Job Description

Position: Associate Director/ Director of Clinical Development

Role description

Millendo is seeking a medical expert (M.D. or D.O.) for assigned clinical trials. This role will provide input into the design and conduct of clinical trials, assessment and interpretation of clinical data, and investigator training.

Location

This role will be based in Ann Arbor, MI

Hours

This is a full-time role

Responsibilities

- Lead medical aspects of medical monitoring.
- Work closely with the CRO's to provide medical input into safety reports, including SAE narratives and analysis of similar events, Suspected Unexpected Serious Adverse Reaction (SUSAR) reports, Investigator Brochure (IB), Risk Management Plans, Integrated Summary of Safety, Clinical Study Reports, and preparation of labels
- Further clinical development programs by assisting in the design and conduct of clinical trials, including: drafting of protocols and respective amendments, informed consent forms, data monitoring committee charters, and other supporting documents
- Provide medical expertise for assigned clinical trials with the expectation to being readily available to advise on trial-related medical questions or problems during the conduct of the trial
- Contribute to site and investigator training
- Assist in medical reviews, assessment and interpretation of efficacy and safety data to ensure that the data are correct and presented with the appropriate medical interpretation
- Responsible for medical monitor input into the development and implementation of standard operating procedures for all aspects of Adverse Event (AE) report handling, aggregate reporting and assuring compliance with global and local regulatory requirements
- Responsible for implementing alignment across policies/procedures and ensuring that data generated are compliant with FDA and ICH guidelines and GCP.

Requirements

- M.D. or D.O., experience in endocrinology would be a plus
- 1-3 years of experience in drug development or clinical research, preferably in the pharmaceutical industry
- U.S. and E.U. experience preferred
- Fluent in oral and written English
- Understanding of local and global drug safety regulations and processes and clinical trial oversight, including global GCPs
- Excellent interpersonal and communication skills with ability to relate to both internal and external stakeholders
- Strong communication and presentation skills as well as an ability to communicate clearly and concisely in writing

Reporting relationships

This role reports into the Senior Medical Director and works closely with the Senior Director of Clinical Operations