Clinical Project Manager (II)

Ariceum Therapeutics GmbH is a rapidly growing clinical stage oncology company focused on developing next generation radiopharmaceutical oncology products. The product pipeline includes satoreotide, a novel potent peptide antagonist with high affinity for tumour cells expressing SST2 receptors. Satoreotide is being developed into products with complementary therapeutic and diagnostic imaging opportunities in a range of solid tumours. Ariceum Therapeutics GmbH is headquartered in Berlin and has employees in a number of European countries, including Germany and the UK.

Position

Department/Function: Clinical Operations

Reports to: Head of Clinical Operations

Location of the role: Europe (UK preferred)

Main Purpose of the Position

Reporting to the Head of Clinical Operations, the Clinical Project Manager is responsible for managing clinical trials sponsored by the company from inception to final report, including management of contract service providers (CROs and other vendors).

As well as operational oversight of the trial, the CPM will be expected to provide relevant scientific and operational input from the protocol planning stage to the reporting stage.

The Clinical Project Manager will also assist with departmental tasks such as creating and reviewing SOPs and departmental level tracking, as well as inputting into development plans.

Key Responsibilities and Tasks

- Manage clinical trials ensuring subjects' rights, safety and wellbeing are protected and that the clinical trial data are reliable
- Management of vendors in accordance with contractual timelines, sponsor specifications, quality, budget, and GCP.
- Assist with, or lead screening, selection, and contracting of vendors.
- Oversee the trial day-to-day operations, monitor and track study status, timelines, and budget; identify opportunities and recommend implementation plan for efficiency measures
- Resolve arising issues with the trial and liaise with the management team as required
- Oversee and input into the eTMF, including design of documentation and TMF QC
- Oversee and input into the data management processes, statistical deliverables and clinical report writing
- Provide operational and scientific input into development programmes
- Co-monitor clinical trial sites as required

- Input into and management of the creation of key study documents such as protocols, SAPs, DMPs and CSRs
- Ensure audit and inspection readiness, and leading/assisting with quality event and CAPA resolution
- Identify critical project success factors and study metrics for tracking, analysis and reporting including impact and probability of project risks.
- In collaboration with the management team, develop a robust project plan including risk assessment and contingency planning, at the start of the study and monitored throughout its duration to study close-out
- Evaluate needs, resources and timelines and create, maintain and report on project plan(s).
- Accountable for overall study budget. Responsible for review of study budget, expense reports and financial records (invoicing/units/expenses) against vendor contracts
- Coordinate assignment of needed resources for study conduct and completion
- Participate in development and review of departmental Standard Operating Procedures (SOPs), guidelines, intradepartmental procedures, and other continuous process improvements programs, as assigned

Experience / Qualification

- Bachelor's degree (or equivalent) in life sciences required. Advanced degree or equivalent clinical research experience preferred.
- 7+ years of pharmaceutical company/biotech experience or equivalent applicable experience.
- 3+ years of study management experience
- Experience in oncology required and diagnostic and therapeutic radiopharmaceuticals preferable.
- Previous experience as a Clinical Research Associate (CRA)

Required Competencies

- Excellent communication skills including verbal, written, and presentational
- Excellent organizational skills
- Strategic thinker with good negotiation skills
- Working knowledge of, and ability to implement project activities in accordance with, ICH/GCP and all applicable regulations and guidelines in the relevant regions
- Ability to travel domestically and internationally
- Ability to leverage scientific knowledge
- Strong regulatory experience in the EU and internationally would be advantageous
- Fluent English

Other information:

- Anticipated to travel internationally circa 20% of the time