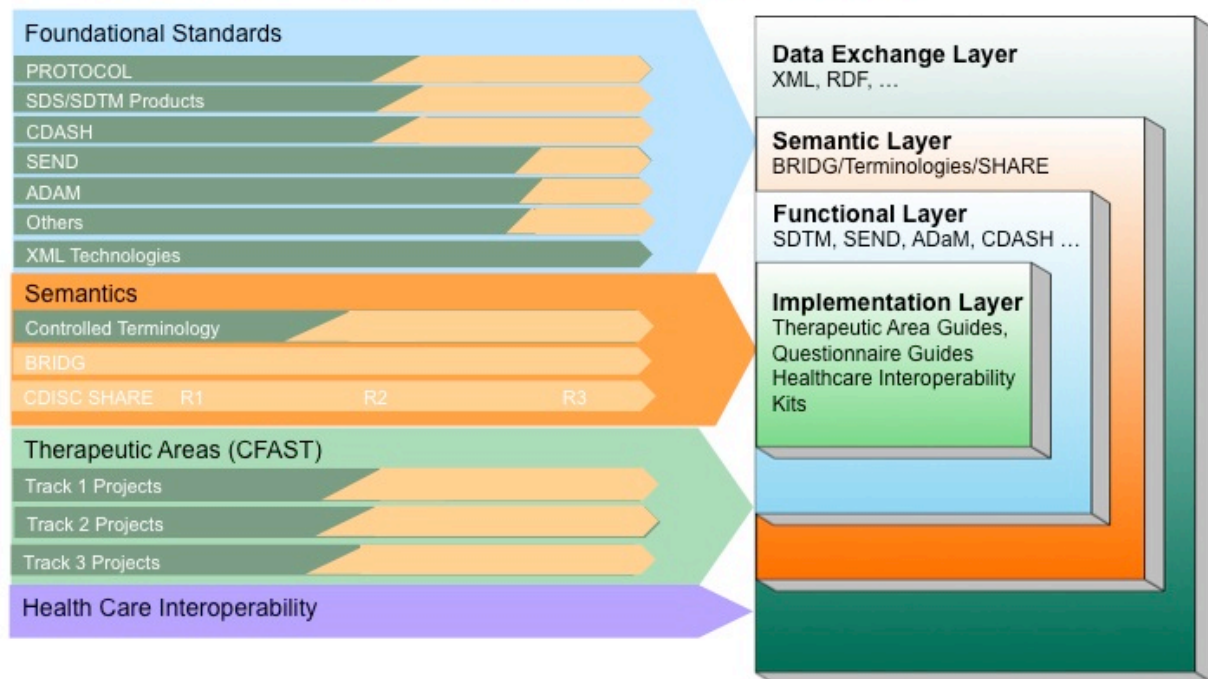


2015 CDISC Technical Plan

The 2015 CDISC Technical Plan summarizes foundational and semantic standard projects in the pipeline for calendar year 2015. In addition to the projects listed on this page, CDISC standard-related activities also include:

- CFAST Therapeutic Area projects, which are listed separately on the CFAST webpage at www.cdisc.org/therapeutic
- SHARE development, details of which are described on the SHARE Wiki Page at <http://wiki.cdisc.org/display/SHARE/SHARE+Release+3>
- Healthcare link activities, which are described on the CDISC webpage at <http://www.cdisc.org/healthcare-link>
- Information on other projects which are being independently conducted outside of CDISC using aspects of the CDISC process may be found under specialty areas at <http://www.cdisc.org/standards-and-implementations/specialty>.

The Technical Plan follows the CDISC Technical Roadmap.



Definitions related to the roadmap can be found on the CDISC Wiki at <http://wiki.cdisc.org/display/TLC/Fundamental+Definitions>. The Roadmap, which was initially designed and presented in 2012, represents current CDISC projects across four fundamental programs:

- Foundational standards, which include the core CDISC structures developed to address various aspects of the research process
- Semantics, which describe model concepts and controlled terms to be used to populate data files built on CDISC standards
- Therapeutic Area projects, which combine foundational and semantic standards in user guides to address the requirements of planning, conducting and analyzing studies in specific therapeutic areas

- Healthcare Link Standards, which describe a set of tools (including IHE profiles) to improve interoperability between the healthcare ecosystem and the world of protocol-driven clinical research.

Within each program are listed individual teams or workstreams. The change in color for a workstream from green to orange depicts a general transition from developing standards using traditional document/spreadsheet-based processes to development within CDISC SHARE.

The Roadmap describes a structured transition from a history of working on individual standards toward a layered, integrated vision that separates content from exchange format, and combines foundational standards and semantics to address end-to-end integration to address specific use cases using an architecture informed by the BRIDG model and based on the SHARE Metadata Repository. The standards vision expressed by the Roadmap is based on using SHARE to develop, align, integrate and distribute all CDISC standards as electronic metadata that can drive end-to-end automation of clinical study conduct and analysis.

The table below lists major foundational and semantic projects planned or already underway for 2015. Beginning in 2015, all major releases are required to publish requirements in advance, represented by the "Reqs. Date" column.

