



GILEAD

Advancing Therapeutics.
Improving Lives.

Job Posting Title: Sr. Clinical Research Scientist

Requisition Number: 623

State: Colorado

Specific Responsibilities:

Requires knowledge of pharmacokinetics, in vitro and in vivo drug metabolism. Training and experience in pharmacokinetic/pharmacodynamic modeling and simulation using WinNonlin, NONMEM or other relevant software is highly desirable. Knowledge of bioanalysis using HPLC-MS/MS is a plus.

This position is responsible for all aspects of clinical science including research, developing and writing study protocol, study summaries and clinical study reports working in close association with cross functional clinical, biometrics and regulatory team.

This position will be responsible for contributing to study design and implementation of study designs across phase 1 through phase 4 studies, with special emphasis on clinical pharmacology.

Essential Duties and Job Functions:

Interfaces with staff to share scientific and clinical information and consistent practices. Leads protocol review discussions concerning scientific and procedural aspects of study design. Serves as resource for junior staff. Oversees the scientific aspects of clinical studies throughout duration of study. Adheres to strict regulatory requirements of study conduct and industry standards of Good Clinical Practice as well as Gilead SOPs. Prepares study protocols, amendments, specific sections of study manuals and Investigator meeting notebooks, and other documents as needed. Supervises or assists other CRS staff with preparation of above. Contributes to the design and development of CRFs, Data Management Manuals and Data Analysis Plans. Helps insure consistency across protocols. Presents scientific information if needed. Addresses questions regarding scientific and related procedural issues from Investigators. Coordinates and implements ongoing data for internal analysis and review. Coordinates the preparation and/or review of data listings, summary tables, study results, scientific presentations, and manuscripts for publication. Coordinates the preparation/review of regulatory documents, IND annual reports, IND safety reports, Investigator Brochures and NDAs. Determines the functions most critical to company success and supports priorities within functional area. Anticipates fairly complex obstacles and client difficulties and implements solutions that meet goals. Creates effective teams with a clear sense of direction. May lead two or more specific components of departmental strategic initiatives.

Knowledge, Experience & Skills:

Excellent verbal and written communication skills and interpersonal skills are required to maintain working relationship with team members to ensure scientific integrity of clinical studies. Is sought out for advice by others within the company to help make better decisions and resolve problems. Examines functional issues from a broader organization perspective. Must be able to design and use all available vehicles for effective scientific communication within the company. Good working knowledge of cardiology and/or pulmonology, treatment, and clinical management along with a good general working knowledge of infectious diseases. Knowledge of clinical trial design to develop specific study concept sheets and protocols is required.

Typically requires a BS degree in Biological Sciences, health care or related field and minimum 11 years of relevant experience or a MS degree and minimum 9 years of relevant experience. Typically a higher degree Pharm.D or Ph.D. in clinical research or clinical pharmacology and experience in a pharmaceutical company or contract research organization along with knowledge of clinical trial design and experience with protocol/report writing is preferred.