

WITH STANDARDS – UNLOCK THE POWER OF DATA



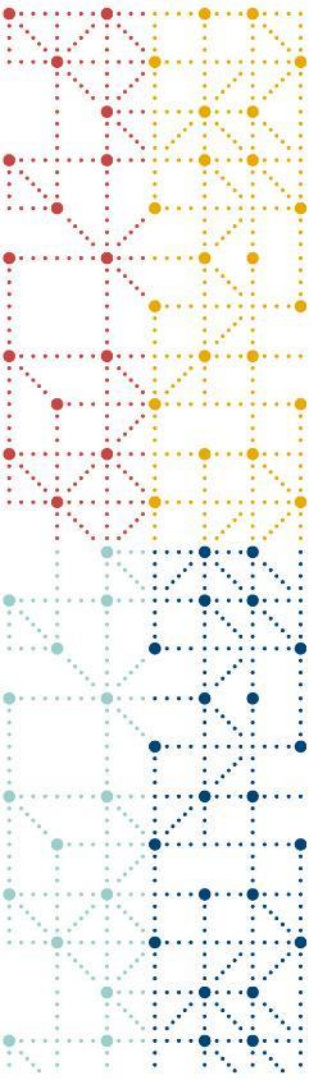
2022

CHINA
INTERCHANGE

29-30 JULY | VIRTUAL EVENT

CDISC Open Strategy

Charles Shadle, Head of Data Science Operations, CDISC



Meet the Speaker

Charles Shadle

Title: Head of Data Science Operations

Organization: CDISC

Charles has spent 30 + years in information technology.

His work experience has included software engineering and architecture, team leadership, business process improvement, project and portfolio management.

For the last 15 years, he's worked in the regulated industries of Food, Life and Health Sciences (Biotech and Pharma), assisting executive management improve critical processes, deliver successful initiatives, and maximize their investments.



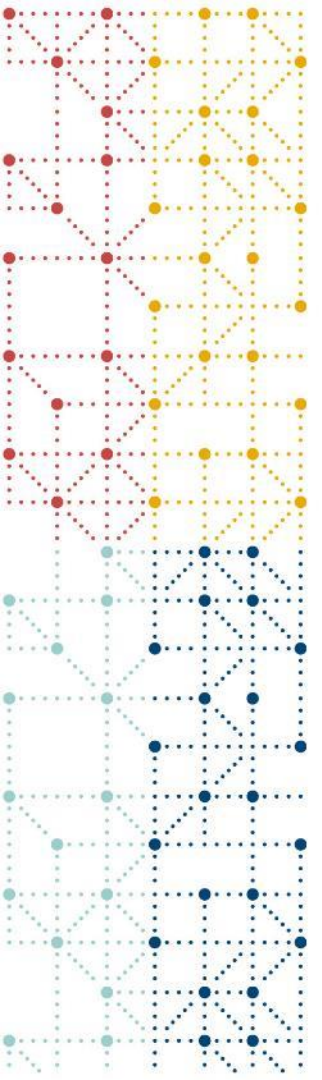
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- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*



Agenda

1. CDISC Open-Source Alliance (COSA)
2. Freemium Project



CDISC Open-Source Alliance (COSA)



Background

- Recent audit of 1250 software applications
 - 99% had open-source software (OSS) in them, whether they were OSS or not
 - Of that 99%, 70% of the code base was open source
- Other recent findings
 - > 40% CIOs have open-source as primary software strategy
 - 96% deployed applications using open-source software
 - 80-90% of code in new applications come from open source
- Open <> free
 - Free <> free



What is COSA

- COSA Mission:

The CDISC Open-Source Alliance (COSA) supports, promotes, and sometimes sponsors open-source and free software development projects that create tools for implementing or developing CDISC standards to drive innovation in the CDISC community.



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Supports

- Assisting collaboration and information exchange
- Sharing best practices and feedback
- Coordinating dependencies
- Input to standard development, CDISC library features, common APIs
- Accelerate open-source
- Drive innovation to standards-based automation



Promotes

- Support for community development
- Venues to present to CDISC members
- CDISC Marketing & Communication
- Promote development and automation approaches for implementing CDISC standards
- Promote technical innovation



Sponsors

- Specific projects important to the CDISC initiatives
 - Software Engineer(s)
 - Infrastructure
 - Project management resources
- CDISC Involvement
 - Digital Data Flow (DDF)
 - CDISC Rule Editor
 - CORE (CDISC Open Rules Engine)
 - CDISC Library Tools (Data Standards Browser and authoring tools)



How does COSA work

- Board

- 7- 9 members
- COSA exec sponsor (CDISC staff)
- 3-5 non-CDISC
- 2 consecutive, 1-year terms
- Then 1 year off
- Meet Bi-weekly

- Decisions include:

- What projects are added to COSA?
- Committees and their remit?
- Who is added to the Board?
- What events to hold?
- What to propose for sponsorship?