Team	Project	Description	Reqs Date	State	Target Date
Foundational Content Standards					
PRG	Protocol Concepts	Protocol Concepts V1.0 spreadsheet release for review and collaboration with TransCelerate Common Protocol Template project (concept mapping to Template)		Draft	Q2
CDASH	CDASHIG v2	CDASH Model, new domains (PR, HO, SR, DD, MI, MO, RP, PC, PP, FA, QS) to correspond to newer SDTMIG v3.2 domains.	2014	Draft	Q4
SDTM	SDTM v1.5	New variables, domain-specific variable class, disease milestones, new special purpose domains to support SEND, PGx, Devices, Human Clinical Trials.	2013	Draft	Q2
SDS	SDTMIG v3.3	<ul style="list-style-type: none"> New Intervention domains: Procedure Agents (AG) and Meal (ML) New Physiology Findings domains: Respiratory (RE), Nervous System (NV), Ophthalmology (OE), Urinary (UR), Cardiovascular (CV) Broadening TU, TR, and RS domains to handle non-tumor lesions Use of "Non-Standard Variables" in parent domains rather than as supplemental qualifiers Disease Milestones 	2013	Final	Q3
SDS	SDTMIG v3.4 Batch 1	New Domains and modeling concepts TBD	Q4	Draft	Q4/Q1 2015
SEND	SENDIG v3.1	New Cardiovascular and Respiratory domains, new variables for MI and EG, changes to VS, corrections	2012	Final	Q2

Team	Project	Description	Reqs Date	State	Target Date
SEND	SEND-DART v1	New IG for Developmental and Reproductive Toxicology	2012	Draft	Q2
ADaM	AResM v1	Analysis Results Metadata Specification for Define-XML Version 2	2013	Final	Q1
ADaM	OCCDS v1	General Occurrence Data Structure	2012	Final	Q1
ADaM	ADaMIG v1.1	General updates to Implementation Guide	2013	Final	Q2
ADaM	ADaMIG v1.2	Add new variables to ADaMIG v1.1	2015	Draft	Q2
ADaM	ADaMIG v2.0	Align ADaM Model v2.1 with ADaMIG v1.2 and Define v2.0 and incorporate ADaM appendices into a portfolio	Q3	Draft	Q4
ADaM	IDS v1	ADaM Data Structure for Integration: ADSL	2012	Draft	Q2
ADaM	IDS v2	ADaM Data Structure for Integration: OCCDS		Draft	Q3
Foundational Exchange Standards					
XML Tech	CTReg v1	New ODM-based XML Schema to support study registration - Clinical Trial Registration and Results	2014	Draft	Q2
XML Tech	Define-UG	New Implementation Guide (User Guide) for Define-XML v2	2014	Draft	Q2
XML Tech	Define v2.1	Update of Define-XML schema	201502	Draft	Q3
XML Tech	Protocol-XML	ODM Extension to support additional protocol content and SDM-XML updates - Protocol-XML	Q3	Draft	Q4
XML Tech	RDF	PhUSE RDF User Guide for CDISC Standards	2014	Final	Q2
Specialty Areas					
PGx	PGx-IG v1	Initial Release of SDTMIG for Pharmacogenomics/Genetics Data	2010	Prov	Q2
Devices	SDTMIG-MD v2	Connecting device components; CDASH models	2012	Draft	Q3
COA	COA Supplements	New Monthly Clinical Outcome Assessments (QS/FT domains) and Clinical Classifications (CC domain) Supplements		Final	Q2
Semantics					
Terminology	Package 21	P21 public review completed 23Jan2015, publication scheduled for 27Mar2015, Terminology updates are scheduled for Device, ECG, General, Lab, Oncology, PK, QS, SEND, Spectype/Speccond, Unit and Virology codelists	Qrtly	Draft	Q1
Terminology	Package 22	P22 terminology public review starts 20Mar2015, publication 26Jun2015		Draft	Q2
Terminology	Package 23	P23 terminology public review starts 19Jun2015, publication 25Sep2015		Draft	Q3
Terminology	Package 24	P24 terminology public review starts 11Sep2015, publication 18Dec2015		Draft	Q4
BRIDG	BRIDG 4.0	External Project to expand BRIDG to include NCI LS-DAM and map to SDTMIG v3.1.3	2012	Draft	Q2
SHARE					

Team	Project	Description	Reqs Date	State	Target Date
SHARE	R3	Incremental (monthly) sprint releases of new content and functionality – see eSHARE catalog and SHARE Wiki for current status.	201412	Draft/ Final	Monthly Release
Healthcare Link					
HcL	ACC ICD Registry	The American College of Cardiology has contracted with CDISC to EHR-enable the population of Implantable Cardioverter Device (ICD) Registry forms using the Retrieve Form for Data Capture (RFD) approach. The project will be implemented at two sites, with process documentation before and after the implementation to demonstrate the benefits of EHR-enablement.	2014	Draft	Q4

The Technical Plan will be reviewed quarterly and updated as necessary. The most current version of the plan can be found at <http://cdisc.org/technical-plan>.