



CDISC Library: Ideas for using the CDISC Library and a Look at What's Coming Next

Anthony Chow, Director, Data Science, CDISC
Sam Hume, Vice President, Data Science, CDISC



THU 8 APR
11:00AM-12:30PM ET



Today's Agenda

1. Housekeeping
2. Presenter Introductions
3. Feature Presentation
4. Question & Answer Session
5. Upcoming Learning Opportunities & Resources



Housekeeping

Housekeeping



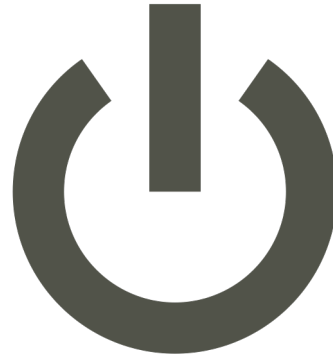
You will remain on **mute**

Housekeeping



There will be a **Q&A** after
the presentation

Housekeeping



Audio issues?

Shut down & restart GoToWebinar

Housekeeping



A recording of this webinar and the slides will be available in the **Members Only** section of CDISC website



Our Presenters

- Anthony Chow, Director, Data Science, CDISC
- Sam Hume, Vice President, Data Science, CDISC



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2021-04-08





Agenda

1. Latest Release: 2021 R1
2. 2021 Planning
3. Common Use of CDISC Library API
4. Wrap Up



CDISC Library 2021 R1

What's Available, What's New



Contents

2021 R1 Release

Added to existing content are:

- 2020 Q3 CT.
 - 2020 Q4 CT.
 - 2021 Q1 CT.
 - SENDIG v3.1.1.
-
- 2020 Q3 CT = 2020-09-25 publications + 2020-11-06 corrections. Effective date is set to 2020-11-06. E.g., `/mdr/ct/packages/adamct-2020-11-06`.



Contents

2021 R1 Release

New content types:

- CDISC Glossary.
- Draft content.
- CDISC Glossary has same CDISC CT structure. E.g.,
`/mdr/ct/packages/glossaryct-2020-12-18.`
- Draft contents = snapshot of normative metadata for preview, prior to their publications. Effective date set to snapshot taken.
 - Inaugural contents: ADaMIG v1.3, SDTMIG v3.4

Draft Content

- Data Standards Browser

Dashboard <

Expand All

- ▼ Data Collection
- ▼ Data Tabulation
- ▼ Data Analysis
- ▼ Terminology
- ▲ Draft Content
 - ADaMIG v1.3 ⚠
 - SDTMIG v3.4 ⚠

ADaMIG v1.3

Status	Effective Date	Implements
Draft	2020-12-09	ADaM v2.1

SDTMIG v3.4

Status	Effective Date
Draft	2021-02-11

- API

- /mdr/products/DraftContent
- /mdr/sdtmig/3-4
- /mdr/adam/adamig-1-3

```
{
  "name": "ADaMIG v1.3",
  "registrationStatus": "Draft",
  "effectiveDate": "2020-12-09",
  "version": "1-3"
}

{
  "name": "SDTMIG v3.4",
  "registrationStatus": "Draft",
  "effectiveDate": "2021-02-11",
  "version": "3.4"
}
```



Reminder

- A software change may require clearing browser local cache and/or cookies
- CDISC Library Knowledge Base article is available
- <https://wiki.cdisc.org/x/EREiBw>



2021 Planning

Content Planned for 2021

- Maintenance of CDISC CT quarterly publications.
- Multiple ADaM publications scheduled.
- CDASH v2.2 scheduled.
- Questionnaires, Ratings & Scales (QRS).
 - QRS Supplement to SDTMIG.
 - Public domain instruments initially.
 - Includes, but not limited to, response metadata, ODM-XML, and eCRF.



Content Planned for 2021 (Con't)

Diffs

Feature highlights (subject to change):

- Describes values add/update/delete, with before & after side-by-side.
- Will work with any standards, e.g., CDASH Model, SDTM, ADaMIG, CT.
- Will work with both successive and skipped versions.
- JSON media type & Excel export.
- Color coded.

