Clinical Scientist

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

IDEAYA Biosciences is seeking a South San Francisco based experienced, motivated, outgoing Clinical Scientist. Reporting to the Chief Medical Officer, the Clinical Scientist will work closely with the clinical leader or CMO, providing medico-scientific expertise to one or more clinical projects.

Typical activities may include but will not necessarily be limited to:

- With the clinical leader, writing clinical development concepts and plans for molecules at all stages of development
- Writing initial and or later drafts of protocol synopses, protocols and protocol amendments
- Writing/reviewing informed consent forms and reviewing/adjudicating site-specific ICF requests
- Partnering with Clinical Operations on site selection, start-up and communication
- Writing or updating clinical sections of investigator brochures and leading the team that writes the initial brochure and subsequent annual updates
- Writing/reviewing clinical/safety sections of NDAs/MAAs
- Representing the medical (clinical) function on one or more clinical study teams, with functional support from the clinical leader
- Serving as a member of the clinical sub team
- Reviewing and interpreting data listings including safety data and serious adverse events
- Assisting with or serving as primary author of clinical study reports and associated publications
- Creating clinical study- or program-related slide decks for internal and external use
- Training of colleagues, CRO and study site staff on the therapeutic area, molecule and protocols as appropriate
- Organizing and participating in opinion leader advisory boards
- Contributing to or performing therapeutic area/indication research and competitor analysis
- Building and maintaining opinion leader/investigator networks
- Support Health Authority (HA) interaction, accountable for providing responses to HA inspection observations and internal audits
- Support HA updates and submissions
- Act as Medical Monitor for Phase 1 clinical trials, accountable to the clinical lead/CMO for patient safety and provide medical guidance during the design, execution, and reporting for clinical studies.

Additional study level activities include presentation of study results to internal and external committees or advisory boards, presentation of data at international scientific meetings and publication of study results in peer-reviewed journals. In addition to study level activities, the Clinical Scientist will participate in program level activities including authoring/reviewing safety and efficacy summaries, clinical overviews, investigator brochures, risk management plans, periodic safety updates and clinical sections of product labels.

QUALIFICATIONS & EXPERIENCE:

- Bachelor's degree and strong knowledge of clinical oncology gained through previous clinical development experience are required. Training and experience in immuno-oncology desired
- Postgraduate qualification in clinical oncology (e.g., Masters degree) would be welcomed as would MD, Nurse Practitioner's License, PharmD or PhD
- Previous participation in a clinical development program is essential, preferably involvement in all stages of clinical trials (i.e., from start up to study report)
- Experience in clinical trials with small molecules preferred
- Skilled in protocol design, interpretation, and medical monitoring
- Experience in assessment of adverse events and safety of patients participating in therapeutic clinical trials is preferred
- Knowledge of Good Clinical Practice
- Excellent written and oral communication
- Capacity to adapt to a fast-paced and changing environment

Candidates with a background in closely related functions (e.g., clinical operations, regulatory affairs, biometrics), having represented their function at project/clinical team level, would also be considered. Fluency in English is required.

Personal Qualities:

The successful candidate will be a confident person keen to take responsibility for assigned activities. Although working under the guidance of a manager and the clinical leader of the program, the clinical scientist will be expected to function largely independently, and would thrive in a mentored rather than a directed environment.

The CS will be able to take on new and varied activities and will enjoy participating at every level of the project, ranging from detailed review of documents/data through to strategic program planning. The CS will be committed to working within a project team structure, will be an excellent negotiator and will be able to manage other functions through a matrix structure.

The CS will feel comfortable presenting data to peers, investigators and senior management/executive committee. The CS will be able to embrace the challenges and opportunities offered in a small company environment and to capitalize on the experience.