

CLINICAL DATA MANAGER, SR.

Job Title: CLINICAL DATA MANAGER, SR.

FLSA: E

Revised Date: 01/03/2025

Job Code: 1335

Job Level: 53

Job Family: JF 05

Occupational Summary

Works with clinical research team members, including PIs, study coordinators, data analysts, and biostatisticians, to ensure that all aspects of the data management process are executed efficiently and accurately. Leads day-to-day operations of managing clinical research data for study teams at the Duke University School of Nursing (DUSON) supporting our shared goal of scientific integrity and the rigor and reproducibility of our research; performs a variety of complex duties involved in planning, oversight, and regulation of the collection, compilation and documentation of clinical research data and metadata to help safeguard data accuracy; data preparation for analysis; completeness and compliance with regulatory requirements, and facilitates researchers in navigating the clinical research environment. Collaborates within DUSON and across campus with other data-focused units of research and technology. Supports adherence to Duke Data Management Policy, provides guidance based on CRU and institutional best practices, and ensures all aspects of the data management lifecycle meet Duke Data Security requirements. Oversees the work of other clinical research staff if needed.

This position is responsible to the Director of the Health Statistics and Data Science Core at DUSON.

Work Performed

Research Operations

In collaboration with the Duke Office of Scientific Integrity, serves as an expert resource to study teams on design, implementation and adherence to data management plans, design of case report forms, developing data entry guidelines and standards and overseeing data quality control processes. Ensures adherence to internal and regulatory institutional policies and processes, and study-level documentation.

Oversees and provides support to study teams for the documentation (e.g., involving datasets from multiple sources, big data, or non-standardized data) and harmonization of discrete, potentially cross-domain datasets for all studies, including those that are complex in nature (e.g., procedural and interventional studies). Plans and implements electronic data capture systems to facilitate efficient data collection.

Clinical data managers also collaborate with study and research teams to address data-related issues promptly and generate accurate data summaries and reports for clinical study reports.

Develops, oversees adherence, and trains in the use and development of standard operating procedures (SOPs) across study teams and works towards helping study teams adhere to regulatory guidelines and SOPs to ensure data integrity and compliance throughout the research lifecycle.

Effectively facilitates or leads, if needed, team meetings to achieve objectives. Ensures effective communication across multiple study teams.

Safety and Ethics

Provides oversight and training to multiple study teams who prepare and submit documents needed for regulatory and safety reporting to sponsors and other agencies, such as the NIH Data Management and Sharing

Plan.

Data

Under direct supervision from Biostatisticians and PIs, may perform basic analyses on a variety of data formats. May provide mentorship or education to others on programs and tools for data cleaning and analysis.

For multiple study teams, selects data capture methods and discusses the advantages and disadvantages of each.

Implements data capture methods at the multiple levels of research units. Independently designs appropriate programs/algorithms to collect data according to protocol. Provides training and oversight into the creation of the data collection programs/algorithms using appropriate data standards.

Oversees the process of depositing data in repositories. In collaboration with Duke Data Curation, provides guidance on the selection of the appropriate repository and any data governance requirements such as the NIH Data Management and Sharing Plan.

Performs de-identification on allowable data to Safe Harbor standards, or on consented data leaving Duke under agreements. Could serve as a Federated Honest Broker. May provide training to others.

Serves as an expert resource to multiple study teams with regard to mapping data flow. Predicts areas of vulnerability in the data flow plan. Determines areas where data provenance may be compromised, and helps study teams work through solutions.

Seeks out, integrates, and applies new technical knowledge towards innovation and performance improvement for multiple research teams, as relevant.

Develops, oversees adherence, and trains study teams on the results reporting for broad dissemination.

Provides guidance based on CRU and institutional best practices.

Awareness of appropriate methods for monitoring study progress based on research design. Uses benchmarks where appropriate to compare to similar studies, networks, or goals and tracks progress and compliance.

Supports DUSON PIs in monitoring sub-awardee data collection and adherence to study data management plans for required reporting to funding agencies.

Scientific Concepts

Independently develops data-specific portions of funding proposals and grants. Assesses and determines solutions for operational shortcomings of proposals.

Independently, using scientific proposals from the PI, develops elements of data management for complex investigator-initiated studies, across multiple PIs or study teams.

Provides significant contribution or leadership on accepted, peer-reviewed publications, or conference presentations. Mentor others in this area.

Leadership and professionalism

Demonstrates interpersonal skills to work efficiently. Uses advanced subject matter expertise in clinical research to solve problems across multiple study teams. Recognizes and escalates organizational issues that could be

optimized to improve the research process.

Actively facilitates or leads study teams in the adoption of change related to data protocols and provenance. Plays a key role on committees and workgroups. Trains others to communicate effectively within teams.

Facilitates resolution of issues associated with teams or communication.

Required Qualifications at this Level

Education/Training:	Completion of a Bachelor's degree program in business, computer science, mathematics, statistics, or social sciences.
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Experience:	Work requires a minimum of 3-5 years of research experience after the Bachelor's degree, in clinical data management or a similar role in the research industry
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Skills:	Work requires extensive knowledge of clinical data management principles, regulatory guidelines, and best practices; knowledge of both statistical analysis and interpretation generally acquired through at least two years of relevant experience. Willing to work independently and collaboratively with study teams to ensure timely and accurate data delivery.
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The intent of this job description is to provide a representative and level of the types of duties and responsibilities that will be required of positions given this title and shall not be construed as a declaration of the total of the specific duties and responsibilities of any particular position. Employees may be directed to perform job-related tasks other than those specifically presented in this description.

Duke University is an Affirmative Action/Equal Opportunity Employer committed to providing employment opportunity without regard to an individual's age, color, disability, gender, gender expression, gender identity, genetic information, national origin, race, religion, sex, sexual orientation, or veteran status. Duke aspires to create a community built on collaboration, innovation, creativity, and belonging. Our collective success depends on the robust exchange of ideas-an exchange that is best when the rich diversity of our perspectives, backgrounds, and experiences flourishes. To achieve this exchange, it is essential that all members of the community feel secure and welcome, that the contributions of all individuals are respected, and that all voices are heard. All members of our community have a responsibility to uphold these values.

Essential Physical Job Functions

Certain jobs at Duke University and Duke University Health System may include essential job functions that require specific physical and/or mental abilities. Additional information and provision for requests for reasonable accommodation will be provided by each hiring department.