

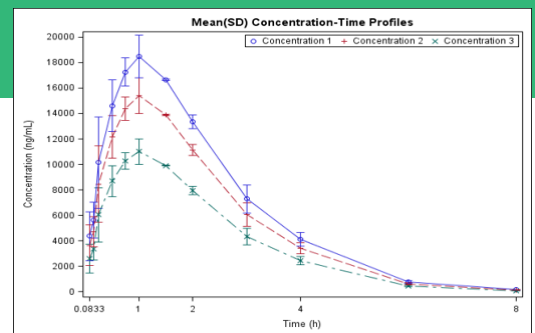
The Right Fit For You.®



SDC has substantial experience conducting Pharmacokinetic (PK) data analysis for clinical trials. From our validated industry-standard Phoenix™ WinNonlin® software to our specialized statistical expertise, SDC is The Right Fit For You.

Study Types

- › Single and Multiple Ascending Dose (SAD/MAD) studies
- › Patient Populations and healthy normal volunteers
- › Bioequivalence, Bioavailability, and Drug-Drug Interaction (DDI) studies
- › Multiple Therapeutic Areas including gastroenterology, infectious disease, neurology, oncology, ophthalmology, etc.



PK Analysis Services

- › PK Strategy Development including study design support and sample size and power calculations
- › Phoenix™ WinNonlin® industry-standard analysis software
- › Non-Compartmental Estimation and compartmental analysis and simulations
- › Dose Proportionality and Multiple Dose Linearity for ascending and repeated dose trials
- › Standard Handling of BLQ with sensitivity analyses for washout period
- › Pharmacodynamic and PK/PD modeling

9 out of 10 Average Customer Satisfaction Score

98% On-time Delivery of Key Project Milestones

Top-Line Analysis 1 Week After Database Lock

The Right Fit For You.®



SDC is a specialized data services CRO providing scalable full service clinical trial solutions via our diverse and complementary strategic partnerships. From protocol consulting to full service clinical trial management and everything in between, SDC is The Right Fit For You.



Clinical Program Design/Development
Regulatory/Submission Guidance
Simulation & Modeling



Biostatistics
Data Management & EDC
IRT/IWRS
DMC/DSMB



Full Service CRO Solutions
Specialty Services
Transition/Rescue Strategy

Mini Case Study

› Phase 1 Single Center study with tight PK timeline requirements

Item	Duration*	Timeline
Protocol Development and Finalization	4 Weeks	
EDC Database Development	4 Weeks	
FPFV - LPLV	3 Weeks	
LPLV - Database Lock	1 Week	
Database Lock - Top-Line Analysis	1 Week	
Top-Line Analysis - Final Analysis	2 Weeks	
CSR Development and Finalization	6 Weeks	
		19 Weeks

*Business Days