



COSA Spotlight Q2 2022

Ippei Akiya, Data Scientist & Software Developer, A2 Healthcare Corporation

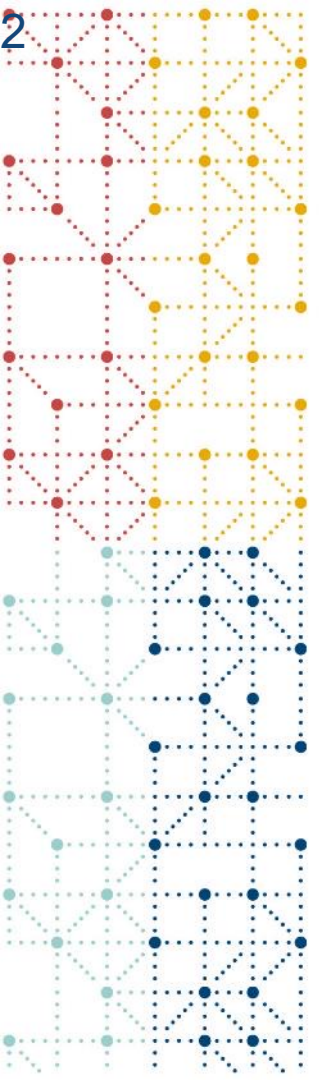
Sam Hume, Vice President, Data Science, CDISC

Charles Shadle, Head of Data Science Operations, CDISC

Ben Straub, Principal Programmer, GlaxoSmithKline

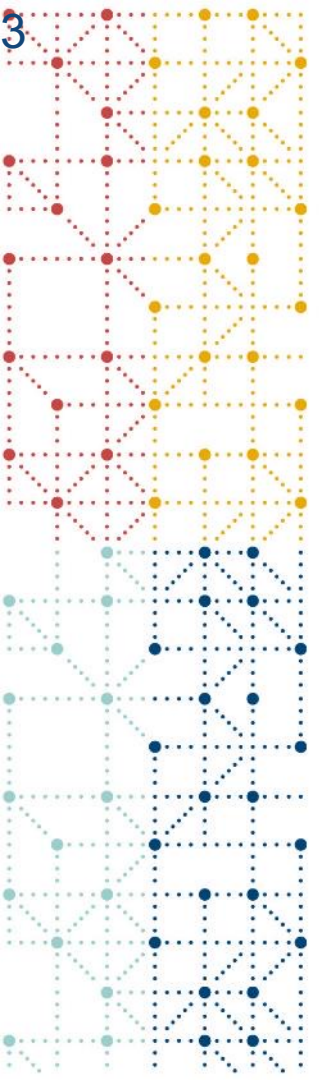


THU 30 JUN
11:00AM – 12:30PM US ET



Today's Agenda

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



Housekeeping

Housekeeping



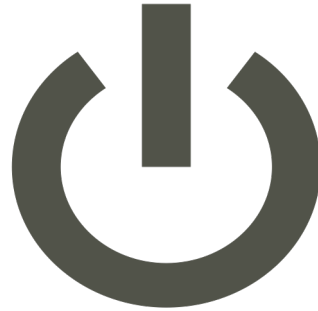
You will remain on **mute**

Housekeeping



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

Housekeeping



Audio Issues?

First, close and restart your Zoom App
Second, check your local internet connection strength

Housekeeping



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

Our Presenters

<p>Ippei Akiya Data Scientist & Software Developer A2 Healthcare Corporation</p>	<p>Sam Hume Vice President, Data Science CDISC</p>
<p>Charles Shadle Head of Data Science Operations CDISC</p>	<p>Ben Straub Principal Programmer GlaxoSmithKline</p>



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COSA Hackathon: Dataset-JSON

COSA Spotlight Webinar

June 30th, 2022

Sam Hume, DSc





Introducing Dataset-JSON

- Dataset-JSON is a draft standard for exchanging tabular datasets using JSON
- It is part of the ODM v2.0 draft standard
- It is based on the Dataset-XML v1.0 specification with enhancements, including
 - Much smaller file sizes
 - The addition of essential metadata to support data browsing
- Dataset-JSON links to a Define-XML file for the complete metadata
- Designed to meet the requirements of the regulatory submission use case
 - As well as other data exchange scenarios



Problem Statement

- Hackathon objective: to create open-source software tools for working with Dataset-JSON
- This hackathon does not restrict the types of software tools developed but does explicitly seeks tools to convert Dataset-JSON to other common formats, such as:
 - SAS v5 XPORT
 - SAS datasets
 - R data frames
 - Python Pandas data frames
 - CSV



Problem Statement, Continued

Other types of software tools could include a:

- Dataset-JSON browser or viewer
- Software for performing quality checks
- Tools that work with Define-XML in combination with Dataset-JSON datasets
- A RESTful API for Dataset-JSON.

