Next Generation CDISC Library

Presented by Sam Hume - VP, Data Science, CDISC Mike Hamidi - Head, Data Science, CDISC Anthony Chow - Director, Data Science, CDISC

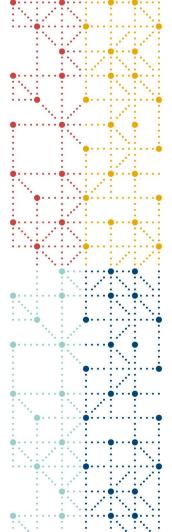
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Agenda

- 1. Introduction
- 2. Timeline of Activities
- 3. CDISC Library Data Standards Browser (DSB)
- 4. Actions for Data Standards Browser (DSB) Users
- 5. CDISC Library API Management Developer Portal (APIM-DP)
- 6. Actions for API Developers
- 7. CDISC Library Demo
- 8. Future of CDISC Library
- 9. Summary
- 10. Q&A



Introduction

What's the Next Generation CDISC Library?

CDISC is quickly moving towards a more technology-based standards future. With the CDISC Library, this technology focused approach is already underway. However, as we continue this journey into the next generation, more advanced and modernized technology suite of tools and services become a requirement.

The CDISC 360 Proof-of-Concept leveraged the Microsoft Azure platform to evaluate if CDISC could achieve the impossible (i.e., an end-to-end transformational pipeline). This also introduced the power of the Microsoft Azure platform and allowed a **partnership** between **Microsoft** and **CDISC** to form.

By CDISC partnering with Microsoft, it allowed the CDISC Library to have that more advanced and modernized technologically stack. In doing so, it allows the CDISC Library to move into the next generation and achieve our short-, medium-, and longer-term goals. Those goals cover the needs of operational, transitional, and maintenance continuum.







Next Generation Requirements

The CDISC Library will utilize the Microsoft Azure technology stack to accomplish the next generation requirements. Those requirement needs are partially defined on this slide.

Operational Needs

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- Cost Mgmt.
- Accessibility •
- Usability •
- Efficiency •
- Transparency •
- Functionality •
- Dependability •
- Security •
- Safety •
- · Standards Mgmt.

Transitional Needs

- Portability •
- Interoperability •
- Reusability •
- Adaptability
- Scalability

Maintenance Needs

- Modularity •
- Maintainability •
- Flexibility •
- Simplicity





Adaptability

Flexibility



Dev. & Maint. Simplification







Accessibility & Usability



Reliability





DevOps Functionality



Efficiency



Analytics





Management

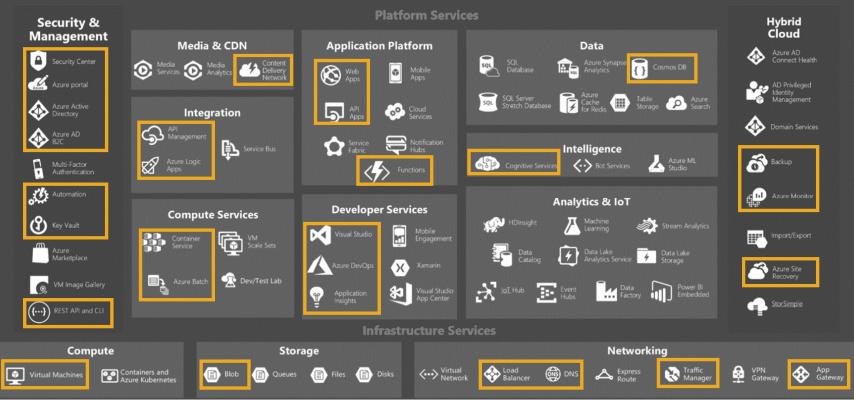








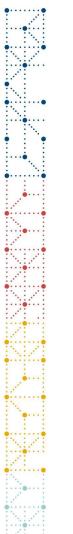
CDISC Library on Azure



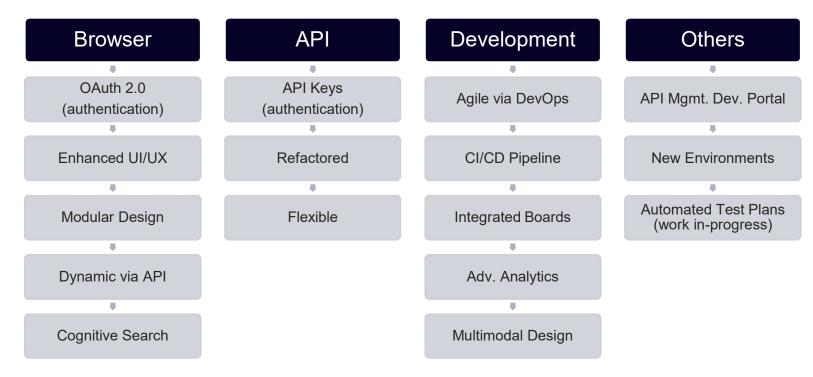
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*As of Oct. 2020. Azure services will evolve as CDISC Library evolves. Additional Azure services may not be represented.

