MONTERIS® MEDICAL	www.monteris.com	**Document Type:** Job Description
	Document Revision History – See Agile	

Department: Clinical Affairs

Supervisor: VP of Clinical Affairs

Classification: Exempt

Purpose and Scope

The Clinical Data Analyst will be responsible for all aspects of the data management function during planning, execution, and completion of a clinical study phases. This will include but is not limited to the design of the most efficient way to collect the data, data management and analysis, and results write-up. It will also involve the proactive work with Key Opinion Leaders (KOL) to assist with abstracts and publications preparation, as well as support of Marketing Affairs with varied commercial tools development. This position will require flexibility with changing priorities based on the study and/or Clinical Affairs needs.

Primary Organization Responsibilities

- Responsible for the management of all data management activities.
  - Designs data collection tools (case report forms, electronic data capture capabilities, etc.).
  - Defines and verifies correct functionality of automated edit checks against protocol requirements, etc.
  - Performs data review regularly and generates queries against data discrepancies to ensure data accuracy.
  - Tracks outstanding data issues and queries to ensure correct and timely resolution.
  - Works closely with the clinical study team and monitoring group to identify and communicate data trends and potential compliance issues.
  - Creates data validation plans and performs data validation.
  - Performs database training with site and sponsor personnel.
  - Manages required regulatory documentation in regards to study data compliance, as directed.
- Responsible for proactively managing and identifying data trends.
  - Tracks and follows up with sites regarding outstanding data issues.
  - Provides data-related support for study-related meetings.
  - Based on data trends, suggest changes to the forms, processes, etc. to increase business efficiency.
- Assists with study reporting, (e.g. annual progress reports, DMC, other required FDA reports) as needed.
- Accountable for data analysis and write up (explanation of the data) for abstracts and manuscripts.
  - Possesses the technical expertise to create datasets (e.g., by merging data tables as needed) and perform basic analysis of the data while working closely with statistician(s) to complete more complex analyses.
  - Assist KOLs with abstracts and publications preparation.
  - Identifies abstract/publication ideas based on the data available (Monteris data vs. competitors data vs. other scientific data available).
  - Assists Marketing Affairs with varied commercial tools development.
- Develops and maintains Clinical Data Management Plans as well as all Statistical Analysis Plans.
- Performs other duties as directed or assigned

Personal Qualifications and Experience

Education/Experience

- Bachelor degree required in statistics or other related field. MS degree is preferred.
- A minimum of three (3) years of statistical data analysis experience, preferably within the medical device industry.

Skills/Abilities

- Possesses strong interpersonal and communication skills necessary to interact with study site personnel and physicians.
- Possesses strong organizational skills and the ability to handle multiple priorities in a fast-paced environment.
- Skilled in Microsoft Office, Word, Power Point, Access, and SQL server.
- Skilled in Excel, Access, and clinical database management software.