

CDISC 360i: Automating from Study Design to Submission

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Agenda

- Automation with 360i
- Achievements and Insights
- The Future



Speaker



Darren Moreland
Director, Digital
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- Darren Moreland is the Director of Digital Transformation at CDISC with over 20 years of technical experience across multiple industries. He has spent the last 10 years working with pharmaceutical companies simplifying clinical trial design, data management and SDTM submissions.

The Problem

- Time-consuming manual processes
- Data duplication
- Operational silos
- High effort to create submission datasets
- Gaps in data traceability





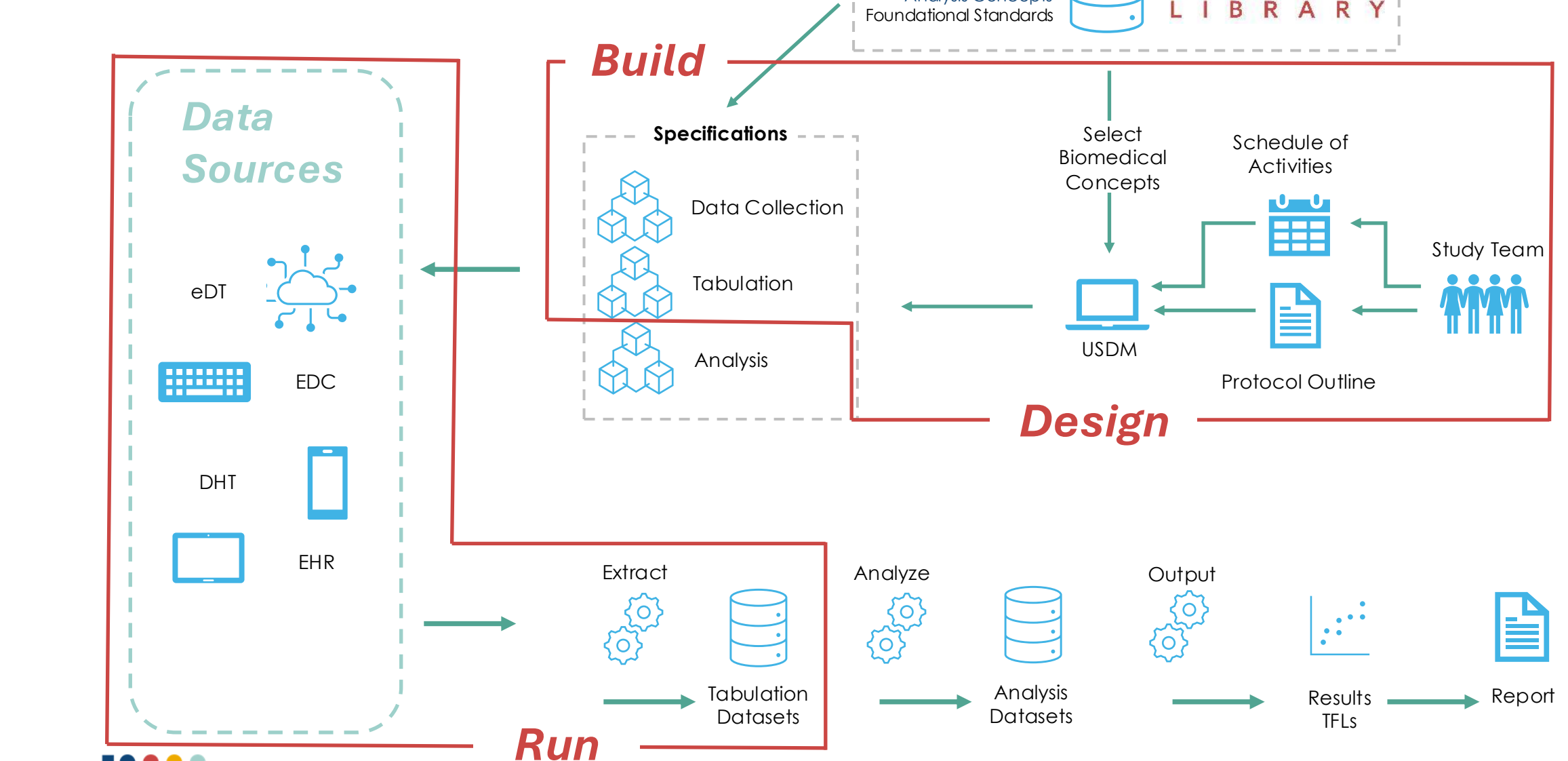
The Vision: CDISC 360i

Strategic Goal

A multi-year strategy transitioning the industry from static, document-based standards and processes to a dynamic, digital data flow beginning with digital protocols



