing and other internal and external partners to support study delivery, regulatory submissions and clinical reporting.

- Give RQ Bio leadership a clear view of study progress, budgets, risks and key decisions, and improve how we plan, oversee and deliver clinical studies.
- Foster a collaborative and delivery-focused culture, enabling effective cross-functional communication and alignment.
- Train, mentor and manage junior team members as company scales.

Essential skills and experience

- A minimum of 8 years' experience in clinical operations and clinical trial management within pharmaceutical, biotechnology or sponsor-led development, ideally including significant sponsor-side experience.
- Proven ability to independently lead global or multi-country studies, managing timelines, budgets, risks and cross-functional delivery with sound financial and analytical judgement.
- Experience overseeing CROs and vendors, developing requests for proposals (RFPs) and scopes of services, and holding partners accountable for delivery.
- Strong working knowledge of GCP, ICH guidance, clinical trial regulations and sponsor oversight, with a commitment to patient safety, data integrity, quality by design and inspection readiness.
- Sound judgement, attention to detail and confidence to challenge partners, resolve issues and escalate, supported by clear study plans and oversight reports.
- Fluent English and strong communication skills to influence stakeholders and build relationships with colleagues, partners, investigators, key opinion leaders and site teams.
- Comfortable taking ownership in a small, fast-moving biotech and delivering hands-on as processes and infrastructure evolve.
- Degree in biological sciences.

Desirable skills and experience

- Project management certification or equivalent training.
- Experience in early- or late-phase, adaptive, decentralised, vaccine or complex interventional studies.
- Experience with clinical trial systems and tools for safety, risk-based quality and project management.
- Experience in infectious diseases, especially influenza, or biologics and monoclonal antibodies.
- Experience supporting audits, inspections, submissions, study reports or marketing authorisations.

Working arrangements and benefits

- Hybrid working is available, with attendance required at team meetings in Cambridge or London up to one day per week. Some work outside standard hours may be needed to collaborate with international partners.
- We offer a competitive salary based on qualifications and experience, plus a benefits package including pension and health insurance.

- Candidates must have the right to work in the UK, or eligibility to obtain it.
- We believe diverse teams are the most innovative and welcome applicants from all backgrounds and identities.

To apply, please email your CV and brief cover note to careers@rqbiotechnology.com quoting reference **RQ2613**. Our Candidate Privacy Notice can be found on the careers section of our website.