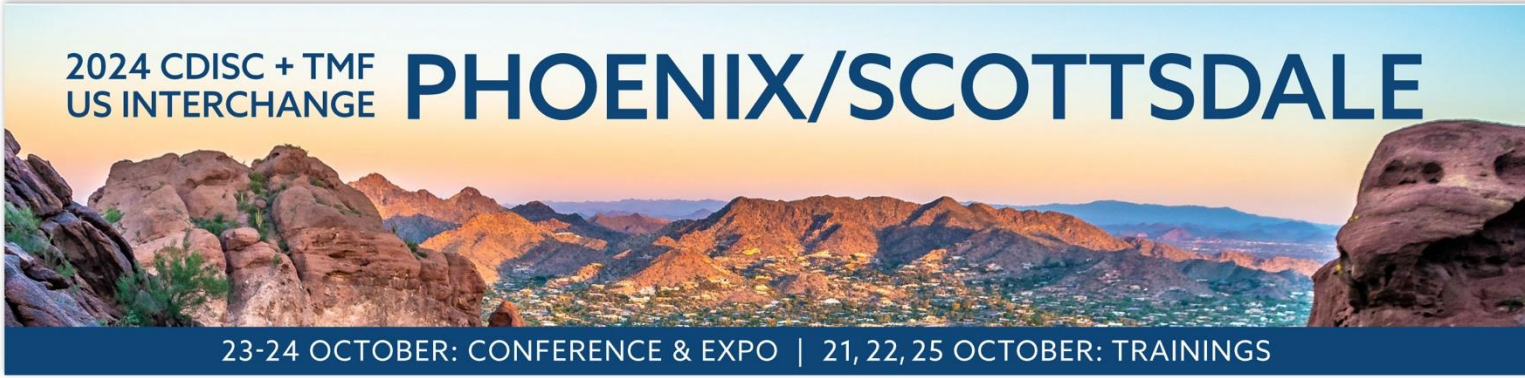


Practical Benefits of the "Enable and Automate" Strategy to Support End-to-End Automation

