WITH STANDARDS – UNLOCK THE POWER OF DATA

cdisc

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

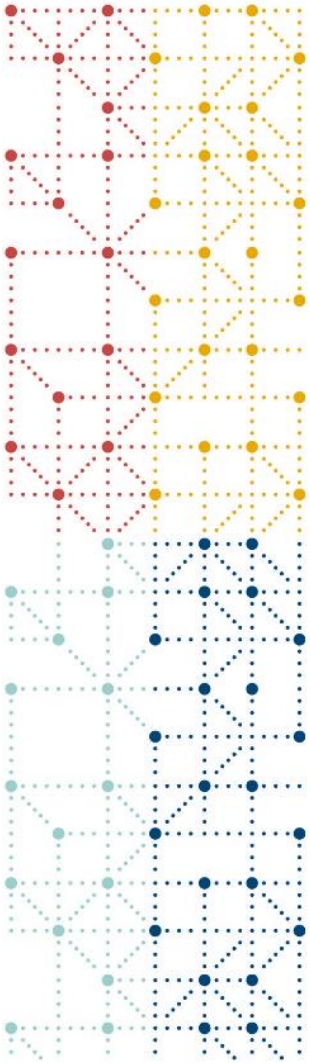
Meet the Speaker

Sam Hume

Title: VP, Data Science

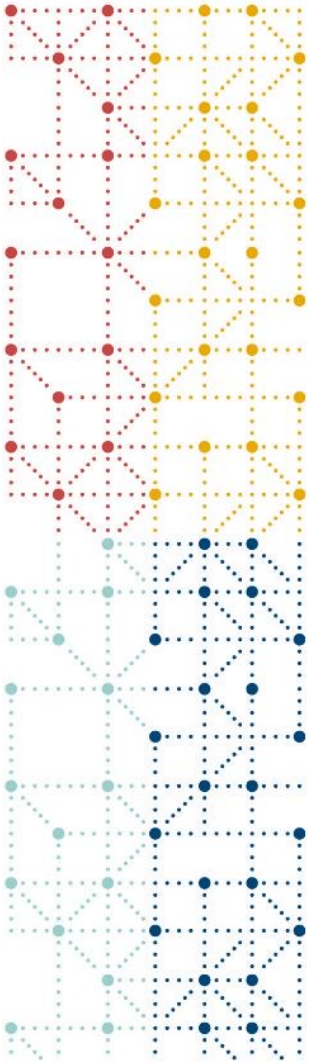
Organization: CDISC

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

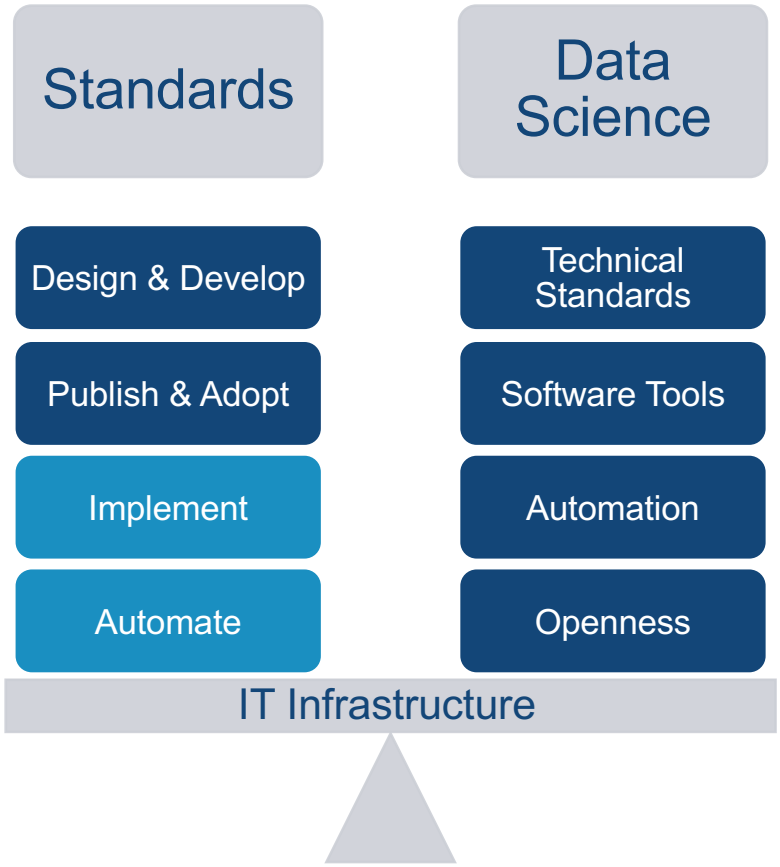
1. Vision
2. Open Access
3. Features & Content
4. Tools
5. Future Developments
6. Conclusion
7. Where to find more information

