Position Title: **Vice President Biometrics**

Reports to: **Executive Vice President, Clinical Operations**

Department: **Clinical Operations**

Created: **April 5, 2021**

General Summary:
Responsible for overseeing the statistics, programming and data management functions within clinical operations and personnel (including consultants and/or vendors) assigned to the planning, execution, analysis, programming and data collection activities on all projects.

Principal Duties and Responsibilities:

- Manage multiple direct reports (all aspects of hiring, mid-year and annual reviews, promotions/demotions and termination)
- Participate in board meetings
- Set, manage, and meet realistic bioinformatics timelines
- Oversee bioinformatics budget
- Develop and oversee execution of Statistical Analysis Plans
- Participate in the development of Clinical Study Reports, Investigator Brochures, NDAs/BLAs, Annual Reports/DSURs, INDs
- Represent the Company externally in scientific, financial and business development communities
- Develop SOPs, job aides, and training relating to all aspects of data analysis, management, and reporting
- Ensure that Bioinformatic and Data Management tasks are conducted in compliance with GCP, TRACON SOPs, applicable regulatory requirements, and industry best practices
- Select and manage vendors as necessary
- Manage data analysis and output in accordance with protocol requirements (e.g. interim, final and data monitoring committee meetings), for publication, for TRACON board meetings (e.g. safety, scientific, corporate), and for clinicaltrials.gov postings
- Oversee the training of staff in the use of software applications that support bioinformatics (programming and statistical analysis software, etc.)
- Oversee the use of data standards for data collection and reporting
- Oversee the reporting of clinical trial data, both for internal use and publication as well as standards compliant reporting for submission to health regulatory agencies
- Oversee programmers using R, SQL, SAS, Python, or other languages as necessary and ensure the control of data, code, and outputs in compliance with 21 CFR Part 11 and other applicable guidance and regulations
- Implement or oversee implementation of coding style guides/standards
- Oversee the management of linux server environments supporting GxP processes
- Liaise with IT and vendors for back-end server and GxP application support and other infrastructure needs
- Participate in the validation of software applications that support clinical data management, biostatistics and programming
- Participate in the qualification of environments for programming and reporting

- Communicate with commercial software solution vendor(s) regarding identified bugs and requested software improvements

Qualifications:

Education

- Master's degree or higher in biostatistics

Experience/Skills

- Minimum of fifteen years of biostatistics and programming experience in the biotechnology or pharmaceutical industry
- Minimum of five years of experience overseeing data management
- BLA filing experience (recent BLA filing experience within the past 5 years preferred)
- Mastery of programming languages for data analysis, visualization, and reporting, including SAS or R
- Demonstrate understanding of all applicable regulations and guidelines governing drug development including ability to apply these to overall strategic drug development
- Excellent working knowledge of Good Clinical Practices; ICH guidelines; trial initiation and management practices and procedures
- Excellent leadership, interpersonal and communication skills
- Works efficiently with others to accomplish goals and resolve problems; encourages cooperation, collaboration, and co-ownership of processes

Position Requirements:

- Ability to work on complex problems where analysis of situations or data requires an in-depth evaluation of various factors.
- Willing to travel for training, audits, conferences, or other events or meetings in support of bioinformatics or corporate goals

NOTE: This description is not intended to be all inclusive or a limitation of the duties of the position. It is intended to describe the general nature of the job which may include other duties as assumed or assigned.