

CDISC Library

CDISC / Microsoft Workshop

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10 Sept 2020



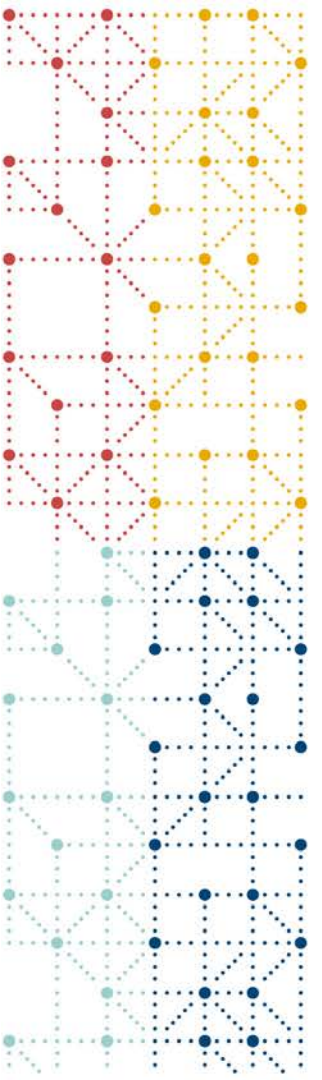


CDISC Library

1. CDISC Library on Azure
2. CDISC 360 Implementation
3. Access and Membership Levels
4. New Environments
5. Private CDISC Library Instances
6. Development Approach

Basic Premise: Solutions Over Specifications

- Standards implementers are interested in solutions to their data processing needs
 - Reduce reliance on experts that have mastered very long and detailed specifications
 - This includes standards development and management
- Embedding knowledge of standards in software tools is the best way to make CDISC standards implementations easier and more consistent
 - Maximize the value members get from their investment in standards
 - Maximize the benefits to members from our investment in CDISC Library
- CDISC 360 and CDISC Library seek to lower barriers to software tool development
 - Make it simpler to build software that automates standards-based processes



1. CDISC Library on Azure

CDISC Library is moving to Azure

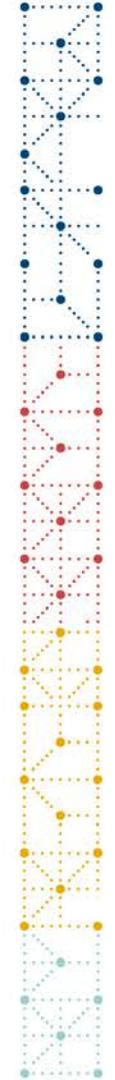
CDISC Library on Azure

- Moving to a new version of CDISC Library hosted on Azure
 - Developed in partnership with Microsoft
 - Maintains the same CDISC Library API and an improved Data Standards Browser
- CDISC has the flexibility to update the code, models, and environment
 - Removes technical and business constraints on how, what, and when we update the system
- Basis for a new platform
 - Authoring standards
 - CDISC 360 support
 - Collaborative curation

The screenshot displays the CDISC Data Standards Browser interface. The main content area shows details for the 'SDTMIG v3.3' domain. It includes a navigation sidebar on the left with categories like 'Data Collection', 'Data Tabulation', and 'Data Analysis'. The main view shows the domain's status (Final), effective date (2018-11-20), and implemented version (SDTM v1.7). Below this, there are tabs for 'Classes' (General Observations, Special Purpose, Interventions, Events, Findings, Findings About, Trial Design, Relationship, Study Reference) and 'Data Sets' (CO, DM, SE, SM, SV). The 'Special Purpose' tab is active, showing the domain name 'SDTMIG v3.3', its structure 'Demographics', and a description: 'A special-purpose domain that includes a set of essential standard variables that describe each subject in a clinical study. It is the parent domain for all other observations for human clinical subjects. (Source: CDISC Controlled Terminology, DOMAIN, C49572, 2018-06-29)'. At the bottom, a table lists the domain's variables.


Ordinal	Name	Label	Description	Data Type	Role	Core	Code List	Described Value Domain	Implements
001	STUDYID	Study Identifier	Unique identifier for a study	Char	Identifier	Req			STUDYID
002	DOMAIN	Domain Abbreviation	Two-character abbreviation for the domain	Char	Identifier	Req			DOMAIN
003	USUBJID	Unique Subject Identifier	Identifier used to uniquely identify a subject	Char	Identifier	Req			USUBJID

CDISC Library on Azure: API Remains Unchanged



GET	<code>/search</code>	Get Search Results Across CDISC Library	🔒
GET	<code>/search/scopes</code>	Get a list of Search Scopes	🔒
GET	<code>/search/scope/{scope}</code>	Get Search Results Limited to Scope	🔒
GET	<code>/mdr/products</code>	Get CDISC Library Product List	🔒
GET	<code>/mdr/products/{product-group}</code>	Get CDISC Library Product List by Product Group	🔒
GET	<code>/mdr/about</code>	Get Information About CDISC Library Product	🔒
GET	<code>/mdr/lastupdated</code>	Get CDISC Library Product Last Updated Dates	🔒
	Controlled Terminology (CT)		>
	Clinical Data Acquisition Standards Harmonization (CDASH)		>
	CDASH Implementation Guide (CDASHIG)		>
	Study Data Tabulation Model (SDTM)		>
	SDTM Implementation Guide (SDTMIG)		>
	SEND Implementation Guide (SENDIG)		>
	Analysis Data Model (ADaM)		>

CDISC Library on Azure: Improved Data Standards Browser



Data Standards Browser

Search Logout

- Dashboard
- Expand All
- Data Collection
- Data Tabulation
 - SDTM v1.8**
 - SDTM v1.7
 - SDTM v1.6
 - SDTM v1.5
 - SDTM v1.4
 - SDTM v1.3
 - SDTM v1.2
 - SDTMIG-MD v1.1
 - SDTMIG v3.3**
 - SDTMIG-PGx v1.0
 - SDTMIG-AP v1.0
 - SDTMIG v3.2
 - SDTMIG-MD v1.0
 - SDTMIG v3.1.3
 - SDTMIG v3.1.2
 - SENDIG-DART v1.1
 - SENDIG-AR v1.0
 - SENDIG v3.1
 - SENDIG v3.0
- Data Analysis
- Controlled Terminology

Special-Purpose **DM**

Name Demographics
Structure One record per subject

Description
A special-purpose domain that includes a set of essential standard variables that describe each subject in a clinical study. It is the parent domain for all other observation Terminology, DOMAIN, C49572, 2018-06-29)

Demographics

	Ordinal ↑	Name	Label	Description	Data Type	Role	Core	Code
<input type="checkbox"/>	1	STUDYID	Study Identifier	Unique identifier for a study.	Char	Identifier	Req	
<input type="checkbox"/>	2	DOMAIN	Domain Abbreviation	Two-character abbreviation for the domain.	Char	Identifier	Req	
<input type="checkbox"/>	3	USUBJID	Unique Subject Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product. This must be a unique number, and could be a compound identifier formed by concatenating STUDYID-SITEID-SUBJID.	Char	Identifier	Req	
<input type="checkbox"/>	4	SUBJID	Subject Identifier for the Study	Subject identifier, which must be unique within the study. Often the ID of the subject as recorded on a CRF.	Char	Topic	Req	
<input type="checkbox"/>	5	RFSTDTC	Subject Reference Start Date/Time	Reference Start Date/time for the subject in ISO 8601 character format. Usually equivalent to date/time when subject was first exposed to study treatment. See Assumption 9 for additional detail on when RFSTDTC may be null.	Char	Record Qualifier	Exp	

Details

Ordinal
1

Name
STUDYID

Label
Study Identifier

Description
Unique identifier for a study.