Name	Company
Bhavin Busa	Independent
Dmitry Kolosov	Parexel and Open-source developer
Jeff Fattic	Microsoft
Katja Glaß	Katja Glass Consulting
Mike Stackhouse	Atorus
Mikkel Traun	Novo Nordisk
Sam Hume	CDISC
Charles Shadle	CDISC, ex officio

<https://cosa.cdisc.org/about>



How to use COSA

- Information Hub
- Lists CDISC standard related open-source solutions

<https://cosa.cdisc.org>

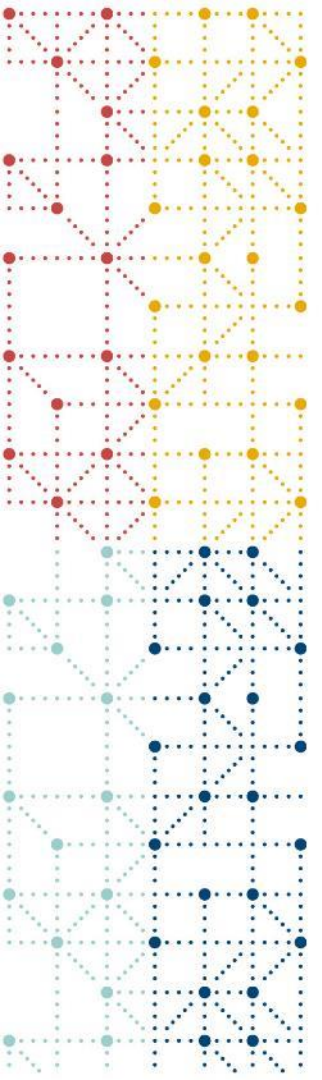
A screenshot of the CDISC Open Source Alliance website's COSA Repository Directory. The page has a dark blue header with the CDISC logo and navigation links: DIRECTORY, ABOUT, EVENTS, APPLICATION, OTHER. Below the header, the title "COSA Repository Directory" is displayed. A paragraph explains that the following repositories are officially recognized by COSA as open-source projects focused on implementing or developing CDISC standards. A search bar is present, followed by a list of repositories with their respective icons and descriptions.

Repository Name	Count	Description
Admiral	9	ADaM in R Asset Library.
Define-XML	7	
ADaM	4	
Dataset-XML	3	
ARM	3	
SDTM	2	
odmliib		odmliib is a Python library that simplifies creating and processing ODM and its extensions, such as Define-XML.
Tplyr		Tplyr is a grammar of data format and summary, designed to simplify the creation of clinical safety summaries.
Open Study Builder		The OpenStudyBuilder is a new approach to working with studies that once fully implemented will drive end-to-end consistency and more efficient processes.



COSA Summer to Remember

- ✓ 30 June – COSA Spotlight Q2
(Admiral, R4DSXML, Dataset-JSON Hackathon)
- 25 August - 19 October – Dataset-JSON Hackathon
- 1 September – CORE & Rule Editor available in public repos
- 13 September - TFL Designer Workshop
 - (start date/registration finalizing this week)
- 29 September – COSA Spotlight Q3
 - (Smart Submission Dataset Viewer, CORE, Rule Editor)



Freemium Project



Purpose (Why)

- Recommendation from the Blue-Ribbon commission
- Recommendation from the board
- Open-Source Requests
- Academia Requests
- Vendors not using Library for products
- PHUSE etc. not using Library for projects
- FDA requires Open Access



CDISC Library Goals

- Increase the number of:
 - Organizations and individuals using the Library
 - Organizations implementing the CDISC standards
 - Software solutions that use the Library
 - Non-members using the Library and Standards
 - Academic and government research organizations using the Library and Standards
- Ensure that CORE can be used by all, including non-members
- Ensure that regulators and the community view the Standards as being open and available to all, including non-members

Two Offerings: Member and Community

Member

- ✓ Unlimited accounts (28 APR)
- ✓ No bandwidth restrictions (28 APR)
- Basic support provided (in progress)
- Business appropriate SLAs (in progress)
- Basic validation included (in progress)
- Free self-paced Library training (pending)