360i Phase 1 Focus



USDM

- Single authoritative source
- Machine-readable, structured study design
- Reliable exchange of data across systems
- Protocol concepts linked to downstream models using semantic layer
 - Shared, interoperable metadata layer linking CDISC standards
 - Biomedical Concepts linked to the Schedule of Activities



Schedule of Activities

Matrix: Main Timeline

		Epoch:->	Screening		Treatment 1			Treatment 2										Treatment 3
		Encounter:->	Screening 1	Screening 2	Baseline	Week 2	Week 4	Week 6	Week 8	Week 8	Week 12	Week 12	Week 16	Week 16	Week 20	Week 20	Week 24	
		Instance:->	Screen 1	Screen 2	Dose	Week 2	Week 4	Week 6	Week 8	Week 8 NPI	Week 12	Week 12 NPI	Week 16	Week 16 NPI	Week 20	Week 20 NPI	Week 24	
		Study Day:->			1.0	14.0	28.0	42.0	56.0	56.0	84.0	84.0	112.0	112.0	140.0	140.0	168.0	
		Timing:->	Screening	Pre-dose	Dosing	Week 2	Week 4	Week 6	Week 8	Week 8	Week 12	Week 12	Week 16	Week 16	Week 20	Week 20	Week 24	
		Visit Window:->		-4.0 hours		-3..3 days	-3..3 days	-3..3 days	-3..3 days	-3..3 days	-4..4 days	-4..4 days	-4..4 days	-4..4 days	-4..4 days	-4..4 days	-4..4 days	
Activity	Concepts																	
Informed Consent	Concepts 1 ▶		X															
Inclusion/Exclusion Criteria	Concepts 3 ▶		X															
Patient Number assigned	Concepts 1 ▶		X															
Demographics	Concepts 5 ▶		X															
Education	Concepts 2 ▶		X															
Hachinski	Concepts 10 ▾		X															
	[S] Abrupt Onset (C112618)																	
	[S] Stepwise Deterioration (C112619)																	
	[S] Emotional Incontinence (C112620)																	
	[S] History or Presence of Hypertension (C112621)																	
	[S] History of Stroke (C112622)																	
	[S] Focal Neurological Symptoms (C112623)																	
	[S] Focal Neurological Signs (C112624)																	
	[S] Somatic Complaints (C112813)																	
[S] Total Score (C112625)																		
[S] Modified Hachinski Ischemic Scale (C112626)																		
MMSE	Concepts ▶		X															
Physical examination	Concepts ▶		X															
Medical History	Concepts 2 ▶		X															
Habits	Concepts 3 ▶		X															
Chest X-ray	Concepts 1 ▶		X															
Apo E genotyping	Concepts ▶					X												
Patient randomized	Concepts 1 ▶				X													
Vital Signs	Concepts 7 ▾		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	Body Temperature																	
	Body Weight																	
	Body Height																	
	Pulse Rate																	
	Respiratory Rate																	
	Body Mass Index																	
	Blood Pressure																	
Aspirator FOC	Concepts ▶																	

360i Architecture

- USDM as single source of truth
- Enables early asset generation
 - Trial Design Domains
 - define.xml
 - CRFs/aCRFs
 - SDTM shell datasets
- Binds protocol concepts defined in USDM to SDTM datasets
- Data persistence and traceability