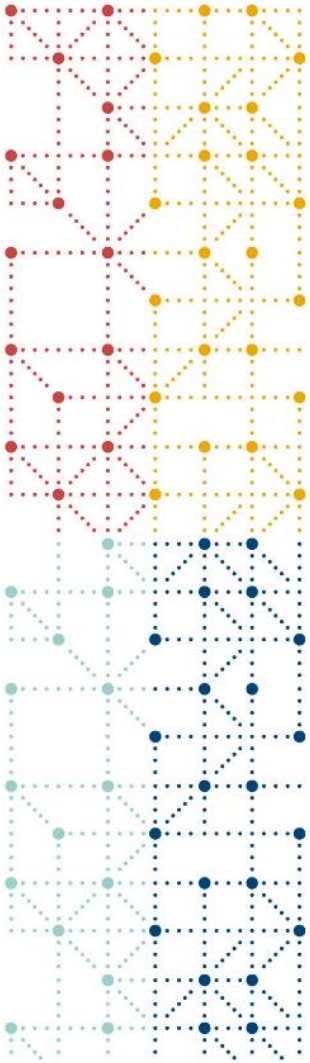


Vision

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

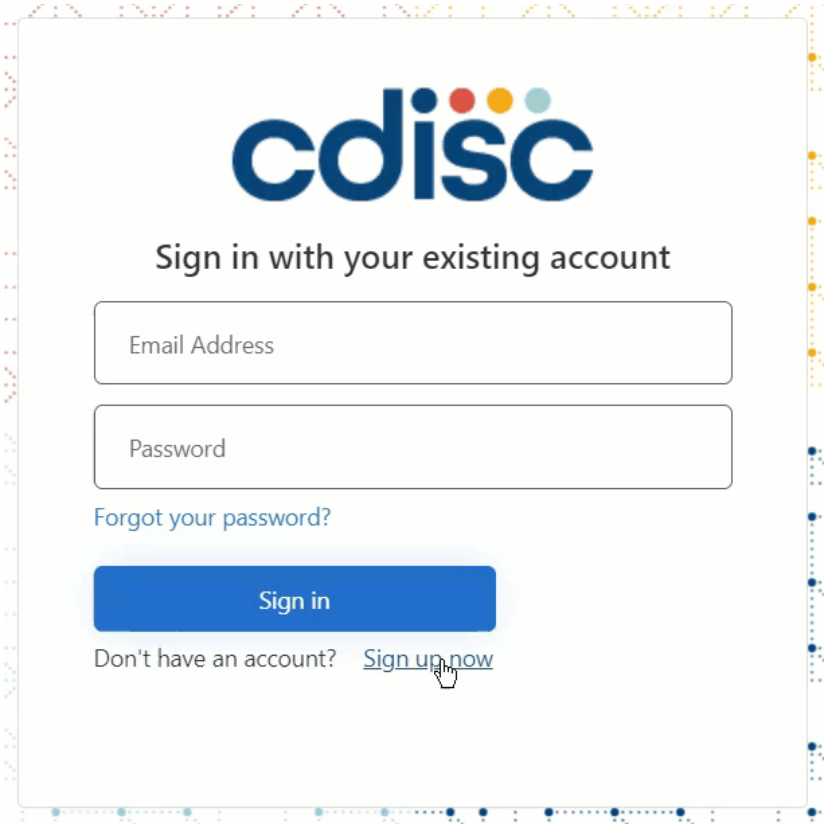
- Unlimited Library accounts
- Same credentials for CORE & Library
- Deprecating Library Archives