Community

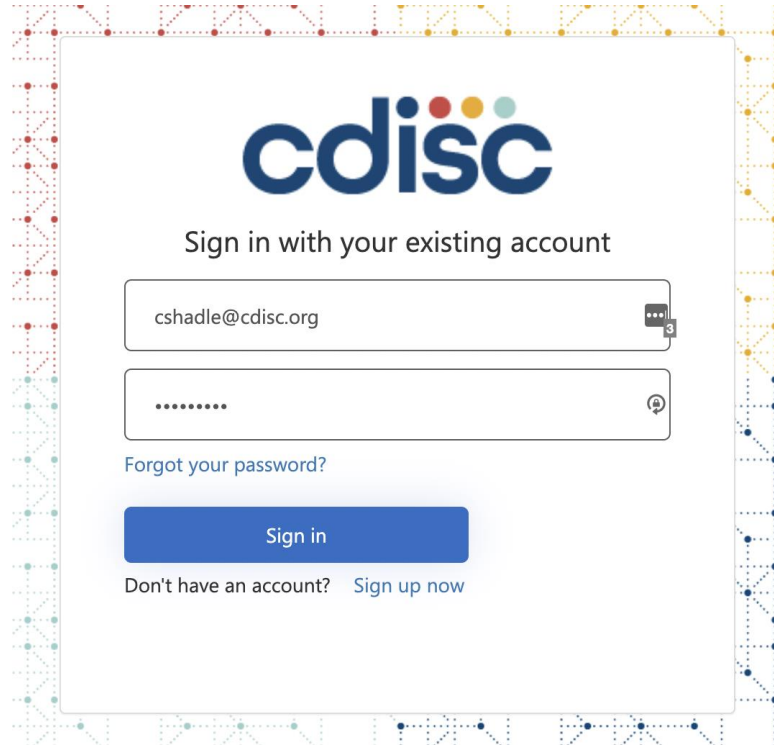
- ✓ Open to non-members (19 JUL)
- Standards Browser Advertising
- No CDISC provided direct support
- Consumer level SLAs only
- No validation
- Throttled access limits
- Lower bandwidth limits
- Fees to cover exceeded usage limits
- Must opt-in to CDISC communication

Two Offerings: Member and Community Compared

- What the two have in common:
 - Both share the same code-base and standards
 - Both have the same content
 - Software tools can use API for either case
 - CORE can use either
- How the two are different:
 - Member includes support and basic validation
 - Member has production SLAs
 - Community has greater restrictions on the number of requests and bandwidth used
 - Community Data Standards Browser includes advertising

Single Sign On (SSO)

- ✓ CORE
- ✓ CDISC Library
- ✓ Rule Editor
- LMS
- Wiki / Jira (Atlassian)
- Website (Drupal)

A screenshot of the CDISC login page. The page features the CDISC logo at the top, followed by the text "Sign in with your existing account". Below this are two input fields: the first contains the email address "cshadle@cdisc.org" and the second contains a masked password ".....". A "Forgot your password?" link is positioned below the password field. A blue "Sign in" button is centered below the input fields. At the bottom, there is a link for "Don't have an account? Sign up now". The entire login form is enclosed in a decorative border with a grid pattern and colored dots.

cdisc

Sign in with your existing account

cshadle@cdisc.org

.....

[Forgot your password?](#)

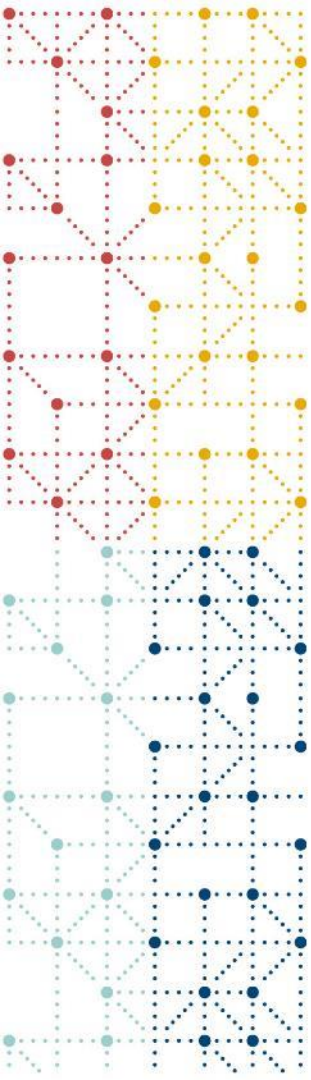
[Sign in](#)

[Don't have an account? Sign up now](#)



Library Vendor License Improvements

- A new commercial EULA is expected by the EOY
- Eliminates revenue sharing
- Refines the definition of what's considered a competitive offering
- Refines the definition of derivative works and distribution of the standards



Thank You!

Charles Shadle

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