Data Type
Char

Role
Identifier

Core
Req

Code List
--

Described Value Domain
--

Implements
[STUDYID](#)

Data Standards Browser: Cognitive Search

✕ Close search results

Search Results

Narrow search results

21 results for "AETERM"

Scope
Product

Scope Value
Select

- CDASHIG v2.0
- CDASHIG v2.1
- SDTMIG v3.1.2
- SDTMIG v3.1.3
- SDTMIG v3.2
- SDTMIG v3.3
- CDASHIG v1.1
- ADaM ADAE v1.0

Reset

AETERM (Data Collection Field)

Clinical Data Acquisition Standards Harmonization Implementation Guide for Human Clinical Trials

AETERM (Data Collection Field)

Clinical Data Acquisition Standards Harmonization Implementation Guide for Human Clinical Trials

AETERM (Data Collection Field)

Clinical Data Acquisition Standards Harmonization (CDASH) User Guide V1.1

AETERM (SDTM Dataset Variable)

Study Data Tabulation Model Implementation Guide: Human Clinical Trials Version 3.1.2 (Final)

AETERM (SDTM Dataset Variable)

Study Data Tabulation Model Implementation Guide: Human Clinical Trials Version 3.2 (Final)

AETERM (Analysis Variable)

Analysis Data Model Data Structure for Adverse Event Analysis Version 1.0

AETERM (SDTM Dataset Variable)

Study Data Tabulation Model Implementation Guide: Human Clinical Trials Version 3.1.3 (Final)

Data Standards Browser: Room to Grow



Data Standards Browser

Search

Logout

Dashboard

Expand All

Data Collection

Data Tabulation

Data Analysis

Controlled Terminology

Dashboard



Welcome to the CDISC Library!

The single, trusted, authoritative source of CDISC standards metadata.

Helpful CDISC Library Resources

[API Documentation](#)

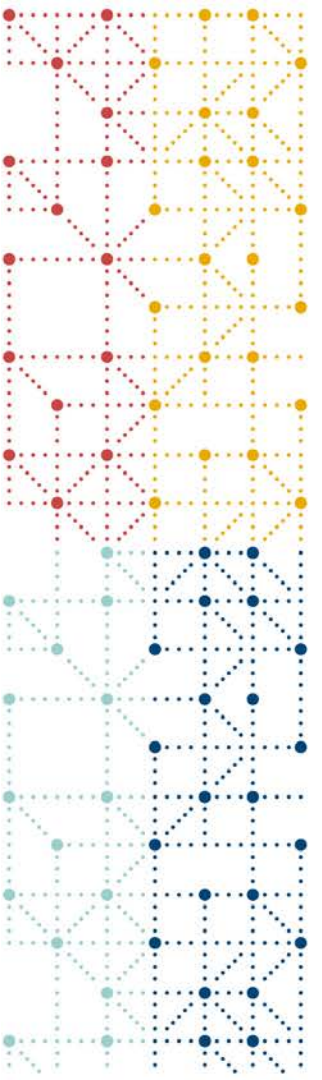
[CDISC Website Landing Page](#)

[Product Inquiry Form](#)

[Service Desk](#)

[Release Notes](#)

[How-to Articles](#)



2. CDISC 360 Implementation

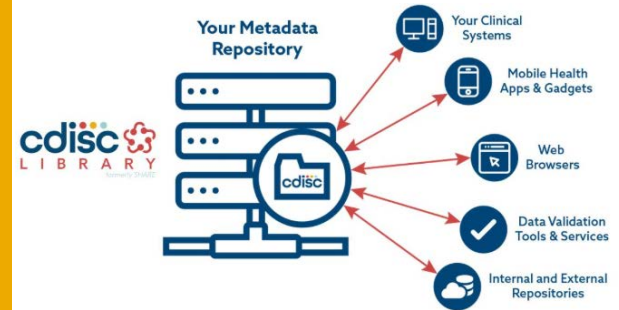
CDISC 360 and the CDISC Library

Goals:

- Increase study implementation automation
- Reduce study implementation variability

Building Tools using the CDISC Library

Use CDISC Library to create additional concept-based metadata to support software tools that will provide additional study implementation automation while reducing the variability across CDISC standards implementations



CDISC Library: Publishing CDISC 360 Pilot Metadata



Enhance Standards



Publish Standards in CDISC Library



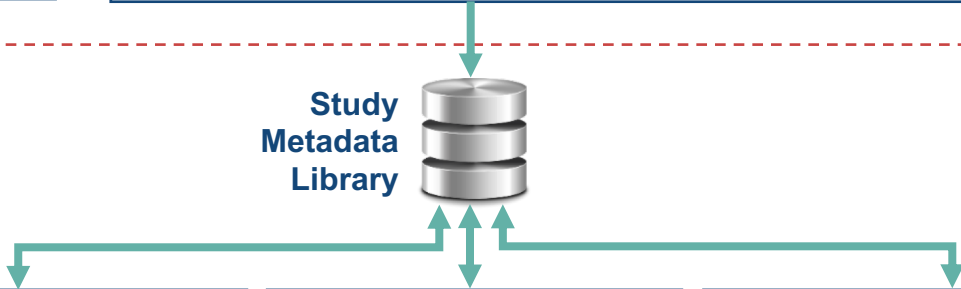
Study Metadata Library



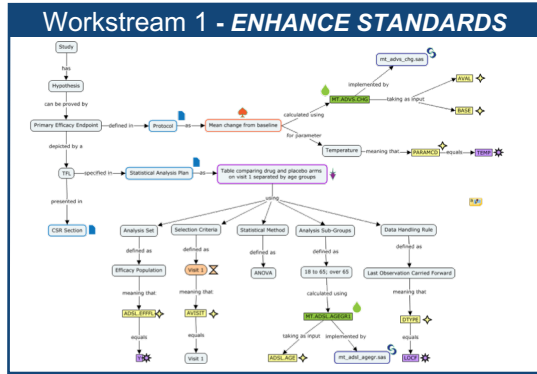
Define

Build

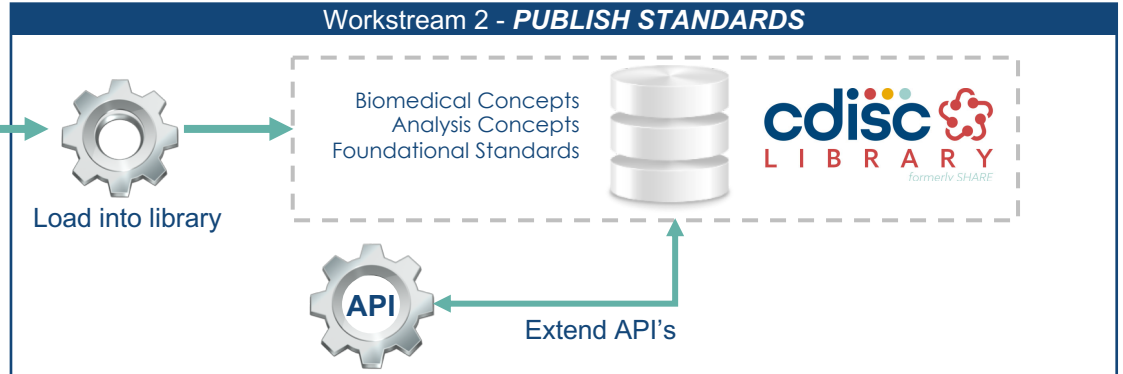
Execute



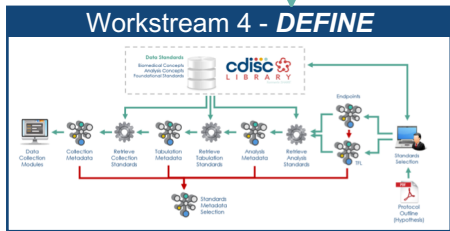
CDISC 360: Applications



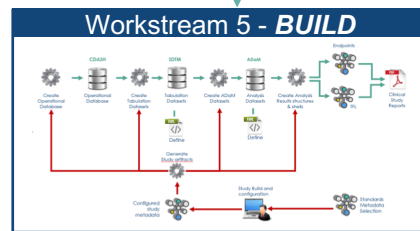
Biomedical, Analysis Concepts, & Templates



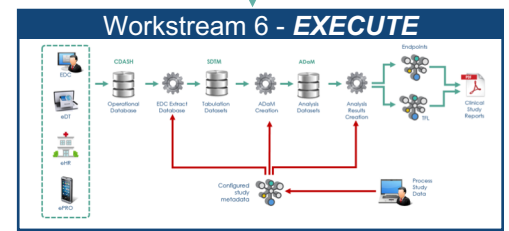
Transform concepts in machine readable form



Identify and select standards specification (Use Case 1)



Configure study specification and create artifacts (Use Case 2)



Automatically process and transform data (Use Case 3)

