



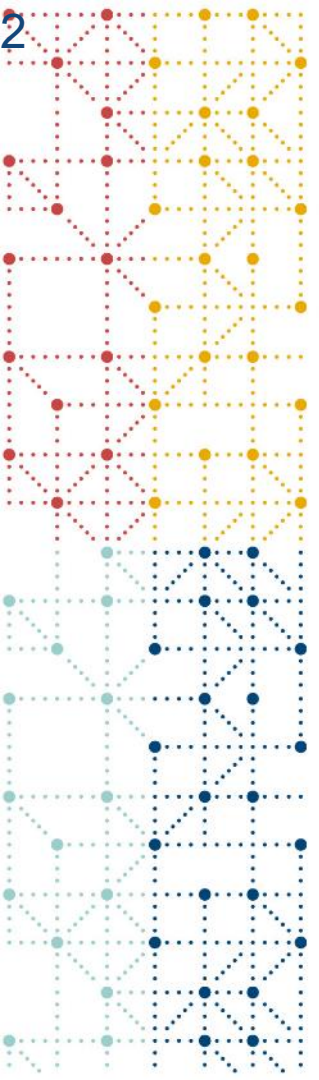
# CO SA Spotlight

## CDISC Open Source Alliance

- 1. Tplyr**
- 2. Define-XML XLS Stylesheets**
- 3. OpenStudyBuilder**

- Sam Hume, VP, Data Science, CDISC
- Charles Shadle, Head of Data Science Operations, CDISC
- Mike Stackhouse, Chief Innovation Officer, Atorus Research
- Eli Miller, Informatics Application Developer, Atorus Research
- Lex Jansen, Sr. Director, Data Science Development, CDISC
- Henrik Lynge, Vice President, Novo Nordisk A/S
- Mikkel Traun, Principal Programmer, Novo Nordisk A/S

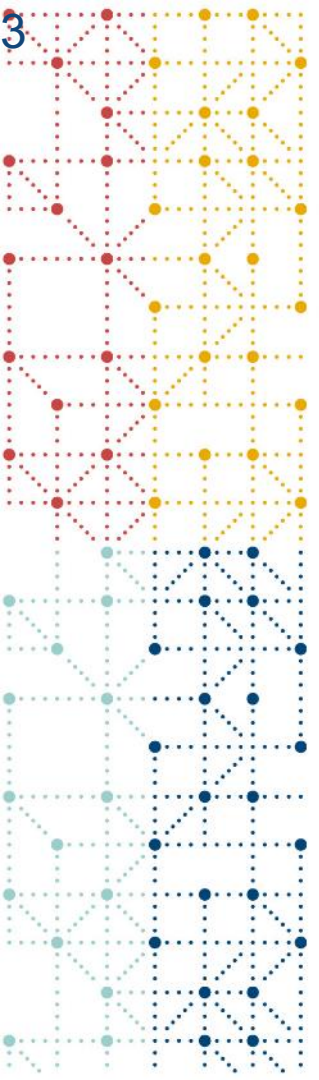
[cosa.cdisc.org](http://cosa.cdisc.org)



## Today's Agenda

1. Housekeeping
2. Feature Presentation
3. Upcoming Learning Opportunities & Events





# Housekeeping

# Housekeeping



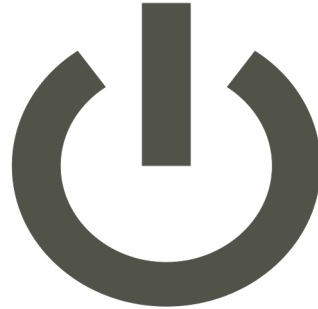
You will remain on **mute**

# Housekeeping



Submit questions at any time via the  
Questions tool on your GTW app

# Housekeeping



## Audio Issues?

First, close and restart your GoToWebinar App  
Second, check your local internet connection strength  
using the Audio tool

