

STRATEGIC SCIENTIFIC CONSULTING



The Right Fit For You.®



Our strategic scientific consultants will guide you through the process of developing the most efficient and effective clinical program. From product portfolio planning to clinical trial design to regulatory meeting support, SDC is The Right Fit For You.



Strategic Scientific Consulting Services

- › Clinical Program Development
- › Protocol Development
 - › Clinical Trial Design
 - › Interim Analysis Planning
 - › Sample Size Calculation
- › Endpoint and Analysis Methodology Development
- › Product Acquisition Due Diligence
- › DMC Planning and Participation
- › Investor, KOL, and Board Meeting Support
- › RBM Modeling Development
- › Ad-Hoc Statistical Analyses
- › Manuscript Development

Regulatory Meeting Representation and Support

- › Pre-IND/IDE and International Equivalents
- › End of Phase 2
- › Pre-Submission: e.g. NDA/MAA/BLA/PMA/510(k)
- › Advisory Committee Meetings
- › Special Protocol Assessment

9 out of 10 Average Customer Satisfaction Score

30+ Product Approvals Supported by Team Members

Monthly Interaction with Regulatory Agencies

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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

› Over 200 Tables Delivered for pooled ISS/ISE analysis across 7 clinical trials

For Each of 7 Studies	For ISS/ISE Analysis
SDTM Datasets	ISS Tables
SDTM aCRF	ISE Tables
SDTM Define.xml (Including Reviewer's Guide)	ADaM Datasets
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