CDISC Library: Author, Publish, and Manage Standards



*Enhance
Standards in
CDISC Library*

*Publish
Standards in
CDISC Library*



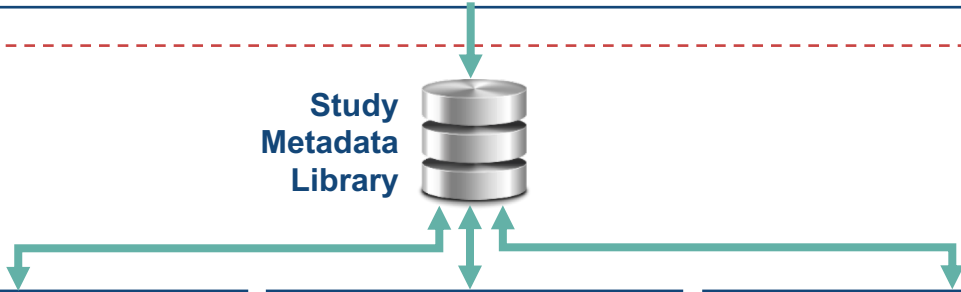
Study
Metadata
Library



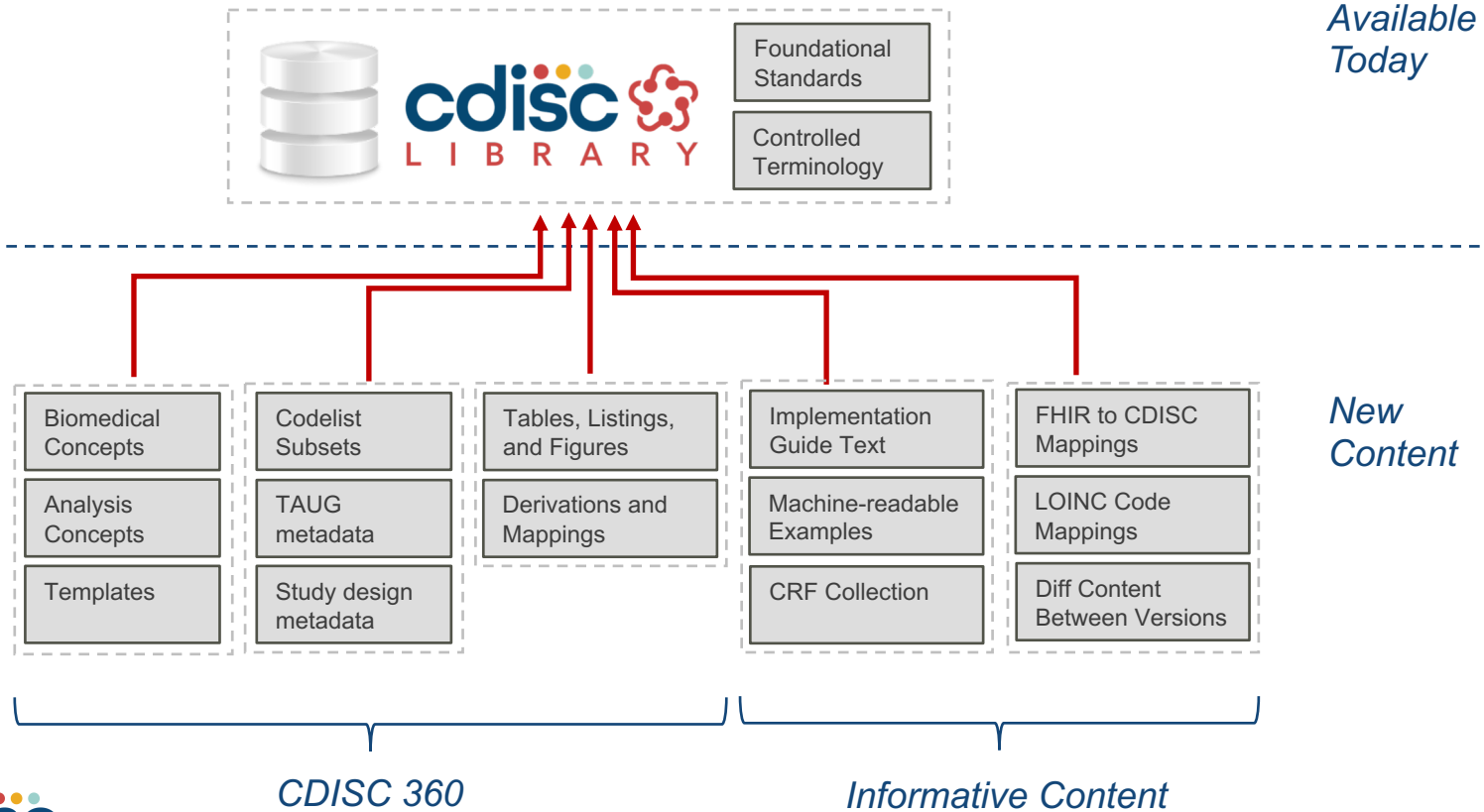
Define

Build

Execute



CDISC Library on Azure: New Content & Tools

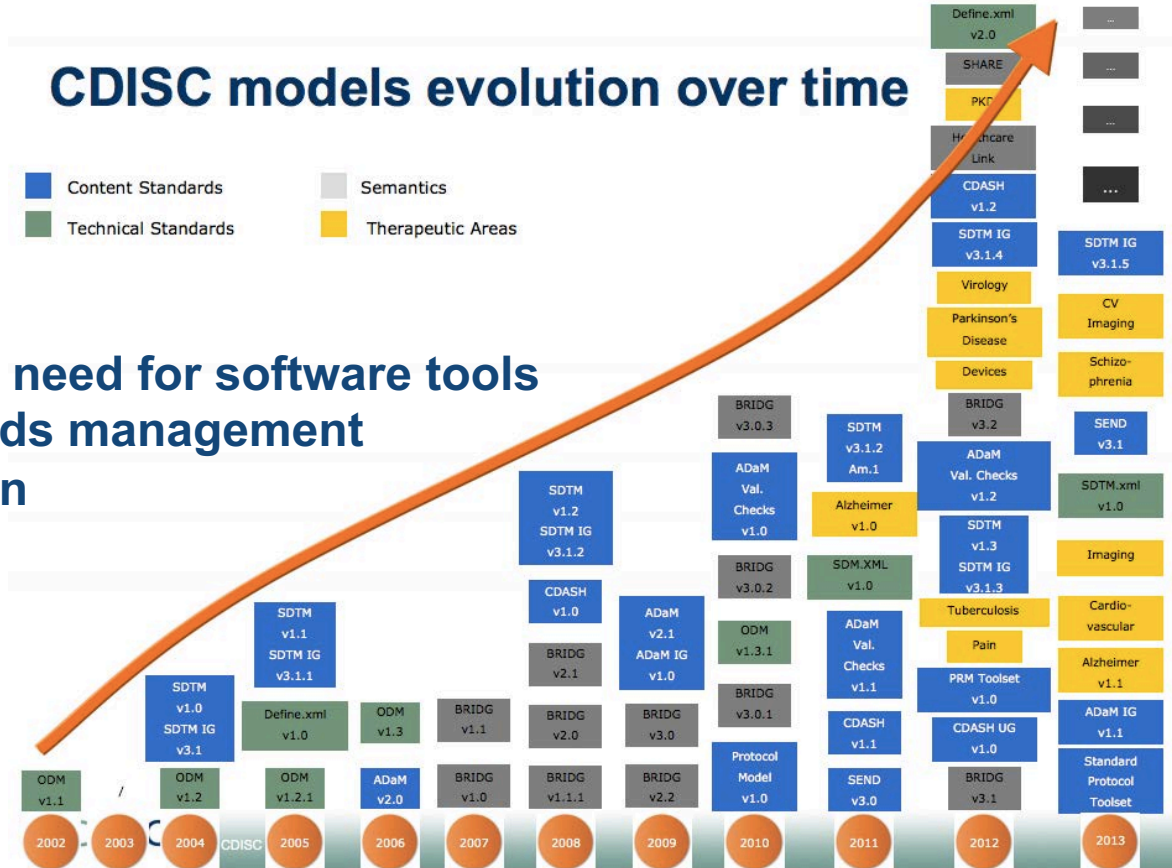


Standards Growth Projections Steepen...