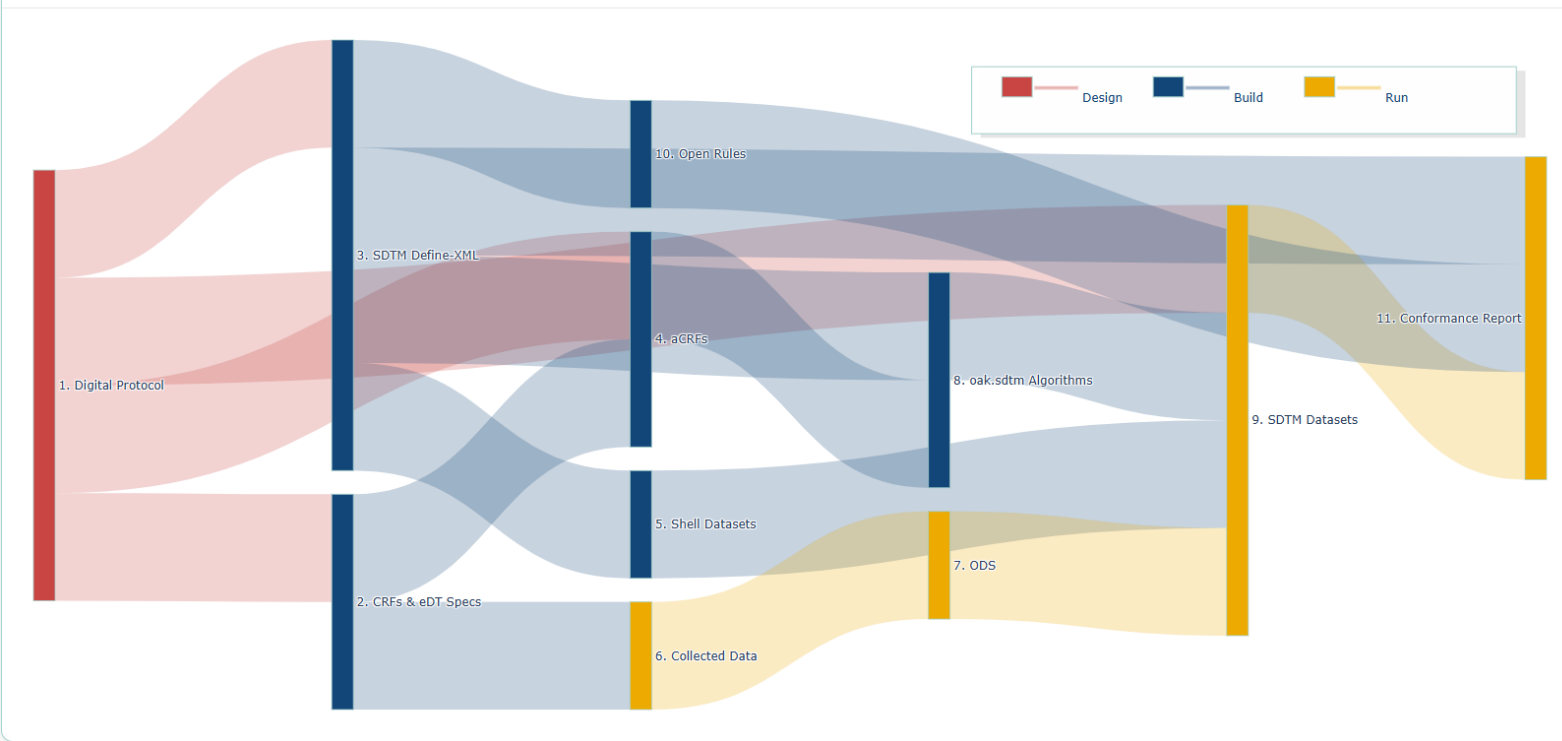
Phase 1

- Integration of independent open-source projects into automated pipeline from UDSM to SDTM
 - CRFs & aCRFs in ODM-XML, Dataset-JSON
 - Define.xml
 - SDTM shell datasets
 - SDTM Trial Design Domains
 - SDTM datasets
 - CORE Conformance reports



Design and Build

360i Flow from Digital Protocol



Methods

- Data store for asset storage and versioning
- Author and validate USDM study design
- Python & R orchestration to create SDTM
- CDISC Open Rules Engine (CORE) for conformance validation
- Google Colab notebooks for accessibility
 - Explanation and instructions inline with code



Early Asset Generation

- Complete USDM allows earlier creation of study assets
 - Trial Design Domains
 - define.xml
 - SDTM Shell datasets
 - CRFs & aCRFs in multiple formats
- Can address issues earlier in the study lifecycle





Tools & Technology

- Use open-source libraries and existing solutions
 - Python & R
 - SQLite
 - CORE validation
 - CDISC Library
 - Data Set Specializations
 - Biomedical Concepts
 - SDTM Controlled Terminology
 - [GitHub](#)