# Housekeeping



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



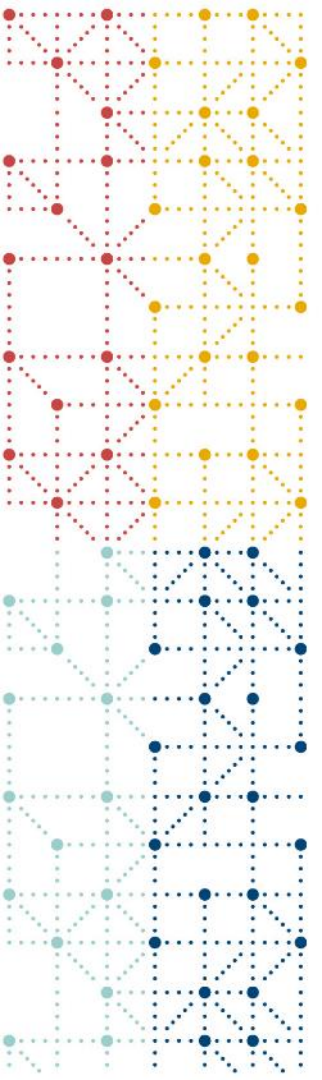


# CDISC Open Source Alliance Spotlight

## CDISC Open Source Alliance

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2. **Define-XML XLS Stylesheets**
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# Questions & Answers

# Audience Questions



ELI:

Is Tplyr built on SAS?

# Audience Questions

ELI:

Is tplyr built on top of dplyr?

Does it inherit all the cool features from dplyr and tidyverse?



# Audience Questions



Can we display scientific notation using Tplyr?



## Audience Questions

Do you have other webinars before this one where you explain the Tplyr package?

Are they available to the public?



# Audience Questions



Can you please share the link for the tplyr shiny app?

# Audience Questions

Is there an updated version of define.pdf in the github?



# Audience Questions



LEX:

Will the localization & translation be reviewed and/or governed to ensure their accuracy?

## Audience Questions

If an xml file contains data specs in multiple languages, will the define.html file, if you create a Japanese one, then automatically display the metadata of the xml file in Japanese language (sure, if included) and the Chinese define.html automatically display the Chinese metadata?





# Audience Questions



MIKKEL:

Do you find Graph API  
useful in your applications?

## Audience Questions

For each presenter who spoke about standardizing the protocol, how do you see the clinicians and other protocol authors interacting with your systems or tools? The tools seem geared towards representing information but that doesn't necessarily reflect the process of creating a protocol.



# Audience Questions



MIKKEL:

Have you thought of adding impact analysis such that users/approvers can review impacts to existing studies prior to applying or approving a change?

# Audience Questions

What is the technological stack of Study Builder?





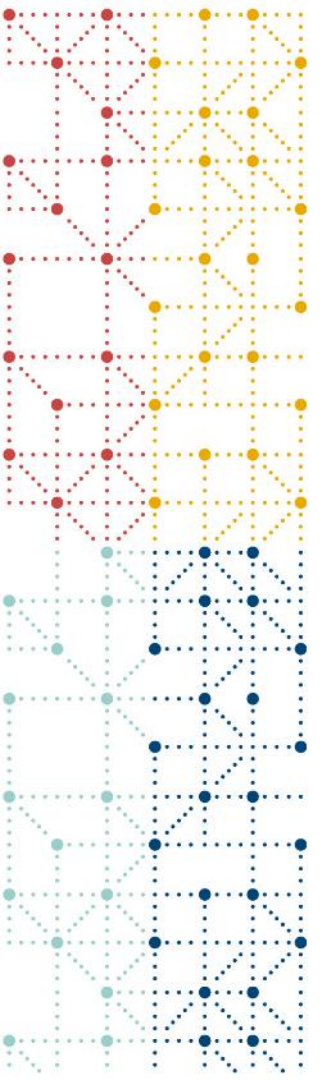
# Audience Questions



MIKKEL:

Thanks for sharing the progress made so far! Looking forward to getting my hands on it. Is the OpenStudyBuilder live and available on Github/Gitlab? If not, what is your timeline? And how does one start using it - access via Web or does it need local download? Is the MDR solution going to be part of the open source solution or is the expectation that the companies will use their own metadata repository? Will the APIs be available as part of the open-source code?