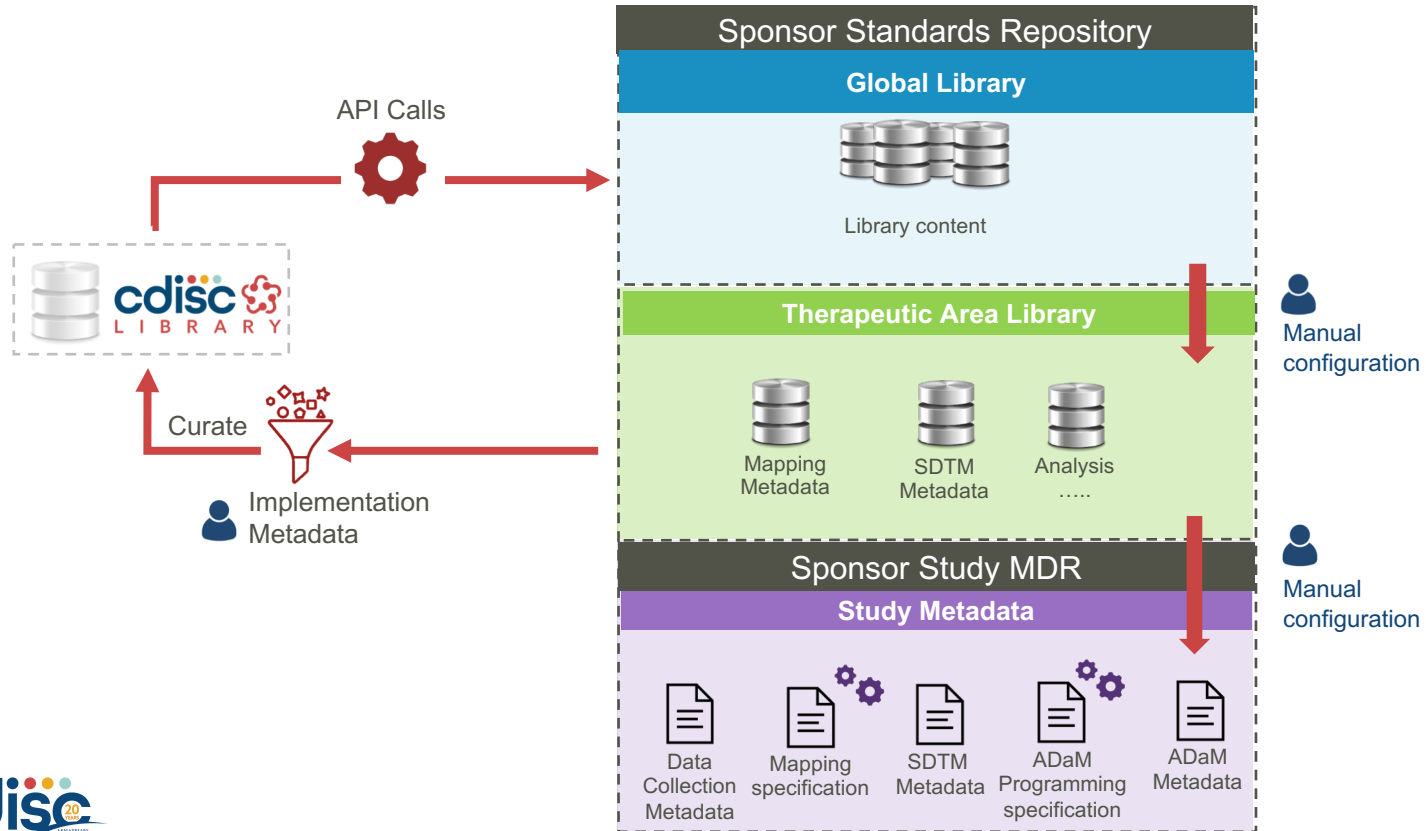
CDISC models evolution over time

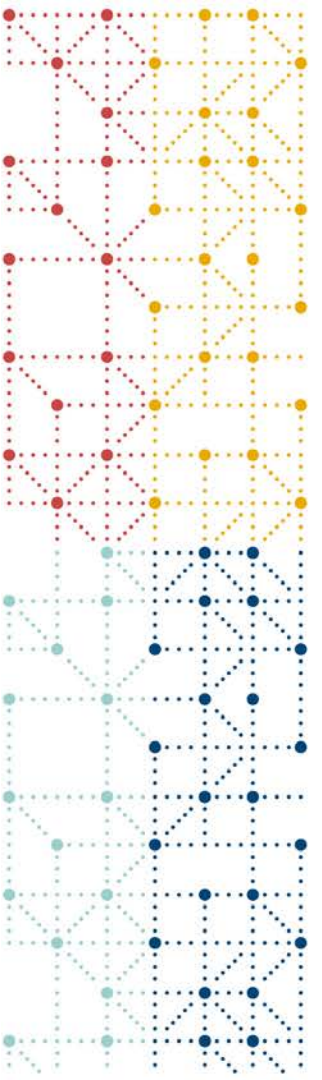


...emphasizing the need for software tools to support standards management and implementation



Collaborative Curation: Collaborative Standards Authoring and Governance





3. Access and Membership Levels

Titanium – New Membership Level

- **Federated Model**
- **Create a Library Advisory Board: Investors have a vote**
 - Functionality priority
 - User Requirements
- **Opens back-end access**
 - Authoring, governance, integrated metadata



No account limitation
(all@company.com)

- Ability to 'deploy' on own environment
- Community curation of content



No bandwidth limit
(fair use policy)

Members – Via CDISC membership

- **Additional functionality**
 - Full Standards download
 - Diff tables



Named accounts



Per plan

Developer
access

Bundles

Bundle Option

10 accounts
20 accounts
50 accounts

Bundle Cost*

\$2,500/year
\$3,500/year
\$5,000/year

Bandwidth Allocation % (per bundle)**

4 GB/month
8 GB/month
20 GB/month

Gold

License	Maximum Bandwidth	Maximum # of Accounts
Member	1.5 GB/month	2
Commercial	2.5 GB/month	3

Platinum

License	Maximum Bandwidth	Maximum # of Accounts
Member	2 GB/month	3
Commercial	3 GB/month	4

Non Members - World – Free of charge

- **“Adoption of standards”**
- Small downloads (XLS – CSV)



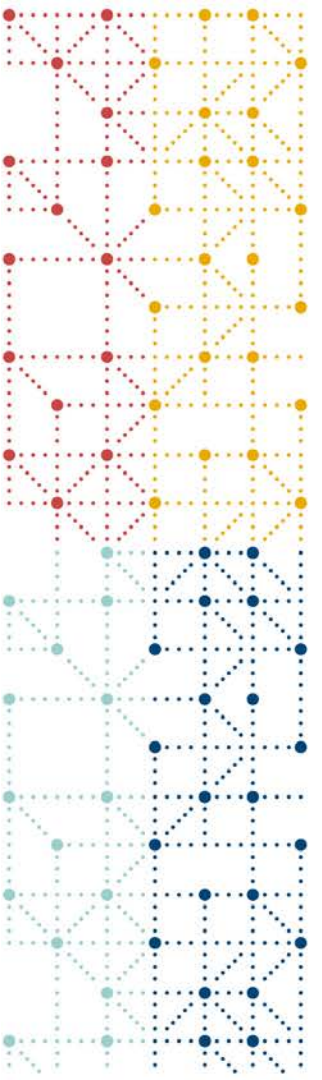
Self sign-up



Limited bandwidth
(browsing only)

