



Powering Standards with Code: The Role of Open Source in CDISC 360i

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Opinions are my own

360i: Powering Standards with Code

Turning data standards from static specs into dynamic, executable solutions

1. Standards implementation focus
2. Solutions over specifications
3. Code as part of standards development
4. Consider the HL7 FHIR example

360i Deliverables

Publish executable study packages that include open-source tools

1. Executable study package
2. Standards Packages
3. Implementation Cookbooks
4. Example Implementations

CI/CD for CDISC

Treating standards as code: version-controlled, testable, and automatable

1. Test standards in an automated pipeline context during development
2. Test data is part of standards development
3. Ensure tooling is available when new standards are released
4. GitHub as a standards development platform

360i Automated Pipeline



360i GitHub webhook test APP 5:58 PM



360i pipeline has started. (Job ID 15151052463)



Installing CORE CLI. (Job ID 15151052463)



CORE CLI installed. (Job ID 15151052463)

5:58



Running CDISC Open Rules against USDM JSON. (Job ID 15151052463)



360i GitHub webhook test APP 6:11 PM



Dataset-JSON files downloaded and verified (Job ID 15151052463)



Checking files using CDISC Open Rules. (Job ID 15151052463)



360i pipeline completed successfully!

Job ID

15151052463

Branch

master

Run

[View Run Details](#)

Repo

chowsanthony/threesixtyeye

Actor

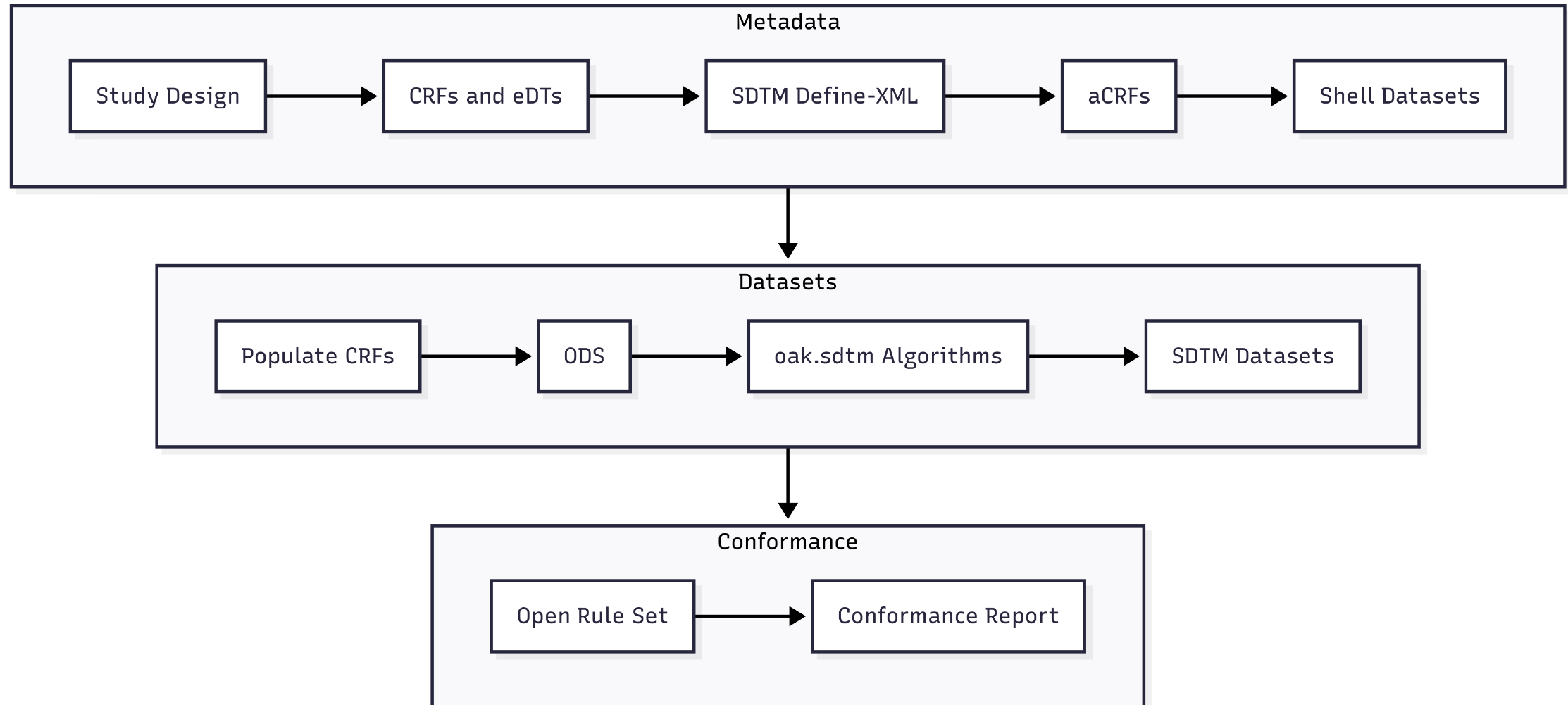
chowsanthony

Why Open-Source Software for 360i?

