



**2022**  
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**INTERCHANGE**  
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## **CDISC Open Source Alliance (COSA) - An Introduction**

Presented by Katja Glaß, Katja Glass Consulting, Germany



Katja Glass  
Consulting

## Meet the Speaker

Katja Glaß

**Title:** Consultant

**Organization:** Katja Glass Consulting

As part time open source consultant, I host a portal about open-source solutions for Pharma ([www.glacon.eu/portal](http://www.glacon.eu/portal)) and perform open-source projects or provide general guidance. My key experiences are SAS, Web Technologies, ADAM, Define.xml and the TLF generation where I worked for several years. I recently joined the COSA board and are also a very active PHUSE member where I chaired the EU Connect in 2018.



# Disclaimer and Disclosures

- *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.*
- *The author(s) have no real or apparent conflicts of interest to report.*



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# Agenda

1. Introduction
2. COSA Work Areas
3. COSA Repository
4. Participation
5. Summary and Outlook



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# Introduction

COSA – CDISC Open Source Alliance – What's it about?

# Introduction

## Mission:

The CDISC Open Source Alliance 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.

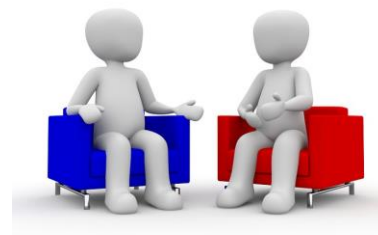


# Introduction

## Support

- Collaborations, including CDISC development teams
- Exchange information, feedback, best practices
- Coordinate dependencies
- Input to standard developments, CDISC library features, common APIs
- Accelerate open-source
- Drive innovation to standards-based automation

Support



# Introduction

## Promote

- Support for community development
- Venues for presenting to CDISC members
- CDISC infrastructure
- Marketing
- Promote development and automation approaches for implementing CDISC standards
- Promote technical innovation

Promote





# Introduction

## Sponsor

- Specific projects important to the CDISC initiatives
  - Developer
  - Infrastructure
  - Project management resources

Sponsor



## CDISC Involvement

- CORE (CDISC Rules Engine)
- Digital Data Flow (DDF)
- CDISC Library Tools (Data Standards Browser and authoring tools)

# Introduction

## How does COSA work?

- Board
  - Bi-weekly meeting
  - Next steps
  - Applications
  - Various topics



Name	Company
Bhavin Busa	Vita Data Sciences
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



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# COSA Work Areas

How does COSA support?

# COSA Work Areas

- Open source project directory
- Webinars, Hackathons, Presentations
- Active project roadmap
- Guidance
  - Open source best practices
  - Open source licensing
  - Repository setup
- Test data



# COSA Work Areas

- Webinars (free for all, recordings available)
  - TFL Designer
  - Visual Define-XML Editor
  - Odmlib
- Tplyr
- Define-XML XLS Stylesheets
- OpenStudyBuilder



# COSA Work Areas

## ➤ Collaborations

- Microsoft
- CDISC Library
- TransCelerate DDF
- PHUSE Open Source Technologies in Clinical Research
- Pharmaverse
- Open source software development teams
- HL7 FHIR community





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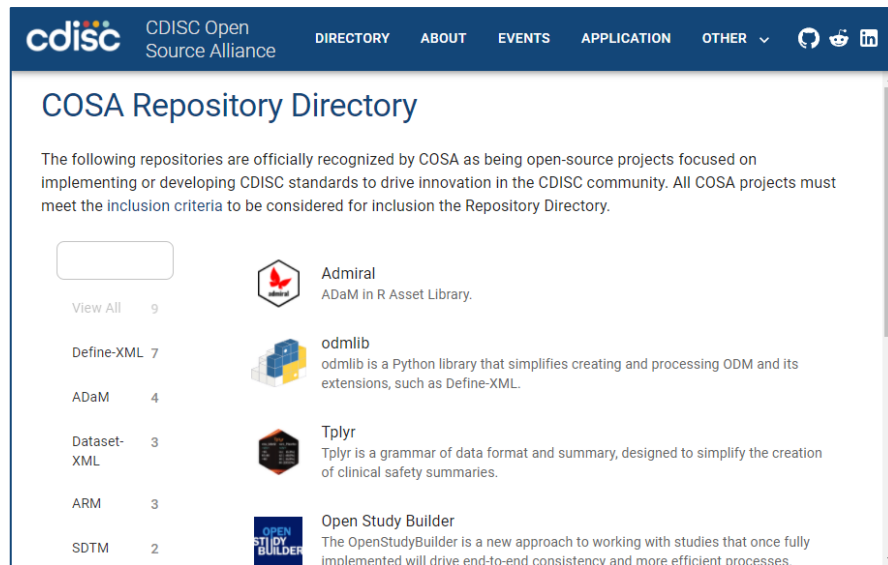
# COSA Repository

What's this?

# COSA Repository

- Information Hub
- Lists CDISC standard related open source solutions

<https://cosa.cdisc.org>



The screenshot shows the 'COSA Repository Directory' page on the CDISC Open Source Alliance website. The page features a search bar, a 'View All' link with a count of 9, and a list of repositories categorized by CDISC standard. The repositories listed are Admiral (ADaM in R Asset Library), odmlib (a Python library for ODM), Tplyr (a grammar for clinical safety summaries), and Open Study Builder (a new approach to working with studies).

CDISC Standard	Count	Repository Name	Description
ADaM	4	Admiral	ADaM in R Asset Library.
Define-XML	7	odmlib	odmlib is a Python library that simplifies creating and processing ODM and its extensions, such as Define-XML.
Dataset-XML	3	Tplyr	Tplyr is a grammar of data format and summary, designed to simplify the creation of clinical safety summaries.
ARM	3	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.
SDTM	2		



# COSA Repository



## Admiral

ADaM in R Asset Library.



