Job Description

Halda Therapeutics – Director of Data Management

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.

Our lead RIPTAC programs are in development for major solid tumor types, prostate cancer and breast cancer, with additional RIPTAC therapeutic programs in our pipeline to treat unmet medical needs in cancer. The company will initiate its Phase 1 trial in metastatic, castration-resistant prostate cancer (mCRPC) in 2025. Halda was founded by Yale Professor Craig Crews and is led by a team with deep expertise in bifunctional drug discovery, platform innovation, and company building and is located in New Haven, CT. The company has raised $202M in funding from top tier investors.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 an experienced, dynamic, and highly skilled **Director of Data Management** to lead and oversee the data management strategy and daily execution of our clinical programs. The ideal candidate will have a strong background in global data management standards and practices, particularly within oncology and/or other complex therapeutic areas. This pivotal role is responsible for driving the successful execution of data management activities across all phases of clinical trials, ensuring the integrity, accuracy, and timeliness of data while ensuring compliance with regulatory requirements and industry standards. The Director will report to the VP of Clinical Operations and will work closely with cross-functional teams to align data management efforts with broader clinical development goals by allowing for accurate analysis to support drug development decisions. This position can be based at our headquarters in New Haven, CT, or performed in a hybrid or remote environment.

Key Responsibilities

Data Management Leadership: Acting in Halda's best interest to lead and oversee the data management strategy for clinical trials across all phases, from planning to closeout, ensuring adherence to industry standards and regulatory requirements.

Operational Oversight: In partnership with Clinical Operations and program management, manage budgets, timelines, and resource allocation for clinical data management activities. Provide strategic recommendations to ensure high-quality execution of clinical trials and program objectives.

Vendor & CRO Management: Participate in the selection and qualification of data-related CROs and vendors. Manage selected external partners by ensuring compliance with regulatory and quality standards and contribute to data integrity throughout the trial lifecycle.

Clinical Document Support: Provide data management guidance and support on the preparation and submission of clinical documents, including protocols, investigator brochures, regulatory submissions, clinical study reports, and other relevant documents.

Performance Monitoring: Collaborate cross-functionally to track the performance of clinical trials, proactively identify and resolve issues, and ensure studies stay on track.

Audit Readiness: Oversee and support inspection readiness activities, including audits and regulatory inspections related to clinical trial conduct.

Best Practices, Process Development & Improvement: Promote the implementation of best practices and data management standards to enhance the efficiency and quality of clinical trial operations. Maintain and update standard operating procedures to ensure compliance in collaboration with Quality Assurance colleagues.

Cross-Functional Collaboration: Work closely with Research and Development, Medical, Clinical, Regulatory, Program Management, Quality Assurance, and other departments to drive the successful progression of clinical trials.

Team Leadership & Culture: Foster a culture of teamwork, innovation, and professionalism within the data management team.

Industry Awareness: Stay informed on the latest data trends, guidelines, and regulatory developments related to oncology clinical trials.

Qualifications

Education & Experience

- Minimum of BA/BS in a related field (advanced degree preferred)
- At least 15 years in clinical trial data management, with proven track record in oncology and/or complex therapeutic area(s)
- Full trial life cycle experience, including study start-up, execution (safety review committees, interim data look) and closeout (database lock).
- Prior experience in leadership or management roles is preferred.

Specialized Knowledge & Skills

- Extensive knowledge of data management policies and processes, including CRF specifications, edit check specifications, user acceptance testing, data standards, data privacy, and risk management, etc.
- Deep understanding of FDA and international data standard requirements for clinical trials.
- Proven experience in managing CRO and vendors to ensure compliance and high-quality data management.
- Strong ability to collaborate with cross-functional teams in a dynamic, fast-paced environment
- Excellent communication, negotiation, and problem-solving abilities.
- Detail-oriented, highly organized, and committed to quality and compliance.

Personal Attributes:

- Strong leadership and decision-making capabilities.
- Ability to thrive in a fast-paced, innovative environment.
- Passionate about advancing cancer therapies and a commitment to continuous learning and improvement.

Compensation

The estimated salary range for this position is $210,000 to $260,000. 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 CV for consideration to HR@haldathera.com.

Halda is an Equal Opportunity Employer.

Principals only.