# Upcoming Events

# April - May

2022



Europe Interchange Trainings

# July

Asia



Virtual Training Event

*Regional discounts will appear at checkout.*

# September

US



Virtual Training Event

- Information available at: [www.cdisc.org](http://www.cdisc.org)
- Register at: <https://learnstore.cdisc.org/>
- Contact us at: [training@cdisc.org](mailto:training@cdisc.org)



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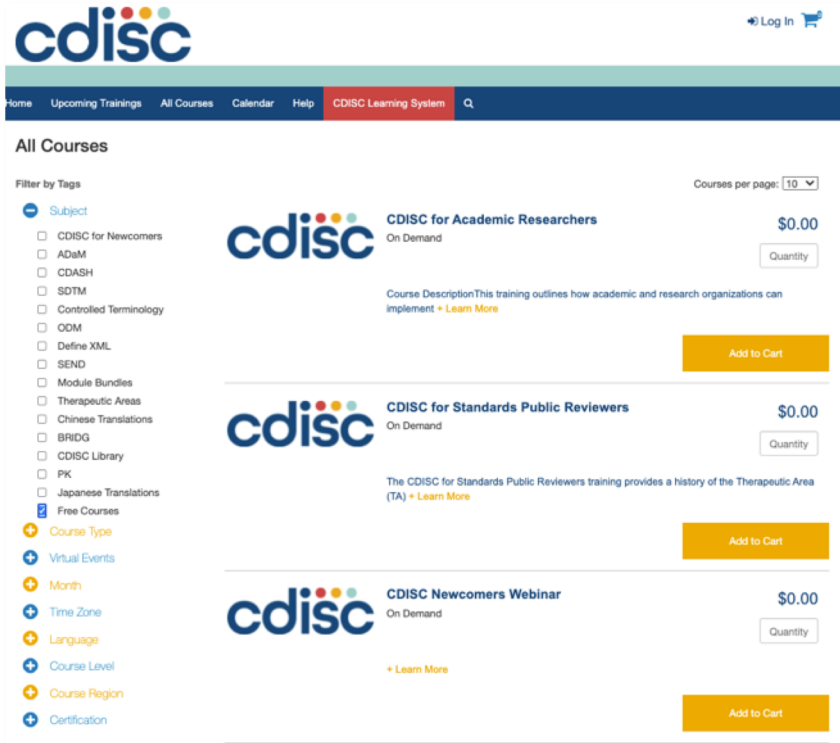


WEBINARS



WORKSHOPS

# Free CDISC Courses



The screenshot shows the CDISC Learning System website. The top navigation bar includes links for Home, Upcoming Trainings, All Courses, Calendar, Help, and CDISC Learning System. The main content area is titled "All Courses" and features a "Filter by Tags" sidebar on the left. The sidebar lists various filters such as Subject, Course Type, Virtual Events, Month, Time Zone, Language, Course Level, Course Region, and Certification. The main content area displays three course cards, each with the CDISC logo, course title, price (\$0.00), and an "Add to Cart" button. The courses are: "CDISC for Academic Researchers", "CDISC for Standards Public Reviewers", and "CDISC Newcomers Webinar".

**cdisc** Log In

Home Upcoming Trainings All Courses Calendar Help **CDISC Learning System** Q

### All Courses

Filter by Tags Courses per page: 10

- Subject
  - CDISC for Newcomers
  - ADaM
  - CDASH
  - SDTM
  - Controlled Terminology
  - ODM
  - Define XML
  - SEND
  - Module Bundles
  - Therapeutic Areas
  - Chinese Translations
  - BRIDG
  - CDISC Library
  - PK
  - Japanese Translations
- Free Courses
- Course Type
- Virtual Events
- Month
- Time Zone
- Language
- Course Level
- Course Region
- Certification

**cdisc** **CDISC for Academic Researchers** \$0.00  
On Demand  
Quantity  
Course Description This training outlines how academic and research organizations can implement [Learn More](#)  
Add to Cart

**cdisc** **CDISC for Standards Public Reviewers** \$0.00  
On Demand  
Quantity  
The CDISC for Standards Public Reviewers training provides a history of the Therapeutic Area (TA) [Learn More](#)  
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**cdisc** **CDISC Newcomers Webinar** \$0.00  
On Demand  
Quantity  
[Learn More](#)  
Add to Cart

[Http://learnstore.cdisc.org](http://learnstore.cdisc.org)



**2022 EUROPE INTERCHANGE  
CDISC VIRTUAL CONFERENCE**

**27-28 APRIL**



**2022 JAPAN INTERCHANGE  
CDISC VIRTUAL CONFERENCE**

**13-14 JUNE**

# COSA OpenStudyBuilder Workshop

Friday, April 29th

Register for FREE!