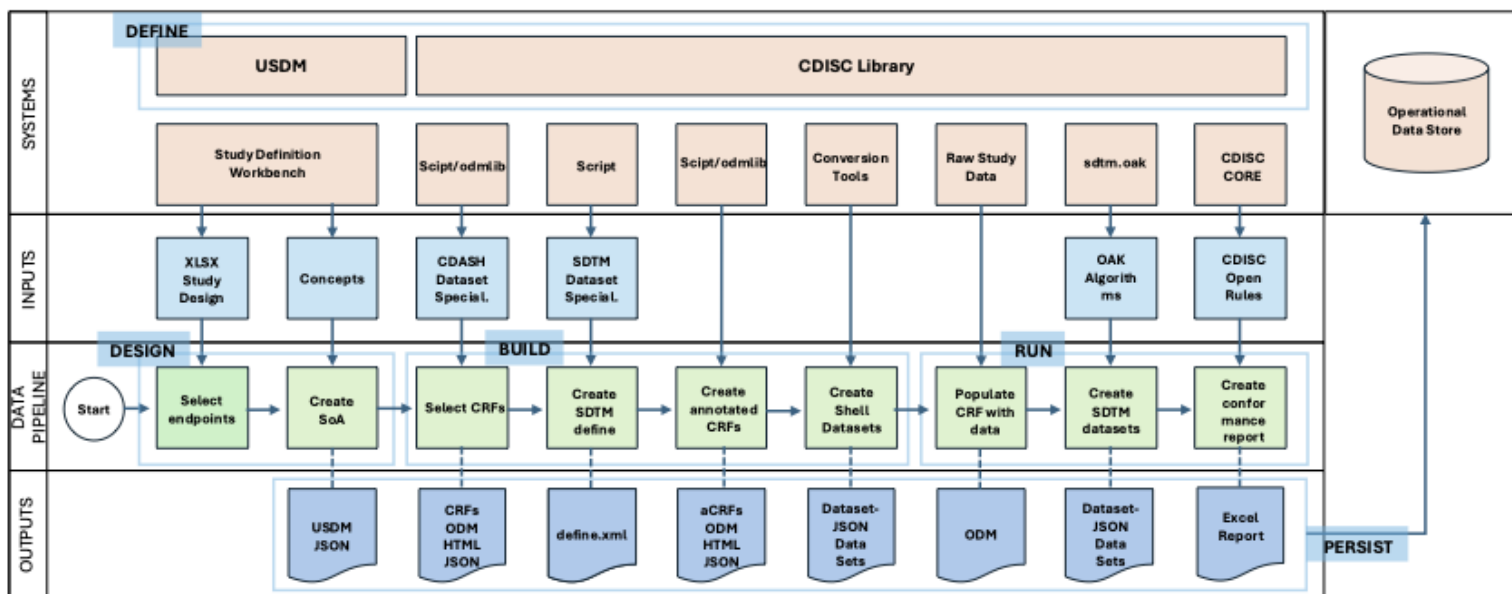


Results

- Automated pipeline integrating independent projects creating SDTM from USDM
 - CRFs & aCRFs – ODM, Dataset-JSON, HTML
 - Trial Design Domains – CSV, XPT, Dataset-JSON
 - define.xml
 - SDTM domains – CSV, XPT, Dataset-JSON
 - All raw data and output stored to operational data store (ODS)



360i Phase 1: Generating SDTM



Lessons Learned

- USDM can drive downstream automation using interoperable metadata
- CORE checks confirm conformance early in the development lifecycle
- Open-source
 - Ensure community involvement
 - Independent workstreams
 - CDISC standards are tool agnostic; allows contributors to focus on solutions over standards using whatever tools meet their needs



The Future

- Phase 2 of the CDISC 360i initiative
 - ADaM and Analysis Result Sets (ARS)
 - Expand concepts for analysis and derivation concepts
 - Define-JSON
 - SoA Workbench
 - Automate impact analysis for protocol amendments



Conclusion

- Structured, interoperable metadata in USDM digital protocol can be used to automate the creation of SDTM
- Focus on solutions over standards to ensure independent development and wider engagement with the open-source community





GitHub References

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

A list of the projects and corresponding GitHub repositories integrated to create the automation

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



Accessing the 360i Notebook

The notebook displayed during this demonstration can be found here:

<https://github.com/cdisc-org/cdisc-360i-notebooks>

- Development of the notebook complete
- Development in other repos may result in some utilities not working
- Raise any issues encountered while using notebooks in GitHub





We need you

- Be part of the team to drive this forward
 - We need committed contributors AND...companies that support the goals
 - Click on QR Code below to volunteer
 - Make sure to select 360i from the list!
-
- <https://www.cdisc.org/volunteer>
 - ✓ Complete CDISC Volunteer Form
 - ✓ Complete 360i Contributor Survey



Thank You!



Questions?



