Associate Director, Data Management and Analytics

Position Summary:

The Associate Director, Data Management and Analytics will serve as the internal lead for establishing and leading all data-related activities across the company's clinical development programs. This role is responsible for oversight of clinical data management, database builds, vendor integrations, coordination with external statisticians and SAP development, and clinical data analytics in a fully outsourced model in support of clinical trial objectives and Trevi's corporate goals.

The successful candidate will act as the bridge between the sponsor and clinical trial vendors, ensuring that data are collected, integrated, and analyzed efficiently, accurately, and in compliance with GCP, ICH E6(R2/R3), and regulatory expectations. This individual will also perform and interpret exploratory analyses to inform clinical and operational decisions and may take a leadership role in designing and executing Phase 1 studies.

This position reports to the Vice President, Clinical Development Operations and will work in a close cross-functional partnership with numerous functions within Trevi Therapeutics, Inc. as well as with Contract Research Organizations (CROs), alliance partners and vendors performing work on behalf of Trevi.

Duties and Responsibilities:

- Oversee CRO data management activities including database design, edit check development, validation, and UAT.
- Lead collaboration with the CRO and external statistician to develop, review, and finalize statistical content within clinical protocols and SAPs, ensuring consistency across data management and analysis deliverables.
- Develop and maintain Data Flow Diagrams, Data Transfer Specifications (DTS), and Data Management Plans (DMPs) to ensure seamless integration across vendors (EDC, eCOA, IRT, central labs, PK/PD, safety, etc).
- Represent data management and analytics during governance meetings, audits, and regulatory inspections, as applicable.
- Develop/oversee the integration strategy and validation of cross-system data transfers (e.g., EDC ↔ IRT ↔ Lab ↔ Safety ↔ eCOA).
- Collaborate with CRO to ensure standardization and compliance with CDISC SDTM/ADaM structures.
- Conduct and interpret exploratory analyses, data visualizations, and interim data reviews (using R, SAS, or Spotfire) to support clinical and operational decision-making.
- Contribute to data-driven risk assessments, protocol optimization, and study design discussions.
- Provide data and statistical oversight for Phase 1–3 studies.
- Participate in protocol and CRF design to ensure data capture aligns with endpoints and regulatory requirements.
- Support database go-live, interim, and final lock activities, ensuring timely, high-quality deliverables from CROs.

- Lead data-driven review meetings and proactively identify issues or trends impacting study integrity or timelines.
- Evaluate and implement tools for improved data review, visualization, and analytics.
- Support inspection readiness activities, contributing to TMF completeness and documentation of sponsor oversight, as applicable.
- Mentor cross-functional colleagues in data literacy and analytics best practices.
- Additional duties as needed.

Qualifications:

To perform this job successfully, an individual must be able to perform each essential duty satisfactorily. The requirements listed below are representative of the knowledge, skills, and/or abilities required. Reasonable accommodation may be made to enable individuals with disabilities to perform the essential functions.

Education and Experience:

Required:

- Bachelor's or Master's degree in Life Sciences, Data Science, Biostatistics, or related discipline.
- Minimum of 3 years of relevant clinical data management experience within the Pharma, Biotech, or CRO industry.
- Demonstrated experience managing CROs and external vendors in a fully outsourced model.
- Strong understanding of clinical data standards (CDISC, SDTM, ADaM) and regulatory requirements (FDA, EMA, ICH).
- Experience with EDC systems (Medidata Rave, Medrio, etc.) and data integration across multiple systems.
- Proficiency with data analytics and visualization tools (R, SAS, Spotfire, or Python).
- Excellent communication and vendor management skills.

Preferred:

- Experience overseeing or executing Phase 1 and Phase 3 trials.
- Familiarity with PK/PD data integration and bioanalytical data workflows.
- Prior involvement in NDA/BLA submission datasets or integrated summaries.
- Experience with inspection readiness, TMF documentation, and sponsor quality systems.

Competencies:

- Able to read, comprehend, write, and speak English fluently.
- Excellent written and verbal communication and interpersonal skills. Able to communicate complex information clearly and succinctly, both in writing and orally
- Ability to communicate complex data management concepts to non-data managers.

- Proficient in Microsoft Office (Word, Excel, PowerPoint, Outlook), SharePoint, Box, Adobe Pro.
- Familiarity with advanced Excel functions, SAS, and SQL is a plus.
- Must be analytical, highly detail-oriented and have strong organizational and time management skills.
- Demonstrated project management experience with the ability to multi-task, manage and prioritize various and differing projects, as well as work effectively toward numerous deadlines.
- Must be able to work independently with minimal supervision.
- Ability to collaborate effectively with the cross-functional study team and external partners.

PHYSICAL AND VISUAL REQUIREMENTS:

While performing the duties of this job, the individual is regularly required to use computers and office equipment, manipulate documents, and work in an office environment and work remotely from home as needed. The individual will experience prolonged periods of sitting and will also be required to talk or hear, reach with hands and arms, walk, bend, and stand frequently and may occasionally move materials up to 15 pounds. Must be able to primarily work remotely and travel to the CT office as needed. The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

Note:

This job description in no way states or implies that these are the only duties to be performed by the employee(s) incumbent in this position. Trevi reserves the right to modify, change or add to the position's job duties and responsibilities as business needs may require. This document does not create an employment contract, implied or otherwise, other than an "at will" relationship.

Trevi Therapeutics, Inc. is an Equal Opportunity/Affirmative Action employer including protected Veterans and individuals with disabilities. Trevi considers applicants for employment without regard to, and does not discriminate on the basis of, an individual's sex, race, color, religion, age, disability, status as a veteran, or national or ethnic origin; nor does Trevi discriminate on the basis of sexual orientation or gender identity or expression.