

CDISC & SUBMISSION-READY DATA SERVICES



The Right Fit For You.®



SDC is a CDISC Registered Solutions Provider for ADaM, CDASH, Controlled Terminology, Define-XML, SDTM, and Study/Trial Design Model standards. SDC's extensive CDISC and submission-ready data experience is The Right Fit For You.



Submission Experience

- › 30+ Product Approvals supported by current SDC team
- › Study-Specific CDASH Forms developed across multiple therapeutic areas
- › Expert Client Representation at regulatory agency meetings to support your submission data
- › CDISC Training completed by SDC project leads and supporting team members

CDISC & Submission-Ready Data Process



Collect data in CDASH-compliant eCRFs using CDSIC Controlled Terminology

Create SDTM and ADaM datasets in parallel with TLFs during study conduct

Validate SDTM and ADaM Datasets using Pinnacle 21 and create Define.xml/.pdf

Convert Legacy Data (if needed) into SDTM and ADaM format for submission package

9 out of 10 Average Customer Satisfaction Score

98% On-time Delivery of Key Project Milestones

CDISC Gold Member and Registered Solutions Provider

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

› Two Pivotal Rescue Trials running in parallel

Study #1		
Item	Duration*	Timeline
eCRF Design, Development, and Approval	26 Days	
DMP Development and Approval	12 Days	
DVM Development and Approval	17 Days	
Release of EDC/IWRS into Production	39 Days	
Study #2		
Item	Duration*	Timeline
eCRF Design, Development, and Approval	26 Days	
DMP Development and Approval	12 Days	
DVM Development and Approval	17 Days	
Release of EDC into Production	39 Days	
Total	44 Days	9 Weeks Total

*Business Days