



Job Description

Director/Associate Director, Medical

Description:

I-Mab biopharma is a growing company aiming to be a China-based global player in innovative biologics in autoimmune and Immuno-oncology TA.

Under I-Mab US office, medical director design and execute clinical trials for I-Mab global portfolio assets. The position will report to the head of US Site.

Location: Rockville, Maryland

Responsibilities:

- Design study protocols and clinical development plans in collaboration with different function teams in US and China for oncology or autoimmune therapeutic areas.
- Author key clinical sections of IB, IND sections, regulatory briefing books, Annual Reports, CSR as well as prepare strategy presentations, present and discuss data with governance, external consultants, KOLs and potentially within regulatory meetings in conjunction with members of the development team.
- Create and/or review study documents/plans including monitoring plan, data management plan, safety review plan, etc.
- Performing ongoing data reviews, and leadership of safety review meetings.
- Communicate internally and externally (oral and written communication) on clinical trial design and results.
- Analyze and synthesize clinical data for publication, conducting and evaluating clinical trials.
- Proactively identify clinical development risks and propose risk mitigations.
- Supervise project team members in planning conducting and evaluating clinical trials.
- Serve as medical monitor with significant responsibility for safety surveillance.
- Collaborate with R&D and other senior management in assessing requirements for emerging products, including next generation candidates.
- Identify, select and train clinical research centers and investigators.
- Overseas planning and management of investigator meetings, advisory boards and other scientific committees as required by the protocol (e.g. independent reviews, DSMB's etc.).
- Participate in the selection of sites, CROs, and vendors.

Qualifications:

- MD with 2-5 years of experience within a pharmaceutical company environment required.
- Working knowledge of medical, scientific and clinical research in the oncology and autoimmune therapeutic areas.