Non-member Access

- Free non-member Library accounts

Library EULA

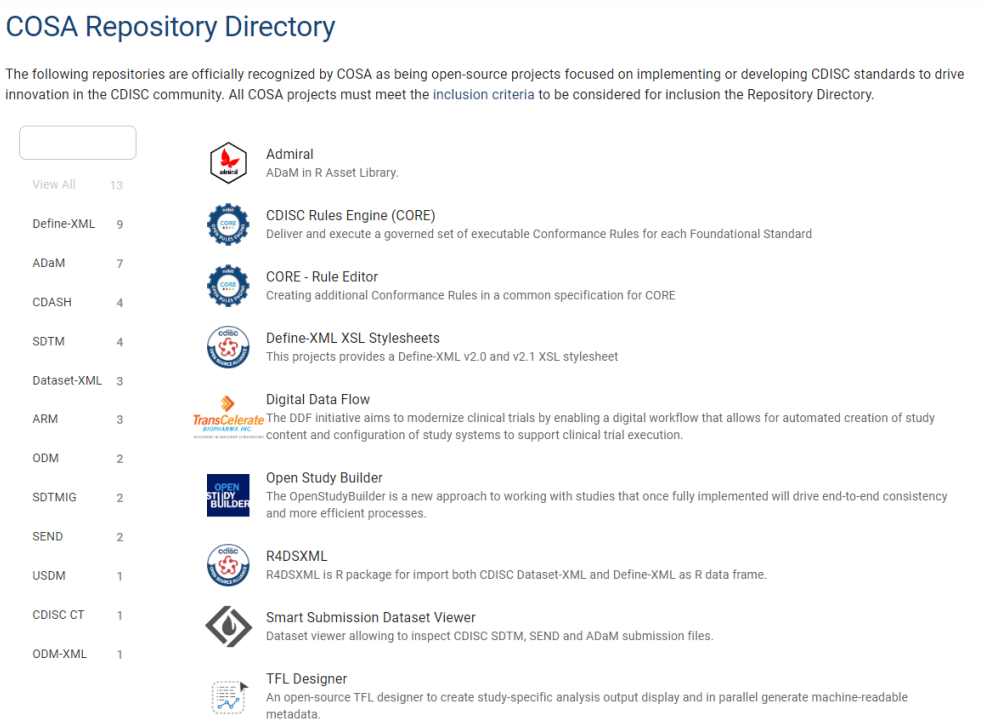
- Updated Library EULA



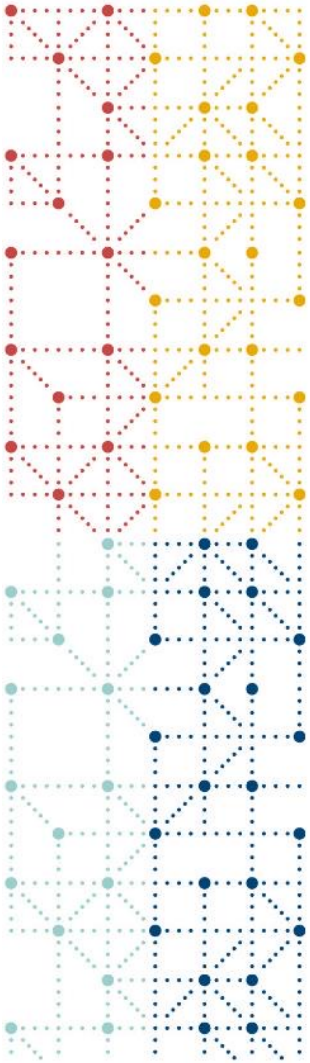
COSA: CDISC Open-Source Alliance

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



https://cosa.cdisc.org/

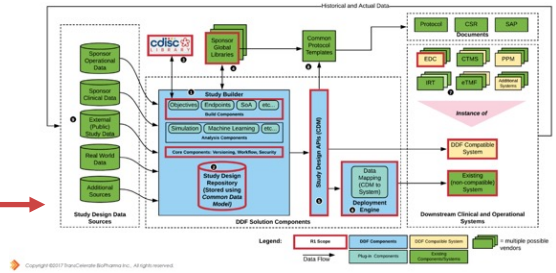


Features & Content

New or underutilized Library features and content

CDISC Library Provides the Foundation

Software Applications Consume Standards Metadata via the API



Executable Conformance Rules

Biomedical Concepts	Codelist Subsets	Dataset Specializations	Implementation Guide Text	Standards Mappings
Analysis Results Standard	TAUG Metadata	Derivations and Mappings	Machine-readable Examples	Draft Standards Metadata
Tables, Listings, and Figures	QRS Metadata	Trial Master File Reference Model	CRF Collection	Diff Content Between Versions

