AVENGE BIO

Job Description: Head of Clinical Operations (VP/Sr Director)

Avenge Bio has an exciting opportunity to join the growing clinical organization as a Head of Clinical Operations. Reporting to the Chief Medical Officer you will be responsible for the management of clinical trial activities, initially for Avenge's lead development program AVB-001. You will support the clinical team with the implementation and oversight of clinical trials, focusing on the areas of clinical operational strategy, trial logistics planning, enrollment, site monitoring, data quality, and study reporting. This role will be the critical interface between Sponsor, CRO, and team at study sites.

Responsibilities:

- Represent all aspects of Clinical Operations and provide updates as required to the Management Team, Project Teams, Board of Directors and other key internal stakeholders
- Responsible and accountable for oversight and management of CRO(s) and other assigned vendors which may include central and specialty labs, imaging, or other vendors as required
- Participate in site identification, evaluation, contracting, initiation, monitoring, and close out visits
- Communicate with clinical site staff, investigators, and CROs as appropriate to ensure optimal Sponsor-site relationships
- Drive traceability procedures for investigational products and closely coordinate clinical supply planning with CMC – this role will include significant cross functional interaction, in particular regarding MFG and coordination of DP delivery to sites
- Support the management of site-related activities, development of tracking tools, and manage recruitment timelines
- Prepare updates on study progress
- Participate in the selection and contracting of third-party vendors
- Prepare the study budgets, and track payment of contracts related to the project
- Accountable for accuracy and timeliness of trial information in all trial databases and tracking systems
- Participate in EDC / IRT set-up by contributing to case report form design, user acceptance testing, completion guideline development, and other related activities
- Monitor clinical data entry progress and follow up with CRO(s) on incomplete data entry and/or outstanding queries
- Anticipate potential study issues and prepare contingency plans with minimal oversight
- Review and approve all study documents such as essential regulatory packages, ICFs, etc. for accuracy and quality content
- Develop study specific documents such as pharmacy manual and informed consent forms
- Build the Clinical Operations function, hire and train CTM and CRO team members and site staff, expand capabilities, as needed
- Responsible for day-to-day management of CRO(s) and other vendors working on assigned study, including setting expectations, training, managing timelines and deliverables, and issue management

- Additional duties and responsibilities as required. Capable of managing multiple projects and shifting priorities associated with an early-stage drug development company.

Qualifications:

- Bachelors in Life Sciences, Nursing Licensure or Pharmacy; an advanced degree (MS or PharmD) is preferred.
- A minimum of 10 years of experience with expertise in the areas of clinical operations development and strategic planning; developing, implementing, and leading early to late-stage clinical trials.
- In-depth understanding and experience across the clinical operations value chain, with a track record of success in study planning, execution, data cleaning, database locking, study report generation and regulatory inspection. Therapeutic experience in oncology coupled with experience with biologics and/or cell therapy clinical trials is highly desirable.
- Experience with global drug development and NDA filing is preferred; experience in developing protocols, SOPs, Clinical Study Reports, INDs, NDAs, as well as other clinical, regulatory, and safety documents preferred.
- Experience leading a rapidly changing organization and integrating new personnel is essential, as well as ability to evaluate and resolve complex problems

Must have a thorough knowledge of clinical research concepts, practices, and FDA regulations and ICH Guidelines regarding drug development phases, clinical trials, clinical study design, and data management methods. Self-motivated to maintain expertise in regulatory requirements and guidance to ensure that the Clinical Operations remains compliant with GCP and other global regulatory guidelines or laws

About Avenge Bio:
Avenge Bio, Inc. (“Avenge”) is an oncology-focused biotechnology company developing transformative cell-based immunotherapeutic products for the treatment of intractable solid tumors by incorporating its LOCOcyte™ platform. The LOCOcyte platform leverages proprietary engineered cells delivered to the local tumor environment that generate high concentrations of immune effector molecules in proximity to the tumor. This initiates a robust, local and durable systemic immune response while avoiding toxicities associated with systemic immunotherapies. Avenge’s most advanced product candidate, AVB-001, produces native IL-2 immunotherapy and is initially being studied in metastatic peritoneal cancers such as ovarian cancer. Avenge has additional pipeline candidates for the treatment of a wide range of cancers including pancreatic, lung and breast cancers.

Avenge was founded in 2019 after in-licensing the exclusive license for the LOCOcyte technology from Rice University. Since inception, Avenge has raised equity from top tier investors including Longitude Capital, Blackstone (CAM Capital), Perceptive Xontogeny Venture Fund, Rock Springs Capital, and Pappas Capital. To learn more about Avenge visit www.avengebio.com.