

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



Clinical Operations
Medical Writing
Specialty Core Lab

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