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
Value Update	CDISC Notes	Minor	Findings	VS	VSPOS	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.
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

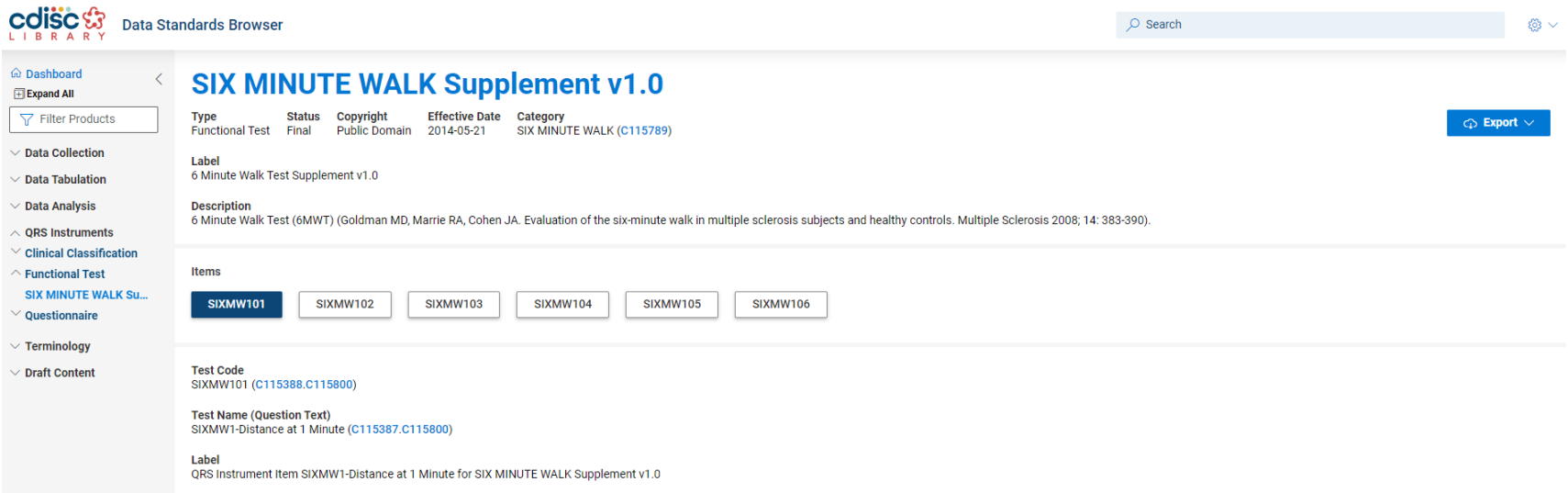
```
/mdr/products/DraftContent
/mdr/sendig/dart-1-2
```

```
"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



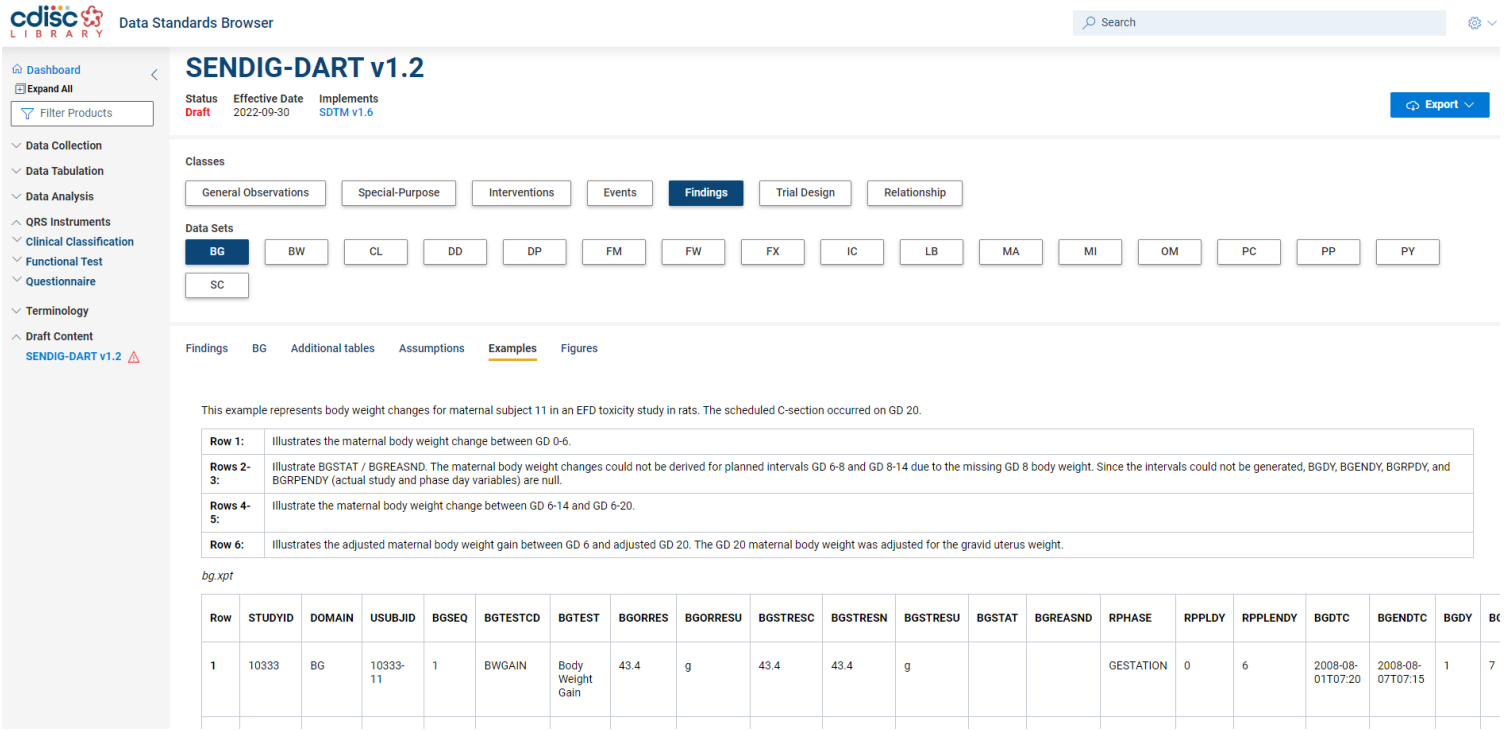
Structured Metadata

CT

Value-Added to CDISC CT

Associating Related CT Terms

