Safety Scientist

A. Introduction to the Organization

The Parker Institute for Cancer Immunotherapy ("PICI" or the "Parker Institute") is a not-for- profit organization whose mission is to accelerate the development of immunological cures for cancer through innovative science, advanced technologies and new modes of research collaboration. The Institute is based in San Francisco, California and officially launched in April 2016.

To achieve its mission, PICI has established significant new cancer immunology research centers at six of the top cancer research and treatment institutions in the country (M.D. Anderson Cancer Center, Memorial Sloan-Kettering Cancer Center, Stanford University, University of California-Los Angeles, University of California-San Francisco, and University of Pennsylvania), and will organize and support a portfolio of advanced, collaborative research efforts across this consortium.

B. Overview of the Role

Key to the success of this effort will be the conduct of single- and multi-center clinical trials. The Parker Institute will conduct early phase investigator-initiated trials as well as partner with biotech and pharmaceutical companies on industry-sponsored trials. The Safety Scientist is responsible for working closely with scientists at member institutions as well as external stakeholders, vendors, and PICI staff to plan, staff, implement, and evaluate collaborative clinical trials across the consortium.

The Safety Scientist is involved in all stages of the clinical trial, including protocol writing, regulatory submissions, development of the pharmacovigilance and risk management plan, managing all pharmacovigilance activities during trial implementation, and contributing to PICI interactions with regulatory authorities. The Safety Scientist is responsible for the day to day activities of the pharmacovigilance team; manages resources, workload quality and metrics; provides updates to senior management on project progress. This person is knowledgeable regarding regulatory requirements, product information and is a subject matter expert on areas of responsibility. The pharmacovigilance team identifies, investigates, mitigates and communicates drug safety issues on PICI clinical trials. They are also focused on assessing risks in the context of a product's benefits, and work collaboratively and strategically with colleagues to achieve this goal. Cross-functional collaboration within PICI and with our collaborators and external partners in terms of people, process, and systems are aimed at achieving a truly proactive approach to patient safety. This will include reviewing emerging data from clinical trials, assessing causality and write narratives.

C. Reporting Structure and Team

The Safety Scientist reports to the VP, Clinical Research and Development and is a key member of the Clinical Research and Development team.

D. Specific Duties

Management

- Manage PICI pharmacovigilance program and pharmacovigilance activities for PICI clinical trials
- Effectively manage team workload and trial responsibilities

Pre-Trial

- Provide development support for clinical plans and individual study protocols
- Contribute to the benefit risk evaluation and to safety risk management
- Contribute to Pharmacovigilance and Risk Management planning for designated trials by analyzing the risks of the agents involved, preparation of safety strategies and highlighting and tracking potential issues
- Supports the preparation and maintenance of safety sections of the Clinical Protocols, Clinical Study Reports as well as the Risk Management Plan
- Represent Safety (Medical Analytics) on study teams
- Write or assist in writing Investigator Brochures, DSURs and other regulatory documents
- Prepare the Adverse Event Reporting Plans (AERP)/Safety Management Plan (SMP) and other program specific plans

Trial Implementation

- Work with study team to ensure the provision of protocol-specific site training
- Participate in safety assessments
- Review and provide clinical scientific input to TLGs and safety narratives
- Review scientific literature
- Assist other team members in Clinical Development in the implementation and conduct of clinical trials which includes but is not limited to review of enrollment packets, review of adverse events and all other clinical data generated during conduct of trial
- Assist in Medical Monitor responsibilities
- Ensure that all relevant clinical and safety data is collected in a timely manner and assist with cleaning of data listings
- Participate in the development of clinical operating guides and maintain secure study files
- Work on problems where analysis of situations or data requires review of a variety of factors
- Apply PICI policies and procedures to resolve a variety of issues
- Provide guidance to study team on triage, coding, assessment queries, aggregate report scheduling
- Ensure follow up information is requested on relevant reports within required timelines

- Manage case processing/data cleaning activities in accordance with aggregate report calendars
- Contribute to the preparation of metrics and custom reports
- Manage the preparation and distribution of SUSAR line listings
- Oversee and/or implement the generation of queries to the sites for clarification and reconciliation of adverse event reports
- Oversee reconciliation of clinical and safety databases
- Assign resources for the evaluation and validation of safety systems (user acceptance testing)
- Aggregate Reports for investigational products such as DSURs, ASRs, IND Annual - collect, collate, format and draft PVRM data contribution
- Collect, collate, format and draft data contribution and perform first review of IND Safety reports
- Pull data and draft responses to regulatory requests in consultation with Medical Director prior to management review
- Perform reconciliation and signoff for database lock
- Participate in interactions with regulatory agencies
- May require travel to field sites and scientific meetings
- Other duties as assigned by management

E. Required Professional Experience

- PhD, PharmD, M.D., R.N, Nurse Practitioner or Physician Assistant required
- Prior experience in CRO or Pharma/Biotech safety department, minimum three (3) years' experience is required
- Minimum of 2 years of medical writing experience (prefer experience in writing pharmaceutical reports such as PSURs, Clinical Study Reports, safety sections of the ISS and/or Common Technical Document, or white paper) and/or experience in Medical Surveillance and Risk Management
- Committed to the values of integrity, collaboration, accountability, transparency, and drive
- Excellent teamwork and collaboration skills
- Ability to build effective working relationships throughout the organization internally and externally to achieve goals
- Flexibility and willingness to solve problems that fall outside of immediate area of expertise
- Clear and concise verbal and written communication skills and strong organizational skills, with an exceptional attention to detail
- History of solving problems while exhibiting superior judgment and a balanced, realistic understanding of issues
- Demonstrated ability to think strategically, provide organizational leadership, and results-oriented performance
- Ability to effectively present ideas and document complex medical/clinical concepts in both written and oral communication

- Ability to work independently in an interdisciplinary, fast-paced, often changing environment
- Familiarity with concepts of clinical research and clinical trial design, including biostatistics
- Medical knowledge in the relevant therapeutic area
- Knowledge of ICH and US regulations and requirements for pharmacovigilance and Risk Management
- At ease with data and statistics
- Familiarity with safety databases, data entry platforms, adverse event data collection process, case processing, call center activities, product complaints, 15-day safety alerts, submissions of safety updates to health authorities, Pharmacovigilance Safety Data Exchange Agreements is required
- Working knowledge of ICH Guidelines and US CFR 314.80, 312.32; MedDRA and WHO_DRUG coding is desirable
- Knowledge of Good Pharmacovigilance Practices
- Fluent in English
- Demonstrated Excellent Documentation Practices
- Experience manipulating/understanding large and complex data sets
- Experience integrating data from multiple sources to answer specific questions
- Experience in interpreting medical safety data
- Basic Project Management skills and Microsoft Word and Excel skills

Apply for this role

To apply, please email your resume and cover letter outlining how you meet the requirements for the position to careers@parkerici.org.