

Manager/Director, Clinical Operations

Reports to: Chief Medical Officer, EVP of Research and Development

Location: Houston, TX

Inquiries and Resumes should be sent to: careers@alaunos.com

About Alaunos

Alaunos is developing commercially scalable, cost-effective T-cell receptor (TCR) T-cell therapies based on its non-viral Sleeping Beauty gene transfer platform targeting solid tumors. The company has clinical and strategic collaborations with the National Cancer Institute and The University of Texas MD Anderson Cancer Center. For more information, please visit www.alaunos.com

Summary

The Manager or Director, Clinical Operations will be responsible for overseeing and supporting all aspects of clinical trial activities for the company's pivotal programs. This will include managing outside vendors in the execution of clinical trials, and development of primary relationships between the Sponsor and key site personnel.

Responsibilities

- This role will play a key role in advancing the near-term pipeline and contribute to future programs in various stages of development.
- The successful candidate will provide operational leadership and expertise in the implementation of clinical development programs.
- Closely monitor adherence to clinical protocols.
- Collaborate with Head of Clinical Operations and Head of Clinical Development to establish program strategy, clearly defined project goals and the clinical development plan.
- Develop and oversee clinical budgeting, accruals and review/approval of clinical invoices
- Oversee/manage direct reports providing direction and guidance on assigned tasks and employee development.
- Mentor Clinical Operations members as needed.
- Develop, inform and drive departmental goals and SOPs as needed.
- Establish and manage adherence to program timelines and goals.
- Provide timely and accurate reports of project status to team members.
- Assist in the authoring of study protocols, investigator's brochures, annual IND progress reports, and departmental SOP's.
- Develop Case Report Forms.
- Work with finance in the development/review of vendor, study and site budgets and administration of site payments.
- Work with legal to view vendor and site contracts.
- Ensure clinical site adherence to Good Clinical Practice.
- Collaborate in contract research organization selection process.
- Provide guidance and input into preparation for external meetings and conferences.

Qualifications

- RN/BS/Masters in a scientific/medical discipline.
- A minimum of five to seven years drug development experience within pharmaceutical/biotech industry working in Clinical Operations in the Pharmaceutical/Biotech industry or a CRO.
- Extensive experience interacting with Contract Research Organizations, international regulatory officials, and clinical investigators, and a proven track record of success as a team player is a must.
- Oncology experience is highly preferred. Cell therapy experience is a plus.
- It is essential that candidates have excellent time management skills and the ability to deal with people, combined with the capacity to be firm on timeliness.
- Must be a very hands-on, detail oriented individual.
- Ability to deal effectively with different types of site and vendor issues, and communicate effectively with the Clinical Operations team, colleagues, contractors, etc.
- Possible travel required.

Alaunos is an equal opportunity employer. As an equal opportunity employer, we are committed to a diverse workforce. Employment decisions regarding recruitment and selection will be made without discrimination based on race, color, religion, national origin, gender, age, sexual orientation, physical or mental disability, veteran status or other non-job related characteristics or other prohibited grounds specified in applicable federal, state and local laws.