Sr Director/Medical Director, Clinical Development

About IDEAYA Biosciences:

IDEAYA Biosciences is an oncology-focused biotechnology company committed to the discovery and development of breakthrough precision medicines for biomarker-defined cancer populations. Our efforts focus on developing targeted therapies, synthetic lethality medicines targeting DNA damage and repair for genetically defined patient populations, and for enhancing immunotherapy responses with immuno-oncology therapies targeting the tumor micro-environment. IDEAYA Biosciences, located in South San Francisco and La Jolla, California, has assembled leading scientists and development personnel with extensive knowledge and expertise in cancer biology, small molecule drug discovery, and drug development. For more information, please visit www.ideayabio.com.

IDEAYA Biosciences is seeking a South San Francisco based, experienced, motivated, outgoing leader to join our Clinical Development team. The Director/Sr Director of Clinical Development is expected to serve as Clinical representative on Project Teams, serve as Subteam Leader where appropriate, and partner with individuals across the R&D spectrum, from drug discovery efforts to clinical trials.

Location: South San Francisco, California

Reporting Relationship: Reports to the Chief Medical Officer

The Opportunity:

The Sr. Medical Director/Medical Director is responsible for providing medical direction, management and review of clinical trials and product development. Specific tasks may include design of a clinical development program plan for new drug candidates, as well as clinical protocol development, medical monitoring of clinical trials, and analysis of study data and preparation of trial reports and related regulatory documents. The individual may also serve as a Development Project Leader for a specific asset and will interact with most functions to ensure the successful progress of projects and clinical trials. This individual will have a solid understanding of all phases of clinical drug development, translational science, and operational excellence. Excellent written and effective verbal communication skills, ability to influence across functions and levels, and flexibility/adaptability to work in a fast-paced environment are essential.

Major Duties/Responsibilities

- Applies disease knowledge to clinical research trial development
- Drives protocol development for clinical studies in collaboration with Clinical Operations and other clinical subteam functions
- Drives preparation of clinical development plans in partnership with cross-functional team
- Works collaboratively with Regulatory Affairs; drafts clinical scientific documents such as IND, IND amendments, Investigator Brochures, Annual Reports (DSUR), and other FDA/HA submissions
- Contributes to CSR preparation and finalization
- Contributes to development of CRFs and data review plans

- Monitors, and reviews safety and efficacy data in ongoing studies
- Serves as primary clinical point of contact (eligibility questions, AE management…) for clinical trial sites
- Develops clinical abstracts, and/or presents data at scientific meetings, SIVs, and conducts protocol training
- Develops and participates in advisory boards
- Keeps abreast of hematology/oncology treatments, drug mechanism of action, approaches to drug development and regulatory requirements
- Acts as a clinical representative in variety of cross-functional teams, including late stage Research teams
- Partners with Research, Translational/Biomarker and other Preclinical teams to help guide advancement of drug candidates with meaningful safety: efficacy profiles
- Serves as clinical partner to Business Development

Personal Strengths:

- A proven self-starter and team player with strong interpersonal skills who establishes & nurtures highly effective relationships with colleagues and key stakeholders to support and advance project goals and objectives
- Critical thinker with a solutions-oriented mindset
- Self motivated to work effectively in a dynamic environment
- Possess strong organizational skills and conflict resolution abilities

Professional Requirements:

- Medical degree required; hematology/oncology training and/or practice highly desired
- Minimum of five years (Sr Dir) of drug development experience
- Thorough understanding of oncology clinical trial design, including first-in-human Phase 1 studies of small molecules
- Experience and understanding of clinical trial data monitoring and all aspects of drug development
- Knowledge of GCP and ICH guidelines is highly preferred
- Leadership and Management experiences highly desirable