Implementation Guide Content



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)

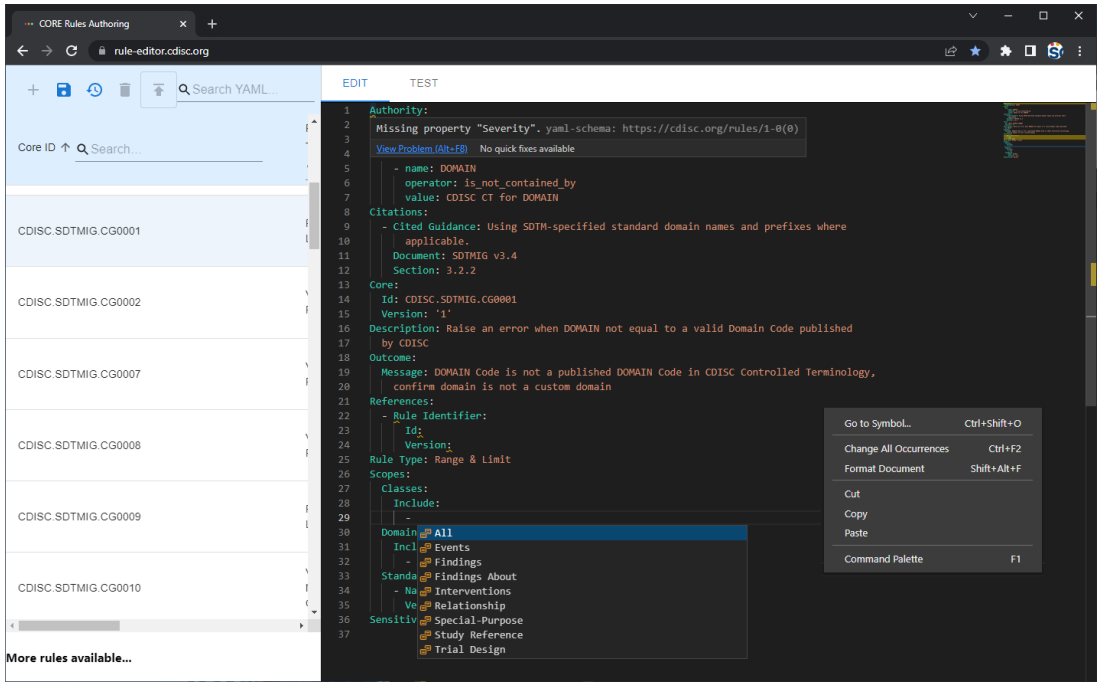
- GET /mdr/specializations/sdtm/packages
- GET /mdr/specializations/sdtm/packages/{package}/datasetspecializations
- GET /mdr/specializations/sdtm/packages/{package}/datasetspecializations/{datasetspecialization}
- GET /mdr/specializations/sdtm/packages/{package}/datasetspecializations/{datasetspecialization}/variables