API



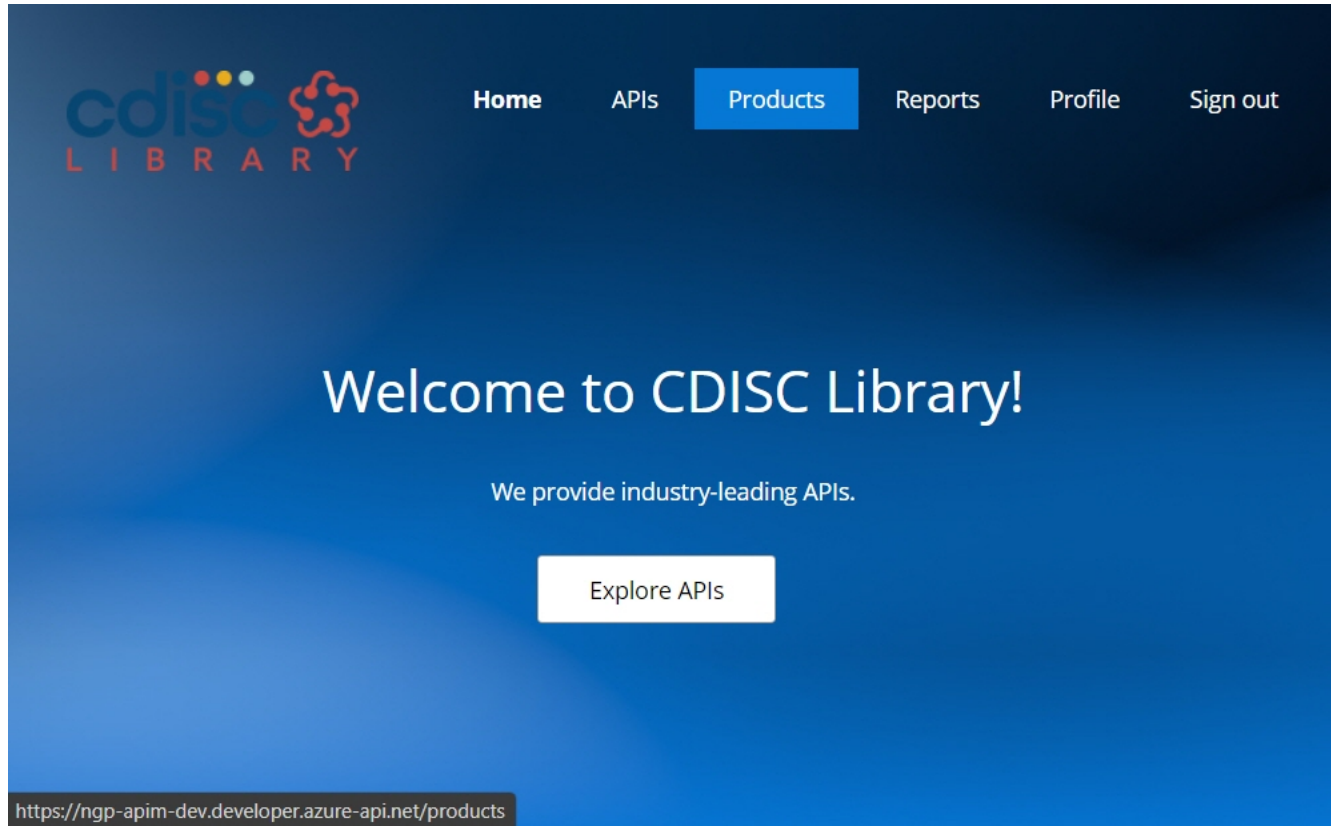


4. New Environments

New CDISC Library Environments

- CDISC Development environments
 - Sandbox
 - Dev
 - Test
- Standards Implementer environments
 - Preview
 - Production
- Dynamic Environments
 - Temporary environments created as needed

API Developer Portal



The screenshot shows the CDISC Library API Developer Portal. The page has a dark blue header with the CDISC LIBRARY logo on the left and a navigation menu on the right. The main content area is a lighter blue gradient with a large white heading and a central button.

cdisc LIBRARY

Home APIs **Products** Reports Profile Sign out

Welcome to CDISC Library!

We provide industry-leading APIs.

Explore APIs

<https://ngp-apim-dev.developer.azure-api.net/products>

API Developer Portal: Documentation and Code Generation

CDISC Library API

Search operations



Group by tag

Analysis Data Model (ADaM)

- GET **Get ADaM Datastructure**
- GET Get ADaM Datastructure Variable
- GET Get ADaM Product
- GET Get ADaM Variable List
- GET Get ADaM Variable Set
- GET Get ADaM Variable Set List
- GET Get Analysis Datastructures

CDASH Implementation Guide (CDASHIG)

- GET Get CDASHIG Class
- GET Get CDASHIG Class Domain List
- GET Get CDASHIG Class List
- GET Get CDASHIG Class Scenario List
- GET Get CDASHIG Domain
- GET Get CDASHIG Domain Field
- GET Get CDASHIG Domain List
- GET Get CDASHIG Domain Variable List
- GET Get CDASHIG Product

<https://ngp-apim-dev.developer.azure-api.net/api-details#>

CDISC Library API

API version:

API definition

Changelog

Public API for CDISC Library

Get ADaM Datastructure

Get ADaM Datastructure

Analysis Data Model (ADaM)

Request

GET `https://ngp-apim-dev.azure-api.net/api/mdr/adam/{product}/datastructures/{datastructure}`

Request parameters

Name	In	Required	Type
product	template	true	string
datastructure	template	true	string

Response: 200 OK

OK

application/ison application/xml text/csv application/vnd.openxmlformats-officedocument.spreadsheetml

Parameters

product

datastructure

+ Add parameter

Headers

Cache-Control Remove

Ocp-Apim-Subscr Remove

+ Add header

HTTP **Curl** C# Java
JavaScript PHP Python Ruby
Objective C

HTTP request

Copy

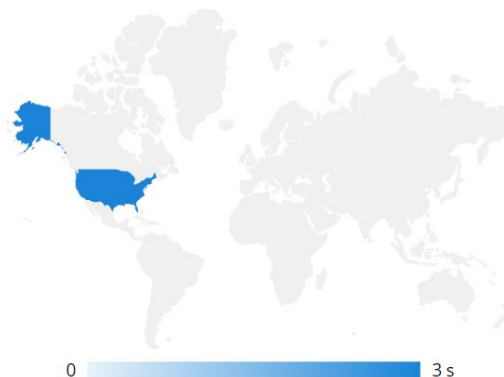
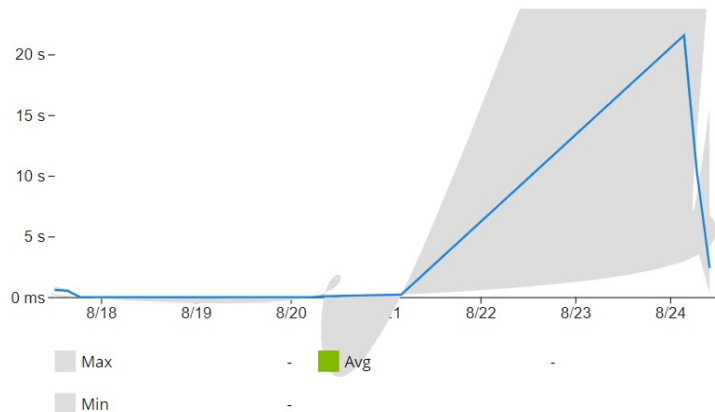
@ECHO OFF

```
curl -v -X GET "https://ngp-apim-dev.azure-api.net/api/mdr/adam/{product}/datastructures/{datastructure}"  
-H "Cache-Control: no-cache"  
-H "Ocp-Apim-Subscription-Key: 11ad5435f8b640d3b528af16d7d11dba"
```

Send

API Developer Portal: Self Service Reports

API response times



Products

Product	Successful calls <input type="text" value="73"/>	Blocked calls	Failed calls	Other calls	Total calls	Average response time	Bandwidth
CDISC Library	73	0	5	0	78	3 s	5 Mb

Subscriptions

Subscription	Successful calls <input type="text" value="70"/>	Blocked calls	Failed calls	Other calls	Total calls	Average response time	Bandwidth
Product CDISC Library subscription	70	0	2	0	72	3 s	4 Mb



5. Private CDISC Library Instances

New Features for Titanium members using a private instance of the CDISC Library to manage standards

