

BIOMETRICS: PK MODELING & STATISTICAL PROGRAMMING

A Flexible Relationship – Decisive Results.



A mid-sized, global pharmaceutical company relies on Labcorp for ongoing pharmacokinetics (PK) modeling and statistical programming support on niche projects. The key objective is to consolidate datasets from global Phase I/II studies of varying complexity. These studies have been conducted by a combination of teams (client, Labcorp or other research organizations) for population PK modeling to support client decision-making regarding drug development.

Understanding the Challenge

- Providing population PK analysis using consolidated data from various Phase I/II studies
- Meeting client requirements for short turnaround times while maintaining high quality of work
- Working closely with the client while functioning as their biometrics department

An Agile and Reliable Relationship Allows Decisive Results

This alliance is founded on the long-term strategic relationship that has been fostered with this client, and the reputation we've built for providing consistently high quality and on-time deliverables, as well as the responsive and comprehensive service we give. The client has confidence in the work Labcorp does and relies on our knowledge and expertise to function as their biometrics group.

In collaboration, and using subject matter experts from appropriate teams, we define the requirements and specifications for data to be consolidated across the Phase I/II studies already conducted. Often complex, these studies will have varying designs and format, and use various versions of industry guidelines. The major challenge for our programming team is to consolidate and merge all the studies together ensuring consistency in formatting and creating one comprehensible, statistically valid output.

Labcorp has a team of approximately 70 programmers, with a vast amount of experience spanning 25 years in biometrics. Our expertise and in-depth knowledge of the client's requirements and needs ensure our ability to provide rapid solutions, quick response and accurate analysis. Biometrics is the mechanism for decision-making across the client's complex, global Phase I/II studies.

The team collects all client requirements and specifications, reviewing all studies involved, as part of the information gathering process. Our programmers then organize the data using a NONMEM® modeling data structure required for our population PK analysis package.

The Labcorp Approach

With our experience and size, we offer enormous flexibility, looking to meet or exceed customer needs at all times. We are vastly skilled in working to strict timelines and adaptable enough to hit last-minute deadlines. Following standard operating procedures and industry guidelines, the team reviews the data for quality and integrity. The client then evaluates all data, requesting any required modifications before final delivery. Positive feedback shows that this ongoing working relationship empowers client decision making by allowing accurate, insightful analysis of combined, global study results.

NONMEM is a registered trademark of the Regents of the University of California.

Learn more at drugdevelopment.labcorp.com

