

WITH STANDARDS – UNLOCK THE POWER OF DATA



2022
US
INTERCHANGE
26-27 OCTOBER | AUSTIN



What you need to know about the CDISC Library

Sam Hume, DSc
VP, Data Science CDISC
Session 2: Second Opening Plenary - CDISC Looking Ahead
Oct. 26, 2022



Meet the Speaker

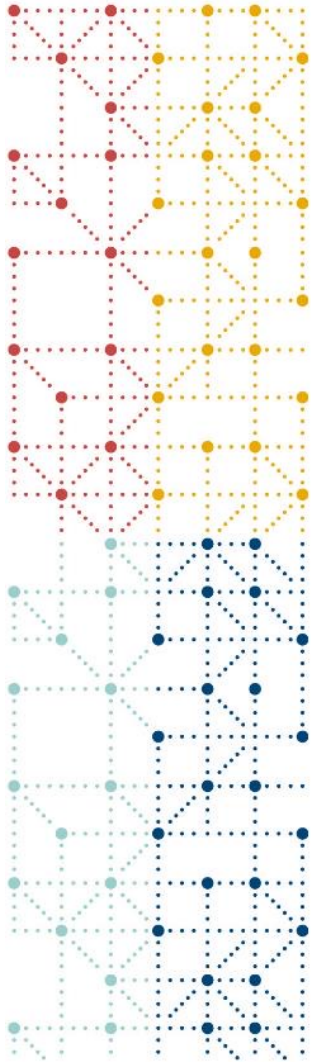
Sam Hume

Title: VP, Data Science

Organization: CDISC

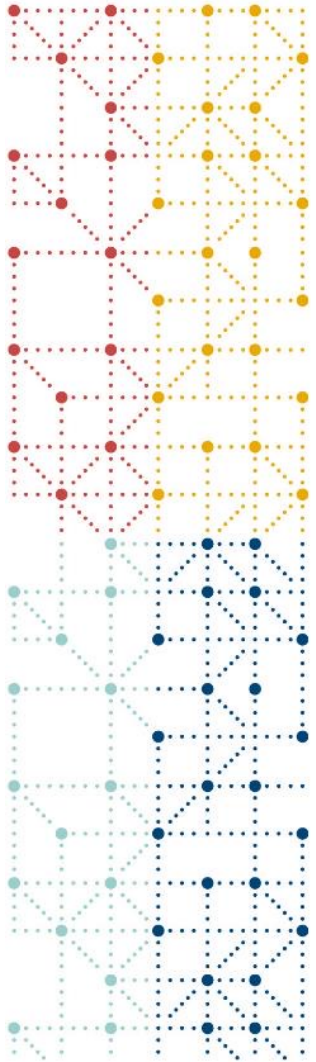


Sam Hume leads the CDISC Data Science team, which collaborates with CDISC staff and stakeholders to develop tools and standards that support clinical and translational data science. Sam directs delivery of the CDISC Library metadata repository that houses all CDISC standards, co-leads the CDISC Data Exchange Standards team, co-leads CORE, and leads the technical CDISC RWD efforts. He has 25 years' experience in clinical research informatics and has held a number of senior technology positions in the biopharmaceutical industry. He holds a doctorate in information systems.



Agenda

1. Vision
2. Open Access
3. Features & Content
4. Tools
5. Future Developments
6. Conclusion
7. Where to find more information