**Register on the Europe Interchange registration page –  
no requirement to register for the main conference.**

The OpenStudyBuilder is an open-source project for clinical study specification. This tool is a new approach for working with studies that once fully implemented will drive end-to-end consistency and more efficient processes - all the way from protocol development and CRF design - to creation of datasets, analysis, reporting, submission to health authorities and public disclosure of study information.





# 2022 CHINA INTERCHANGE

29 - 30 JULY | BEIJING



WITH STANDARDS – UNLOCK THE POWER OF DATA



# 2022 US INTERCHANGE

26-27 OCTOBER | AUSTIN, TX



WITH STANDARDS – UNLOCK THE POWER OF DATA



# Upcoming Webinars

Date	Webinars
5 April	Controlled Terminology Updates for Q1 – P49 Publication / P50 Public Review
19 April	QRS Office Hours
21 April	SDTM Genomics Findings Office Hours (registration coming soon!)
28 June	Controlled Terminology Updates for Q2 – P50 Publication / P51 Public Review

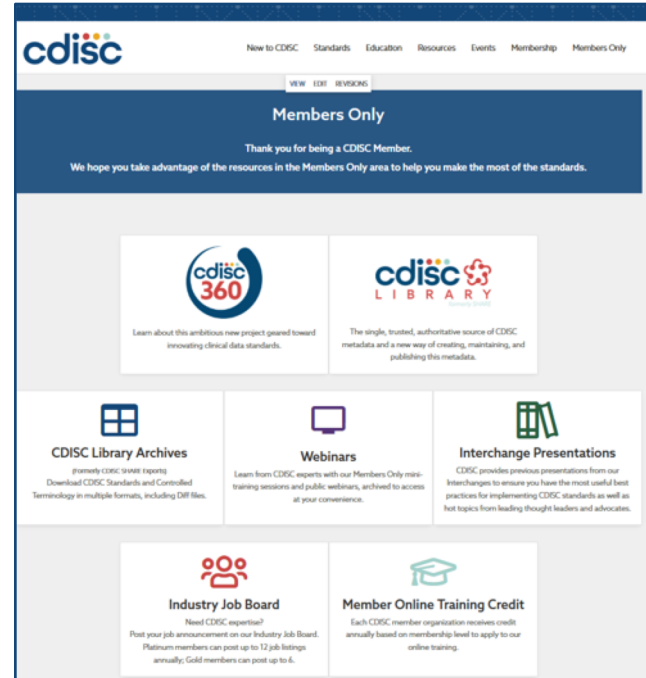
Webinars – Dates TBD	
SDTM Genomics Findings Office Hours	ADaM Office Hours
SEND Office Hours	QRS Quarterly Updates

Ideas or suggestions for webinar topics?  
Any topics you would love to see us cover?

Let us know via our topic suggestion form:  
<https://www.cdisc.org/form/webinartopicreg>

# 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**: Learn about this ambitious new project geared toward reworking clinical data standards.
- cdisc LIBRARY**: The single, trusted, authoritative source of CDISC metadata and a new way of creating, maintaining, and publishing this metadata.
- CDISC Library Archives**: formerly CDISC Grant Reports. Download CDISC Standards and Controlled Terminology in multiple formats, including DDF files.
- Webinars**: Learn from CDISC experts with our Members Only mini-training sessions and public webinars, archived to access at your convenience.
- Interchange Presentations**: 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**: 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**: Each CDISC member organization receives credit annually based on membership level to apply to our online training.

# 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.

JOIN US



Email: [membership@cdisc.org](mailto:membership@cdisc.org)



# Thank you!



Contact the Events inbox:  
[events@cdisc.org](mailto:events@cdisc.org)



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[training@cdisc.org](mailto:training@cdisc.org)



Contact Bernard directly:  
[bklinke@cdisc.org](mailto:bklinke@cdisc.org)