

## 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



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