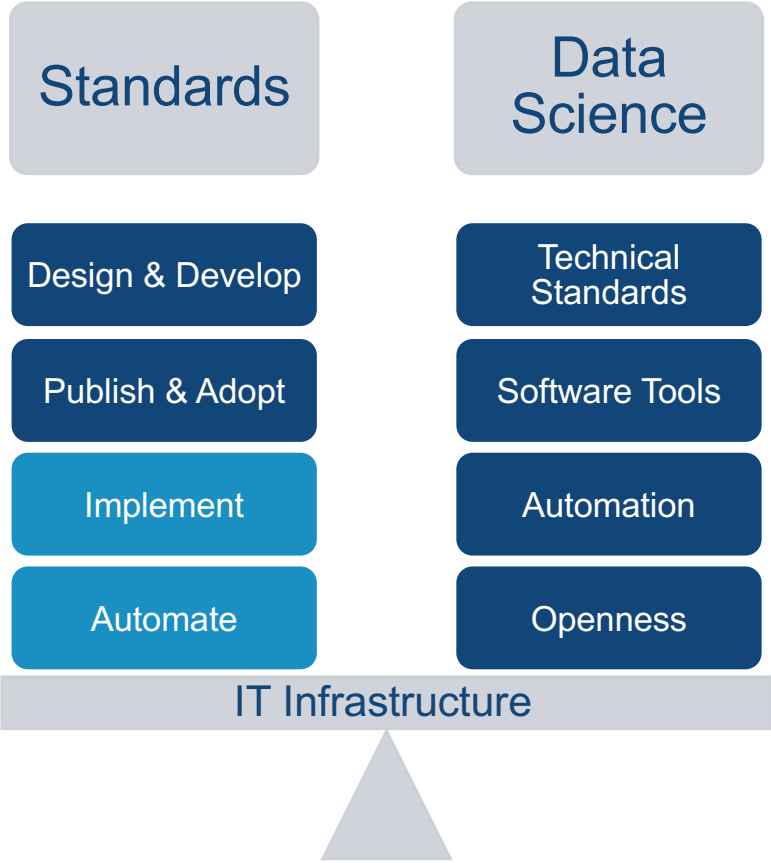


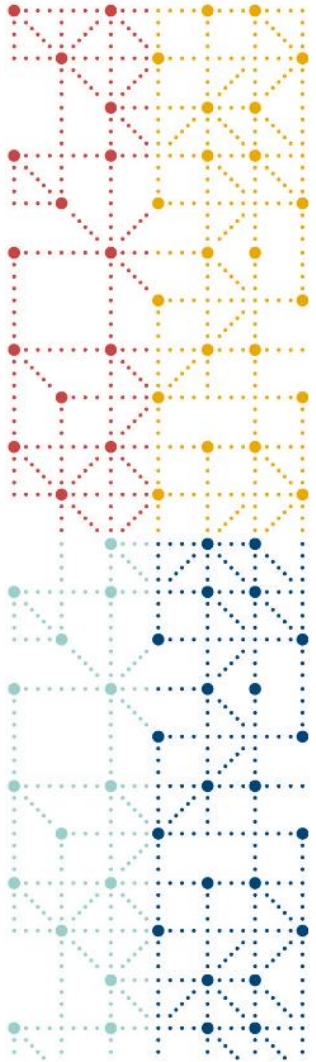
Vision

How the CDISC vision has emphasized standards implementation and driving automation



Technical Standards and Standards Implementation





Openness

Driving towards increased openness and transparency

CDISC Library Access for All

Unlimited Member Access

- Unlimited Library accounts
- Same credentials for CORE & Library
- Deprecating Library Archives

Non-member Access

- Free non-member Library accounts

Library EULA

- Updated Library EULA

A screenshot of the CDISC sign-in page. The page has a white background with a decorative border of colored dots. At the top center is the CDISC logo. Below the logo is the text "Sign in with your existing account". There are two input fields: "Email Address" and "Password". Below the "Password" field is a link "Forgot your password?". At the bottom is a blue "Sign in" button. Below the button is the text "Don't have an account?" followed by a link "Sign up now" with a mouse cursor pointing to it.

cdisc

Sign in with your existing account

Email Address

Password

[Forgot your password?](#)

Sign in

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

COSA: CDISC Open-Source Alliance

The COSA Repository Directory lists COSA open-source projects:










- ~ 16 projects
- Diverse project types
- Different maturity levels
- Primarily authored by members of the CDISC community



