Title: Senior Director, Pharmacovigilance

Location: Waltham MA (preferred) or London, UK

About Us: At Nightstar, our mission is to maintain and restore sight in patients with inherited retinal diseases. We are a clinical-stage company focused on developing and commercializing a pipeline of novel and potentially curative, one-time retinal gene therapies for patients suffering from rare inherited retinal diseases that would otherwise progress to blindness, and, for which, there are no currently approved treatments.

Job Purpose: Reporting to the Chief Medical Officer, Senior Director, Pharmacovigilance is accountable for all global pharmacovigilance activities for all clinical programs, including activities performed at Clinical Research Organizations and in collaboration with partners on clinical trials to ensure compliance with regulatory requirements, internal procedures and policies, GCP, and to ensure readiness for regulatory inspections and audits, complying with all EU and US regulations and timelines. This individual will oversee multiple studies with changing priorities and work independently and/or collaboratively in a matrix environment.

About the role:

- Accountable for identification, initiation, development and implementation of PV process
- Collaborate with case processing team at CRO or inhouse and develop and report internal tracking metrics related to clinical trial SAE processing and vendor management
- Ensure adequate safety management plan (SMP) is in place for each study/protocol as well as review relevant eCRF forms from clinical database for alignment with safety forms and reconciliation (e.g., AE, study drug administration, disposition)
- Provide PV representation on program teams and close collaboration with colleagues in other disciplines, particularly clinical development, clinical operations, translational, research, and CMC
- Provide PV support for safety sections of clinical documents, including the review and approval of the safety portion of protocols, statistical analysis plans, annual reports, clinical study reports, investigator brochures, NDA and/or BLA submissions and other documents
- Provide guidance and appropriate study configuration to safety data management for SAE/AE reconciliation process
- Assist in single case & end-of-study unblinding, deviation memo preparation, deletion/admin edit requests and approvals, review protocol update request forms for accuracy
- Perform and/or provide oversight for the medical review of safety events to ensure accuracy and completeness of safety information, and to ensure consistency of medical coding of safety data
- Lead Safety Review Committee and Safety Data Review Meeting, and safety related meetings with partners
- Accountable for identification, initiation, development and implementation of PV process improvements, tools, systems and procedures to ensure quality and consistency in safety operations, and data output
- Work closely with Regulatory Affairs regarding assessment and submission of individual case safety reports (ICSRs), aggregate reports, IND and BLA annual report summary statements, and all other relevant regulatory communication
- Responsible for the safety strategy during drug development, including development and implementation of Risk Management Plans, and monitoring and analysis of cumulative safety information in the context of the benefit-risk profile
- Lead the process of safety vendor selection and evaluation process as needed

- Manage CROs/vendors to ensure all timelines are met, potential issues are being communicated and resolution is achieved in a timely manner
- Serve as subject matter expertise in Pharmacovigilance Operations and GCP/ICH compliance requirements and guidelines and for audits and inspections as well as ensure preparedness for all safety-related documentation to be filed properly for inspection
- Work closely with department head and QA/Regulatory to maintain an effective and compliant system for monitoring the safety profile for individual compounds as well as the platform
- Author and train to SOPs as required per job function
- Assist in the budget planning for the safety operations function and report on ongoing budget initiatives

Critical Competencies:

- Advanced degree in life sciences, pharmacy or medicine; MD, PhD, or PharmD (MD is preferred, however a strong PhD and PharmD candidate will be considered) with a minimum of 3 years of management experience overseeing a Pharmacovigilance staff or a CRO and at least 8 years' experience with Pharmacovigilance Operations in a biopharma company in both clinical trial and post marketing environment.
- A thorough understanding of the global PV regulatory environment with working knowledge of EU and US regulations, ICH guidelines, and GCP, a working understanding of drug safety databases, effective project management skills, a demonstrated ability to provide critical and timely insight, and analytical problem-solving skills with a broad perspective
- Thorough understanding of the clinical drug development process Phase 1 through BLA or NDA
- Experience with safety databases (i.e. Argus) and safety coding dictionaries (i.e. MedRA, WHODRUG)

Behavioral and Interpersonal:

- Excellent interpersonal skills, organizational and decision-making skills, and ability to adapt to a dynamic and complex regulatory and business environment while working with cross functional teams
- Flexibility and agility to function on various levels of the role as required in a fast growing environment

Contact: Katherine Danyluk, Recruiting Coordinator
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