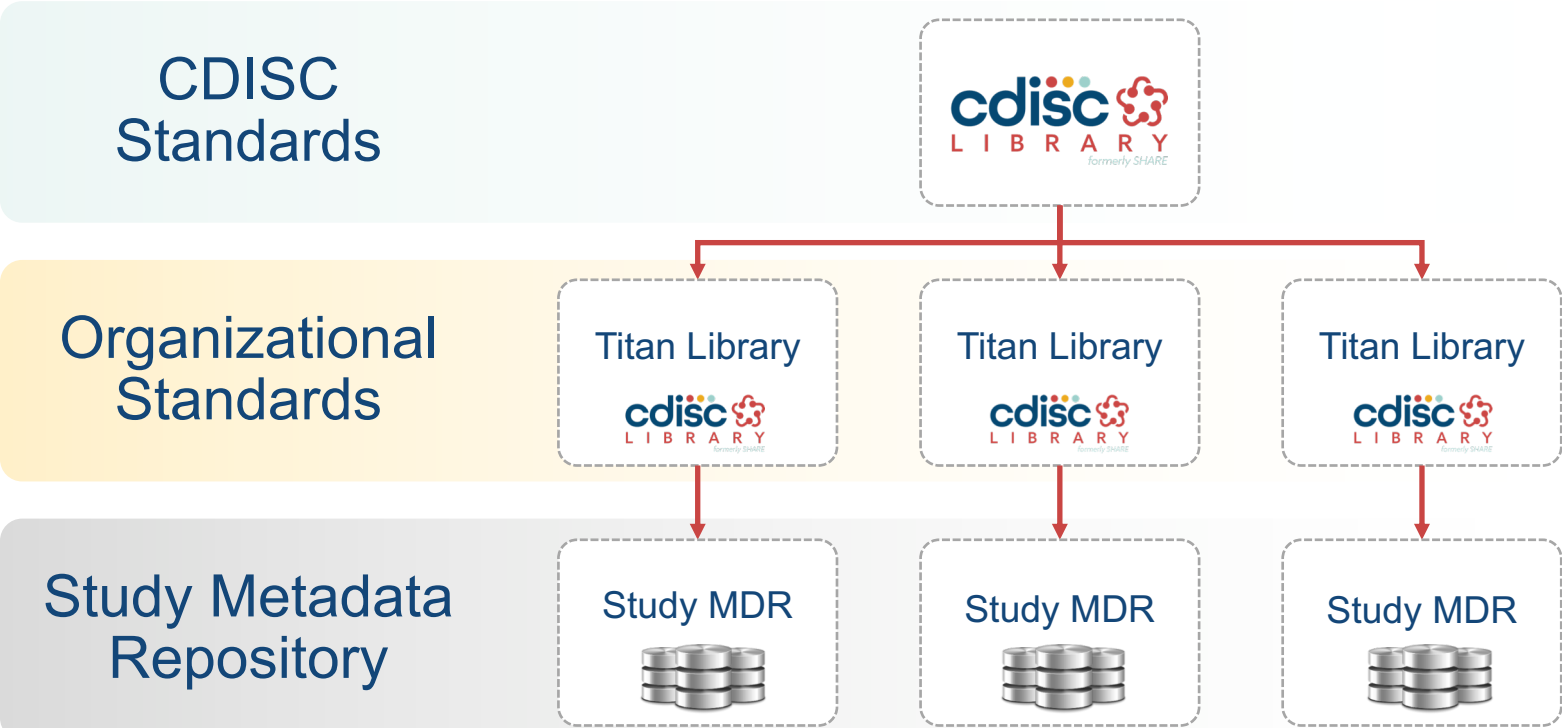
CDISC Library: Private Instance of CDISC Library

- Every private instance starts with the same content as the CDISC Library
 - Primary / replica architecture
 - Create sponsor, therapeutic area, and project level standards based on the CDISC standards
- Every private instance of CDISC Library starts with the same code base
 - CDISC Library API
 - Provides standards management tools such as authoring and governance
 - Create sponsor-specific additions and extensions
- Provides tools to help up-version organizational standards for new versions of CDISC standards

Common API Across all CDISC Library Instances

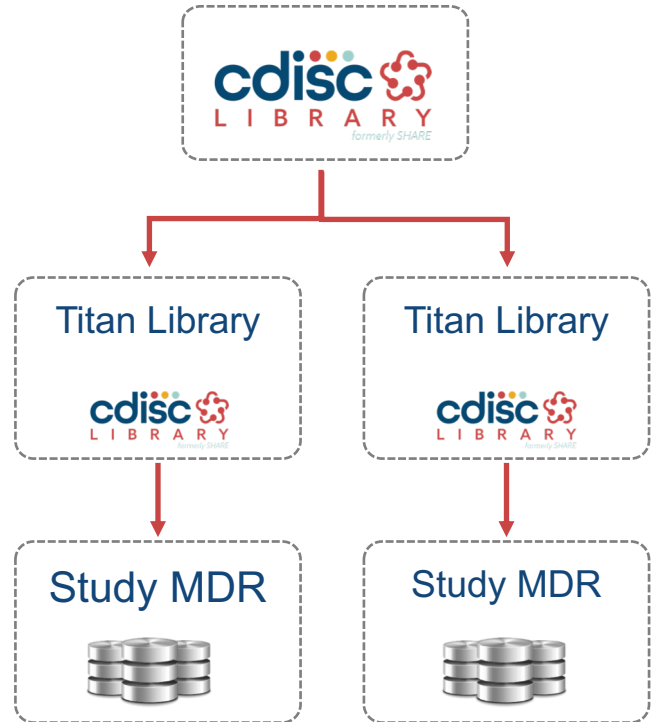
- Every CDISC Library instance has a common API making it easy for vendors to build applications that target all instances
- Vendor applications that target the API have a ready-made market
 - Enables a ecosystem of vendor applications that use the CDISC Library API

CDISC Library: Syndicated Standards



CDISC Library: Syndicated Standards

- Industry standards published to member Libraries
 - Primary / replica architecture
- Members add organization, TA, project, and study level standards
 - Members configure standards for their needs
 - Automation support or up-versioning
- Detailed study metadata is maintained in a local MDR
 - Studies configure organizational standards
- The Study MDR integrates with operational systems



CDISC Library Titanium: Authoring Sponsor Standards



CDISC Sponsor

Search

Data Collection

CDASH Model v1.0

CDASHIG v2.0

CDASHIG v1.1

Data Tabulation

SDTM v1.2

SDTM v1.3

SDTM v1.4

SDTM v1.5

SDTM v1.6

SDTM v1.7

SDTM v1.8

SDTMIG v3.1.2

SDTMIG v3.1.3

SDTMIG v3.2

SDTMIG v3.3

SDTMIG-AP v1.0

SDTMIG-MD v1.0

SDTMIG-MD v1.1

SDTMIG-PGx v1.0

SENDIG v3.1

SENDIG v3.0

SENDIG-AR v1.0

SENDIG-DART v1.0

Data Analysis

ADaM ADAE v1.0

ADaM BDS for TTE v1.0

ADaM OCCDS v1.0

ADaM v2.1

CDASHIG v2.0

Status
Final

Effective Date
2012-05-08

Implements
ADaM v2.1 ADaM v2.2 ADaM v2.3

Data Structures
DBS for TTE

Export

Classes

Interventions Events **Findings** Special-Purpose

Domains

DA DD EG IE LB MI PC PE SC RP SR VS FA +

Scenarios

DA - Denormalized Options: Horizontal-Example DA - Implemented Options: Horizontal-Generic

Findings

DA DA - Denormalized Options: Horizontal-Example

Name
Findings Observation Class Ordinal
2

Description

The Findings class includes CDASH domains that define collection standards for results from evaluations such as physical examinations, laboratory tests, ECG testing, and responses to questionnaires. (Source: CDASHIG v2.0, Section 8.3)

Drug Accountability

DA - Denormalized Options: Horizontal-Example

Highlight changes

Ordinal	Name	Label	Definition	Question Text	Prompt
1	STUDYID	Study Identifier	A unique identifier for a study.	What is the study identifier?	[Protocol/Study]
2	SITEID2	Study Site Identifier	A unique identifier for a site within a study.	What is the site identifier?	Site (Identifier)
3	SUBJID	Subject Identifier for the Study goes here	A unique subject identifier within a site and a study.	What is the subject identifier?	Subject
4	VISIT	Visit Name	The name of a clinical encounter that encompasses planned and unplanned trial interventions, procedur...	What is the visit name?	[Visit]
5	VISDAT	Visit Date	Date the clinical encounter occurred (or started).	What [is/was] the date of the visit?	Visit Date
6	DAPERF	Drug Accountability Performed	An indication whether or not a planned drug accountability assessment was performed.	Was drug accountability performed?	Drug Accountability Performed

CDISC Library Titanium: Managing Sponsor Standards

▼ Data Collection

CDASH Model v1.0

CDASHIG v2.0

CDASHIG v1.1

▼ Data Tabulation

SDTM v1.2

SDTM v1.3

SDTM v1.4

SDTM v1.5

SDTM v1.6

SDTM v1.7

SDTM v1.8

SDTMIG v3.1.2

SDTMIG v3.1.3

SDTMIG v3.2

SDTMIG v3.3

SDTMIG-AP v1.0

SDTMIG-MD v1.0

SDTMIG-MD v1.1

SDTMIG-PGx v1.0

SENDIG v3.1

SENDIG v3.0

SENDIG-AR v1.0

SENDIG-DART v1.0

Home

Changes Made

Last 7 days ▼



Original Data Points: 3,335
Sponsor Updated Data: 1,560

[View full report](#)