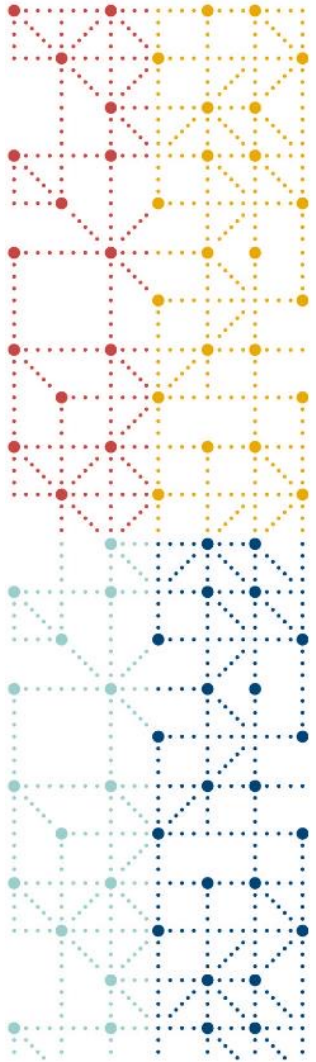
COSA Repository Directory

The following repositories are officially recognized by COSA as being open-source projects focused on implementing or developing CDISC standards to drive innovation in the CDISC community. All COSA projects must meet the inclusion criteria to be considered for inclusion in the Repository Directory.

<input type="text"/>	
View All	13
Define-XML	9
ADaM	7
CDASH	4
SDTM	4
Dataset-XML	3
ARM	3
ODM	2
SDTMIG	2
SEND	2
USDM	1
CDISC CT	1
ODM-XML	1

	Admiral ADaM in R Asset Library.
	CDISC Rules Engine (CORE) Deliver and execute a governed set of executable Conformance Rules for each Foundational Standard
	CORE - Rule Editor Creating additional Conformance Rules in a common specification for CORE
	Define-XML XSL Stylesheets This projects provides a Define-XML v2.0 and v2.1 XSL stylesheet
	Digital Data Flow <i>TransCelerate</i> The DDF initiative aims to modernize clinical trials by enabling a digital workflow that allows for automated creation of study content and configuration of study systems to support clinical trial execution.
	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.
	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.

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

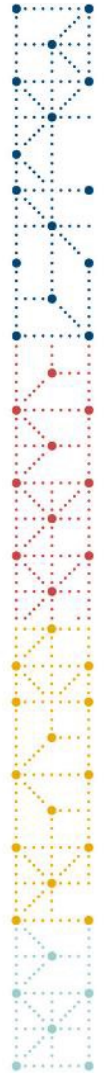
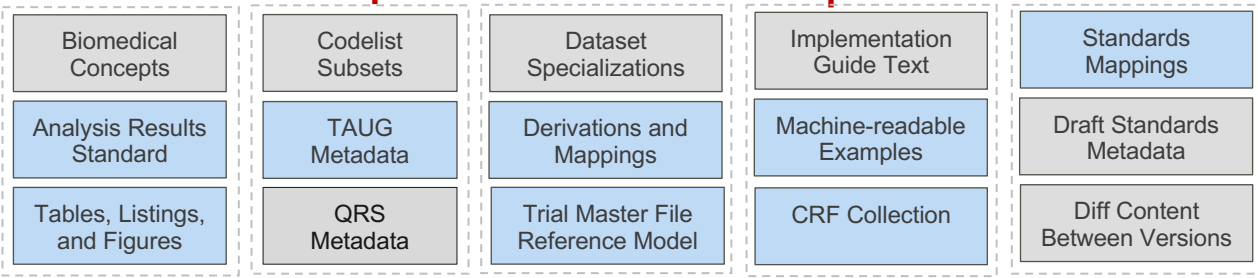
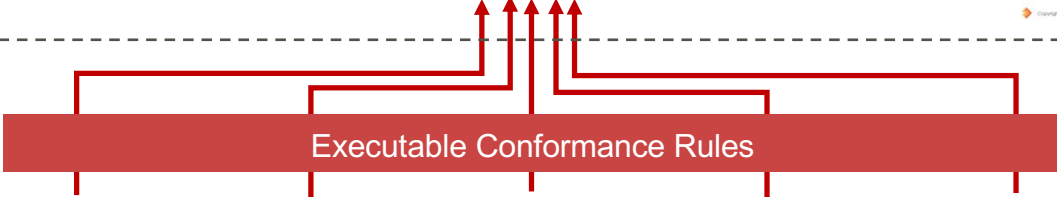
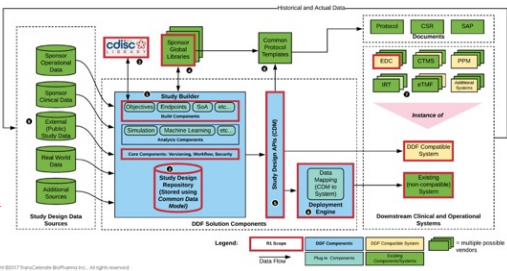