- GET /mdr/specializations/sdtm/packages/{package}/datasetspecializations/{datasetspecialization}/variables/{variable}

Hierarchical Biomedical Concept System

Dataset Specializations

More Metadata And Relationships

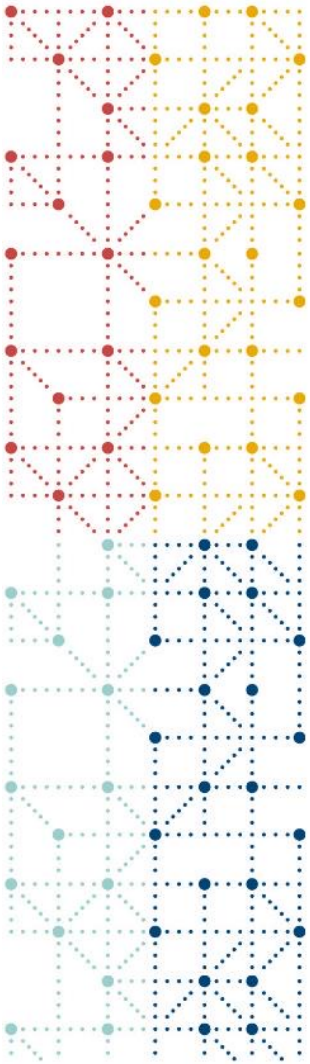
Conformance Rules



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)

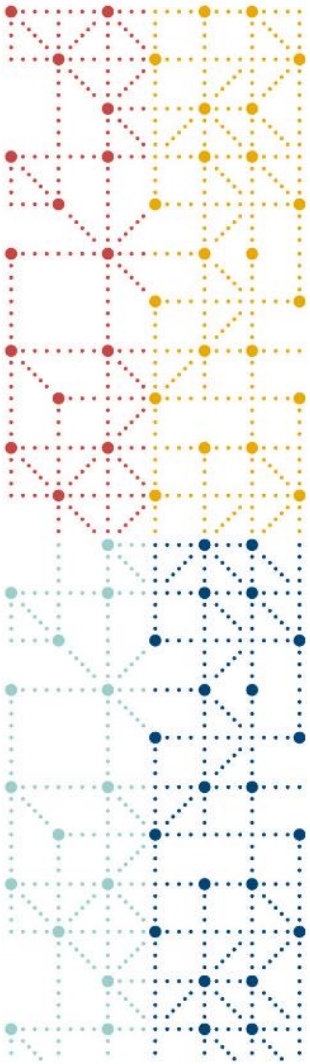
Commercial Software using the Library API

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

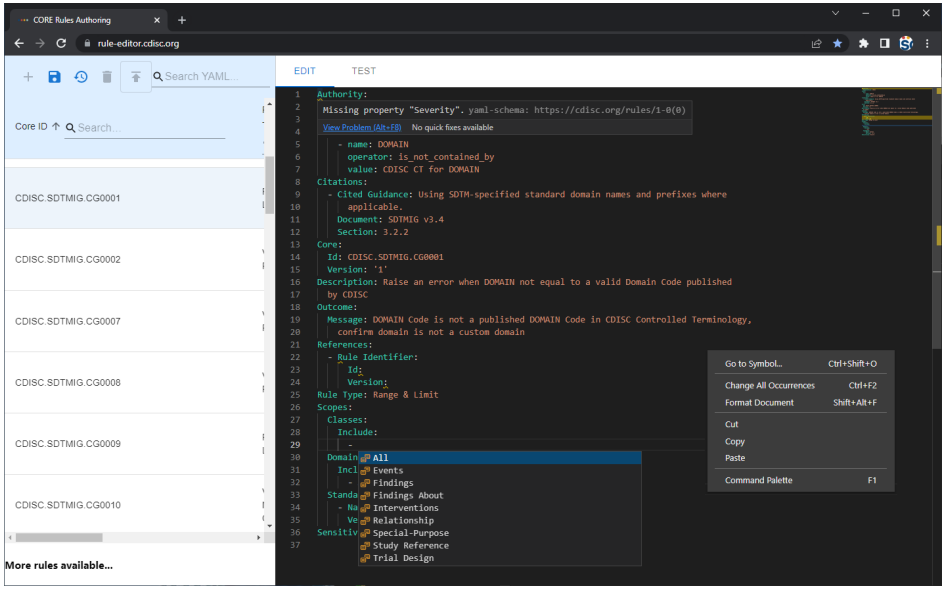
