Clinical Scientist, Clinical Development

POSITION SUMMARY

Reporting to the Head of Clinical Development, the Clinical Scientist, Clinical Development is responsible for supporting development and execution of our global clinical strategy and tactical plans. This person will engage and establish credibility with the medical community and, working with the Head of Clinical Development and other team members, will ensure alignment and execution of internal and external priorities and activities.

The successful candidate must be able to quickly adopt evolving circumstances and be able to succeed in a fast-paced environment.

ESSENTIAL FUNCTIONS AND RESPONSIBILITIES

- Serve as the medical science liaison to support clinical development activity
- Support the medical monitor for clinical trials
- Establish and maintain professional relationships with key opinion leaders and study investigators
- Help preparation of the clinical portions of regulatory documents including INDs, NDAs, investigator brochures, drug safety update reports, and clinical study reports
- Support clinical protocol development and preparation
- Participate in 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 for publication
- 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

QUALIFICATIONS AND EXPERIENCE

- MD, Pharma D, or PhD in biology or relevant field is required
- At least 2 years drug development experience within the biotechnology or pharmaceutical industry, preferably in oncology and CNS disease
- Understand good clinical practices (GCP), and pharmaceutical clinical development
- Possesses at least a basic understanding of biostatistics

- Ability to work collaboratively in a dynamic team-based, matrixed environment
- Experience managing clinical development programs
- Ability to travel domestically and internationally

Please note this job description is not designed to cover or contain a comprehensive listing of activities, duties or responsibilities that are required of the employee for this job. Duties, responsibilities and activities may change at any time with or without notice.

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 central nerve system (CNS) diseases by defining biomarkers that identify patients most likely to benefit from these treatments. Several investigational drugs are in different phase clinical trials.