Content Planned for 2021 (Con't)

Diffs example output, SDTMIG v3.3 against v3.2, about VS domain:

Action	Impact	Change Level	Class	Dataset Name	Variable Name	Attribute (updated)	Attribute (previous)
Value Update	Core	Major	Findings	VS	VSBLFL	Perm	Exp
						Position of the subject during a measurement or examination. Examples: "SUPINE", "STANDING", "SITTING".	Position of the subject during a measurement or examination. Examples: SUPINE, STANDING, SITTING.
Value Update	CDISC Notes	Minor	Findings	VS	VSPOS		
Add	Variable	Major	Findings	VS	EPOCH	EPOCH	
Add	Variable	Major	Findings	VS	TAETORD	TAETORD	
Add	Variable	Major	Findings	VS	VSLOBXFL	VSLOBXFL	

Content Planned for 2021 (Con't)

- ODM media type
 - ODM for CDASHIG
 - Define-XML for SDTMIG, SENDIG, and ADaMIG
 - CT-XML for Controlled Terminology
- Implementation Guide Assumptions
- Conformance Rules
- Initial CDISC 360 Content (draft)



Common Use of CDISC Library API

Common uses of the API

Retrieve the latest versions of the standards and CT for loading into internal metadata repositories

Build Standards-aware study design tools

Check conformance against standards metadata

Search across all versions of all standards and CT

ETL designer tools

Impact / change management

Novel metadata simplifies task automation (e.g. QRS)

Standards visualization, browsing, and retrieval (e.g. Data Standards Browser)

Retrieve using multiple media-types including ODM and Define-XML



How to find more information

CDISC Library On-line Resources

- CDISC LMS: <https://learnstore.cdisc.org/Course/view/1828249>
- API Documentation: <https://www.cdisc.org/cdisc-library/api-documentation>
- Release Notes: <https://wiki.cdisc.org/display/LIBSUPRT/Release+Notes>
- Knowledge Base: <https://wiki.cdisc.org/display/LIBSUPRT/How-to+articles>
- Product Inquiry & Enhancement Request: <https://www.cdisc.org/cdisc-library/api-account-product-inquiry>



API Client Tools

- Free and open-source options are aplenty, examples that we use:
- cURL command line interface (binaries & documentations): <https://curl.haxx.se>
- Postman: <https://www.getpostman.com>



Thank You!





Questions & Answers

Audience Questions

Could you please talk about CDISC Library access authorization for 1) Members, 2) Individuals in member organization, and 3) non-member

+

Does our firm's membership entitle us to use the Library data standards browser? (Applies to "Diff" use also)



Audience Questions



When will the diff functionality be available?

Audience Questions

How often do you do new releases in the Library?



Audience Questions



Are you planning to include the ADaM ADQRS supplements in the CDISC Library? If so, please contact the ADQRS sub-team so we can make sure you have everything needed.

Audience Questions

In the Differences reports, how is the change level determined (Major vs. Minor)?



Audience Questions



Sam mentioned that assumptions will be added to the library. In the next-generation CDISC Library presentation last year it was said that a non-normative part (descriptions/examples/instructions) of CDISC standards will be added to CDISC Library. Is it in 2021 plans or in plans at all? Ability to look at CDISC standards in non-PDF format will be very helpful.

Audience Questions

CDISC Library API is a great tool for developers, but even within organizations which have full access to the CDISC Library the API key is not shared with employees. So tools build based on it are easily usable by end users. Will it be possible to authenticate a user in a different way, for example using CDISC web page login?



Audience Questions



Are there many open source developers using CDISC Library API?
If there are, are there plans to organize a CDISC library hackathon?

Audience Questions

Like CDISC teams are helping to develop standards, are there plans to involve non-CDISC members to help with the development of the CDISC Library? I mean not technical, but more a content-wise development or feature ideas.



Audience Questions



You showed SDTMIG v3.4 in the draft content. This version implements SDTM v2.0. Will SDTM v2.0 be available too?



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30 APRIL 2021

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2021

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Beijing | 6-7 August

Conference | Trade Show



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EVENT!



Washington, DC, or Virtually

18-22 October

Conference & Trade Show



2021 Webinars

Date	Webinar Title
22 APR	CDASH SAE v2.0 Supplement Publication Release
1 JUL	Controlled Terminology Updates for Q2 2021
30 SEP	Controlled Terminology Updates for Q3 2021
Coming Soon	CDASH "Office Hours"; ADaM "Office Hours"; more public reviews!