Latest Changes

Name	Label	Definition	Action
STUDYID	Study Identifier	A unique identifier for a study.	View
SITEID	Study Site Identifier	A unique identifier for a site within a study.	View
SUBJID	Subject Identifier for the Study	A unique subject identifier within a site and a study.	View
VISIT	Visit Name	The name of a clinical encounter that encompasses planned and unplanned trial interventions, procedures...	View
VISDAT	Visit Date	Date the clinical encounter occurred (or started).	View
DAPERF	Drug Accountability Performed	An indication whether or not a planned drug accountability assessment was performed.	View
VISDAT	Visit Date	Date the clinical encounter occurred (or started).	View
DAPERF	Drug Accountability Performed	An indication whether or not a planned drug accountability assessment was performed.	View

CDISC Library Titanium: Standards Change Management

- ▼ Data Collection
 - CDASH Model v1.0
 - CDASHIG v2.0
 - CDASHIG v1.1
- ▼ Data Tabulation
 - SDTM v1.2
 - SDTM v1.3
 - STDM v1.4
 - STDM v1.5
 - STDM v1.6
 - STDM v1.7
 - STDM v1.8
 - SDTMIG v3.1.2
 - SDTMIG v3.1.3
 - SDTMIG v3.2
 - SDTMIG v3.3
 - SDTMIG-AP v1.0
 - SDTMIG-MD v1.0
 - SDTMIG-MD v1.1
 - SDTMIG-PGx v1.0
 - SENDIG v3.1
 - SENDIG v3.0
 - SENDIG-AR v1.0
 - SENDIG-DART v1.0
- ▼ Data Analysis
 - ADaM ADAE v1.0
 - ADaM BDS for TTE v1.0
 - ADaM OCCDS v1.0
 - ADaM v2.1
 - ADaMIG v1.0

CDASHIG v2.0

Status: Final | Effective Date: 2012-05-08 | Implements: ADaM v2.1

Classes

Interventions | Events | **Findings** | Special-Purpose

Domains

DA | DD | EG | IE | LB | MI | PC | PE | S

Scenarios

DA - Denormalized Options: Horizontal-Example | DA - Implemented C

Findings | DA | DA - Denormalized Options: Horizontal-Example

Name: Findings Observation Class | Ordinal: 2

Description: The Findings class includes CDASH domains that define collection standard (Source: CDASHIG v2.0, Section 8.3)

Drug Accountability | DA - Denormalized Options: Horizontal-Example

Ordinal	Name	Label	Definition
1	STUDYID	Study Identifier	A unique id
2	SITEID2	Study Site Identifier	A unique id
3	SUBJID	Subject Identifier for the Study goes here	A unique si
4	VISIT	Visit Name	The name planned an
5	VISDAT	Visit Date	Date the cli
6	DAPERF	Drug Accountability Performed	An indicati accountabi
7	DACAT	Category of Drug Accountability Assessment	A grouping defined chi

Drug Accountability

CDISC STANDARD | Version: 2.0

Ordinal: 2

Name: SITEID

Label: Study Site Identifier

Definition: A unique identifier for a site within a study.

Question Text: What is the site identifier?

Prompt: Site (Identifier)

Data Type: Character

Completion Instructions: --

Implementation Notes: While this field is not typically captured on a CRF, it should be displayed clearly on the CRF and/or the EDC system. This field can be included into the database or populated during SDTM-based dataset creation before submission.

Mapping Instructions: Maps directly to the SDTMIG variable listed in the column with the heading "SDTMIG Target".

Mapping Targets: STUDYID

Drug Accountability - v2.1

Ordinal: 2

Name: SITEID2

Label: Study Site Identifier

Definition: A unique identifier for a site within a study.

Question Text: What is the site identifier?

Prompt: Site (Identifier)

Data Type: Character

Completion Instructions: --

Implementation Notes: Lorem ipsum dolor sit amet, consectetur adipiscing elit. Duis iaculis pellentesque consectetur. Mauris id volutpat nisi. Nam ultricies pharetra nisi, ac tincidunt dui aliquam non. Aliquam augue dolor, tempus non viverra id, vulputate vehicula ante. Morbi sit amet lacus non justo lacinia rhoncus. Proin ac pharetra eros.

Mapping Instructions: Maps directly to the SDTMIG variable listed in the column with the heading "SDTMIG Target".

Mapping Targets: STUDYID

Code List: --

CDISC Library Titanium: Standards Change Management

Export

CDASHIG v2.0

Current Standard Version History

CDASHIG v2.0

CDASHIG v1.9

Ord.	Class	Dataset Name	Variable Name	Variable Label	Type	Role	Co	Ord.	Class	Dataset Name	Variable Name	Variable Label	Type	Role	Co
1	Events	AE	STUDYID	Study Identifier	Char	Identifier	Re		Events	AE	STUDYID	Study Identifier	Char	Identifier	Re
2	Events	AE	DOMAIN	Domain Abbreviation	Char	Identifier	Re		Events	AE	DOMAIN	Domain Abbreviation	Char	Identifier	Re
3	Events	AE	USUBJID	Unique Subject Identifier	Char	Identifier	Re		Events	AE	USUBJID	Unique Subject Identifier	Char	Identifier	Re
4	Events	AE	AESEQ	Sequence Number	Num	Identifier	Re		Events	AE	AESEQ	Sequence Number	Num	Identifier	Re
5	Events	AE	AEGRPID	Group ID	Char	Identifier	Re		Events	AE	AEGRPID	Grouping ID	Char	Identifier	Re
6	Events	AE	AEREFID	Reference ID	Char	Identifier	Per		Events	AE	AEREFID	Reference ID	Char	Identifier	Per
7	Events	AE	AESPID	Sponsor-Defined Identifier	Char	Identifier	Rec		Events	AE	AESPID	Sponsor-Defined Identifier	Char	Identifier	Rec
8	Events	AE	AETERM	Reported Term for the Adverse Event	Char	Topic	Rec		Events	AE	AETERM	Reported Term for the Adverse Event	Char	Topic	Rec

Variable Label Change History ✕

Date changed	To	From	By
7/9/2020	Group ID	Grouping ID	John Doe

Reason
I sort of just felt like it.