Features & Content

New or underutilized Library features and content

CDISC Library Provides the Foundation

Software Applications Consume Standards Metadata via the API





Diff Report to Compare Standards Versions

Action	Impact	Change Level	Class	Dataset Name	Variable Name	Attribute (updated)	Attribute (previous)
Value Update	Core	Major	Findings	VS	VSBLFL	Perm	Exp
						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.
Value Update	CDISC Notes	Minor	Findings	VS	VSPOS		
Add	Variable	Major	Findings	VS	EPOCH	EPOCH	
Add	Variable	Major	Findings	VS	TAETORD	TAETORD	
Add	Variable	Major	Findings	VS	VSLOBXFL	VSLOBXFL	



Add, Change & Delete



Any 2 versions



Programmatic & Machine-readable



Color-coded Outputs



Draft Content for Preview

Data Standards Browser **SENDIG-DART v1.2**

Status	Effective Date	Implements
Draft	2022-09-30	SDTM v1.6

- ∨ Data Collection
- ∨ Data Tabulation
- ∨ Data Analysis
- ∨ QRS Instruments
- ∨ Terminology
- ∧ Draft Content
 - SENDIG-DART v1.2** ⚠

API

/mdr/products/DraftContent
/mdr/sendig/dart-1-2

```
"description": "TBD",  
"effectiveDate": "2022-09-30",  
"label": "Standard for Exchange of Nonclinical",  
"name": "SENDIG-DART v1.2",  
"registrationStatus": "Draft",  
"source": "CDISC SEND Reproductive Toxicology",  
"version": "dart-1-2"
```



Point-in-time
snapshot



Final normative
metadata

Questionnaires, Ratings, and Scales



Data Standards Browser

Search



Dashboard

Expand All

Filter Products

Data Collection

Data Tabulation

Data Analysis

QRS Instruments

Clinical Classification

Functional Test

SIX MINUTE WALK Su...

Questionnaire

Terminology

Draft Content

SIX MINUTE WALK Supplement v1.0

Type	Status	Copyright	Effective Date	Category
Functional Test	Final	Public Domain	2014-05-21	SIX MINUTE WALK (C115789)

Export

Label
6 Minute Walk Test Supplement v1.0

Description
6 Minute Walk Test (6MWT) (Goldman MD, Marrie RA, Cohen JA. Evaluation of the six-minute walk in multiple sclerosis subjects and healthy controls. Multiple Sclerosis 2008; 14: 383-390).

Items

SIXMW101 SIXMW102 SIXMW103 SIXMW104 SIXMW105 SIXMW106

Test Code
SIXMW101 (C115388.C115800)

Test Name (Question Text)
SIXMW1-Distance at 1 Minute (C115387.C115800)

Label
QRS Instrument Item SIXMW1-Distance at 1 Minute for SIX MINUTE WALK Supplement v1.0



Structured Metadata



Value-Added to CDISC CT



Associating Related CT Terms

Implementation Guide Content

- Dashboard
- Expand All
- Filter Products
- Data Collection
- Data Tabulation
- Data Analysis
- QRS Instruments
- Clinical Classification
- Functional Test
- Questionnaire
- Terminology
- Draft Content
- SENDIG-DART v1.2 ⚠️