Hackathon Rationale



Promote the use of Dataset-JSON as a SAS v5 XPORT alternative for exchanging tabular datasets



Encourage a pilot to use Dataset-JSON for regulatory submissions to the FDA



Provide seed tools for Dataset-JSON to CDISC Community



Provide feedback to improve Dataset-JSON



Build support for Dataset-JSON as an alternative data exchange format

Additional Problem Statement Background

This hackathon is virtual without any attendance requirements

Example Dataset-JSON or SAS v5 XPORT SDTM and ADaM datasets will be provided

A Define-XML file will be included with supplied example datasets

Creating new projects or extending existing projects to use Dataset-JSON are both acceptable options

If you're ready to start before the kickoff on August 25th, please do

Virtual Hackathon Timeline



Registration

Register on the CDISC Web Site using the URL below

Very simple registration page with basic information requested

No fee for participation

Registration starts July 1st and ends August 19th

Once you're registered you can start working on your solution

You must be registered to be included in the US Interchange and the Webinar Demonstrations

Open-source Solutions



As a COSA sponsored hackathon the solutions must use an accepted open-source license



Most open-source licenses are acceptable, especially those listed by the [Open Source Initiative](#)



Authors interested in COSA that meet the requirements will be asked to join



Participating projects provide a public GitHub or other source repository for their project



Each project should include a README.md describing their solution



We do support open-source projects that require proprietary software to run

What do Participants who Complete a Project Receive?

- Each tool that can be demoed will receive:
 - Exposure for their tool during the US Interchange
 - Demo their tool during a CDISC webinar after the US Interchange
 - Completed open-source projects will be offered a place on the COSA directory
 - Promote their tool in future COSA events
 - COSA Swag (a t-shirt)
- Every person or team that completes at least an MVP tool that can be demoed is considered a winner

Marketing

- Promote the Hackathon via:

- COSA Webinar
- COSA Website
- eBlast
- CDISC Website
- Social media (LinkedIn)

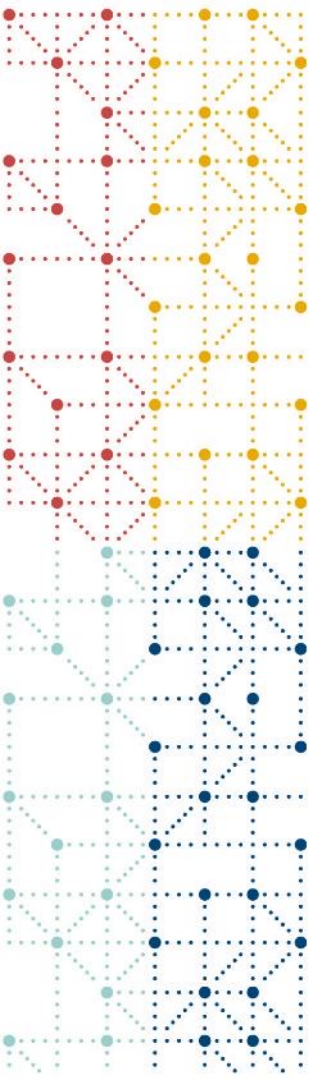


- Participants are encouraged to contribute to raising awareness of the event via social media, blog posts, or other appropriate mechanisms
- CDISC will continue to help promote COSA solutions after the completion of the hackathon

Dataset-JSON Subject Matter Experts to Help

- Hackathon will setup a Slack Workspace for all participants to exchange information and get questions answered
- A Wiki space will be created to house hackathon resources
- The draft Dataset-JSON standard and example datasets are available on GitHub





Additional Resources

Additional Resources

- Dataset-JSON GitHub repository
 - <https://github.com/cdisc-org/DataExchange-DatasetJson>
- Dataset-JSON ODM v2.0 draft specification
 - <https://wiki.cdisc.org/display/ODM2/Dataset-JSON>
 - <https://wiki.cdisc.org/display/NONXMLODM/Introduction>
- 2017 PHUSE Transport for the Next Generation (submission requirements)
 - <https://wiki.cdisc.org/display/NONXMLODM/Introduction?preview=/129046003/129046004/Transport%20for%20the%20Next%20Generation%20Version%201.0.pdf>
- 2015 FDA Test Report for DS-XML Pilot
- 2022 Working with Dataset-JSON using SAS (Lex Jansen)
 - https://www.lexjansen.com/cgi-bin/xsl_transform.php?x=pharmasug2022#pharmasug2022.ad150
- COSA Directory
 - <https://cosa.cdisc.org>

Submissions Use Case



Test Report for DS-XML Pilot

Center for Drug Evaluation and Research
(CDER)
Center for Biologics Evaluation and Research
(CBER)

April 8, 2015



Requirements for an Alternative Transport Format

Transport for the Next Generation

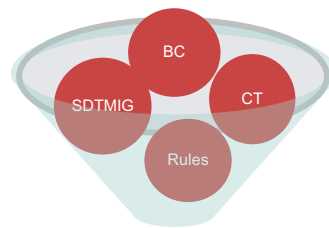
Version 1.0
Created 30 Apr 2017

A White Paper by The PhUSE Alternative Transport Format Working Group - Part of the PhUSE Emerging Trends and Technologies Computational Science Symposium Collaboration.