Code is becoming a critical part of data standards

1. 360i seeks to promote a common set of tools for standards-driven automation
2. Promotes consistency and interoperability while lowering barriers to adoption
3. New sophisticated standards models, like USDM, require tooling to use
4. Pharmaverse / PHUSE collaboration

360i Phase 1 Roadmap



Phase 1: Study Design through SDTM Generation

New approaches to old problems

1. Using USDM + BCs + DSS to drive automated SDTM generation pipeline
2. Identifying and filling gaps in the process
3. Creating recipes that will allow the development of common tools
4. Uses Open Study Builder, sdtm.oak, odmlib, Dataset-JSON tools, etc.

Phase 2: ADaM through TLF Generation

Phase 2 is where we focus on clinical reporting

1. Defining Analysis Concepts
2. Makes use of the ARS standard
3. Uses the Phase 1 SDTM datasets as input
4. Will use siera, Admiral, and other Pharmaverse packages

Example: Automated SDTM Define-XML Generation

Replace manual metadata sourcing with reusable recipes and code

1. What's different about 360i: use USDM + BCs + DSSs
2. USDM + BCs + DSSs are not sufficient
3. Plan to generate metadata templates from a variety of sources
4. Sustaining vs. disruptive innovation

Lucy, you've got a lot of explaining to do

360i open-source gives us the bazaar; a messy, fast-moving place where innovation happens

1. The cathedral and the bazaar - Eric Raymond
2. Coding, as with painting, starts with sketching - Paul Graham
3. Plan to throw one away; you will, anyhow - Fred Brooks
4. Open-Source as experimentation and communication: Sandboxes

Dumbing it Down

Open-source is how we scale standards adoption

1. Code libraries make it simpler to implement complex data standards
2. Abstractions in code are essential to simplifying implementation
3. Code helps reduce the variability in standards implementations
4. See FHIR and OMOP as examples where tooling plays a major role

OSS and Risk Taking

Open-source enables innovation that commercial models often can't

Factor	Open-Source	Commercial
Speed of Innovation	Often faster	Slower but more polished
Scope of Innovation	Broader and grassroots	Focused; customer-driven
Community Involvement	High	Low to none
Risk Taking	High	Lower (ROI focused)
Resource Constraints	May limit scope	Can fund ambitious R&D
UX and Enterprise Fit	Often weaker	Often stronger

Call to Action

The future of standards depends on who shows up

1. Participate in the 360i program: <https://www.cdisc.org/cdisc-360i>
2. Submit solutions to COSA for listing: <https://cosa.cdisc.org>
3. Participate in COSA-sponsored hackathons to accelerate 360i
4. Contribute to standards content creation



Questions?

If we want standards to be usable, they need to be executable, and that starts with us. I'd love to hear your thoughts.

Reference: USDM + BC + DSS

Standard / Program	Reference
USDM	https://www.cdisc.org/ddf
Biomedical Concepts	https://www.cdisc.org/cdisc-biomedical-concepts https://github.com/cdisc-org/COSMoS/tree/main/bc_starter_package
Dataset Specializations	https://github.com/cdisc-org/COSMoS/tree/main/bc_starter_package
CDISC 360i	https://www.cdisc.org/cdisc-360i

Reference: CDISC 360i Phase 1 OSS

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

Reference: CDISC 360i Phase 1 OSS (continued)

Application	Repository
Dataset-JSON Conversion (SAS)	https://github.com/lexjansen/dataset-json-sas
Dataset-JSON Conversion (R)	https://atorus-research.github.io/datasetjson/index.html
Dataset-JSON Viewer	https://github.com/defineEditor/vde-dataset-viewer
Define-XML Stylesheet	https://github.com/lexjansen/define-xml-2.1-stylesheets

Reference: CDISC 360i Phase 1 OSS (continued)

Application	Repository
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