SENDIG-DART v1.2

Status: **Draft** Effective Date: 2022-09-30 Implements: SDTM v1.6

Export

Classes

- General Observations
- Special-Purpose
- Interventions
- Events
- Findings
- Trial Design
- Relationship

Data Sets

- BG
- BW
- CL
- DD
- DP
- FM
- FW
- FX
- IC
- LB
- MA
- MI
- OM
- PC
- PP
- PY
- SC

Findings **BG** Additional tables Assumptions Examples Figures

This example represents body weight changes for maternal subject 11 in an EFD toxicity study in rats. The scheduled C-section occurred on GD 20.

Row 1:	Illustrates the maternal body weight change between GD 0-6.
Rows 2-3:	Illustrate BGSTAT / BGREASND. The maternal body weight changes could not be derived for planned intervals GD 6-8 and GD 8-14 due to the missing GD 8 body weight. Since the intervals could not be generated, BGDY, BGENDY, BGRPDY, and BGRPENDY (actual study and phase day variables) are null.
Rows 4-5:	Illustrate the maternal body weight change between GD 6-14 and GD 6-20.
Row 6:	Illustrates the adjusted maternal body weight gain between GD 6 and adjusted GD 20. The GD 20 maternal body weight was adjusted for the gravid uterus weight.

bg.xpt

Row	STUDYID	DOMAIN	USUBJID	BGSEQ	BGTESTCD	BGTEST	BGORRES	BGORRESU	BGSTRESC	BGSTRESN	BGSTRESU	BGSTAT	BGREASND	RPHASE	RPPLDY	RPPLENDY	BGDTC	BGENDTC	BGDY	B
1	10333	BG	10333-11	1	BWGAIN	Body Weight Gain	43.4	g	43.4	43.4	g			GESTATION	0	6	2008-08-01T07:20	2008-08-07T07:15	1	7



From Document to Structured Metadata



Context-aware IG Content



Accessible via API



Biomedical Concepts

Biomedical Concepts (BC) ^

- GET `/mdr/bc/packages` ∨
- GET `/mdr/bc/packages/{package}/biomedicalconcepts` ∨
- GET `/mdr/bc/packages/{package}/biomedicalconcepts/{biomedicalconcept}` ∨
- GET `/mdr/bc/packages/{package}/biomedicalconcepts/{biomedicalconcept}/dataelementconcepts` ∨
- GET `/mdr/bc/packages/{package}/biomedicalconcepts/{biomedicalconcept}/dataelementconcepts/{dataelementconcept}` ∨

Study Data Tabulation Model Dataset Specializations (SDTM) ^

- GET `/mdr/specializations/sdtm/packages` ∨
- GET `/mdr/specializations/sdtm/packages/{package}/datatasetspecializations` ∨
- GET `/mdr/specializations/sdtm/packages/{package}/datatasetspecializations/{datatasetspecialization}` ∨
- GET `/mdr/specializations/sdtm/packages/{package}/datatasetspecializations/{datatasetspecialization}/variables` ∨
- GET `/mdr/specializations/sdtm/packages/{package}/datatasetspecializations/{datatasetspecialization}/variables/{variable}` ∨



