BIOF 084: Pharmacometric Dose-Response Analyses in Clinical Trials using R

In order for a drug to get approved by the FDA for market in the USA, the sponsor must ultimately demonstrate the drug has: 1) a predictable exposure profile with dose; 2) a good safety profile; and 3) is effective at safe doses. Therefore, the pharmacology of a drug is essentially being reviewed by the FDA. The ability of scientists to analyze drug exposure/response relationships is crucial to understanding what exposure amount will elicit the safest, most effective response, and ultimately what dose amount and frequency will produce the optimal exposure amount. Additionally, the ability to identify sub-populations that may produce differing exposure or response levels is key to providing as many subjects as possible a safe and effective dose. This quantitative exposure/response analyses, often referred to pharmacometrics, is key to making go/no go decisions both during clinical trials by investigators and by the FDA during the subsequent review period. Participants will learn basic pharmacology theory with introductory statistics using a popular open-source software program (R Studio) that is capable of conducting pharmacokinetic (PK) exposure and pharmacodynamic (PD) response analyses from example clinical trial data. Ultimately, the framework of analyzing exposure/response relationships will be demonstrated in order to make go/no go decisions. This course is designed for researchers and clinicians interested in learning how to utilize freely available software to explore, visualize, and understand drug exposure/response relationships where responses include any clinical endpoint collected on a trial, or for researchers and clinicians interested in understanding and predicting the effect of different doses on drug exposure as well as the effect of exposure on a variety of clinically relevant response endpoints (biomarkers), or for medical, pharmacy, dental, nursing, and lab-based graduate-school students interesting in obtaining a deeper understanding of pharmacokinetics, exposure/response analyses, as well as a broad understanding of clinical drug development and the impact of pharmacometrics on decisions.

Credits: 4
Class Type: Workshop
Program: Bioinformatics and Data Science