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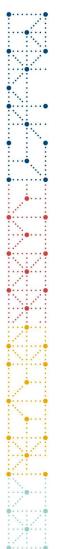


Summary of Key Changes

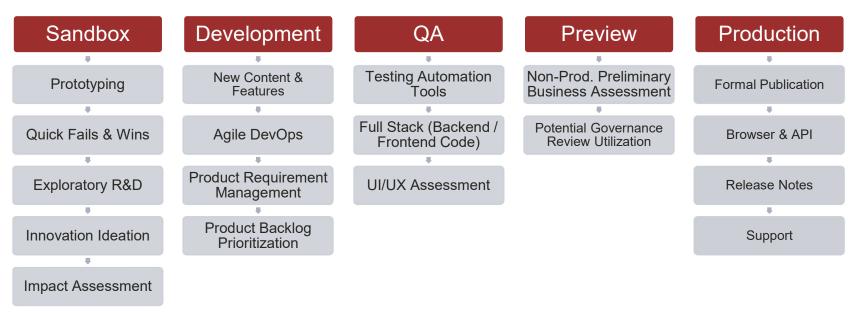




* The full details on all changes will be provided as part of the release notes. **UI/UX**=User Interface and User Experience; **CI/CD**=Continuous Integration & Continuous Delivery/Deployment



CDISC Library Environments



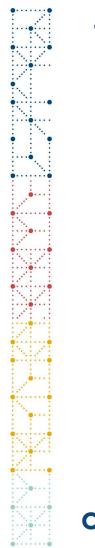
Continuous Integration & Continuous Delivery Pipeline



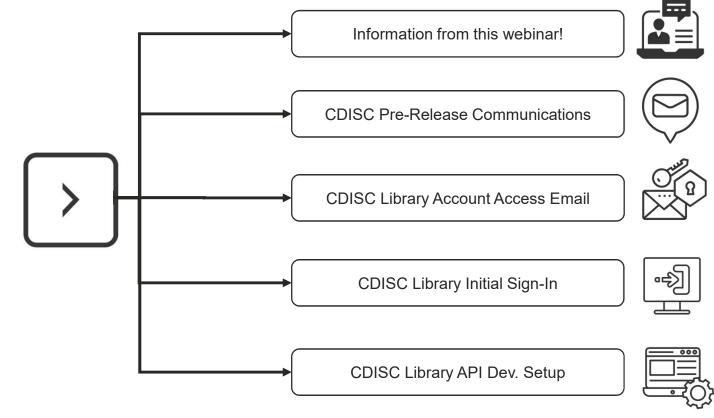
* Representative of current and future state concepts. **UI/UX**=User Interface and User Experience; **CI/CD**=Continuous Integration & Continuous Delivery/Deployment

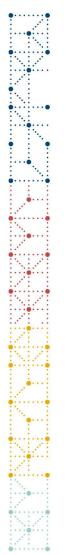




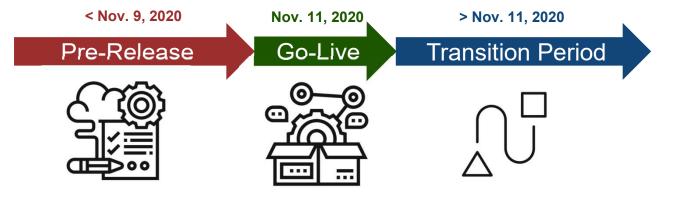


What's Happens Next?





Timing of Release Activities



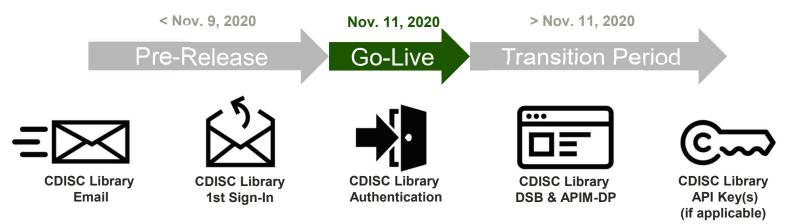
Go-Live:

- CDISC instructions on key actions to be taken
- Make any necessary technical changes to API code (e.g., retrieving API Keys for CDISC Library API access)
- Initial setup period should generally take minutes-to-hours at most
- CDISC Library account setup instructions via email communication
- Notifying your internal organization of changes (spread the word)
- Release maintenance window will occur between Nov. 9th to Nov. 11th



*Official release go-live timing may change **Operational acceptance period is defined to identify any immediate bugs/issues post go-live

Existing CDISC Library Accounts

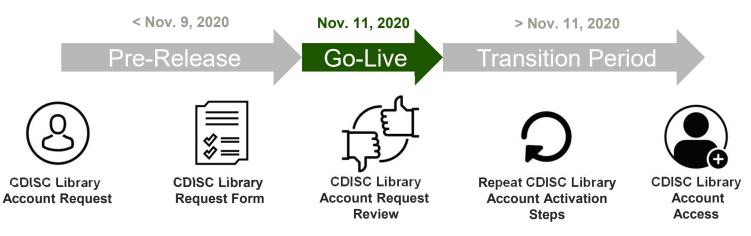


- All existing CDISC Library accounts will be automatically migrated over to Microsoft Azure
 - CDISC will have a release maintenance window from Nov. 9th to Nov. 11th
- Your CDISC Library first sign-in instructions will be sent to your existing account email address
- You will verify and authenticate your CDISC Library account
- Access to the CDISC Library DSB and CDISC Library API Mgmt. Dev. Portal
 - If you are not a developer using the API, then all you need is the DSB
- A CDISC Library API Key is necessary to access the CDISC Library API (more on this later)
 - The CDISC Library API Mgmt. Dev. Portal provides developers access to the API Keys, Reports, etc.



