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

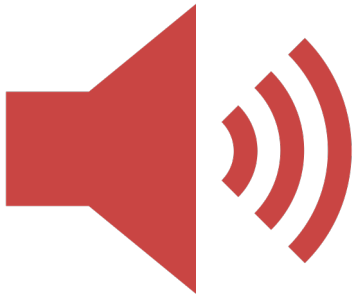
THU 8 APR
11:00AM-12:30PM ET

Today's Agenda

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

Housekeeping

Housekeeping

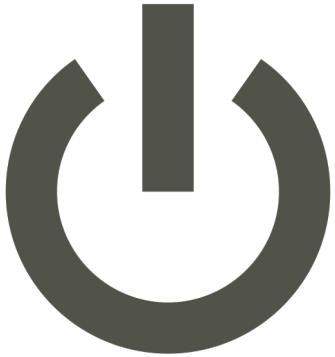


You will remain on **mute**

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

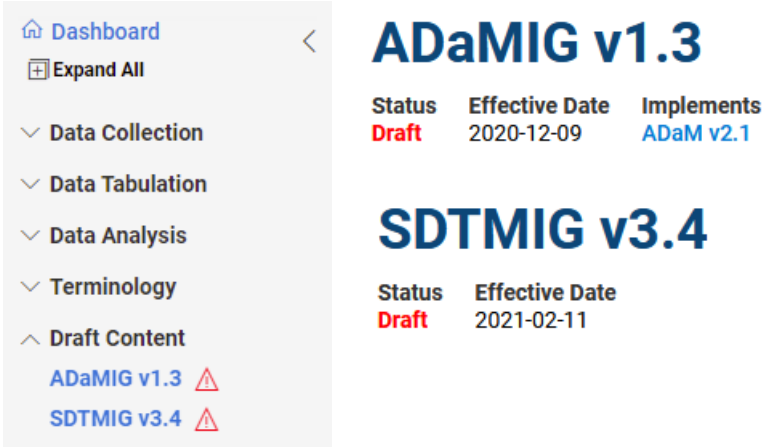
New content types:

- 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



- 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
Value Update	CDISC Notes	Minor	Findings	VS	VSPOS	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.
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)

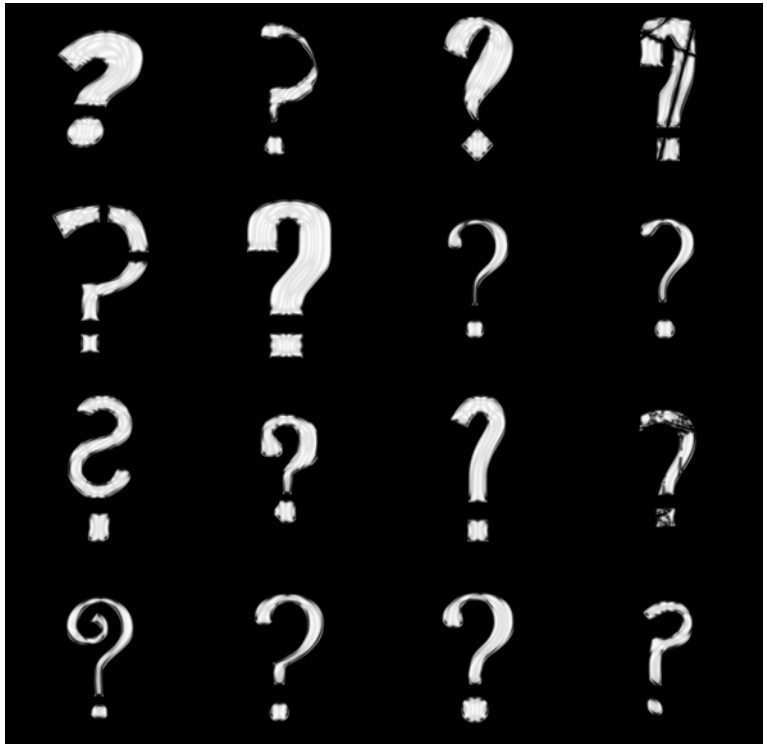
Audience Questions

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?

Upcoming Learning Opportunities

New Virtual Training Methods

- Information available at: www.cdisc.org
- Register at: https://learnstore.cdisc.org/
- Contact us at: training@cdisc.org

BLENDED LEARNING | VIRTUAL TRAINING | CLASSROOM TRAINING | PRIVATE TRAINING | WEBINARS | WORKSHOPS

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2021 EUROPE INTERCHANGE
With Standards – Science Will Prevail!
VIRTUAL EVENT!
Live Stream | 28-30 April
Conference | Trade Show | TechniCon
NEXT GENERATION TECHNOLOGY SOLUTIONS
TechniCon
30 APRIL 2021
A VIRTUAL CDISC EVENT
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2021 JAPAN INTERCHANGE
With Standards – Science Will Prevail!
VIRTUAL EVENT!
Live Stream | 10-11 June
Conference | Trade Show

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2021 CHINA INTERCHANGE

With Standards – Science Will Prevail!

Beijing | 6-7 August

Conference | Trade Show

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2021 US INTERCHANGE

With Standards – Science Will Prevail!

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!

Join nearly 500 member organizations that contribute to bringing clarity to data.

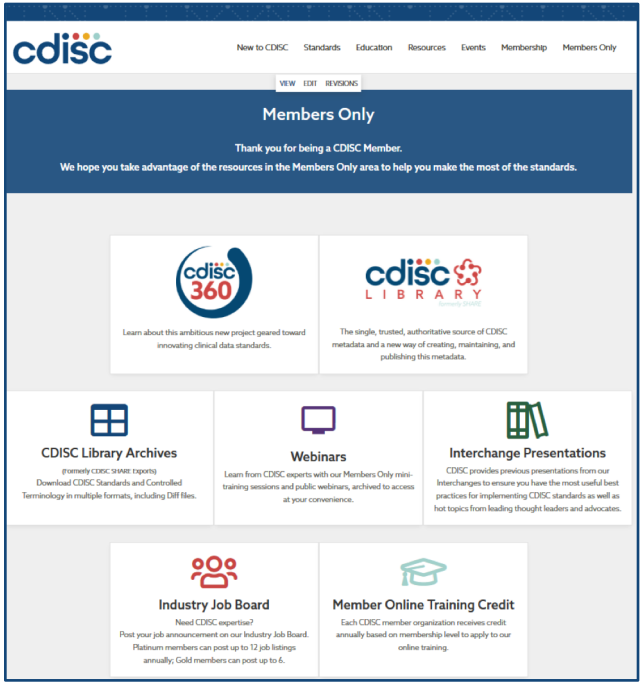
Already a Member?

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

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



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!