Job Posting

Posting Date: ___4-16-2021____ **Internal Closing Date:** __4-23-2021___

Salary Range: $__negotiable____ **Status:** ☒ **Exempt** ☐ **Nonexempt**

☒ **Full-time** ☐ **Variable Hour**

Notes: Position posted on LinkedIn at: URL

Job Title

Summary: The Medical Director is a member of the Translational Medicine Core Team and is ideally a board-certified physician who has experience in clinical trials and significant history in the diabetes-related cardiovascular and/or metabolic disease therapeutic areas. An ideal candidate should have significant experience in management of **Type 1 diabetes** and would thrive on proactively engaging internal and external leaders. S/he is accountable for the development and execution of Clinical Trial Safety and Medical Plans.

Other Information:

- For the right candidate this position may be up to 90% remote (from NC region is preferred) with travel to corporate office or other locations for specific meetings with FDA, PIs, KOLs, or business development purposes, etc.)

Essential Duties and Responsibilities:

- Provides medical expertise across the entire scope of clinical development; participates in strategic planning for programs and clinical trials
- Utilizes clinical trials safety expertise and oversees strategic clinical trial progression across the company pipeline
- Develops study specific safety management, pharmacovigilance, and risk management plans
- Leads drug safety teams to evaluate serious adverse events (SAEs)
- Responsible for safety of subjects enrolled in company sponsored clinical studies, assuring medical oversight, including safety reviews and ongoing assessment of risk-benefit within individual studies and overall programs; provides medical input for dose escalation decisions
- Reviews and oversees safety data for both clinical and preclinical studies
- Interacts with external experts, regulatory agencies, and partner/co-development companies
- Directs the setup of safety procedures and development of safety exchange agreements for co-development projects
- Maintains intimate knowledge of safety, including any emerging safety concerns and risk/benefit profiles for company compounds, with input for other compounds as needed
- Represents medical affairs within legal, medical, and regulatory review committees
- Applies medical and clinical expertise to inspire internal teams and external stakeholders

- Plays an integral role in the planning and participation of national and regional medical advisory boards
- Flexibly supports compounds/initiatives outside of primary therapeutic area(s) as directed by business and departmental needs
- Responsible for keeping senior and executive management informed of clinical progress and any critical clinical issues, especially the emerging safety profile
- Tracks emerging study data to ensure appropriateness of the chosen subject population; proactively assesses the performance of techniques used for endpoint measures on an ongoing basis to ensure data quality
- Contributes in close collaboration with Program Leads to the design, execution, safety monitoring, interpreting, and reporting of clinical research studies
- Contributes to authoring and development of clinical documents (e.g. clinical development plans, protocols and amendments, informed consent forms, clinical study reports, clinical components of regulatory submissions, clinical components of investigator brochures, etc.), including scientific interpretation of data, discussion, and conclusions
- Contributes to authoring summary sections of regulatory applications, such as INDs, CTAs, NDAs, etc., and other regulatory submissions, including safety updates
- Provides input into the operational strategy and feasibility of clinical research studies in conjunction with Clinical Operations and Translational Medicine
- Presents clinical aspects of compound development, including milestones, strategies, recent data, to senior management and external audiences
- May be contributor on blind data review teams
- May contribute to the preparation of abstracts, manuscriptions and other presentations for scientific meetings
- Maintains a high degree of awareness of the external environment, including maintaining medical and scientific expertise in therapeutic areas and educating colleagues and project team members

Supervisory Responsibilities:

Although this position does not have any direct reports, incumbent may be delegated responsibility for managing consultants and/or vendors supporting the scope of Clinical Development and Translational Medicine activities.

Education, Experience, and Other Requirements:

- MD degree required, (or combination of MD with another graduate degree, such as PhD); board certification preferred; active medical license preferred
- Experience in phase II-III clinical trials is essential
- Clinical specialization (residency completion, board certification or equivalent) in Internal Medicine, Endocrinology or Pediatric Endocrinology is preferred
- Experience in Endocrinology (with diabetes related Cardiometabolic experience) clinical trials and familiarity with the use of electronic portals
- At least 4 years of experience in metabolic diseases (with diabetes related cardiovascular experience), with at least 2 years in the pharmaceutical industry; experience in clinical trials in Type1 diabetes desired
- Experienced writing clinical study reports, poster presentations, and manuscripts for publication in scientific journals
- Demonstrated competence in a pharmaceutical industry medical role, such as: Research Physician, Study Director, Medical Monitor, Clinician or Clinical Scientist, Principal Investigator or Sub-Investigator, Clinical Researcher, Medical Advisor, Study Physician or Clinical Development Physician, or similar roles
- Prior experience working with the FDA or EMEA on responses to inquiries for study related information is not required but is preferred
- Must have excellent communications skills, strong interpersonal skills, leadership, and

presentation skills
- Strategic problem solver with understanding of operations and execution process related to clinical research involving both single and multiple centers
- Broad interdisciplinary understanding of pharmaceutical drug development processes is desired, including contributions from functional lines, such as CMC, drug supply, regulatory, data management, biostatistics, clinical pharmacology (PK, PKPD)
- Must have a strong knowledge of GCPs, ICH guidelines, and industry standards
- Prior medical affairs experience is desired
- Leadership experience representing the medical function in both strategic and scientific team meetings
- Effective interpersonal skills; able to negotiate and build consensus for plans and priorities; demonstrated competence building strong working relationships with colleagues and stakeholders through collaboration
- Proficiency using Office 365, Acrobat Reader, and various internet browsers
- Experience with JMP Clinical, J-Review, or similar medical review software is a plus

This job description is a summary and is not intended to be comprehensive in detail.

Internal Number: 20210415