*Detailed instructions and support references will be provided upon go-live. **DSB**=Data Standards Browser, **APIM-DP**=API Management Development Portal

New CDISC Library Accounts



- For new CDISC Library accounts, you will still request a CDISC Library account vis CDISC website
- · Complete the CDISC Library account request form
- Your CDISC Library account request will be reviewed by CDISC
- · CDISC Library account would be activated and ready for use
 - · Same steps from the previous slide would be repeated, where applicable
- You can then access both the CDISC Library DSB and API Mgmt. Dev. Portal



*Detailed instructions and support references will be provided upon go-live.
 DSB=Data Standards Browser

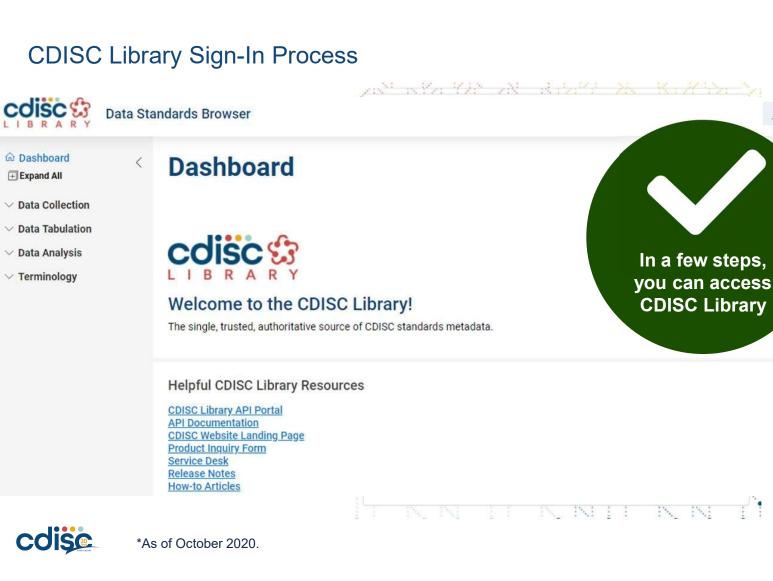
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CDISC Library Communication Plan

Timing Phase	Est. Timing	Communication	Target
Pre-Release	~Nov. 2nd	First notice of release maintenance downtime*	Existing CDISC Library accounts
Pre-Release	~Nov. 6th	Second notice of release maintenance downtime*	Existing CDISC Library accounts
Day of Release	Nov. 11th	Official release launch notification and account details emailed	Existing CDISC Library accounts
Post-Release	~Nov. 17th	First global communication of CDISC Library release	Existing CDISC Library accountsWider CDISC community
Post-Release	~Dec. 2nd	Second global communication of CDISC Library release	Existing CDISC Library accountsWider CDISC community

*The CDISC Library release maintenance downtime will occur between **Nov. 9th** and **Nov. 11th**. There will be **no access** to CDISC Library during this time. Note: Estimated dates may change as deemed necessary by CDISC





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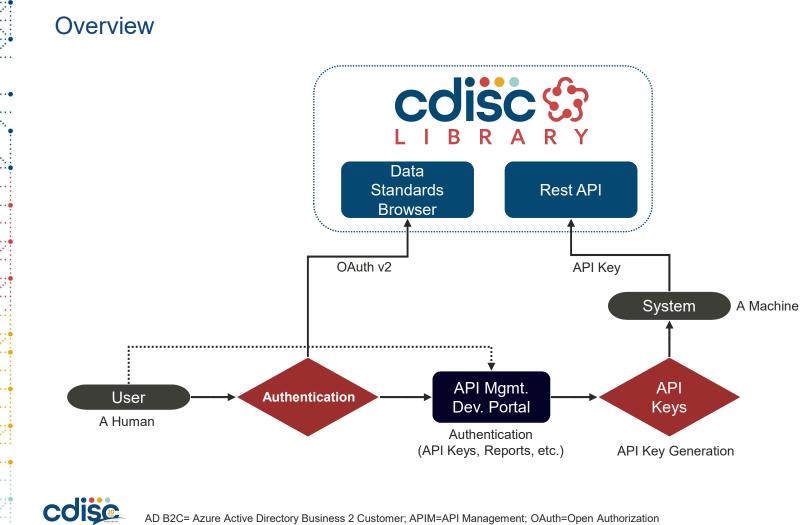
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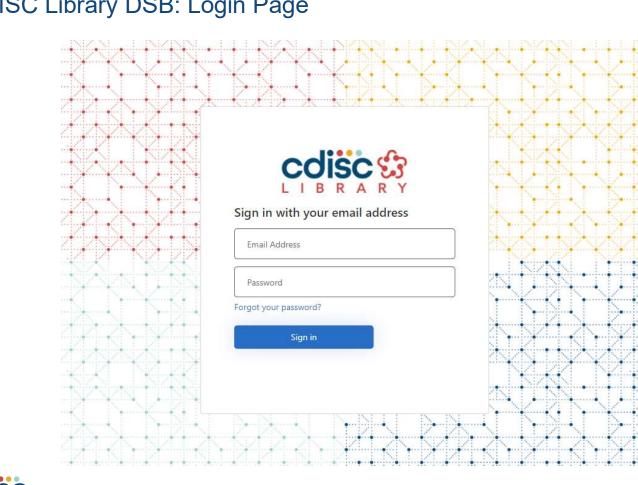
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O Search