Hierarchical Biomedical
Concept System



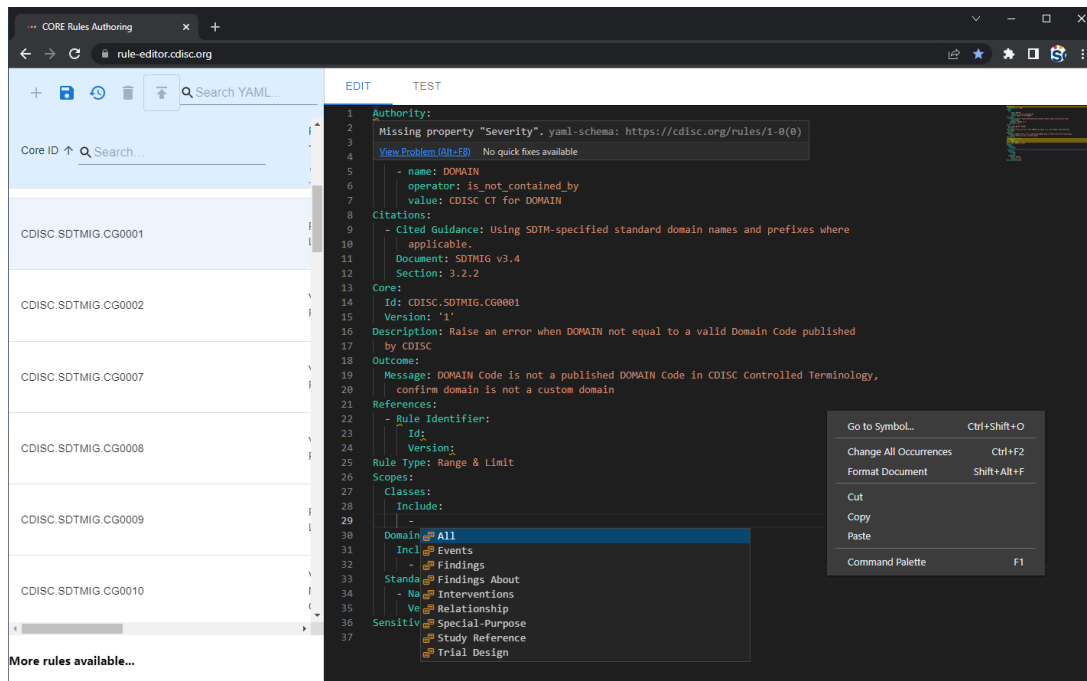
Dataset
Specializations



More Metadata
And Relationships



Conformance Rules



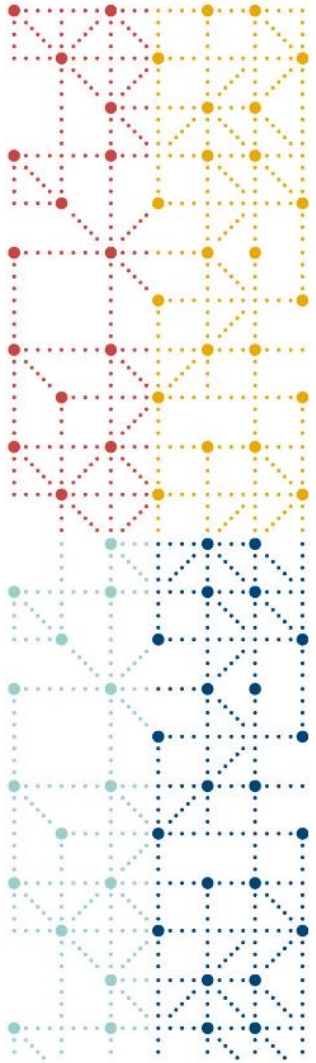
Executable
Conformance Rules



Collaborative Conformance
Rule Authoring



Consistent
Results



Software Tools



COSA: Open-source Software using the Library API

- Growing number of open-source software tools using the Library API
- New EULA makes it easier for open-source software developers



Example COSA projects that use the Library API:

- CORE
- DDF
- OpenStudyBuilder
- Visual Define-XML Editor
- Smart Submission Dataset Viewer
- Library Client (coming soon)