In many instances, the Library is the only source for certain standards metadata



Looking Ahead

Collaborative Authoring

- Conformance rules
- Biomedical concepts
- Mapping

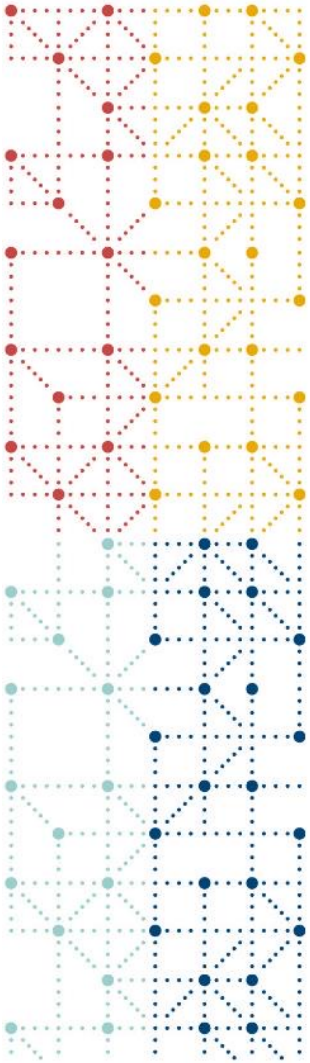


Validation Package

- 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

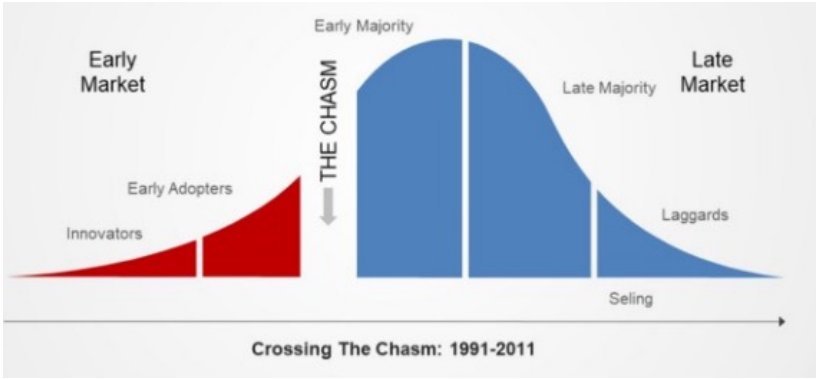


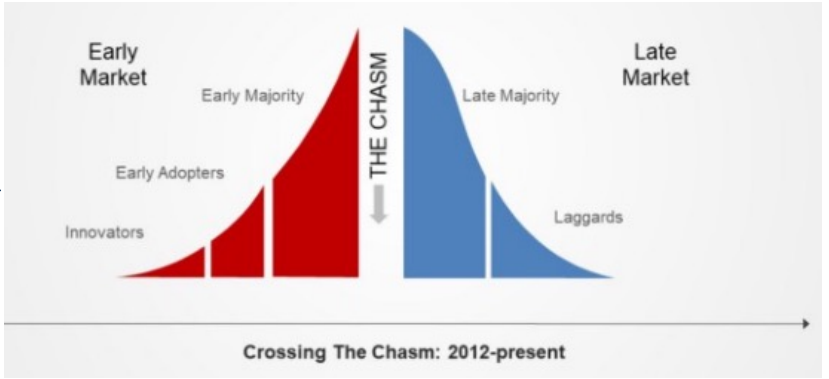
Conclusion

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



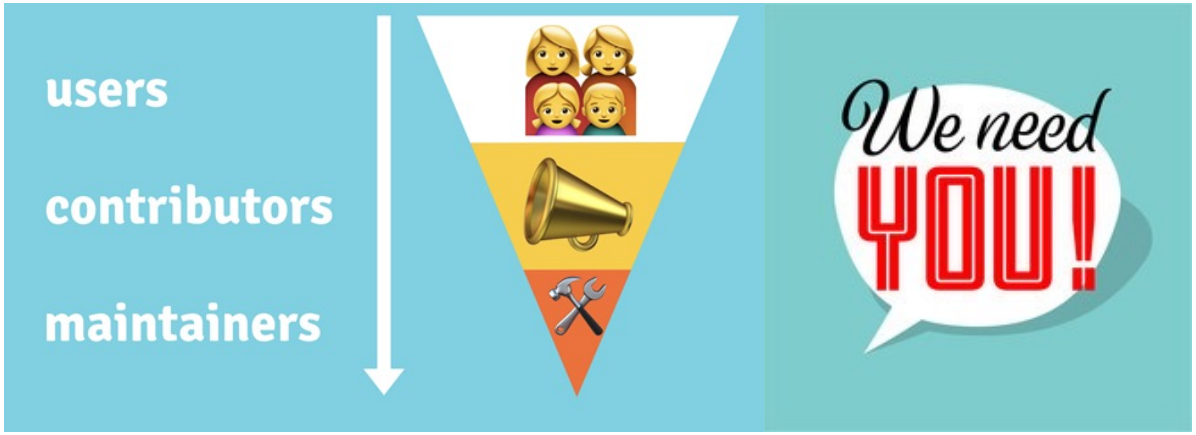