CDISC Library Data Standards Browser (DSB)



AD B2C= Azure Active Directory Business 2 Customer; APIM=API Management; OAuth=Open Authorization

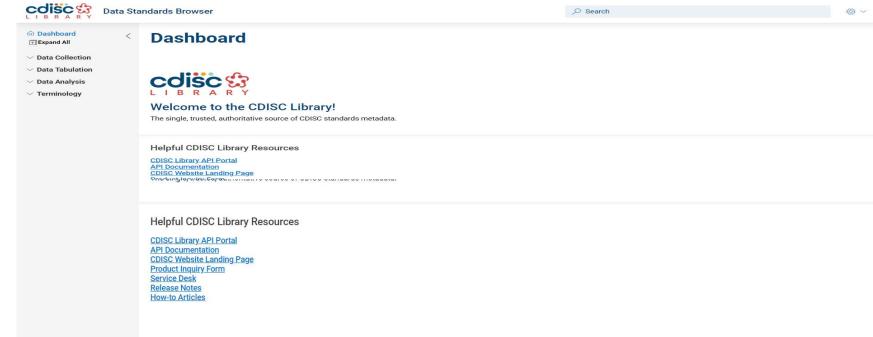








CDISC Library DSB: Dashboard





CDISC Library DSB: Product Page

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	Data Analysis

CDISC Library DSB: Quick View

Data Standards Browser

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		Ordinal ↑	Name	Label	Description	Data Type	Role	Or
	•	1	STUDYID	Study Identifier	Unique identifier for a study.	Char	Identifier	7
	E	2	DOMAIN	Domain Abbreviation	Two-character abbreviation for the domain.	Char	Identifier	Na VS
		3	USUBJID	Unique Subject Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Char	Identifier	Vit De Sh
	•	4	VSSEQ	Sequence Number	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Num	Identifier	de wi fo
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	E	5	VSGRPID	Group ID	Used to tie together a block of related records in a single domain for a subject.	Char	Identifier	is th: "S
	E	6	VSSPID	Sponsor- Defined Identifier	Sponsor-defined reference number. Perhaps pre- printed on the CRF as an explicit line identifier or defined in the sponsor's operational database.	Char	Identifier	Da Ch
	E	7	VSTESTCD	Vital Signs Test Short Name	Short name of the measurement, test, or examination described in VSTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in VSTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). VSTESTCD cannot contain characters other than letters, numbers, or underscores. Examples: "SYSBP", "DIABP", "BMI".	Char	Торіс	Ro To Re Co Co De

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*Screenshot as of October 2020

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lame /STESTCD

D Search

.abel /ital Signs Test Short Name

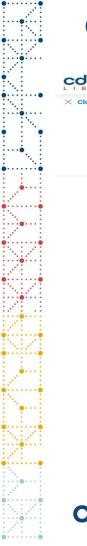
Description Short name of the measurement, test, or examination described in VSTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in VSTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" than letters, numbers, or underscores. Examples. "SYSBP", "DIABP", "BMI".

Data Type Char

ole ormat. The value in VSTESTCD cannot be longer than 8 haracters, nor can it start with a number (e.g., "1TEST" s not valid). VSTESTCD cannot contain characters other nan letters, numbers, or underscores. Examples: SYSBP", "DIABP", "BMI".

escribed Value Domain

21

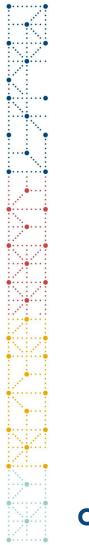


CDISC Library DSB: Search Results

	Standards Browser				× & ~
imes Close search results	20 results for "AETERM"	Narrow search results Scope S Class Selected Filters (1) hide X Class: Events	Scope Value Events	 ✓ Reset 	
	AETERM (Data Collection Field) The reported or pre-specified name of the adverse event. Clinical Data Acquisition Standards Harmonization Implementat	tion Guide for Human Clinical Trials V	ersion 2.0		
	AETERM (Data Collection Field) Verbatim (i.e., investigator-reported term) description of the adve Clinical Data Acquisition Standards Harmonization (CDASH) Use				
	Clinical Data Acquisition Standards Harmonization Implementat	tion Guide for Human Clinical Trials V	ersion 2.0		
	AETERM (Data Collection Field) Verbatim (i.e., investigator-reported term) description of the adve Clinical Data Acquisition Standards Harmonization (CDASH) Use				
	AETERM (Data Collection Field) The reported or prespecified name of the adverse event. Clinical Data Acquisition Standards Harmonization Implementat	tion Guide for Human Clinical Trials V	ersion 2.1		
	AETERM (SDTM Dataset Variable) Verbatim name of the event. Study Data Tabulation Model Implementation Guide: Human Clir	nical Trials Version 3.2 (Final)			



Actions for Data Standards Browser (DSB) Users



Actions for DSB Users





Step 3:

