360i and the OSS Community

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Meet the Speakers

Sam Hume, DSc

Title: Principal Consultant

Organization: CDISC

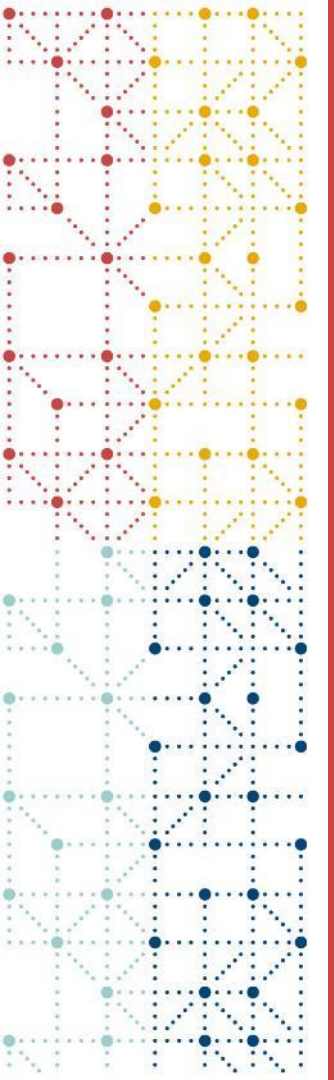
Sam is a research data engineer committed to open-source software and data exchange standards. Sam co-leads the CDISC 360i and Data Exchange Standards teams. He is an active contributor to the CDISC and PHUSE communities.

Anthony Chow, MS-HIA

Title: Executive Director

Organization: CDISC

Anthony is the product owner for CDISC Library. He co-leads a few 360i subteams. He is a technology tinkerer.



Agenda

1. Why OSS?
2. 360i Deliverables
3. The Role of COSA
4. OSS Solutions for 360i Roadmap
5. Experimentation & Sandboxes
6. Free Tools
7. Call to Action

Why OSS for 360i?

- Why do we highlight OSS or free tools for 360i? Why are they important?
- How do organizations benefit from them?
- Not all OSS is the same. Some are built to meet specific 360i needs, while others are meant to show that there's more than one way to solve the same problem.
  - Open-source as experimentation
  - Open-source as solutions
  - Multiple, alternative open-source solutions
  - Commercial solutions using open-source software

360i Deliverables and OSS

- Linked and executable metadata from study endpoint through analysis
- Includes concepts, rules, & sample data

Standards Packages

- Instructions to build standards packages
- Recipes to implement packages within your processes

Implementation Cookbooks

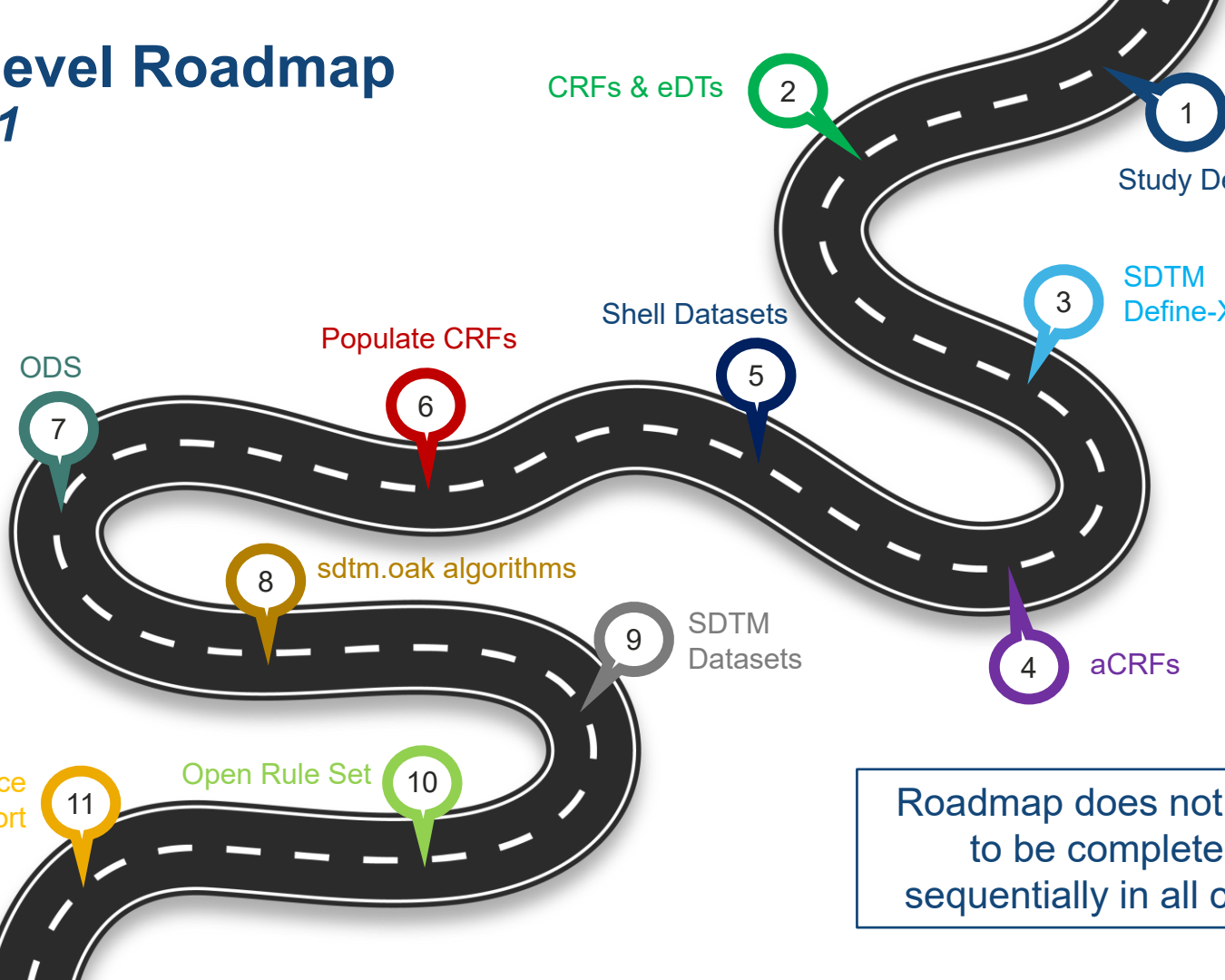
- Technology enabled example leveraging packages & recipes
- Library of community based open-source tools

