Director/ Sr. Director, Biostatistics

Reports to: Chief Medical Officer or VP, Clinical Development

Classification: Exempt

Summary:
Responsible for leading statistical and analytical services in support of clinical trials, regulatory submissions, quality initiatives, as well as providing guidance on standards, processes, and technical topics within the statistics function. The program conducted at CymaBay Therapeutics currently target inflammatory liver diseases. The lead compound, seladelpar, is entering phase 3 with a goal of a New Drug Application for Primary Biliary Cholangitis, a rare orphan liver disease. Ensure statistical analyses are conducted with the highest level of scientific integrity, while meeting timelines and budgets. This position will work collaboratively with study clinicians, medical affairs, clinical operations managers, data managers, and statistical programmers in the planning, conduct, and analysis of clinical studies in all phases of development. The Director/ Sr. Director, Biostatistics will also support CymaBay scientific exchanges (e.g. congresses abstract(s) and peer-reviewed publications).

Essential Functions and Job Responsibilities:

- Collaborate interdepartmental and scientific activities, especially collaboration with medical monitors on study protocols design and writing (author or supervisor statistical methods section and generate study randomization)
- Generate statistical analysis plan for study protocols
- Develop statistical programs as necessary to perform analysis, prepare data displays, verify data accuracy and validity
- Supply statistical input for IND and NDA submissions and in response to FDA or global Health Authorities queries
- Provide support for scientific publications
- Contribute to peer-reviewed articles independently, in coordination with the lead author/physician
- Responsible for ensuring compliance with departmental and company goals
- Effectively communicate timely and relevant updates to all team members involved
- Manage CROs regarding statistical activities to ensure timely delivery of quality analysis results
- Provide guidelines and standards to CROs to ensure quality of deliverables
- Complete other responsibilities as assigned

Minimum Qualifications:

- Ph.D. in Biostatistics or closely related discipline with a minimum of 12 years' experience in pharmaceutical and biotech industry, or an MS in Biostatistics or equivalent with a minimum of 12 years' experience in pharmaceutical and biotech industry
- Previous experience with all phases of clinical research and NDA
- Excellent oral and written communication skills as well as well-developed organizational skills and ability to multi-task are essential
- Ability to work in a fast-pace, hands-on environment, typical of a small and growing biotech

- Thorough understanding of statistical principles and clinical trial methodology with the ability to practice and implement them
- Able to explain methodology and consequences of decisions in lay terms; able to understand requests for complex analyses
- Proficiency in SAS programming is required, and detailed knowledge of SAS procedures and other statistical software
- Working knowledge of regulatory guidelines relating to statistical analysis, study reports and statistical components of regulatory submission