## odmlib

odmlib is a Python library that simplifies creating and processing ODM and its extensions, such as Define-XML.



## TpIyr

TpIyr 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 Repository



## Define-XML XSL Stylesheets

This projects provides a Define-XML v2.0 and v2.1 XSL stylesheet



## R4DSXML

R4DSXML is R package for import both CDISC Dataset-XML and Define-XML as R data frame.



## Smart Submission Dataset Viewer

Dataset viewer allowing to inspect CDISC SDTM, SEND and ADaM submission files.



## TFL Designer

An open-source TFL designer to create study-specific analysis output display and in parallel generate machine-readable metadata.



## Visual Define-XML Editor

Visual Editor for Define-XML 2.0 and ARM standards.

# COSA Repository

- Support CDISC related open-source tools
- Support usage of these
  - Huge projects planned to join COSA
    - CORE
    - DDF
- Accelerate Open-Source!





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# COSA Participation

How to get involved?

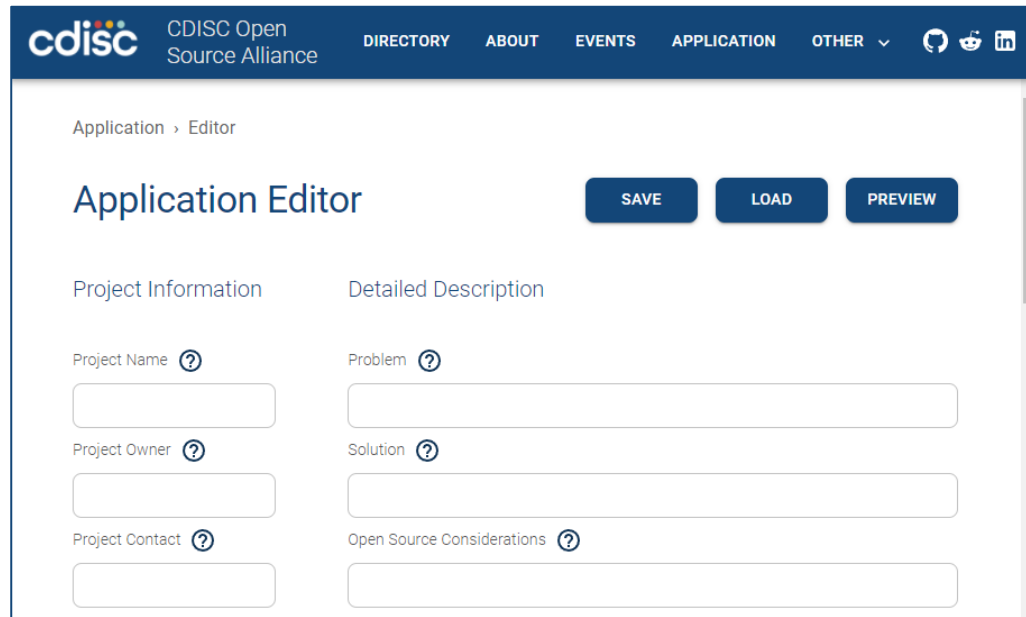
# COSA Participation

- Develop/Include CDISC related open-source tools
- COSA inclusion criteria
  - Project minimum
  - CDISC related
  - Ethics requirements and no conflicts of interest
  - Must be open-source (license)



# COSA Participation

- Application process documented, form available <https://cosa.cdisc.org/application>



The screenshot shows the 'Application Editor' interface for the CDISC Open Source Alliance. The top navigation bar includes the CDISC logo, the text 'CDISC Open Source Alliance', and links for DIRECTORY, ABOUT, EVENTS, APPLICATION, and OTHER. There are also social media icons for GitHub, Docker, and LinkedIn. The main content area is titled 'Application Editor' and features three buttons: SAVE, LOAD, and PREVIEW. Below these buttons, the form is divided into two columns: 'Project Information' and 'Detailed Description'. The 'Project Information' column contains three input fields: 'Project Name', 'Project Owner', and 'Project Contact', each with a question mark icon. The 'Detailed Description' column contains three input fields: 'Problem', 'Solution', and 'Open Source Considerations', each with a question mark icon.

cdisc CDISC Open Source Alliance

DIRECTORY ABOUT EVENTS APPLICATION OTHER

Application > Editor

Application Editor

SAVE LOAD PREVIEW

Project Information Detailed Description

Project Name ? Problem ?

Project Owner ? Solution ?

Project Contact ? Open Source Considerations ?

# COSA Participation

- Get in contact
  - [LinkedIn](#), Mail ([cosa@cdisc.org](mailto:cosa@cdisc.org))
  - Contact with board members
  - Become a board member
- Address topics
  - Discussions on licenses, maintenance models etc.
  - Address interest areas, e.g. XPT-replacement
  - Guidance on open-source topics





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# Summary and Outlook

What's next?



# Summary and Outlook

- Enable and support open source
- CDISC organisational support
  - Focus on standards, support tools that implement these
  - Harmonization, Library as platform to support tool developers
  - First learnings coming
  - Information and guidance



# Summary and Outlook

- What's there?
  - Repository
  - Contacts for questions & suggestions
- What's next?
  - Guidance
  - Template repository



# Summary and Outlook

## ➤ Resources

- COSA repository – [cosa.cdisc.org](http://cosa.cdisc.org)
- Open Source Portal – [glacon.eu/portal](http://glacon.eu/portal)
- Pharmaverse – [pharmaverse.org](http://pharmaverse.org)
- PHUSE Open Source Working Group
- Many more





**Thank You!**

**cdisc**



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