Job Description

Halda Therapeutics – Director of Clinical Operations

Halda Therapeutics is a New Haven CT based, venture-backed biotechnology company focused on the development of a proprietary RIPTAC™ (Regulated Induced Proximity TArgeting Chimeras) therapeutics that work by a novel "hold and kill" mechanism for the precision treatment of cancer. The novel mechanism of action of RIPTAC therapeutics is uniquely designed to address cancer's ability to evolve bypass mechanisms of resistance, a common limitation of today's precision oncology medicines.

Halda was founded by Yale Professor Craig Crews and is led by a leadership team with deep expertise in bifunctional drug discovery, platform innovation, and company building, and is located in New Haven, CT. We are funded by top tier venture capital firms.

At Halda, our team is a collective force for drug innovation to conquer cancer. Halda is a place where you can embrace your purpose and be your true self. Learn more about us at www.haldatx.com.

The Position

Halda is seeking a dynamic and experienced Director of Clinical Operations to lead and oversee clinical operations for our oncology programs. The ideal candidate will have a strong background in global clinical operations, particularly in the field of oncology, and experience in prostate cancer is a significant advantage. This position will be responsible for initiating and leading clinical trials across all phases, including overseeing CROs and vendors. This position will work collaboratively across the therapeutic area and cross-functional teams on the execution and strategy of development programs and related studies to ensure successful execution of clinical trials. This position will report to the Chief Scientific Officer and have matrixed relationships with key consultants across development and medical. The position will be located at our headquarters at Science Park in New Haven, CT with possibility of a hybrid working environment.

Key Responsibilities

- Acting in HALDA'S best interest, lead and manage the clinical operations to ensure the successful execution of clinical trials, from planning through closeout.
- Accountable for delivery of assigned clinical program/studies budget, timelines, and resource management with focus on quality, including making recommendations and decisions regarding operational strategies to support study and/or program objectives.
- Oversee the selection, qualification, and management of CROs, vendors, and clinical sites, ensuring compliance with regulatory and quality standards.
- Experience in providing guidance and support for the preparation and submission of relevant clinical documents such as the protocol, investigator brochure, regulatory documents, clinical study reports and other documents and plans as appropriate.
- Working with the Project Manager/Clinical Protocol Manager, monitor and evaluate the performance of clinical trials, identifying and bringing attention to any issues that may arise during the study.
- Oversee site feasibility/capability assessments in collaboration with the CRO and cross-functional team and contribute to inspection readiness activities that support audits and regulatory inspections related to clinical trial conduct.
- Ensure the implementation of best practices and industry standards in clinical operations, contributing to process improvement and efficiency and maintain organizational SOPs to ensure compliance.
- Collaborate with cross-functional teams, including medical affairs, regulatory affairs, and research and development, to drive clinical trial progress.

- Foster a culture of teamwork, professionalism, and innovation within the emerging clinical operations department.
- Along with other Clinical Development personnel, represent Halda externally to Investigators, site staff, and Key Opinion Leaders
- Maintain up-to-date knowledge of industry trends, guidelines, and regulations related to clinical research in oncology.

Qualifications

- Minimum of BA/BS; advanced degree preferred.
- Minimum of 12 years of trial and clinical program experience, including independent clinical trial management experience and full trial life cycle experience (e.g., start-up, conduct, closure).
- Management experience is preferred.
- Proven track record of leading successful clinical trials in oncology, with a focus on prostate cancer as a significant advantage.
- Multi-dimensional Clinical Operations background with capability of devising plans for operational challenges such as site activation, subject enrollment, monitoring oversight, protocol deviation management, data cleaning, etc.
- In-depth knowledge of FDA and international regulatory requirements for clinical trials.
- Cross-Collaboration proficiency with other functions such as Regulatory, CMC, Biostatistics, Data Management, Finance, Program Management, etc.
- Ability to work effectively in a fast-paced and collaborative environment in the context of a multi-disciplinary team in the biotech or pharmaceutical industry.
- Excellent communication, negotiation, and problem-solving abilities.
- Detail-oriented, highly organized, and committed to quality and compliance.

Compensation

The estimated salary range for this position is $175,000 to $250,000. Actual compensation will be dependent on candidate experience and other factors.

The compensation will also include an annual bonus and equity.

Benefits

Halda offers a competitive benefit package, including subsidized medical, dental, vision, ST/LT disability, a 401k Plan with generous company contribution and free parking at our New Haven headquarters. We also offer tuition reimbursement and paid parental leave.

If you are interested in this opportunity and meet the requirements, please submit your resume and cover letter for consideration.

Halda is an Equal Opportunity Employer.

Principals only.