ENTREMED GLOBALIZING ENTREPRENEURIAL MEDICINE

JOB DESCRIPTION

Position: Director, Clinical Operations

Company: EntreMed, Inc.

Location: Rockville, Maryland

Reports to: VP, Medical Affairs

Background: Small public biotech company based in Rockville and Beijing conducting Phase 2 oncology studies seeks experienced clinical manager, preferably with some FDA/regulatory experience. Full-time position but will consider part-time and flexible arrangements.

QUALIFICATIONS:

The Director, Clinical Operations should have a minimum of 8 years experience in the pharmaceutical industry, with minimum 5 years direct experience in planning and managing clinical trials. The candidate must have solid understanding of pharmaceutical clinical development processes and have experience with clinical monitoring. The candidate should have significant experience with responsible roles in the conduct or management of Phase I and II clinical trials. The candidate must have a BA/BS degree or equivalent; health science degree or biologic science degree is preferred. The candidate must have a good working knowledge of medical terminology, physiology and pharmacology and an excellent knowledge of applicable U.S. and international regulations and guidelines. Excellent oral and written communication, organizational and planning skills are required, with a proven ability to manage budgets. The candidate should be detail-oriented, a self-starter and be comfortable with broad responsibilities in an entrepreneurial, fast-paced, small company environment.

Directly related to this position (helpful but not required): Regulatory/FDA experience; Mandarin speaking; familiarity with global trials

DESCRIPTION:

The Director of Clinical Operations will manage all aspects of clinical development and data collection and be responsible for oversight of adverse event reporting, safety responsibilities, monitoring, adherence to protocols and determining study completion. The Director of Clinical Operations will also be responsible for the development of budgets, and work with management when input is necessary.

RESPONSIBILITIES:

- Ensures that clinical trial projects are properly resourced, managed and executed within budget and in accordance with established timelines and quality standards
- Lead manager of protocols; prepares protocol, amendments, CRF, informed consent form, operations and other documentation required for conduct of a clinical trial
- Maintains and manages internal clinical trial files and documents
- Prepare required regulatory documents, such as annual reports, updating of the IB, and final study reports for assigned protocols
- Serve as clinical monitor
- Manages the day-to-day clinical operations, including management of vendors (e.g., CRO) and coordination of activities
- Participates in investigator meetings and follow up
- Coordinates and plans for the availability of clinical and non-clinical supplies necessary to meet study requirements
- Travel to sites when necessary
- Maintains proper communications with other departments to ensure communication and good relationships in connection with matters related to clinical trial projects
- Other duties as assigned