GI Dynamics Career Opportunity

Title: Manager, Clinical Studies: India
Location: India

Company Information

GI Dynamics® Inc. is committed to alleviate the symptoms of type 2 diabetes and obesity for patients fighting these global epidemics worldwide. The company's revolutionary EndoBarrier® is the first endoscopically delivered device therapy for the treatment of type 2 diabetes and obesity. EndoBarrier® is aimed to bridge the gap between pharmaceuticals and surgery by providing an alternate treatment option to help reduce HbA1c and weight for individuals who are underserved by drugs and injections, but for whom surgery is not an option.

Position Overview

GI Dynamics is seeking a Clinical Studies Manager to join the Clinical team. Reporting to the Vice President of Clinical and Regulatory Affairs, this individual will provide technical, educational and initial clinical study support to assist in meeting company objectives. The Clinical Studies Manager will gather key insights through customer engagement to ensure all studies meet compliance, regulations and standards. This is a critical position that will work proactively and independently, reporting into the home office in the United States.

Key Responsibilities

- Contributes global clinical affairs strategies, in collaboration with regulatory affairs, marketing, research & development, reimbursement and outcomes planning, and obtain approvals by the most effective method possible.
- Executes Clinical Affairs Strategy to generate data for both marketing and regulatory purposes.
- Travels to clinical sites for training and clinical trials monitoring purposes.
- Enroll and manage KOL/physician-clinician engagement and lead the management of all Clinical Affairs investments and required support.
- Execute studies in India in full compliance with all applicable GCP and local requirements, regulations and standards.
- Reviews and negotiates contracts and budgets with sites, CRO's and vendors.
- Contributes to data collection, analysis, and presentation to company management.
- Contributes to preparing data for publication, white papers, presentations, etc.
- Prepare protocols for projects; reviews final study conduct documents such as study manuals, study plans, study tools, etc.
- Develops staffing plans according to needs.
- Initiate investigator and coordinator meetings.
- Participate in Risk management and R&D reviews and meetings.
- Provides oversight of individual clinical trials to ensure full compliance with GCP and local requirements and that safety concerns and/or adverse events are identified and appropriate responses to such concerns are executed.
- Provides advice to the customer complaint reportability team of adverse events and other clinical trial issues to regulatory agencies.
- Reviews and approves Clinical Risk Benefit Analyses.

- Reviews and approves study corrective action plans. Prepares for and participates in internal/external study-related audits.
- Demonstrates thorough knowledge of and coaches others in the appropriate application of clinical research conduct, laws, regulations, standards, and compliance with applicable SOPs and policies.

Qualifications

- Bachelor's degree in health profession, science and/or engineering field; advanced degree preferred.
- A minimum of 10 years of clinical affairs experience in the medical device industry. Previous experience leading a clinical research study strongly preferred.
- Must be knowledgeable in GCP's and DCGI requirements/regulations.
- Must have strong interpersonal and analytical skills; computer literacy and data management familiarity.
- Must have excellent written and verbal communication skills (English and Local Dialect(s).
- Must be able to manage projects and resources; have organizational skills and attention to detail.

Physical Requirements

- Must be located in India and will require 60% travel to clinical sites.

GI Dynamics is an equal opportunity employer and will not discriminate against any employee or applicant based on age, color, disability, gender, national origin, race, religion, sexual orientation, veteran status, or any classification protected by federal, state, or local law.

GI Dynamics does not accept unsolicited resumes from any source other than directly from a candidate.