Free Access to the Library is Available

Sources:

- CDISC Wiki
- YAML Editor
- NCI EVS FTP Site
- ODM or Define-XML
- API Endpoints



Standards Pipeline



CDISC Library API

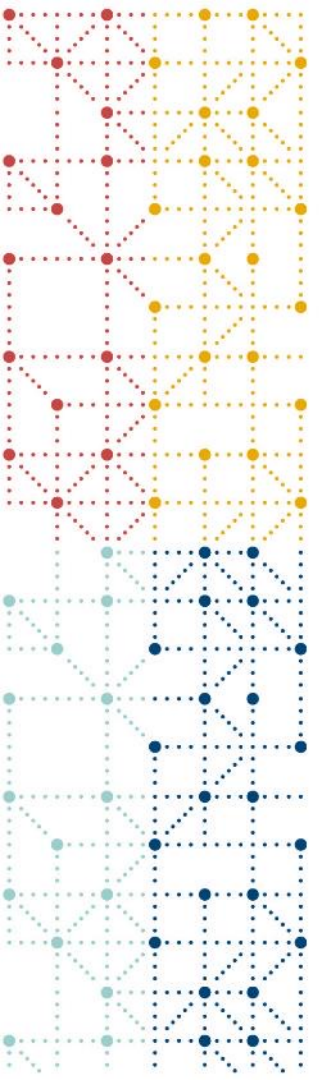
COSA & Vendor Apps

Data Standards Browser

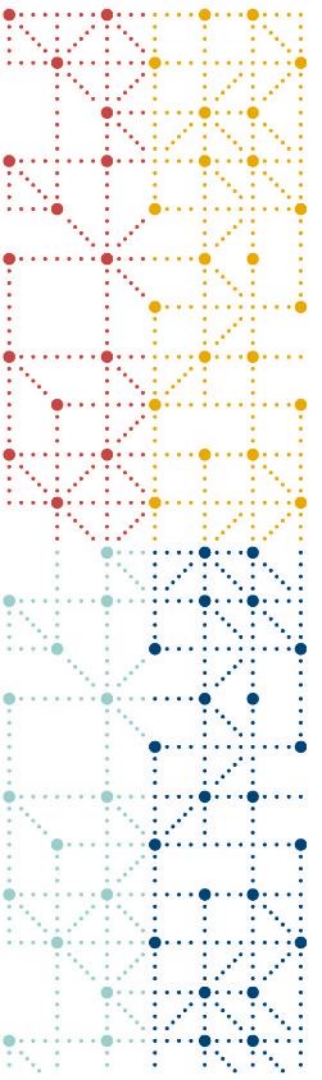
CORE

DDF

Biomedical Concepts



Questions & Answers



Upcoming Events

July

Asia



Virtual Training Event

Regional discounts will appear at checkout.

September

US



Virtual Training Event

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



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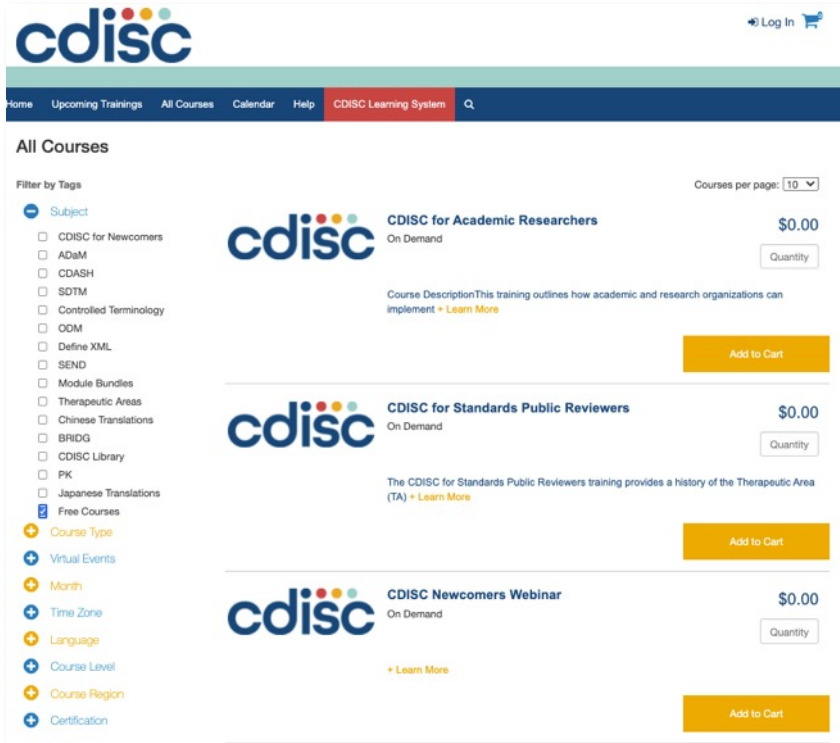


