

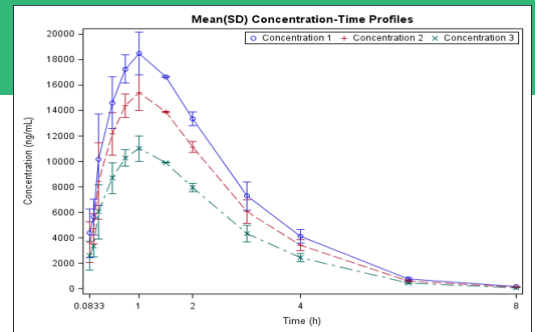
The Right Fit For You.®



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

CDISC-compliant Top-line Analysis 1 Week After DBL

## 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**



**Clinical Operations**  
**Medical Writing**  
**Specialty Core Lab**

### 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	
		<b>19 Weeks</b>

\*Business Days