Data Collection

CDASH Model v1.0

CDASHIG v2.0

CDASHIG v1.1

Data Tabulation

SDTM v1.2

SDTM v1.3

SDTM v1.4

SDTM v1.5

SDTM v1.6

SDTM v1.7

SDTM v1.8

SDTMIG v3.1.2

SDTMIG v3.1.3

SDTMIG v3.2

SDTMIG v3.3

SDTMIG-AP v1.0

SDTMIG-MD v1.0

SDTMIG-MD v1.1

SDTMIG-PGx v1.0

SENDIG v3.1

SENDIG v3.0

SENDIG-AR v1.0

SENDIG-DART v1.0

Data Analysis

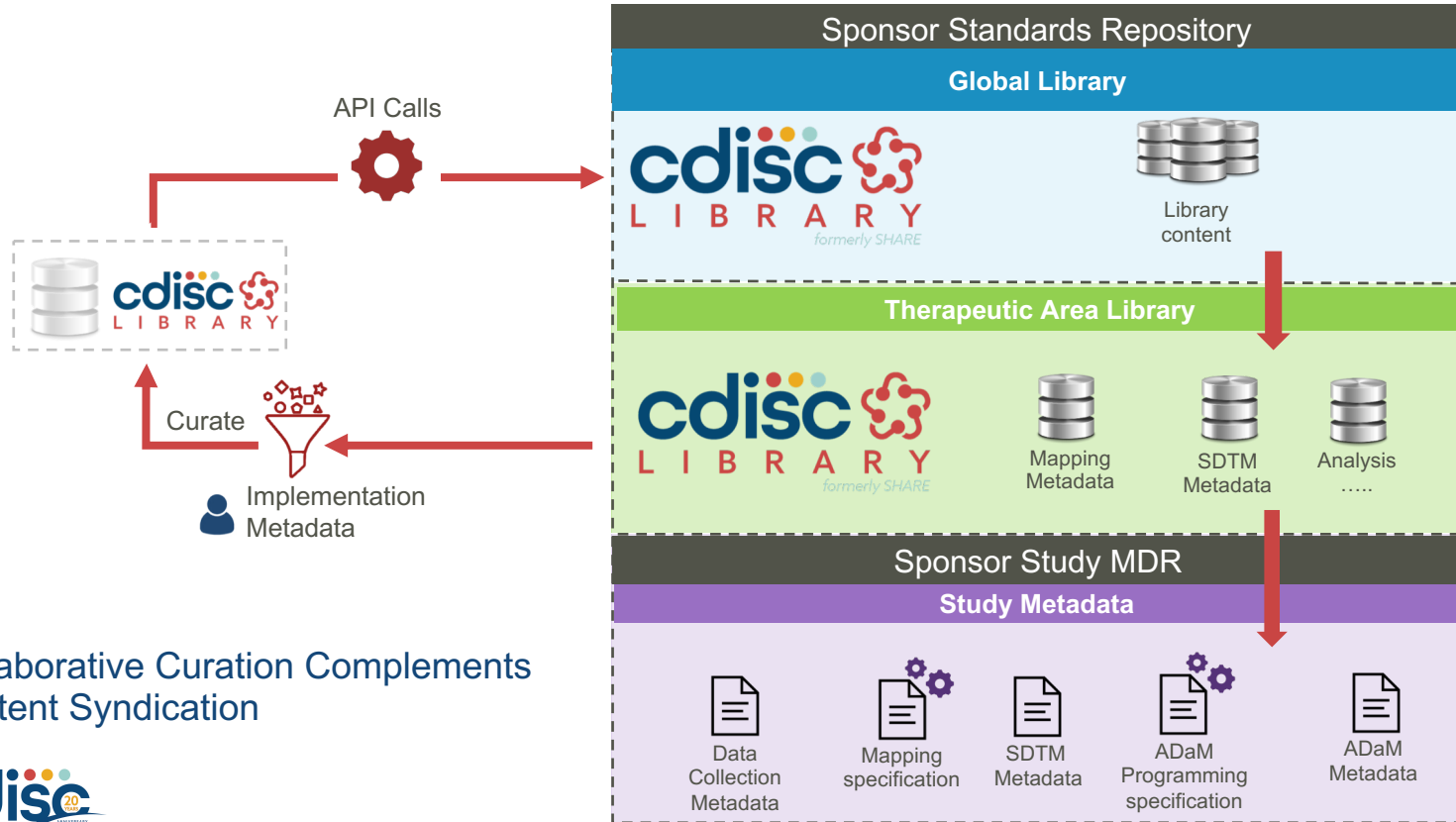
ADaM ADAE v1.0

ADaM BDS for TTE v1.0

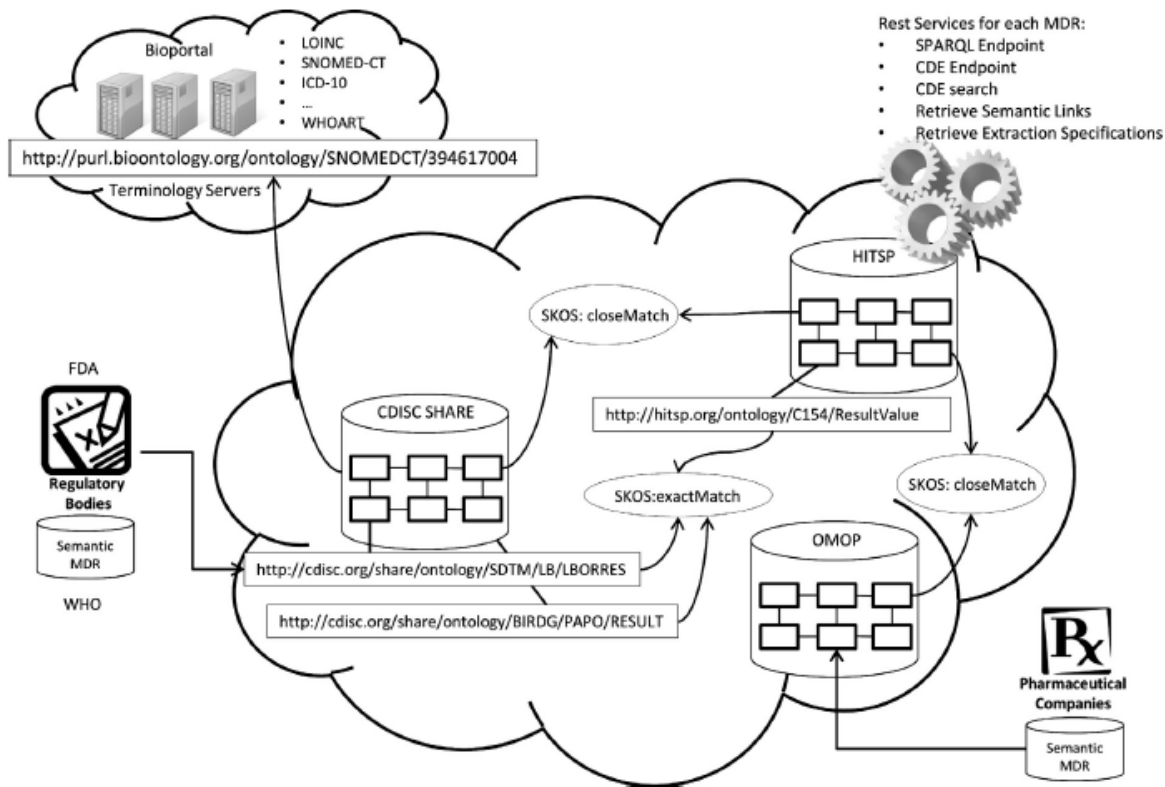
ADaM OCCDS v1.0

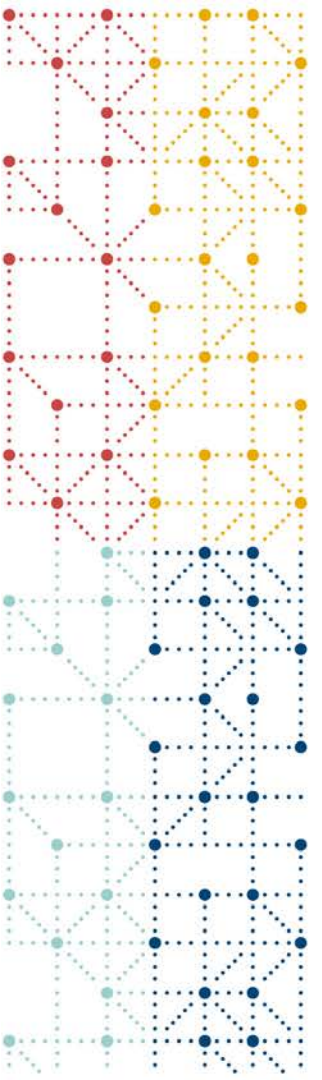
ADaM v2.1

Common CDISC Library Authoring and Governance Tools Enable Collaborative Curation



CDISC Library: Federated MDRs



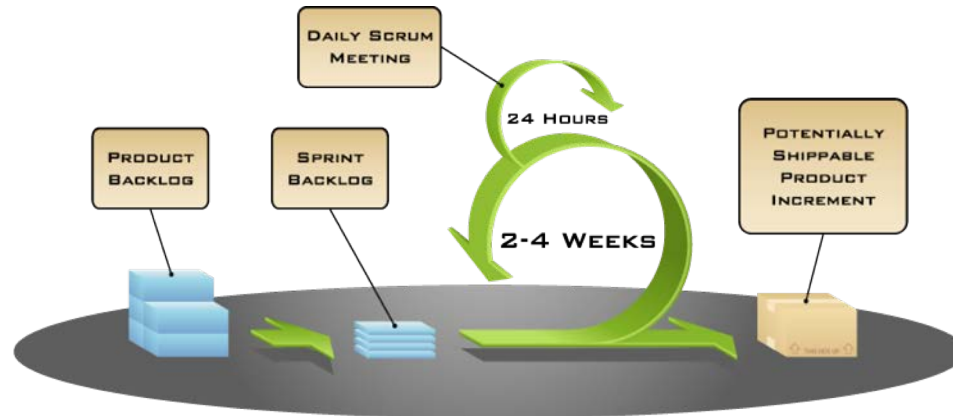


6. Development Approach

High-level thoughts on our approach to software development

Agile Development Process

- Scrum-based process
- 1 dedicated CDISC Library development team to create all the new features
- New features from numerous projects are fed into 1 product backlog and prioritized
- Commit to delivering potentially shippable increments after each sprint





Thank You!