Bussang, J. After 30 years, Crossing the Chasm is Due for a Refresh – Why Markets are Larger than they Appear. Medium.com (2021)

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/

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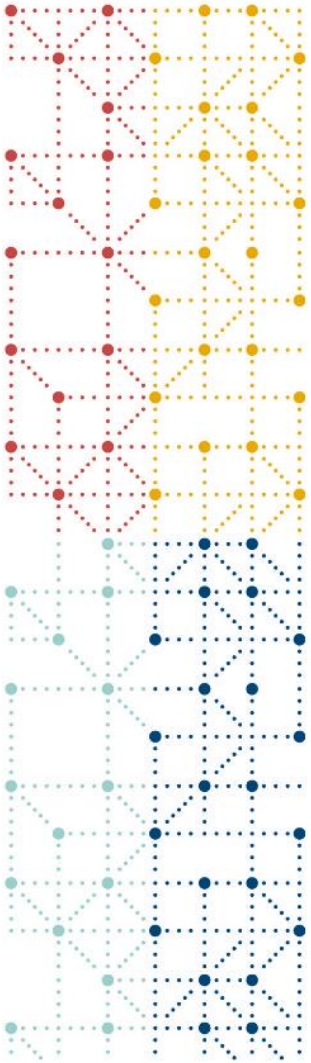

Thank You!

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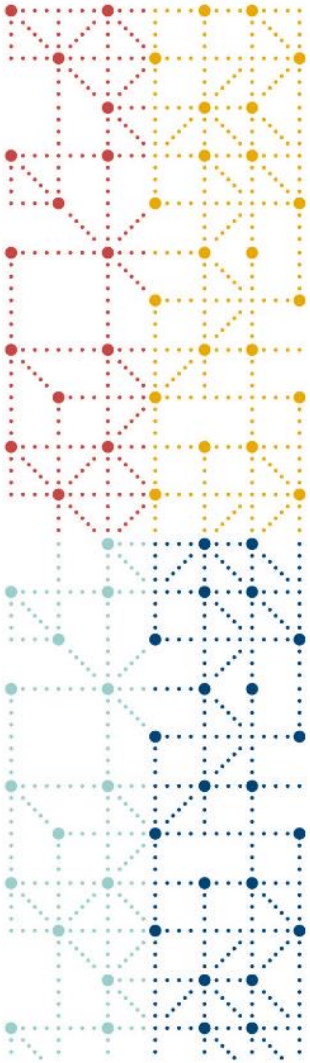

Where to Find More Information

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/