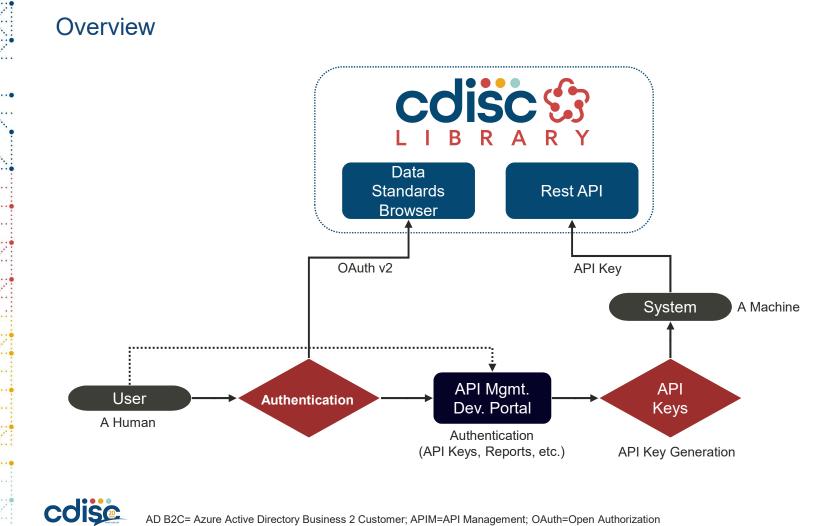
- Access the CDISC Library Data Standards Browser. Done!



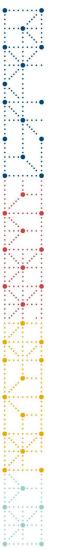
DSB=Data Standards Browser







AD B2C= Azure Active Directory Business 2 Customer; APIM=API Management; OAuth=Open Authorization



CDISC Library APIM-DP: Dashboard

CDISC Library Browser Reports API Tester API Key Sign out

Welcome to the CDISC Library API Manager

To access your API key, please use the CDISC Library login to sign in at top right.

To access your API key, please use the CDISC Library login to sign in at top right.

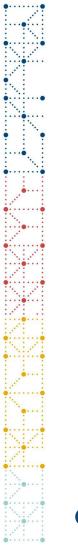




CDISC Library APIM-DP: Reports

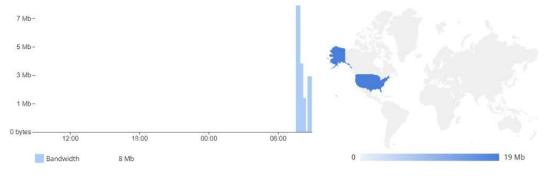




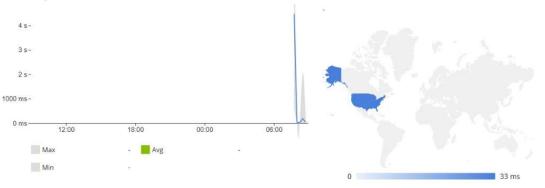


CDISC Library APIM-DP: Reports (cont.)





API response times





CDISC Library APIM-DP: Reports (cont.)

Products

Product	Successful calls	Blocked calls	Failed calls	Other calls	Total calls	Average response time	Bandwidth
CDISC Library API	2.78 K	0	350	350	3.46 K	33 ms	19 Mb
Subscriptions							
Subscription	Successful calls	Blocked calls	Failed calls	Other calls	Total calls	Average response time	Bandwidth
chowSubscriptionTest	2.78 K	0	350	350	3.46 K	33 ms	19 Mb
ADIc							

APIS

API	Successful calls	Blocked calls	Failed calls	Other calls	Total calls	Average response time	Bandwidth
CDISC Library API	2.78 K	0	350	350	3.46 K	33 ms	19 Mb

Operations

Operation	Successful calls \bigtriangledown	Blocked calls	Failed calls	Other calls	Total calls	Average response time	Bandwidth
/mdr/root/ct/{productGroup}/codelist	804	0	0	350	1.13 K	12 ms	1 Mb
/mdr/cdashig/{version}/classes - GET	176	0	0	0	176	12 ms	346 Kb
/mdr/cdashig/{version}/domains - GET	175	0	0	0	175	73 ms	524 Kb
/mdr/cdashig/{version}/domains/{do	175	0	0	0	175	74 ms	582 Kb
/mdr/cdash/{version}/domains - GET	175	0	0	0	175	11 ms	350 Kb



*Screenshot as of October 2020

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CDISC Library APIM-DP: API Tester

CDISC Library API

♀ Search operations

No API selected

/mdr/sdtmig/{version}/datasets - GET Get SDTMIG Dataset List

SDTM Implementation Guide (SDTMIG)

Request

 GET
 /mdr/adam/{product}-GET
 Request

 GET
 /mdr/adam/{product}/datastructures...
 GET
 https://api.library.cdisclibrary.org/api/mdr/sdtmig/{version}/datasets

Group by tag

- GET /mdr/adam/{product}/datastructures/...
- GET /mdr/adam/{product}/datastructures/...

Analysis Data Model and Implementation Guide (ADaM and ADaMIG)

- GET /mdr/adam/{product}/datastructures/... GET /mdr/adam/{product}/datastructures/...
- GET /mdr/adam/{product} GET
- GET /mdr/adam/{product}/datastructures ...
- GET /mdr/adam/{product}/datastructures/...

