Job Title: Clinical Data Monitor, AACR Project GENIE

About the Project
AACR Project Genomics, Evidence, Neoplasia, Information, Exchange (GENIE) is a publicly accessible international cancer registry of real-world data assembled through data sharing between 19 of the leading cancer centers in the world. Through the efforts of strategic partners Sage Bionetworks and cBioPortal, the registry aggregates, harmonizes, and links clinical-grade, next-generation cancer genomic sequencing data with clinical outcomes obtained during routine medical practice from cancer patients treated at these institutions.

Job Summary:
The Project Coordinating Center is seeking an experienced data monitor and clinical research professional who coordinates data collection and data quality efforts across participating sites of an expanding international network performing retrospective clinical research projects by working with data managers and researchers at each participating site, project leadership, and strategic informatics partners. The candidate must be able to work both independently and in a team environment. The ideal candidate is an experienced and highly organized individual, able to lead and inspire clinical data managers distributed across multiple cancer centers.

Major Duties & Responsibilities:
- Organizes and leads a combination of data review and on-site monitoring visits, if necessary. Team of external data coordinators to harmonize submission of high-quality data according to consistent specifications.
- Ensures adherence to applicable ICH/GCP guidelines, local policies, and standard operating procedures.
- Adhere to monitoring plan protocols by utilizing monitoring tracking forms and other monitoring related tools and templates.
- Monitor progress through a
- Coordinates with strategic informatics partners and the site contacts to ensure that all project data:
    - is delivered on time and is compliant with data specifications and SOPs; and
    - meets or exceeds established quality and completeness criteria.
- Assists in the development and implementation of data monitoring plans to facilitate collection of consistent data elements across diverse sites.
- Assists in the design of data quality checks on site data, including validating site data against source documentation. Resolves data quality issues in a timely manner.
- Performs routine descriptive analyses for research cohorts including missing data and unknown data reports and distributes to clinical investigators.
- Collaborates with and responds to queries from statistical programmers regarding data elements and their specification.
- Anticipates potential data issues based on working knowledge of site EMRs and works to prevent or remediate the issues.
- Willingness to travel as needed.

Job Qualifications
- Five or more years of experience in clinical research (3+ years of study experience, 2+ years of monitoring experience) preferably in a multi-site clinical research setting.
- Prior experience in oncology clinical trials or clinical research studies in research/academic medical centers.

- Working knowledge of oncology data systems, including EHR, clinical databases/eCRFs, tumor registries.
- Experience in electronic medical records abstraction.
- Excellent verbal and written communications skills.
- Excellent interpersonal and organizational skills with demonstrated attention to detail.
- Must be able to prioritize, multi-task, and work in a fast-paced environment.
- Managerial experience supervising and motivating research assistants or clinical data specialists strongly preferred.
- Computer literacy with proficiency in MS Office including Word, Excel, and PowerPoint.
- Proficiency with the REDCap EDC a plus.
- Proficiency with statistical software such as R, SPSS, a plus

Education Requirements

- B.S. or equivalent in a related health profession (B.S.N) or a field related to research compliance.
- M.S or equivalent preferred
- Nationally recognized certification (CRA, CRC, CHRC, CCRP or similar)

Interested candidates can apply at:

https://careers-aacr.icims.com