



cdisc® 2026 Europe Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



MILAN, ITALY | MAIN CONFERENCE: 20-21 MAY | TRAININGS & WORKSHOPS: 18, 19, & 22 MAY

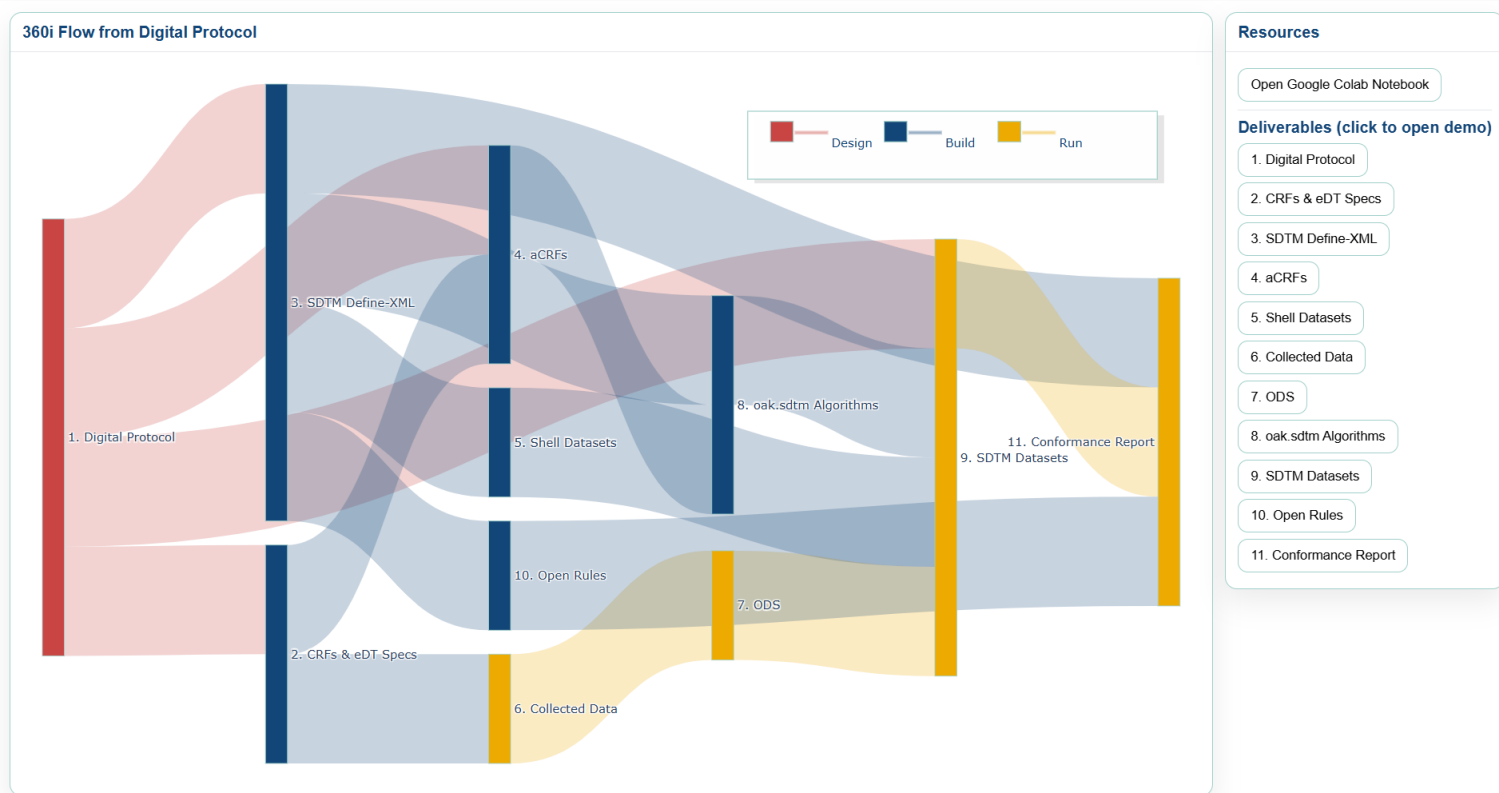
360i in Action: From Vision to Demonstration

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CDISC 360i Demos

cdisc CDISC 360i — Design / Build / Run



Video Links:

1. [Digital Protocol](#)
2. [CRFs & eDT Specs](#)
3. [SDTM Define-XML](#)
4. [aCRFs](#)
5. [Shell Datasets](#)
6. [Collected Data](#)
7. [ODS](#)
8. [oak.sdtm Algorithms](#)
9. [SDTM Datasets](#)
10. [Open Rules](#)
11. [Conformance Report](#)

[Download](#) diagram to access the notebook and videos



Accessing the 360i Notebook

The notebook displayed in this demonstration can be found here: <https://github.com/cdisc-org/cdisc-360i-notebooks>

- The repository is under continued development; follow repository for latest releases
- There are multiple notebooks
- Raise any issues encountered while using notebooks
- To contribute to the CDISC project:
 - Fork the repo and create a new branch
 - Once changes are made and tested, raise a Pull Request



GitHub Repositories Used in the Demo

Purpose	Location
Study Definition Workbench	https://github.com/data4knowledge/study_definitions_workbench
Open Study Builder	https://gitlab.com/Novo-Nordisk/nn-public/openstudybuilder/OpenStudyBuilder-Solution
Study USDM documents	https://github.com/cdisc-org/360i/tree/main/data/protocol/LZZT/usdm
USDM validation utility	https://github.com/pendingintent/cdisc-json-validation
CDISC CORE Rules Engine	https://github.com/cdisc-org/cdisc-rules-engine
CRF creation	https://github.com/lexjansen/cdisc360i-pocs
Trial Design Dataset creation	https://github.com/pendingintent/cdisc-usdm-utils
Define-XML template creation	https://github.com/dostiep/360i
Define-XML creation	https://github.com/swhume/template2define
Raw subject data	https://github.com/alidootson/UpdatedCDISCPilotData/tree/main/UpdatedCDISCPilotData/CDASH



Using GitHub

The GitHub repositories used in the demo are public and use open-source libraries

The process for using these libraries is consistent:

- Fork the original public repository into personal GitHub repository
- Create new branch in personal GitHub repository
- Edit code to meet individual requirements, add features or fix issues
- Commit changes to personal branch
- If proposing change to parent (original) branch to share with wider community:
 - Raise a Pull Request with original repository owner
 - Original repository owner will review the Pull Request and work with requestor to evaluate and test Pull Request
 - Merge new code in Pull Request with original parent branch



360i Phase 2: Key Deliverables

Digital Protocol & Impact Analysis Reporting: Machine-readable protocol model with automated amendment and impact analysis

Automated Define & Dataset Generation: Generation of Define.xml and datasets integrated with study workflows

Digital Data Transfer Agreement Model: Technical DTA model and standardized template aligned with the digital protocol

Standardized Analysis Concept Model: Configurable, machine-readable analysis concepts driving automated analysis artifacts



Thank You!





Questions?

