

## The Right Fit For You.®



Integrated Summaries of Safety and Efficacy (ISS/ISE) are an integral part of the submission process for approval. With in-depth experience providing statistical services for ISS/ISE projects across multiple therapeutic areas, SDC is The Right Fit For You.



### Integration Benefits

- › Summarize Data across all clinical trials for your product
- › Identify Broader Correlations and trends across overall population
- › Detect Potential Safety Trends that may not arise from a single study
- › Perform Subgroup Analysis for pediatrics and demographic subcategories

### ISS/ISE Services

- › Statistical Analysis Plan, TLF Programming, and Independent Validation for ISS/ISE analysis
- › Analysis Dataset Creation & Programming for ISS/ISE and legacy data conversion
- › Legacy Data Conversion (SDTM, ADaM, Define.xml) for non-CDISC compliant clinical trial data
- › Definition Documentation Creation for ISS/ISE and all integrated data
- › Final Integration Report review and statistical input
- › Medical Coding for consistency of dictionary versions, if needed
- › Submission Experience to FDA, EMA, PMDA, CFDA, and other international regulatory authorities

9 out of 10 Average Customer Satisfaction Score

98% On-time Delivery of Key Project Milestones

15+ Submission Integrations to Global Regulatory Authorities

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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



Full Service CRO Solutions  
Specialty Services  
Transition/Rescue Strategy

### 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
ADaM Datasets	ADaM Define.xml (Including Reviewer's Guide)
ADaM Define.xml (Including Reviewer's Guide)	