

Clinical Data Analyst Job Description

Duties and Responsibilities:

- Responsible for all data management activities for assigned studies
- Undertake Protocol and Statistical Analysis Plan (SAP) review and input
- Develop and maintain Case Report Form (CRF)
- Responsible for developing and maintaining Data Management Plan
- Undertake Data Quality Checks and discrepancy management to ensure accuracy of data
- Responsible for data analyses and identification of trends/pattern in data
- Responsible for the preparation of data tables for reports
- Perform database setup testing and edit check programming testing
- Study specific activities and participate in post market surveillance reporting when necessary
- Actively participate in efforts to improve data management processes as needed
- Represent the data management group at study team meetings and on cross-functional task forces as assigned
- Provide subject matter expertise in one or more areas within data management
- Contribute input to departmental Standard Operating Procedures (SOPs), Departmental Work Instruction (DWIs), and guidelines
- Comply with applicable company policies, operating procedures and processes, as well as regulatory requirements such as, U.S. Food and Drug Administration (FDA) regulations.

Clinical Data Analyst Requirements – Skills, Knowledge, and Abilities

- Education: A minimum of Associate degree is acceptable, but most often, a Bachelor's degree in Computer Science, Health Sciences, or Informatics is required, and a Master's degree may be preferred

- Experience: Depending on the recruiting organization, applicants for the position of clinical data analyst may require a 3-4 years experience working in a clinical research environment
- Knowledge: They must possess a general understanding of the clinical trial process and regulations that apply, and a good understanding of clinical data management processes. They also require the ability to use development environment, classification, analytical, and other industry-specific software tools. They must possess good technical skills in querying and analyzing data (SQL, Oracle, SAS or equivalent)
- Organizational skills: It is essential that they can effectively prioritize assignments and handle multiple tasks, as well as complete projects within deadlines or in a timely manner
- Project management skills: They also require the ability to leverage on the skills and competencies of others; engage others to accomplish projects within specified time-frames
- Attention to detail: The clinical data analyst job description requires them to ensure the accuracy and validity of data and trial results. Hence, they must pay meticulous attention to detail, factoring every piece that might alter the validity of data
- Computer skills: They must possess advanced skills with MS Office applications, especially Excel, Word, Publisher, and PowerPoint.
- Data management: They require strong ability to work with clinical data management systems
- Team work abilities: They must be able to work effectively in a team oriented environment, and as an individual contributor in a fast-paced and changing environment
- Communication skills: They must possess strong verbal and written communication skills to communicate and collaborate with all levels of employees, customers, contractors, and vendors.