Visit <https://www.cdisc.org/education/webinars> for information on additional Public Training events.

CDISC MEMBERSHIP

Become a Member!

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Thank you! It is our members' support which enables us to develop standards, keeping it free and accessible to all.

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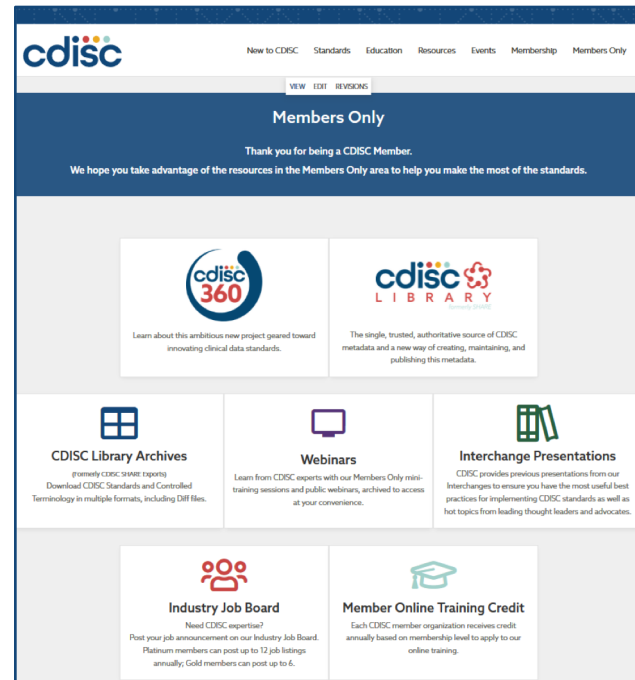


Email: membership@cdisc.org



Why Become a Member?

- To ensure the CDISC standards remain open and free
- To support CDISC in the development and maintenance of global standards
- To work with the CDISC community and be a voice in the development of clinical research standards
- To impact the development of regulatory requirements for submissions
- To access members only resources and benefits
- To gain visibility in the marketplace



The screenshot displays the CDISC website's 'Members Only' section. At the top, the CDISC logo is on the left, and navigation links for 'New to CDISC', 'Standards', 'Education', 'Resources', 'Events', 'Membership', and 'Members Only' are on the right. Below the navigation is a 'VIEW EDIT REVISIONS' button. The main heading is 'Members Only' with a sub-heading 'Thank you for being a CDISC Member.' and a message: 'We hope you take advantage of the resources in the Members Only area to help you make the most of the standards.'

The content is organized into several tiles:

- cdisc 360**: A tile with the CDISC 360 logo and text: 'Learn about this ambitious new project geared toward innovating clinical data standards.'
- cdisc LIBRARY**: A tile with the CDISC LIBRARY logo and text: 'The single, trusted, authoritative source of CDISC metadata and a new way of creating, maintaining, and publishing this metadata.'
- CDISC Library Archives**: A tile with a grid icon and text: 'formerly CDISC 360 reports. Download CDISC Standards and Controlled Terminology in multiple formats, including DDF files.'
- Webinars**: A tile with a monitor icon and text: 'Learn from CDISC experts with our Members Only training sessions and public webinars, archived to access at your convenience.'
- Interchange Presentations**: A tile with a book icon and text: 'CDISC provides previous presentations from our Interchanges to ensure you have the most useful best practices for implementing CDISC standards as well as hot topics from leading thought leaders and advocates.'
- Industry Job Board**: A tile with a group of people icon and text: 'Need CDISC expertise? Post your job announcement on our Industry Job Board. Platinum members can post up to 12 job listings annually. Gold members can post up to 6.'
- Member Online Training Credit**: A tile with a graduation cap icon and text: 'Each CDISC member organization receives credit annually based on membership level to apply to our online training.'

Don't forget to fill out the feedback survey!



Contact the Membership Team:
membership@cdisc.org



Contact the Education Team: training@cdisc.org



Contact the Events Team: events@cdisc.org



Contact Bernard directly: bklinke@cdisc.org



Thank You!

Questions, comments, concerns? Email bklinke@cdisc.org

Don't forget to fill out the feedback survey!

