Director, Clinical MD
United States - Pennsylvania - Collegeville
United States - New York - Pearl River

Candidate demonstrates a breadth of diverse leadership experiences and capabilities including: the ability to influence and collaborate with peers, develop and coach others, oversee and guide the work of other colleagues to achieve **meaningful outcomes and create business impact.**

ROLE SUMMARY

- The clinician medical monitor is accountable for providing

medical and scientific expertise and oversight for Clinical Trials and serves as a single point of accountability for design, execution, monitoring, delivery and reporting of one or more clinical studies and to ensure patient safety.

- The clinician medical monitor may be required to design a

development strategy for multiple protocols designed to
obtain worldwide approval for a compound or group of compounds.

- In addition to study level activities, the clinician medical

monitor may participate in standing committees, review
compounds for potential in-licensing, including performance of due diligence reviews, and provide assistance to new business development on market opportunities and the target product profile.

ROLE RESPONSIBILITIES

Accountable for safety across the study:

- Provide study team with medical advice for all medical issues during risk assessment and mitigation planning to enable quality, compliance and patient safety at the trial, site and patient level.
- Ensures development of and adherence to the Safety Surveillance Review Plan (SSRP). Consistent with the SSRP, performs and documents regular review of individual subject safety data, and performs review of cumulative safety data with the safety risk lead. As appropriate, the clinician medical monitor may delegate these responsibilities to the study clinician scientist identified in the SSRP. The specific components of safety data review are detailed in the appropriate SOPs and the "Safety Data Review Guide - for Clinicians."
- Monitor study safety issues and provide input to serious adverse events (SAEs) reports. Provides appropriate medical context in terms of risk factors, medical history and other important medical factors required to put the SAE or AE into appropriate medical context required for benefit-risk assessments.
- Participates in the Safety Review Team to evaluate medical benefits/risks to support targeted clinical indications.
    - Reviews literature as needed to respond to safety questions or those posed by the Safety Review Team, Data Monitoring Committee (DMC) or other individuals or bodies involved with the study.
    - Communicates safety information to sites across the study and provides responses to questions on safety.

Protocol design and strategy:

- Provide medical input during development and updates to the clinical development plan.
- Designs clinical studies to meet the stated objectives. Assures that clinical trial objectives fit with the clinical program strategy.
- Ensure that documents (protocol, Informed Consent Document [ICD], etc.) meet regulatory requirements and company policy and has been reviewed by IRB/IECs.
- Provides medical input into country feasibility.

Support study team

- Provides clinical input to protocol/study team for monitoring guidelines, statistics analysis plans, ICDs, clinical review forms, data edit checks, data quality planning, as needed (ultimately oversees work of protocol/study team).
- Contributes to contract research organization / vendor selection to ensure study is conducted consistent with protocol requirements, clinical plan expectations, and study timelines; this includes ensuring medical/technical requirements for data integrity are applied. .
- Works with study team to ensure high quality of data e.g. appropriate patient population, adequacy of clinical assessments as study is ongoing.
- Conducts medical review and interpretation of efficacy and safety data from clinical trials; this may include delivery of top-line report in collaboration with study statistician, and delivery of clinical study report in collaboration with medical writer and accountable for overall quality and timeliness of analysis and reporting.
- Ensures the medical and scientific validity of study report, especially conclusions regarding efficacy and safety. Responsible for disclosure of appropriate safety and efficacy data and conclusions (ClinicalTrials.gov, EudraCT, or Pfizer.com).
- Provides protocol specific training to study team, investigators, clinical research associate, and others.

- Interacts with healthcare professionals at sites (leveraging the RMMs when assigned) during the conduct of the study to enable quality, compliance and patient safety at the trial, site and patient level.
- Interacts with DMCs and steering committees as required.
- Notify appropriate study team personnel of the need to inform investigators of any changes in research activity and any significant new adverse events.
- Monitor investigator compliance with protocol and regulatory requirements.
- Support study team in issues resolution, study closeout,

audit responses, inspection readiness, etc.

Supports the program team:

- Authors clinical sections of regulatory documents (Investigator Brochure, Annual Reports, lnvestigational

New Drug sections, clinical study report).

- May co-author abstracts, posters, presentations and publications.
- May contribute budget execution of protocols

Interact with regulatory authorities, key opinion leaders, and principal investigators:

- Supports Clinical Regulatory Authority interactions accountable for providing responses.
- Liaise with Key Opinion Leaders and Principal Investigators in countries to build a Key Opinion Leaders

/Principal Investigators network for new trials

BASIC QUALIFICATIONS

- Licensed by a health authority to prescribe medicines (independent of supervision) for at least one year (post "intern/houseman" year) and has utilized the license to prescribe medicines in a patient care setting for an aggregate duration of at least one year.
- Possesses the ability to critically evaluate medical/scientific information.
- Excellent written an oral communication.
- Understands the design, development, and execution of clinical programs and studies.
- Capacity to adapt to a fast pace and changing environment.
- Documented experience in the pharmaceutical industry related to clinical research programs and registration activities.
- Responsible for managing multiple studies

PREFERRED QUALIFICATIONS

- Medical degree (M.D./D.O. or equivalent).
- Documented work experience/knowledge of statistics.
- Training and experience in infectious diseases and/or infection control in the hospital setting is preferred.
- Experience with investigational clinical trials is preferred

Other Job Details:

- Eligible for Relocation Package
- Eligible for Employee Referral Bonus
- #LI-PFE

Sunshine Act

Pfizer reports payments and other transfers of value to health care providers as required by federal and state transparency laws and implementing regulations. These laws and regulations require Pfizer to provide government agencies with information such as a health care provider's name, address and the type of payments or other value received, generally for public disclosure. Subject to further legal review and statutory or regulatory clarification, which Pfizer intends to pursue, reimbursement of recruiting expenses for licensed physicians may constitute a reportable transfer of value under the federal transparency law commonly known as the Sunshine Act. Therefore, if you are a licensed physician who incurs recruiting expenses as a result of interviewing with Pfizer that we pay or reimburse, your name, address and the amount of payments made currently will be reported to the government. If you have questions regarding this matter, please do not hesitate to contact your Talent Acquisition representative.

EEO & Employment Eligibility

Pfizer is committed to equal opportunity in the terms and conditions of employment for all employees and job applicants without regard to race, color, religion, sex, sexual orientation, age, gender identity or gender expression, national origin, disability or veteran status. Pfizer also complies with all applicable national, state and local laws governing nondiscrimination in employment as well as work authorization and employment eligibility verification requirements of the Immigration and Nationality Act and IRCA. Pfizer is an E-Verify employer.