Clinical Pharmacology, Pharmacokinetics, Pharmacodynamics, and Modeling

CLINICAL PHARMACOLOGY, PHARMACOKINETICS, PHARMACODYNAMICS, and MODELING go hand in glove and are core services offered by B2S Consulting. The successful development and commercialization of today’s biotechnology and conventional drugs requires the careful execution and analysis of a series of Clinical Pharmacology studies conducted in Phase 1 to Phase 4. Data from such investigations take a prominent place in product labeling, provide an underpinning for the mechanism of action, define exposure-response relationships, and establish dosing requirements in different populations. Clinical Pharmacology studies often include a critical focus on bioavailability, bioequivalence, biopharmaceutics, drug distribution, metabolism, elimination, clearance, dose proportionality, pharmacogenomics, pharmacodynamics, drug-interactions, or organ (e.g. cardiovascular) safety. Typical they are performed in healthy adults, elderly, pediatric patients, or special populations having various physiological or disease-specific impairments. At the heart of Clinical Pharmacology studies are robust bioanalytical measurements of the drug substance in human tissues and the application of state-of-the-art pharmacokinetic or pharmacodynamic analyses using specific models to assess and summarize the important findings. Pharmacokinetic and pharmacodynamics analyses are essential to define dose-exposure-response-time relationships and these are core services offered by B2S Consulting. Our consultants have years of experience and can help develop successful strategies for implementing these procedures in Clinical Pharmacology studies. We use validated Phoenix® WinNonlin®, SAS®, SigmaPlot®, JMP®, R and other software; provide a full complement of bioanalytical, toxicology, clinical pharmacology, metabolism, pharmacokinetic, and statistical support; and report the data, methodological details, and results of our analyses in ready-to-file regulatory quality reports.

B2S Consulting Clinical Pharmacology, Pharmacokinetics, and Modeling Services include:

✓ Designing Clinical Pharmacology Studies to Support Development and Commercialization
✓ Assessing Requirements for Sampling and the Number of Subjects
✓ Planning PK/PD Analyses and Outlining the Scope of PK/PD Assessments for Specific Studies
✓ Evaluating PK/PD Data Using Non-Compartmental Models
✓ Modeling Concentration-Time-Response Relationships Using Compartmental and Effect Models
✓ Interpreting PK/PD Results and Providing Strategic Decision Support for Projects
✓ Reporting PK/PD Results in QA/QC’ed Reports
✓ Assisting Clients with PK/PD Regulatory Interactions and Engagement

Contact B2S with your Clinical Pharmacology plans or questions to get a quote or proposal and let B2S provide an answer your Clinical Pharmacology resource needs

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