Commercial Software using the Library API



Growing number of commercial software tools using the Library API



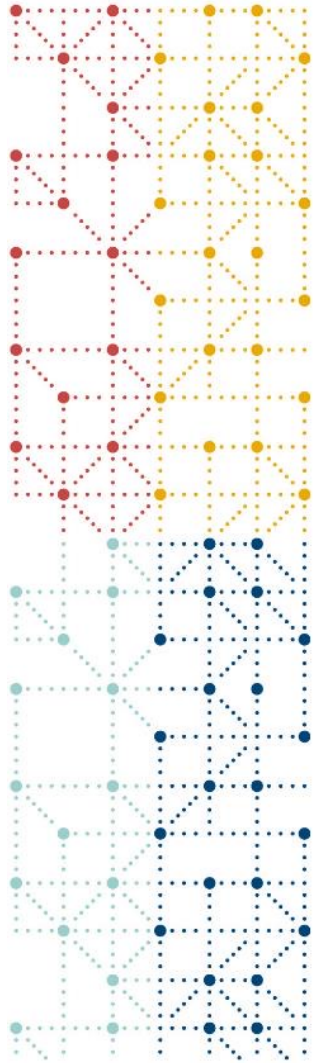
New EULA is having an impact on getting existing vendors to use the Library



Library API is the simplest way to automate the retrieval of CDISC standards



In many instances, the Library is the only source for certain standards metadata



Looking Ahead



Collaborative Authoring

- Conformance rules
- Biomedical concepts
- Mapping



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Validation Package

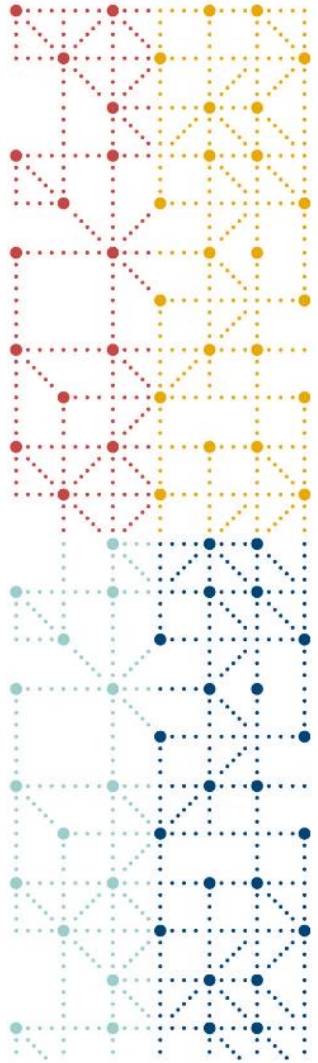
- Starting with a validation package for CORE
 - CDISC leads a community-based effort to create and maintain a validation package
 - Open-source development model
- Will then create a basic validation package for the Library
- Automated testing
- SLA and an improved support model





New Features and Content

- Implementation ready example studies
 - End-to-end machine-readable study metadata + test data
- Analysis Results Standard
- Trial Master File Reference Model
- New versions of foundational standards, terminology, and code list subsets



Conclusion

Software is eating the (clinical research) world

Andreessen, M. (2011). Why software is eating the world. Wall Street Journal, 20(2011), C2.

- This is an iterative journey and we've made substantial progress
- We're collaborating with open-source and commercial software developers
- An ecosystem of software tools are needed to drive standards-based automation