Example Implementations

COSA: CDISC Open-Source Alliance & 360i

- Ideally, 360i helps to grow the set of COSA open-source tools to demonstrate end-to-end automation
  - New tools and new features
  - There's more than one way to do it (TMTOWTDI)
  - Submit your open-source applications to be part of COSA
- COSA hackathons will help accelerate 360i
  - New applications (e.g. Dataset-JSON Viewers)
  - New features (e.g. Smart Submission Dataset Viewer)
- COSA will add a directory of open-source applications used by 360i
  - https://cosa.cdisc.org/
- Seek to collaborate with pharmaverse and PHUSE

High-level Roadmap
Phase 1



Roadmap does not need to be completed sequentially in all cases

Sample of OSS for 360i Phase 1 Roadmap

Roadmap Marker	Maintainer	Tool	Link to Tool Website
11. Conformance Report	CDISC	CORE CLI	https://www.cdisc.org/core
1. Study Design	data4knowledge	Study Definition Workbench	https://d4k-sdw.fly.dev
1. Study Design	Novo Nordisk	OpenStudyBuilder	https://www.openstudybuilder.com
8. sdtm.oak Algorithms	pharmaverse	sdtm.oak	https://pharmaverse.github.io/sdtm.oak/index.html
9. SDTM Datasets	ClinLine	USDM 4.0 to SDTM Trial Design Domain Tool	https://github.com/ClinLine/USDM_SDTM_mapper
4. aCRF	Lex Jansen	aCRF from BC	https://github.com/lexjansen/cdisc360i-pocs

Open-Source: COSA Applications (360i Phase 1)

Application	Repository
CDISC Library Client	https://github.com/cdisc-org/cdisc-library-client
CORE	https://github.com/cdisc-org/cdisc-rules-engine
CORE Rule Editor	https://github.com/cdisc-org/conformance-rules-editor
CDISC-ODM-XML-CRF-SDTM-Annotations	https://github.com/jmangori/CDISC-Define-XML-SAS-XMLMAP
Dataset-JSON Conversion	https://github.com/lexjansen/dataset-json-sas https://atorus-research.github.io/datasetjson/index.html
Define-XML Stylesheet	https://github.com/lexjansen/define-xml-2.1-stylesheets
odmlib	https://github.com/swhume/odmlib
Open Study Builder	https://github.com/NovoNordisk-OpenSource/openstudybuilder-solution
sdtm.oak	https://github.com/pharmaverse/sdtm.oak
Study Definitions Workbench	https://github.com/data4knowledge/study_definitions_workbench

Open-Source as Experimentation: Sandboxes

- Sandboxes are used for experimentation and exploration
- Sandbox code may evolve quickly and change significantly
- Sandbox code is open-source
- GitHub and hosted notebooks as a platform for 360i collaboration

Contributor	Sandbox Repository
Jeremy Teoh	https://github.com/TeMeta/define-json
Lex Jansen	https://github.com/lexjansen/cdisc360i-pocs
Santosh Karra	https://github.com/santoshrk11/acrf_pdf_extractor https://github.com/santoshrk11/360i-playground
Pierre Dostie	https://github.com/dostiep/360i
Anthony Chow	https://github.com/chowsanthony/usdm_bc https://colab.research.google.com/drive/13nabDKiLIV8lkA55_1J6rXO6Xhi0tvJR
Sam Hume	https://github.com/swhume/threesixtyeye

Sample Free-to-use Tools

- CDISCDataset.com - An online data generation tool for SEND, SDTM, and ADaM data sets. Could be generic or TA-specific. Also has APIs.
- NCI's EVS Explore - https://evsexplore.semantics.cancer.gov - A tool to browse, search, and retrieve content from NCI Thesaurus (NCIt) and other medical terminologies. Contains all CDISC CT.
- Posit Cloud - https://posit.cloud - A cloud platform for doing and sharing data science work in a web browser, especially using R and Python.
- Google Colab - https://colab.google - A hosted notebook service that requires no setup to use and provides free access to computing resources.

Call to Action

- Participate in 360i: https://www.cdisc.org/cdisc-360i
- Submit solutions to COSA for listing: https://cosa.cdisc.org
- Participate in COSA-sponsored hackathons
- Contribute to content creation
  - 360i end-to-end use cases: RWD, DHT, eDT
  - Collaborative development for CDISC Biomedical Concepts: https://github.com/cdisc-org/COSMoS/blob/main/bc_starter_package