Job Title: Clinical Trials Manager (Hiring for Q4 2020)

Reports to: Director Clinical Operations

FLSA /Pay Grade: Exempt/Professional

Why Artiva

Over the past decade we have seen stunning advances in the cellular immunotherapy therapy field in particular, with dramatic rates of clinical response in hematological malignancies, and rapid evolution of our understanding of factors that could extend this success to solid tumors. However, these transformative therapies are often accompanied by severe and potentially life-threatening toxicities, and patient access is limited by such factors as complex, time-consuming patient-specific manufacturing, variable product quality, and cost.

Our Mission

At Artiva, our mission is to deliver highly effective cell therapies that are also safe and immediately available and accessible to any patient who stands to benefit.

Scope of Role

Reporting to the Director, Clinical Operations, the Clinical Trials Manager is responsible for oversight and execution of the operational aspects of one or more clinical studies from protocol development through database lock. Ensures timely conduct of clinical studies according to protocols, Good Clinical Practice (GCP), Standard Operating Procedures (SOPs), and all applicable regulations and guidelines governing the conduct of clinical trials. The Clinical Trials Manager provides oversight of the CRO and other third-party vendors on their assigned study as well as expertise to internal teams (regulatory affairs, medical writing, biometrics, pharmacovigilance, and product manufacturing) to ensure quality processes and deliverables.

Role & Responsibilities

- Assist with third-party vendor training on protocols and practices. Coordinate the logistics of Artiva product readiness with sites and internally within Artiva. Work cross-functionally with product manufacturing, QA and supply chain management, to coordinate site training, product

delivery, supply management to ensure readiness and product availability prior to patient treatment.

- Developing and maintaining good working relationships with CRO, investigators and study staff.
- Ensure studies are carried out according to the study protocol, SOPs, and ICH/GCP regulations and study-specific manuals and procedures.
- Ensure timely response to queries and monitoring discrepancies.
- Manage the investigational product (IP) and non-IP study accountability and reconciliation process.
- Oversee the performance of CROs and third-party vendors, including co-monitoring, to ensure compliance with study protocol and in accordance with scope of work; identify areas of concern and escalate to Clinical Operations Managers.
- Perform clinical data review of data listings and summary tables, including query generation.
- Perform initial review of CRO and other third-party study vendor invoices for correctness.
- Plan and conduct investigator meetings as directed.
- Review key study quality metrics (e.g. patient eligibility, primary endpoint data, etc.) and determine appropriate action in conjunction with study team.
- Review and/or approve IP release packages.
- Tracking and report on current progress of the study including site activation, patient enrollment, monitoring visits and data submission backlogs.
- Contribute to the preparation of clinical protocols, amendments, informed consent forms, study manuals and guides, electronic case report forms, and any other clinical research related documents.
- Participate in the planning of quality assurance activities, coordinating the resolution of applicable audit findings.
- Ensure audit-ready condition of clinical trial documentation including central clinical files; review monitoring visit reports to ensure quality and resolution of site-related issues; coordinates and assist in the planning of regulatory or ethics committee activities, as appropriate.
- Collaborate with cross-functional teams (e.g. Medical Monitor, Regulatory Affairs, CRO, vendors and Investigators/site staff).
- Prepare and/or review study-related documents (e.g., Monitoring Plan, Laboratory Manual, Patient Diary, Pharmacy Manual, CRF Completion Guidelines, etc.).
- Prepare/review site study documents (i.e., site-specific informed consent, study tools/worksheets, investigator contracts, and site payments).
- Manage clinical monitoring activities (including approval of visit report templates, monitoring plan, etc.) ensuring compliance with ICH/GCP and applicable regulations, including the management through resolution (e.g. CAPA) of any site or study level issues, deviations, etc.
- Participate in the selection, training, and evaluation of study personnel (contract and internal) to ensure the efficient operation of the function.

Experience, Education and Specialized Knowledge and Skills

Must thrive working in a fast-paced innovative environment while remaining flexible, proactive, resourceful, and efficient. Excellent interpersonal skills, ability to develop important relationships with key stakeholders, conflict management and negotiation skills, ability to analyze complex issues to develop relevant and realistic plans and recommendations. Demonstrated ability to translate strategy into action. Excellent analytical skills, ability to communicate complex issues in a simple way. and ability to orchestrate plans to resolve issues and mitigate risks.

- Undergraduate degree in life sciences, graduate degree preferred.
- Therapeutic experience in cell therapy and oncology strongly preferred.
- Five or more years' experience managing clinical trials as the sponsor; prior working experience at a CRO is a plus.
- Thorough knowledge of clinical research concepts, practices, FDA regulations and ICH guidelines regarding drug development and data management methods.
- Experience monitoring sites and conducting other site management activities.
- Proven experience in early phase clinical trials.
- Strong site management and CRO management skills required.
- Proven communicator, both oral and written.

Competencies

- Decision Making
- Time Management
- Strategic Thinker
- Operations Management
- Risk Management
- Business Planning
- Implementing Plans
- Analysis & Reporting

Attributes

- Honesty/Ethical
- Self-starter
- Creative/Imaginative
- Self-controlled
- Positive
- Ambitious/Driven
- Collaborative
- Communications
- Forward Thinking
- Confident
- Intuitive
- Committed
- Agile
- Transparent

We look for talented, entrepreneurial people who share our values.

We are called to put the **safety** of our patients and employees first, and to act with **integrity** and the highest ethical standards. To achieve our mission, we must collaborate across the Company at all levels, and we must hold ourselves and our teams **accountable** for delivering the progress we commit to, on the timelines we set. We embrace **diversity**, we include people and their ideas, and we aspire to **excellence** by listening, understanding, sharing and responding. We want you to be fully **engaged**, to develop personally and professionally through this chapter in your life, and to have **fun** along the way.

Artiva Biotherapeutics is an equal opportunity employer that is committed to providing a work environment free of harassment and discrimination based upon a protected category, as well as an environment free from retaliation for protected activity.

Benefits

- The opportunity to work with a team of highly experienced professionals from clinical to regulatory to CMC to research
- To be part of building a company on the cutting edge of cell therapy that may be a game changer to patients in a culture that is entrepreneurial, highly collaborative and innovative
- Competitive compensation, including bonus
- Equity program
- Health and welfare benefits – Medical, Dental, Vision, Life, 401K, EAP

To apply, please send cover letter and resume/CV to: hr@artivabio.com.