CDASH Implementation Guide (CDASHIG)

- GET /mdr/cdashig/{version} GET
- GET /mdr/cdashig/{version}/classes GET
- GET /mdr/cdashig/{version}/classes/{class}...
- GET /mdr/cdashig/{version}/classes/{class}...

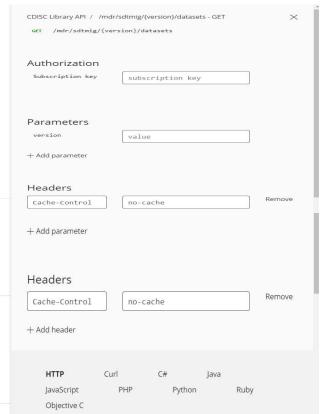
Request parameters Name In Required Type version template true string Request GET https://api.library.cdisclibrary.org/api/mdr/sdtmig/{version}/datasets Request parameters

Name	In	Required	Type	
version	template	true	string	

Response: 200 OK

OK

application/json application/xml text/csv







CDISC Library APIM-DP: API Tester

CDISC Library Browser Reports API Tester API Key Sign out

Account and API Key

Account details

Email
First name
Last name
Registration date



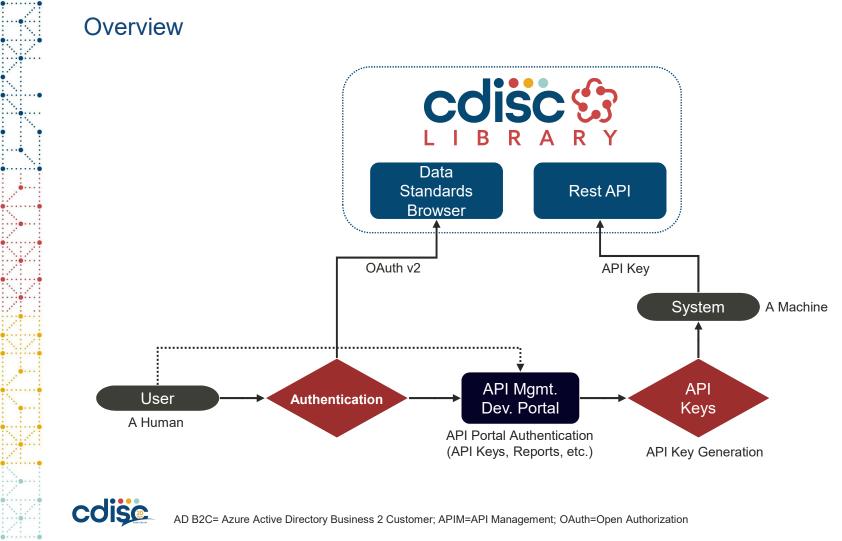
Subscriptions

Subscription details		Product	State	Action
Name		Rename	Active	Cancel
Primary key	200000000000000000000000000000000000000	Show Regenerate		
Secondary key	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	Show Regenerate		









AD B2C= Azure Active Directory Business 2 Customer; APIM=API Management; OAuth=Open Authorization



Pre-Release Preparation Activities



Pre-Release Guidance



Pre-Release Code Preparations

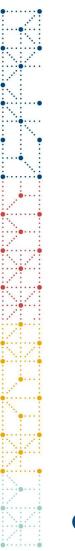


Pre-Release Communication Awareness

Pre-Release Communication Awareness:

- CDISC will be communication key announcements prior to the release
- Communication details will describe the maintenance downtime and availability
- Follow any additional instructions described within those communications





On & Post-Release Activities



API Key(s)



Integrate API Key(s)



Review Release Notes & Guidance

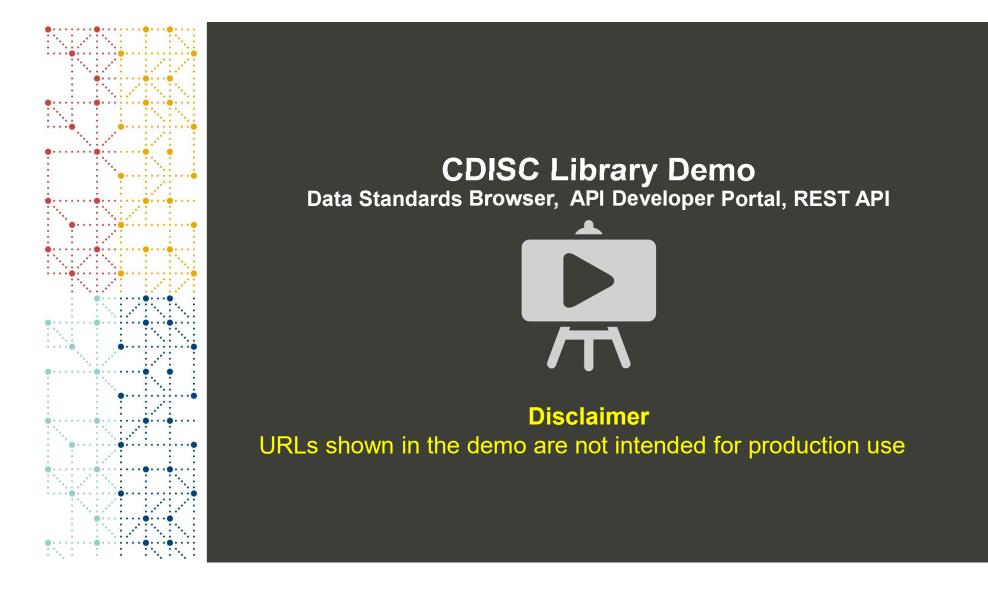


Ask for Help (if necessary)

