DIRECTOR/SENIOR DIRECTOR, CLINICAL DEVELOPMENT

COMPANY DESCRIPTION

Denovo Biopharma LLC, a clinical-stage biotechnology company that employs novel and proprietary biomarker discovery methodology to advance drug development. Our primary strategy is to rescue promising therapies in oncology and CNS diseases by defining biomarkers that identify patients most likely to benefit from these treatments. Three assets are in development and a global phase 3 clinical trial is currently enrolling patients.

POSITION SUMMARY

Reporting to the Head of Clinical Development, the Director/Senior Director, Clinical Development is responsible for developing and executing global clinical strategy and tactical plans for one or more asset. This person will engage and establish credibility with the medical community and, working with the Head of Clinical Development, will ensure alignment and execution of internal and external priorities and activities.

The successful candidate must be a creative leader who adapts quickly to evolving circumstances and is able to succeed in a fast-paced environment.

ESSENTIAL FUNCTIONS AND RESPONSIBILITIES

- Serve as the medical and clinical lead for one or more asset
- Serve as the medical monitor for one or more clinical trial
- Provide medical and clinical development expertise
- Participate in defining and implementing clinical strategy for one or more asset
- Establish relationships with key opinion leaders and ensure that significant developments in the field are identified and monitored; serve as the clinical lead for advisory meetings
- Responsible for preparing clinical portions of regulatory documents including INDs, NDAs, investigator brochures, drug safety update reports, and clinical study reports
- Accountable for clinical protocol development and preparation
- Responsible for pharmacovigilance activities for clinical studies, including the review and reporting of SAEs (with support from the pharmacovigilance team)
- Participate in the oversight and management of vendors/CROs

- Prepare manuscripts and abstracts and make presentations at scientific meetings
- Provide Medical/Clinical support to other functional areas
- Participate in business development processes as needed, including due-diligence, and partnering activities
- Perform other duties as required

JOB QUALIFICATIONS

Education, Certifications, Experience

- MD required
- At least 4 years drug development experience within the biotechnology or pharmaceutical industry, preferably in oncology
- Demonstrated understanding of FDA requirements, good clinical practices, and pharmaceutical clinical development in oncology
- Demonstrated ability to contribute meaningfully to deliver clinical development strategy
- Possesses at least a basic understanding of biostatistics and pharmacokinetics
- Ability to work collaboratively in a dynamic team-based, matrixed environment
- Experience leading and managing clinical development programs
- Ability to travel domestically and internationally