**Director, Medical Science**

Position Type: Full-time

Location: Rockville, MD

Immediate Supervisor: Vice President, Medical Sciences

**Summary:** The Director is responsible for oversight of a single or several smaller clinical development programs or leading multiple studies or single complex/novel studies, such as platform or basket trials. The scope will differ depending on the exact nature of the clinical program. The Director Study Leader also provides expert input to improvement projects to enhance the overall clinical development program.

**Responsibilities**

* Evaluate pre-clinical and translational work for the purpose of generating early clinical development plan and Investigational New Drug applications;
* Provides expert therapeutic advice on clinical development strategies for investigational drugs for treatment of cancer in the U.S. and Europe in the context of the overall global development program; closely coordinates with peers in China on global development strategies; and reviews and assesses new information within to assess risks to development strategies and integrates emerging data into new plans;
  + Liaises with the internal and external medical community (e.g., Key External Experts (KEEs), Key Opinion Leaders (KOLs), Advisory Boards) to follow developments within areas of expertise
* Designs clinical trials (study design, operational plans, settings), for the US and globally, based on the proposed clinical development strategies;
* Provides expert therapeutic input for project or study level documents, including but not limited to the clinical development plan, clinical study protocol, and clinical study reports to ensure compliance with GCP and applicable regional regulations as well as ensuring the scientific integrity of individual studies and the development program;
* Monitors and manages the conduct of ongoing or new clinical trials for investigational drugs for the treatment of cancer in the US and Europe;
* Defines strategies for, or leads regulatory response to, complex technical issues for specific medical aspects on current projects, new projects and the broader therapeutic area; leads medical aspects of regulatory communications (written and verbal) for investigational drugs and marketing applications.
* Directs and reviews the analysis and summaries of clinical findings from clinical studies to support decisions regarding safety and efficacy throughout the development program and in support of new drug applications, clinical study reports, and/or publication;
* Participates in research project teams on the development of investigational drugs and the further study of marketed drugs.
* Work closely with a cross-functional group of experts in regulatory affairs, statistics, clinical pharmacology, nonclinical toxicology and manufacturing to manage clinical development projects. Coordinates with counterparts in China on global clinical development programs. Assists the Senior Medical Director in ensuring that appropriate company personnel are informed of the progress of studies of our company's and of competitors' drugs and provides internal and external expert opinion on scientific questions relevant to his/her areas of responsibility.
* Authors detailed development documents, presentations, and position papers for internal and external audiences
* Facilitates collaborations with external researchers around the world
* Participates in conference calls approximately up to two times per week that may occur outside of normal business hours and may travel up to five (5) percent of the time to manage future or ongoing clinical research projects.

**Minimum Qualifications**

**Education:**

* M.D or M.D./Ph.D.

**Required:**

* Minimum of 3 years of clinical medicine experience
* Minimum of 10 years of experience in the field of drug development or biomedical research
* Strong interpersonal skills, as well as the ability to function in a team environment are essential.

**Preferred:**

* Board Certified or Eligible in Oncology
* Prior specific experience in clinical research conduct or evaluation and prior publications

**Please send your Resume/CV to** **jobs@topalliancebio.com, Attn: Emily Xu, HR**