WEBINARS



WORKSHOPS

Free CDISC Courses



The screenshot displays the CDISC Learning System interface. At the top, the CDISC logo is on the left, and a 'Log In' button with a shopping cart icon is on the right. A navigation bar below the logo contains links for 'Home', 'Upcoming Trainings', 'All Courses', 'Calendar', 'Help', and 'CDISC Learning System'. The 'All Courses' page is active, showing a list of three free courses. On the left, a 'Filter by Tags' section includes 'Subject' (with a list of checkboxes for various CDISC topics) and 'Free Courses' (which is selected). Below these are expandable sections for 'Course Type', 'Virtual Events', 'Month', 'Time Zone', 'Language', 'Course Level', 'Course Region', and 'Certification'. The main content area lists three courses, each with the CDISC logo, title, 'On Demand' status, '\$0.00' price, a 'Quantity' input field, and an 'Add to Cart' button. The first course is 'CDISC for Academic Researchers', the second is 'CDISC for Standards Public Reviews', and the third is 'CDISC Newcomers Webinar'. Each course has a 'Learn More' link.

cdisc Log In

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

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
Course Description This training outlines how academic and research organizations can implement [Learn More](#)

cdisc **CDISC for Standards Public Reviews** \$0.00
On Demand
The CDISC for Standards Public Reviews training provides a history of the Therapeutic Area (TA) [Learn More](#)

cdisc **CDISC Newcomers Webinar** \$0.00
On Demand
[Learn More](#)

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

Upcoming Webinars

Date	Title
7 JUL	Developing Standards for Cell and Gene Therapy Product Monitoring
12 JUL	Pediatrics User Guide Public Review
8 SEP	QRS Office Hours
15 SEP	Genomics Findings Office Hours
29 SEP	COSA Spotlight Q3 (registration coming soon!)
4 OCT	Controlled Terminology Updates: P51 Publication / P52 Public review

Do you have a suggestion or idea for a webinar topic you'd like us to cover?

<https://www.cdisc.org/form/webinartopicreq>

2022 CHINA INTERCHANGE

CDISC VIRTUAL CONFERENCE

29-30 JULY

2022

US

INTERCHANGE

26-27 OCTOBER | AUSTIN, TX

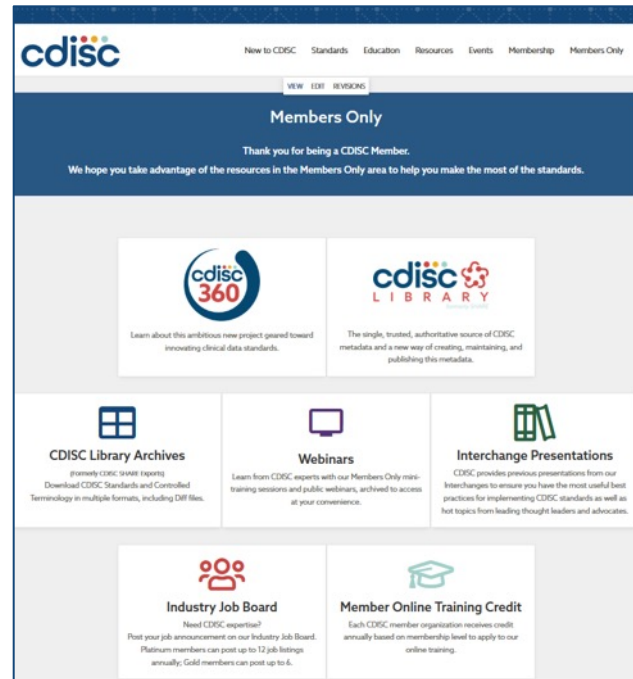


WITH STANDARDS – UNLOCK THE POWER OF DATA

cdisc

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' link. 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 renovating clinical data standards.
- cdisc LIBRARY**: The single, trusted, authoritative source of CDISC metadata and a new way of creating, maintaining, and publishing the metadata.
- CDISC Library Archives**: Promotes CDISC credit reports. Download CDISC Standards and Controlled Terminology in multiple formats, including DDF files.
- Webinars**: Learn from CDISC experts with our Members Only 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



Thank you!



Contact the Events inbox:
events@cdisc.org



Contact Education inbox:
training@cdisc.org



Contact Bernard directly:
bklinke@cdisc.org