Regor Therapeutics Group is a clinical stage company dedicated to the discovery and development of innovative and clinically differentiated medicines by leveraging the proprietary CARD (Computer Accelerated Rational Discovery) Platform. The company focuses mainly on three therapeutic areas, oncology, immunology, and metabolic disorders. By seamlessly integrating CARD with structural biology, computational chemistry, therapeutic biology, medicinal chemistry, and clinical development, Regor has successfully assembled a world-class scientific team and established a highly efficient new drug innovation engine to enable the discovery and development of best- and first-in-class molecules.

Summary/Job Purpose

The Clinical Data Manager is responsible for developing, deploying, managing, and governing clinical data standards. This role ensures that clinical data standards are consistent, accurate, and complete across all clinical trials. The Clinical Data Manager works closely with the multiple functional groups to ensure that clinical data standards are implemented effectively and that all stakeholders are aware of and compliant with the standards.

Essential Duties And Responsibilities

- Provide recommendations for developing and maintaining operational (CRF and non-CRF) data standards.
- Create metadata and mapping between operational (CRF and non-CRF) to SDTM and document the use of standards.
- Participate in relevant study and project team meetings as a standards SME and provide input for standards components, such as CRF design, CRF Completion Guidelines, programmed edit checks, Data transfer specifications, and eCRF implementation guide.
- Collaborate on the development of eCRFs to support database build and standardization efforts.
- Lead and participate in developing cross-functional SOPs, Working Procedures, Guidance documents, and job aids.
- Provide end-to-end data standards subject matter expertise and support questions the Clinical Development team raised.
- Actively communicate submission standards and guidance documents, regulatory agency expectations, and industry trends to Regor's organization.
- Provide technical input on data management plans and other CDM documentation.

Education/Experience

- BS/BA degree in related discipline and a minimum of nine years of related experience; or,
- MS/MA degree in related discipline and a minimum of 7-10 years of related experience; or,
- Equivalent combination of education and experience.

Experience

- Bachelor's degree in STEM field or equivalent in a health-related field preferred.
- At least 7+ years of relevant industry experience with clinical trials, preferably with clinical data standards as a focus.

Knowledge/Skills

- Experience in Industry Standards (e.g., CDISC) in the collection (CDASH), tabulation (SDTM) or analysis (ADaM) models.
- Experience with Medidata Rave (EDC) and Metadata Repository (MDR) is preferred.
- Demonstrated application of Good Clinical Practices (GCP), data management best practices, and regulatory requirements in the execution of clinical trial operations.
- Experience and understanding of collection and mapping of variety of lab data types like genetics, immunogenicity, PK/PD.
- CDISC and SDTM terminology expertise is required.
- Ability to negotiate and gain acceptance of others.
- Strong oncology experience is preferred.
- Attention to detail and the ability to work individually, within a multi-disciplinary team, as well as with external partners and service providers.

Please send your resume to: humanresources@regor.com