



TITLE: MEDICAL DIRECTOR/PRINCIPAL INVESTIGATOR **LOCATION:** HACKENSACK, NJ
TO APPLY: SEND RESUME TO: GVERDI-FRANCESCO@FRONTAGELAB.COM & REFERENCE JOB TITLE IN SUBJECT LINE
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DUTIES:

Responsible for providing medical monitoring in clinical studies, serving as the Principal Investigator and Medical Safety Officer for Phase I-IV clinical studies performed at the Frontage Clinical Research Center (CRC) and in assuring that studies are conducted in compliances with applicable regulations and GCP guidelines. Responsible for medical safety assessments for research subjects. In conjunction with Director, Clinical Operations, this position will be responsible for supervising: Assistant Medical Director, other sub-investigators including consultant medical specialists, Clinical Research Coordinators, Pharmacists, Nurses, Laboratory Technicians, Medical Assistants, and other investigational staff with respect to clinical trials (functional reporting responsibility).

QUALIFICATIONS:

- Must have an MD or DO degree (General/Family Practice or Internal Medicine) - Practitioner with current medical license in the State of New Jersey
- At least five (5) years clinical practice. Clinical Research experience at a clinical research site, pharmaceutical company or CRO is preferred
- Detailed knowledge of medical safety assessments & Knowledge of FDA regulatory requirements is necessary, particularly as they pertain to Principal Investigator responsibilities and safety requirements (ie. treatment-emergent, adverse events, serious adverse events)
- Familiarity with Good Clinical Practices and ICH guidelines
- Must be self-motivated, have the ability to work independently, and to organize and prioritize multiple projects

RESPONSIBILITIES:

- Fulfill Principal Investigator responsibilities in compliance with FDA regulations
- Medical supervision as the Principal Investigator for Phase I studies in healthy volunteers and outpatient Phase II-IV clinical studies in selected patient populations
- Perform physical examinations and efficacy and safety assessments on healthy volunteers and patient
- Review and clinical interpretation of serious and non-serious adverse events, laboratory test results, efficacy and safety assessments, physical examinations, medical and surgical histories, and ECG interpretations
- Work with Drug Safety Associate and other drug safety personnel in the assessment of and narrative preparation for adverse events
- Case report form review and sign-off
- Manage and/or supervise management of adverse events and medical emergencies
- Establish strategic relationships with physician specialists (e.g., cardiologists, endocrinologists, urologists, ophthalmologists, fertility/reproductive medicine clinic, radiologists) and scientists in the surrounding medical and scientific community and adjacent medical centers
- Provide input into study protocol feasibility assessments and study protocol design