POSITION TITLE	**MEDICAL MONITOR**
REPORTS TO	**CHIEF MEDICAL OFFICER**
MANAGES	**THE STRATEGIC OBJECTIVES OF THE CLINICAL TRIALS**
LOCATION	**PREFERRED LOCATION IS CHARLOTTE, NC**

DUTIES AND RESPONSIBILITIES

- Represents, leads, plans and coordinates the strategic objectives and tactical execution of the clinical investigation, ensuring compliance with regulatory and ethical requirements;
- Ensures high quality in the design, development, execution, statistical analysis, interpretation and reporting of clinical studies, and ensures studies are continuously inspection ready;
- Monitors the data generated by CROs involved in the Clinical Research projects;
- Provides medical oversight regarding protocol exemptions, protocol violations, protocol eligibility issues, concomitant medications and general medical-related study issues;
- Reviews laboratory alerts, and coordinates appropriate follow-up with study site;
- Conducts medical review of the SAP, project plan, tables and listings and clinical study reports;
- Conducts training for the project team regarding the disease, drug, study design and procedures;
- Provides consultation to the study team during review of out-of-range laboratory values for clinical and/or protocol significance;
- Previews listings, lab reports and subject profiles; ensures all protocol inquiries are documented;
- Visits sites, and attends and participates in Investigator meetings; and
- Reviews study reports, prepares and reviews subject narratives as well as periodic safety reports.

EDUCATION, BACKGROUND, KNOWLEDGE AND SKILLS

- MD is required—Cardiology specialization preferred;
- At least five (5) years of clinical development expertise and deep understanding of the process to progress a new chemical through the necessary stages to allow testing in human clinical trials;
- Good Clinical Practice (GCP) knowledge—able to ensure an investigation is conducted according to GCP regulation and documentation to protect the rights, safety and well-being of the subjects;
- A record of applying medical expertise to make good clinical decisions in accordance with SOPs;
- Demonstrated understanding of rigorous data generation and disciplined stewardship of the data;
- Medical monitoring and pharmacovigilance expertise to detect, investigate, assess and prevent adverse effects of medicines on patients; and
- Excellence in scientific writing and presentation to produce publications with clarity, accuracy and rigor, and to communicate concepts simply and concisely to diverse audiences.

KEY ATTRIBUTES

- An ethical, resourceful, confident physician with deep clinical research experience and knowledge, as well as proven leadership abilities;
- A strategic thinker who ensures the application of principles, tools and systems from Simplifying Clinical Development;
- Exceptional verbal and written communication abilities;
- A natural partner with high standards and capability to firmly advocate for them; and
- Excellent teamwork and interpersonal skills, and high emotional intelligence.

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Disclaimer: The above declarations are not intended to be an all-inclusive list of the duties and responsibilities of the job described, but rather are intended only to describe the general nature of the position.