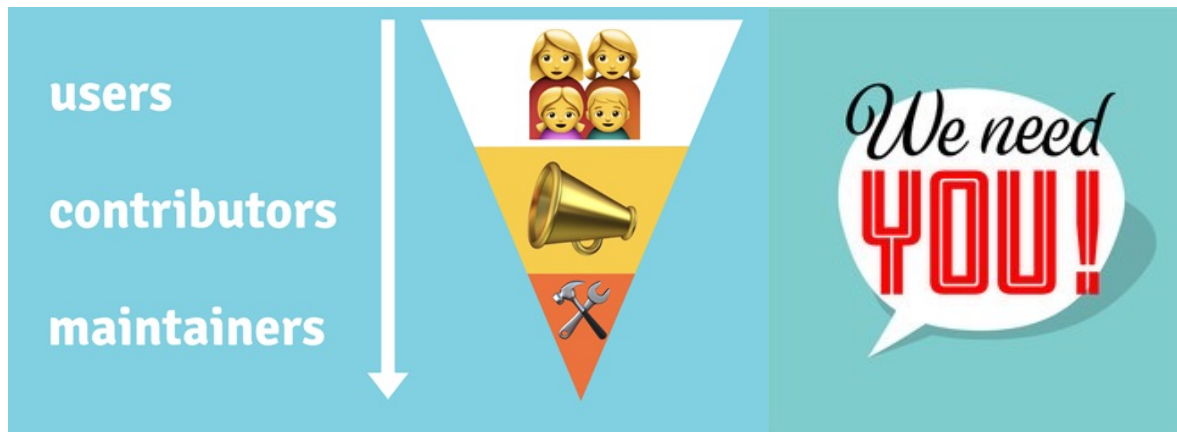


Bussang, J. After 30 years, Crossing the Chasm is Due for a Refresh – Why Markets are Larger than they Appear. Medium.com (2021)

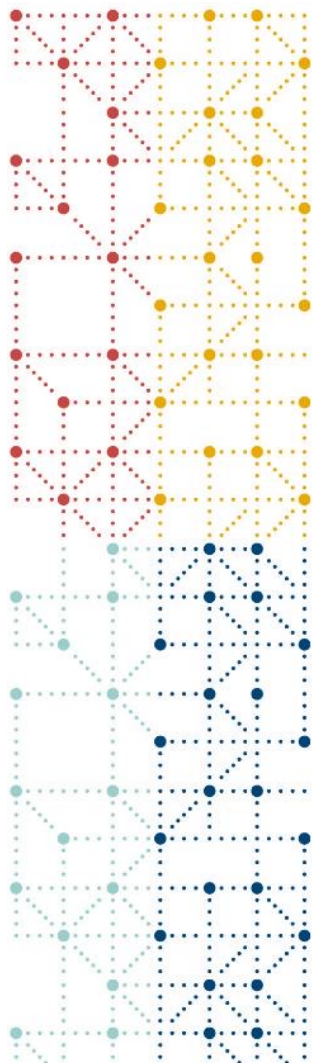
Community-driven Development Requires Contributors

Volunteer Contributors Needed

- Library API Open-source and Commercial Software Developers
- CORE Software and Conformance Rules Developers Wanted
- Biomedical Concept Developers

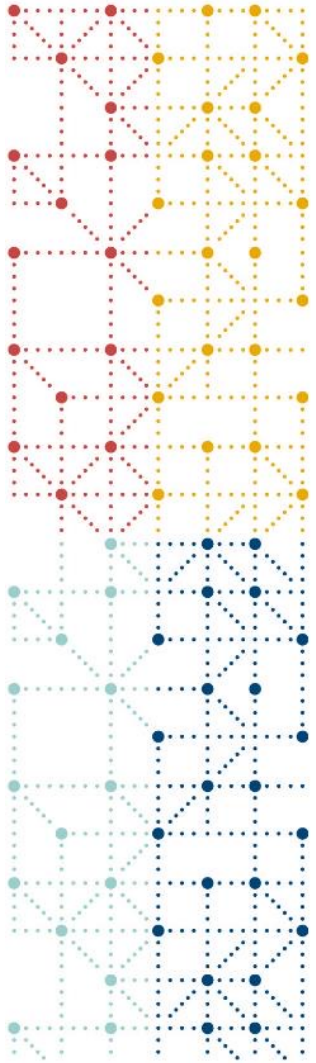


From <https://opensource.guide/building-community/>



Thank You!

cdisc



Where to Find More Information



Information Sources to Bookmark

- How To articles: <https://wiki.cdisc.org/display/LIBSUPRT/How-to+articles>
- Web site: <https://www.cdisc.org/cdisc-library>
- COSA: <https://cosa.cdisc.org/>
- GitHub: <https://github.com/cdisc-org>
- Webinars: <https://www.cdisc.org/events/webinars/upcoming>
- Hackathons: <https://cosa.cdisc.org/events>
- Conferences: <https://www.cdisc.org/events>
- LinkedIn CDISC Group: <https://www.linkedin.com/groups/56393/>