Clinical Trial Director (CTD)

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 potent 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 with a subsidiary in Basel and employees in a number of European countries.

Position

Department/Function:	Development Operations
Reports to:	Head of Clinical Operations
Number of reports	0-5 direct reports, matrix & vendor management
Financial responsibility	Responsible for financial & resource allocation of assigned trials
Location of the role:	Basel (office-based with hybrid component)

Main Purpose of the Position

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

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

The Clinical Trial Director will also assist with departmental tasks such as creating and reviewing SOPs and departmental level tracking, as well as providing input to development plans.

Key Responsibilities

- Manage clinical trials ensuring subjects' rights, safety and wellbeing are protected and the clinical trial data are reliable
- Lead and manage global trial teams and clinical trial managers to ensure Management of vendors in accordance with contractual timelines, sponsor specifications, quality, budget, and GCP.
- Lead internal clinical meetings related to the clinical trial(s).
- Accountable for the writing of clinical protocols and related documents
- Assist with, or lead screening, selection, and contracting of vendors
- Lead investigators meetings and contribute to trial-related advisory boards. Lead protocol training meetings
- 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
- Accountable for 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
- Accountable for the development, management and tracking of trial budget,
- Assess resource needs with management to ensure appropriate staffing
- Identify critical 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.
- 5+ years of study management experience
- Experience in oncology required; experience with radiopharmaceuticals preferable.
- Previous experience as a Clinical Research Associate (CRA) desired.

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 internationally (anticipated requirement: 20% of the time)
- Ability to leverage scientific knowledge
- Regulatory experience would be advantageous
- Fluent English