CDISC References

Most Current Versions as of November 2014

Operational Data Model (ODM) 1.0	XML specification supporting interchange of data, metadata or updates of both between clinical systems
Clinical Data Acquisition Standards Harmonization (CDASH) 1.0	Data model for a core set of global data collection fields (element name, definition, metadata)
Study Data Tabulation Model (SDTM) version 3.1.3, IG 3.1.2 **Validation Checks 3.1**	Data model supporting the submission of data to the FDA including standard domains, variables, and rules
Analysis Dataset Models (ADaM) version 2.1, IG 1.0 **Validation Checks 1.2**	Data model closely related to SDTM to support the statistical reviewer by providing data and metadata that is analysis ready
Define.xml 2.0 **Based on ODM 1.3.2, SDTM IG 3.1.2, ADaM 1.0, SEND 3.0**	XML Specification to contain the metadata associated with a clinical study for submission
Standards for the Exchange of Non-clinical Data (SEND)	Data model extending SDTM to support the submission of animal toxicity studies
Protocol Representation Model (PRM)	Metadata model focused on the characteristics of a study and the definition and association of activities within the protocols, including "arms" and "epochs"
Control Terminology **SDTM - June 2013** **ADaM – Sep 2014**	Standard list of terms across all the CDISC data models
OpenCDISC 1.5, June 2013, FDA uses 1.2	Tool for ensuring clinical data compliance with CDISC standards, including SDTM, ADaM, SEND, Define.xml, and others.
PROC CDISC SAS 9.2, 9.3	Tool to validate 3.1 SDTMs, Read and create ODM-XML files
SAS Clinical Standard Toolkit 1.6	Tool for ensuring clinical data compliance with CDISC standards, including SDTM, ADaM, Define.xml, and others.
Study Data Standardization Plan	Define standard metadata models to describe usage, structure, content & attributes of case report tabulations, and analysis datasets submitted to the FDA.
Study Data Specifications (eCTD) 1.5.1	Directory structure of SDTMs, ADaMs, DEFINE.PDF/.XML, etc.
Study Data Reviewer's Guide Version 1.1, 2015-03-07	Used as FDA Reviewer's single point of orientation to the SDTM datasets.
Analysis Data Reviewer's Guide Version	Used as FDA Reviewer's single point of orientation to the ADaM datasets.
Validation and Data Interpretation Report	Document that explains details of any known issues with the data from the process of converting legacy data to CDISC SDTM.

Submission Specifications Review and QC Specifications

Setup ODM, CDASH, SEND, PRM, eCommon Technical Document	**Study Setup and Review Guide Deliverables** Study Data Standardization Plan Study Data Reviewer's Guide Analysis Data Reviewer's Guide
Deliverables SDTMs, ADaMs Specifications	**Data Deliverables** SDTM and ADaM Validation checks

SDTM Domains

Special Purpose	DM, CO, SE, SV
Interventions	CM, EX, SU
Events	AE, MH, CE, DS, DV
Findings	LB, EG, QS, VS, MB, IE, PE, SC, DA, MS, PC, PP
Findings About	FA
Trial Design	TA, TE, TV, TI
Special Relationship	SUPPDM, RELREC

ADaMs

Subject Level **One record per subject**	ADSL
Basic Data Structure (BDS) **One record per subject, per analysis parameter, per time point**	ADLB, ADVS, ADEFF, ADTTE
Other - Events **One record per subject, per time point, per event**	ADAE, ADCM

Getting Started with CDISC

SASSavvy.com CDISC MindMaps	SASSavvy.com Clinical Study Process Flow MindMap
Introduction to CDISC Standards	CDISC: Why SAS Programmers Need to Know
Case Report Form Annotated with SDTM variables	How to annotate CRF with SDTM variables
Toward a Comprehensive CDISC Submission Data Standard	Practical Methods for Creating CDISC SDTM Domain Data Sets from Existing Data
Using PROC CDISC	XML for SAS Programmers
From ODM to SDTM: An End-to-End Approach Applied to Phase I Clinical Trials	Deep Dive into ODM Validation

Study Data Tabulation Model (SDTMs)

SDTM Excel file specifications	SDTM Questionnaire Domains
SDTM Reference Manual 1.2	SDTM Implementation Guide 3.1.2
SDTM Validation Checks 3.1	

Analysis Data Model (ADaMs)

ADSL Guide 0.2	ADAE Guide 1.0
ADAM Common Statistical Analysis Methods	ADAM Validation Checks 1.2
ADAM Reference Manual 2.1	ADAM Implementation Guide 1.0

Control Terminology and Metadata

National Cancer Institute	Download Control Terminology files
SDTM Control Terminology Listing	Metadata Submissions Guidelines 1.0 (DEFINE.XML, Guidelines for Annotating CRFs)

CDISC.ORG References

CDISC.ORG	CDISC DEFINE.XML, Example, StyleSheet
CDISC SDTM	CDISC FAQ
CDISC ADAM	CDISC Devices Implementation Guide 1.0
CDISC Devices	CDISC ODM 1.3.2, Online Reference
CDISC Portals	CDISC CDASH 1.1
Case Report Tabulation Data Definition Specification (define.xml)	XML Schema Validation for Define.xml

FDA References

FDA 21CRFPart11	FDA.ORG
FDA Data Exchange Standards Catalog	FDA Medical Devices
FDA Study Data Specifications	FDA Study Data Standards Resources
FDA Technical Conformance Guide	FDA Electronic Format Standardized Study Data
FDA Study Data Submissions to CBER	FDA Guidance Documents
FDA Electronic Common Technical Document (eCTD)	FDA's Drug Review Process
CDER Common Data Standards Issues Document	

SAS Institute References

SAS ADAM	SAS Clinical Standards Toolkit
SAS Clinical Standards Toolkit Value-Level Metadata	9.2 PROC CDISC User Guide, 9.3 PROC CDISC User Guide
9.2 LIBNAME to access/convert to/from ODM XML/SAS Datasets	PROC CDISC to access/convert to/from ODM XML/SAS Datasets, Example ODM XML file
PROC CDISC qc of SDTMs	

Other References

BRDGE Model	Open CDISC Tool
Medra 16.1	International Conference on Harmonization
PHUSE Wiki – SDTM Validation Rules	CDISC Wiki
PHUSE Wiki – Analysis Study Data Reviewer's Guide	PHUSE Wiki – Study Data Reviewer's Guide