Chief Medical Officer/VP Clinical

Arvinas, a new start-up company based in New Haven, CT, plans to develop novel, targeted therapeutics that will benefit patients suffering from cancer. To help lead this endeavor, we are seeking an innovative, collaborative and experienced leader with expertise in Clinical Oncology drug development to manage the clinical efforts of our Oncology development pipeline, moving targeted protein degraders from IND into and through early clinical development.

This position will lead the Oncology Clinical Teams and will provide strategic and technical guidance for all Oncology development assets, as well as coordination, support and contribution to other drug development activities, including Monitoring, Safety, and Regulatory. This person will have a major role in outreach to medical advisors and clinical investigators, and will be responsible for gathering and evaluating strategic competitive clinical information, and using this information to formulate and revise clinical development plans.

Education and Experience

M.D., with 15+ years of Pharma/Biotech drug development and project leadership experience, with multiple projects in oncology.

Board certified/eligible in Oncology or equivalent qualification. Active medical license a plus.

Responsibilities

- Provides overall clinical leadership for the Company, serving as the lead representative for clinical development and strategy both internally as well as externally – including internal clinical staff, CROs, clinical investigational sites, key opinion leaders, investors, & analysts.
- Serves as cross functional leader for all clinical trial workstreams, including clinical pharmacology, statistics, regulatory affairs, translational medicine, and clinical operations. Lead clinical interface with other functional areas, such as biology, chemistry, manufacturing, commercial, and business development.
- Subject matter expert on all clinical strategic initiatives. Stays current vis-a-vis developments in the field in both competitive and complimentary products, technologies and companies.
- Oversees and directly contributes to the clinical development plan for all clinical compounds, including input into and review of the pre-clinical package, as well as review with and endorsement from key stakeholders for go/no-go development decision criteria.
- Responsible for the design and authorship of study protocols and interpretation of clinical study data.
- Implements safety strategy across studies, including regular review of safety data and response to safety issues.
• Leads clinical sections of regulatory documents – in particular INDs, since all drug candidates are currently in preclinical development; key contributor in preparation for meetings with FDA.
• Organizes and prepares for Advisory Board meetings.
• Serves as an exemplary leader for the clinical team to train, develop, & mentor staff as needed.
• Manages clinical budget & resources, ensuring appropriate balance between internal and external FTEs in order to meet strategic product development plans and timelines.

Requirements

• Innovative, motivated, clinical drug developer with strong problem solving and communication skills
• Strong expertise in oncology clinical drug development strategies and scientific translational approaches
• Strength and detailed knowledge in early clinical stage oncology drug development efforts; can provide clinical strategic and technical input to support efforts as needed, in particular transition of preclinical compounds from Research through IND enabling studies and into first-in-human trials
• Ability to prepare documents needed for clinical development; to coordinate review and sign-off processes to ensure high-quality document submissions to IRBs and Health Authorities
• Demonstrated success in leading cross-disciplinary, clinical development project teams; integrating and evaluating the work of multiple groups / functions; managing both internal and contract resources
• Molecular-genetic understanding of cancer and cancer therapy; ability to strategically incorporate this knowledge into drug development and regulatory plans
• Solid understanding of how to leverage biomarkers and translational research to guide clinical development of personal medicine
• Knowledge of assays & metrics that report on safety, clinical PK, and clinical outcomes
• Ability to recruit, train, develop, mentor and manage staff, both internal and external
• Flexibility and drive for results - willingness to embrace change and be able to work in a changing environment while being driven to achieve goals
• Self-motivated, approachable, articulate team player who values collaboration and transparency and who possess the highest level of integrity, with core values that are consistent with those of the organization as a whole

- See more at: http://www.arvinas.com/careers