



Director Clinical Operations

General Scope and Summary

Avila is transitioning from a research organization to an R&D organization as our first product candidate advances into clinical development. We now seek to add Clinical Operations leadership to the company as we initiate our first clinical trial and develop additional clinical protocols and programs within our growing pipeline.

In this newly created position you will oversee the design, planning, and implementation of Avila's clinical trial programs, including the further development and design of the infrastructure and processes needed for the successful implementation of clinical trials, managing ongoing clinical trials to monitor adherence to protocols, and adherence to aggressive clinical timelines. Additional responsibilities include accountability for the clinical milestones and budgets and working with the Head of Clinical Research and Leadership Team to define the overall clinical strategy for Avila.

Roles and Responsibilities

- Accountable for clinical trial execution
- Recommend and implement processes governing clinical trials management and timelines
- Manage project planning, budget, and resource deployment for clinical studies
- Collaborate with others in design and implementation of clinical protocols, clinical data collection, and quality management
- Ensure compliance with GCP and regulatory guidelines
- Ensure timely completion of clinical trial milestones
- Oversee selection and management of CROs, including RFP process, selection of vendors, contract negotiation and management of overall project timelines and deliverables
- Oversee management of study sites
- Collaborate on, author, and review of clinical documents (e.g., Investigator Brochures, Annual IND Safety Reports, protocols, study reports, etc.)
- Manage and support investigators for studies and ensure compliance with protocol and overall clinical objectives
- Participate in clinical drug supply planning and tracking, as appropriate
- Participate as an integral member of development team to provide clinical operational input in overall product development planning
- Evaluate information from clinical trial literature, government agencies and outside experts relevant to ongoing projects
- Travel to field sites to supervise and coordinate clinical studies, as needed

Experience, Education and Specialized Knowledge and Skills

- B.S or B.A. in a scientific or health-related field is required. Advanced degree preferred (PharmD)
- Minimum of ten years experience in all aspects of clinical trial management involving the establishment, planning, operation, and successful and timely completion. Thorough knowledge of US and EU regulations

and study management. Also should have at least 5 years of experience in managing staff , working with internal/external teams and or project management issues.

- Strong experience with the development and successful management of CRO's
- Strong background in oncology. Autoimmune disease knowledge a plus.
- Superb intellect balanced with keen intuition, excellent written and verbal communications skills, and a good sense of humor
- Ambitious with a strong sense of urgency and flexibility to work in a highly entrepreneurial and fast-paced organization. The ability and strong desire to "make things happen".
- Decisive as well as collaborative.