CLINICAL TRIAL DIRECTOR (CTD)

Ariceum Therapeutics GmbH is a rapidly growing clinical stage oncology company focused on developing innovative radiopharmaceuticals. Ariceum is headquartered in Berlin with subsidiaries in Basel and Boston. The clinical pipeline includes Satoreotide, a potent antagonist of the somatostatin receptor that is overexpressed by several solid tumors, including Small Cell Lung Cancer and Merkel Cell Carcinoma.

Position

Department/Function:	Development Operations
Reports to:	Head of Development 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/Berlin/US East Coast (office-based, hybrid component tbd)

Main Purpose of the Position

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

In addition to operational leadership, the CTD is expected to provide relevant scientific and operational input from the protocol planning stage to the reporting stage.

The CTD will also assist with departmental tasks such as creating and reviewing SOPs and departmental tracking and provide 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, lead internal clinical meetings related to the clinical trials
- Write/co-author/review clinical protocols, SAPs, DMPs, CSRs and related documents
- Lead protocol training meetings, investigator meetings and contribute to trial-related advisory boards
- Assist with, or lead screening, selection, and contracting of vendors
- Manage vendors in accordance with sponsor specifications, contractual timelines, quality, budget, and GCP.
- Oversee the trial day-to-day operations, monitor and track study status, timelines, and budget; identify opportunities and recommend implementation plan for efficiency measures
- In collaboration with the management team, develop a robust project plan including risk assessment and contingency planning, at the start of the study and monitor throughout its duration to study close-out. Evaluate needs, resources and timelines and create, maintain and report on project plan(s)

- Develop, manage and track trial budgets. Review study budget, expense reports and financial records (invoicing/units/expenses) against vendor contracts. 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
- 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
- Co-monitor clinical trial sites as required
- Provide operational and scientific input into development programs
- Ensure audit and inspection readiness, and lead/assist with quality event and CAPA resolution
- Participate in development and review of departmental SOPs , guidelines, departmental procedures, and other continuous process improvement 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