Ask for Help:

- If the release notes or guidance does not help
- Please reach out to the CDISC Library Support team
- Accessible via https://www.cdisc.org/cdisc-library (under Product Inquiry tab)









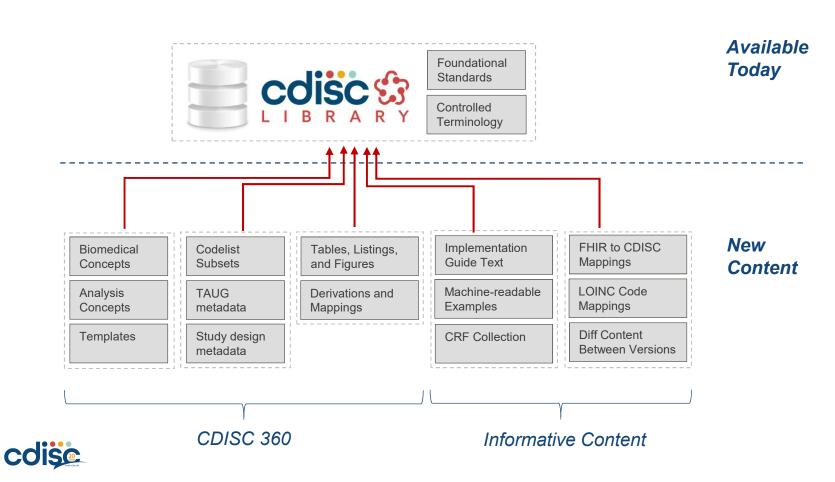
CDISC Library Vision: Today vs. Tomorrow <u>Today's CDISC Library</u>

- Single source of normative metadata
- All versions of all standards
- CDISC Data Science loads content
- Read-only content
- Software tools adding API support
- Library hosted by CDISC

Tomorrow's CDISC Library

- Source of record for published standards
- Authoring tools for standards development
- Create, read, and update standards
- Informative and normative content
- Contains concept metadata
- Numerous software tools use Library
- Titanium members host private Libraries
- Promotes a common API for standards content
- Authoring tools for Titanium members
- Collaborative curation

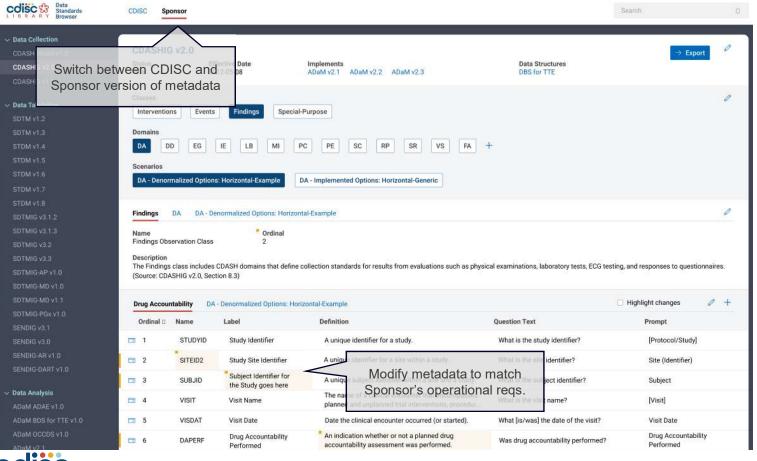




Future Roadmap: New Content

	Titanium – New Membership Level						
	Create o Create o Constant of the second seco	ed Model Library Advisory Boar Functionality priority User Requirements back-end access Authoring, governance, i	d: Investors have a vote ntegrated metadata		2	No account limitation (all@company.com)	
) 'deploy' on own envi nity curation of conter			¢	No bandwidth limit (fair use policy)	
	Members – \	/ia CDISC membershi	р				
	• Full	al functionality Standards download tables			8	+ Named accounts	
Developer					e) Per plan	
access	Bundles						
	Bur	Bundle Option Bundle Cost*		Bandwidth Allocation % (per bundle)**			
		accounts	\$2,500/yea			3/month	
		accounts	\$3,500/yea			3/month	
	50	accounts Gold	\$5,000/year 20 GB/mon		·B/month		
	License	Maximum Bandwidth	Maximum # of Accounts	License	Platinum Maximum Bandwidth	Maximum # of Accounts	
	Member	1.5 GB/month	2	Member	2 GB/month	3	
	Commercial	2.5 GB/month	3	Commercial	3 GB/month	4	
	Non Membe	rs - World – Free of cl	arda				
		on of standards"			2	Self sign-up	
	Small do	wnloads (XLS – CSV)			Ø	Limited bandwidth (browsing only)	

Future Roadmap: Standards Authoring Capabilities



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*Screenshot is a wireframe concept and not indicative of a final product. Certain features may be restricted to membership access. 42

Future Roadmap: Up-version & Change Management

COISC ST Data Standards Browser	CDISC Sponsor		Search 🛛		
∽ Data Collection		Drug Accountability	Drug Accountability - v2.1		
CDASH Model v1.0	CDASHIG v2.0	brug noodintability	C Edit Compare Origina		
CDASHIG v2.0	Status Effective Date Implements Final 2012-05-08 ADaM v2.1 AE	CDISC STANDARD Version 2.0 V	es		
CDASHIG v1.1	Switch between	different	2		
✓ Data Tabulation	Classes		Name		
SDTM v1.2	Interventions Events Findir Sponsor man	SITEID	SITEID2		
SDTM v1.3	Domains metadata ver	sions	Lloor friendly motodate		
STDM v1.4	DA DD EG IE LB MI PC PE S	Study Site Identifier	User friendly metadata		
STDM v1.5		Definition	management features (e.g., edit, compare, etc.)		
STDM v1.6	Scenarios DA - Denormalized Options: Horizontal-Example DA - Implemented (A unique identifier for a site within a study.			
STDM v1.7		Question Text	Question Text		
STDM v1.8		What is the site identifier?	What is the site identifier?		
SDTMIG v3.1.2	Findings DA DA - Denormalized Options: Horizontal-Example	Prompt	Prompt		
SDTMIG v3.1.3	Name • Ordinal	Site (Identifier	Site (Identifier		
SDTMIG v3.2	Findings Observation Class 2	Data Type	Data Type Character		
SDTMIG v3.3	Description The Findings class includes CDASH domains that define collection standard	Character			
SDTMIG-AP v1.0	(Source: CDASHIG v2.0, Section 8.3)	Completion Instructions	Completion Instructions		
SDTMIG-MD v1.0		2			
SDTMIG-MD v1.1	Drug Accountability DA - Denormalized Options: Horizontal-Example	Implementation Notes	Implementation Notes		
SDTMIG-PGx v1.0 SENDIG v3.1	Ordinal Dame Label Definition	While this field is not typically captured on a CRF, it should	Lorem ipsum dolor sit amet, consectetur adipiscing elit.		
SENDIG V3.0	Easily distinguish differences	be displayed clearly on the CRF and/or the EDC system. This field can be included into the database or populated	Duis iaculis pellentesque consectetur. Mauris id volutpat nisi. Nam ultricies pharetra nisi, ac tincidunt dui aliguam		
SENDIG-AR v1.0	hetween metadata versions	during SDTM-based dataset creation before submission.	non. Aliquam augue dolor, tempus non viverra id, vulputate		
SENDIG-DART v1.0		>	vehicula ante. Morbi sit amet lacus non justo lacinia rhoncus. Proin ac pharetra eros.		
	or changes made				
🗸 Data Analysis	The name (Mapping Instructions Maps directly to the SDTMIG variable listed in the column	Mapping Instructions Maps directly to the SDTMIG variable listed in the column		
ADaM ADAE v1.0	planned an	with the heading "SDTMIG Target".	with the heading "SDTMIG Target".		
ADaM BDS for TTE v1.0	5 VISDAT Visit Date Date the cli	Mapping Targets	Mapping Targets		
ADaM OCCDS v1.0	6 DAPERF Drug Accountability An indicatic Performed accountability	STUDYID	STUDYID		
ADaM v2.1	Category of Drug A grouping		Code List		
ADaMIG v1.0	T DACAT Category of brug A grouping A groupi		**:		



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*Screenshot is a wireframe concept and not indicative of a final product. Certain features may be restricted to membership access. 43



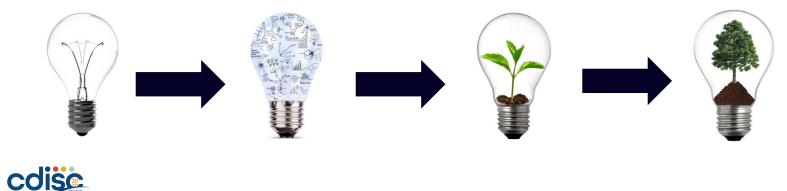
Summary

Summary

CDISC is moving towards a more technology-enabled standards future. Our partnership between Microsoft is the beginning of the CDISC Library next generation capabilities. CDISC's ability to achieve operational, transitional, and maintenance continuum will allow us to innovate and remain nimble in our technological journey.

The next generation CDISC Library allows CDISC to provide new authentication and security measures, features and functionality, and content types. As the next generation CDISC Library release gets closer, our CDISC Library team will be hard at work on the next phase of development activities. Stay tuned and join the **2021 TechniCon** for further details.

This is an exciting time for CDISC! We hope it's just as exciting for the CDISC Library community.





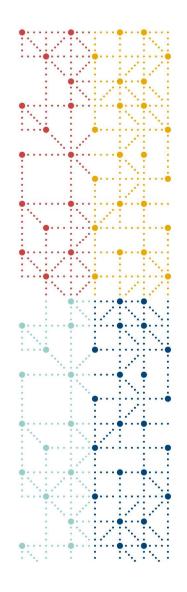
Please look for upcoming CDISC Library communications!



https://www.cdisc.org/cdisc-library/getting-started









Sam Hume - VP, Data Science, CDISC Mike Hamidi - Head, Data Science, CDISC Anthony Chow - Director, Data Science, CDISC