Sam Hume, D.Sc., CDISC

Session 6A: 360i - Moving from Proof of Concept to Implementation

October 24, 2024

Meet the Speaker

Sam Hume

Title: Principal Consultant

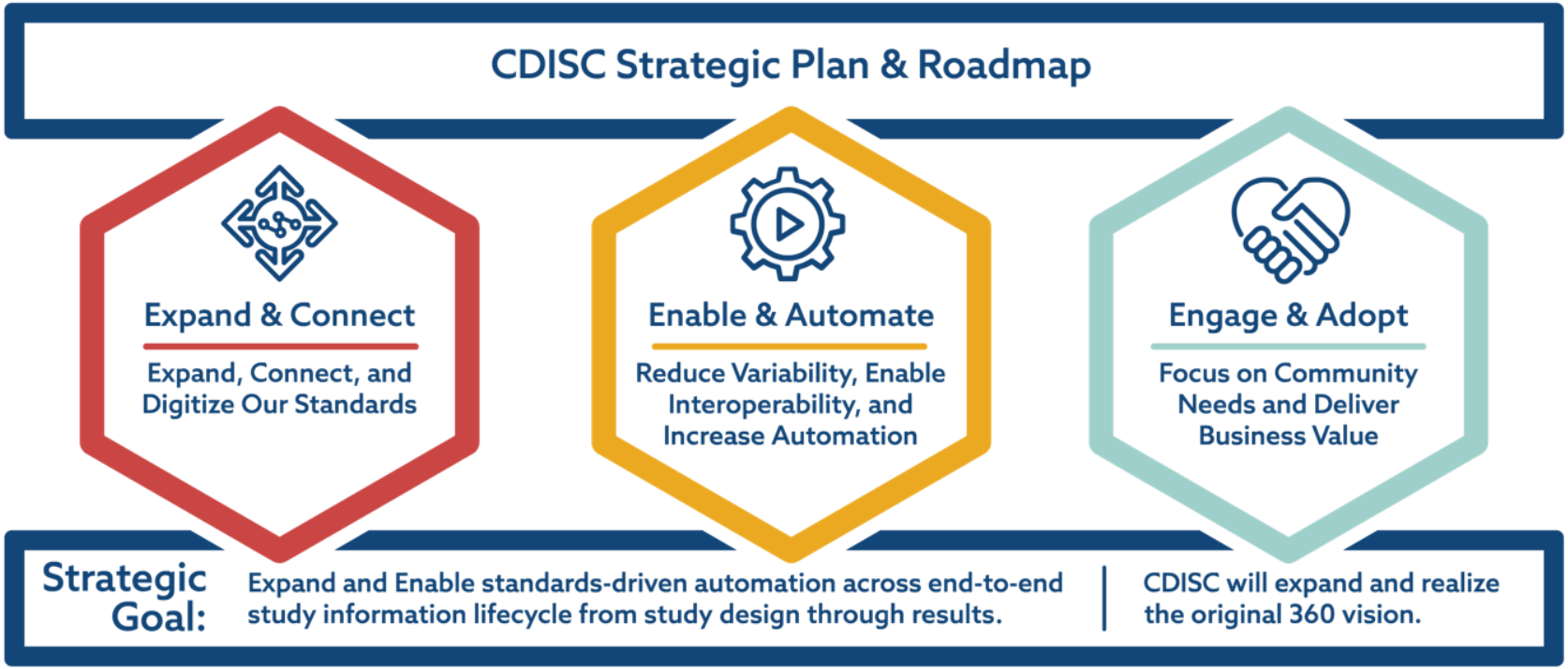
Organization: CDISC

Sam Hume co-leads the CDISC Data Exchange Standards team, advises CDISC leadership on strategy and technical topics, and contributes to COSA, CORE, CDISC Library, and other CDISC projects. Sam formerly served as the CDISC VP of Data Science. During his 30 years in the biopharmaceutical industry, he has held several senior-level technology positions. Sam is an active PHUSE contributor. He holds a doctorate in Information Systems.

Defining the Enable and Automate Strategic Pillar

A brief overview of the Enable and Automate pillar within the CDISC strategy and how it fits into 360i

Realizing the CDISC Mission



Roadmap Pillars and Objectives

Expand & Connect

- Embrace and adopt digital study design
- Expand and connect standards across the clinical research information lifecycle
- Define clear pipeline for integration of new data sources

Enable & Automate

- Develop **ready to use** implementation standards
- Create **open-source technology** enabled standards
- Establish and manage a **conformance** framework

Engage & Adopt

- Establish a continuous feedback loop across the CDISC community
- Shift focus to producers/consumers needs and lower the barrier to use
- Prioritize communication to enable our stakeholders

Practical Benefits of Enable and Automate

What practical benefits are expected when we're Done with the Enable and Automate pillar of the CDISC Strategy?

Practical Benefits: Reduce Variability, Enable Interoperability, and Increase Automation

Develop pre-configured, ready-to-use standards

- Less sponsor-specific metadata simplifies standards management and maintenance
- Less sponsor-specific metadata reduces variability between studies
- Simplifies building software tools that automate standards-based data processes

Create technology enabled standards

- Automated processes reduce the variability between studies
- Automated processes increase efficiency and quality
- Automated processes enables standards testing to improve quality

Establish and manage a conformance framework

- Conformance rules published with standards reduces variability
- Automated conformance checking across the lifecycle improves efficiency and quality
- Conformance rules for DTAs enhance interoperability

Definition of Done

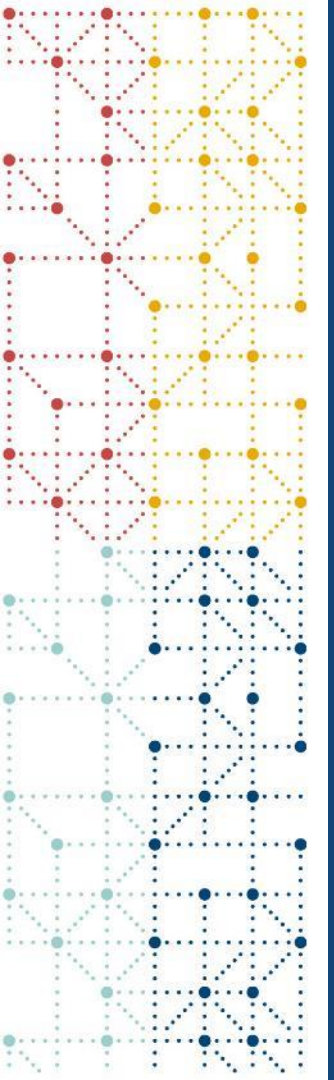
How do we define done for the Enable and Automate strategic pillar within the 360i project?

Description of the End State

360i has published a complete preconfigured study package with all the components defined in metadata from study design to submission, test data for the study, and software to execute the study data pipeline to generate analysis results

360i Study Package Acceptance Criteria

Metadata	Data	Software	Demonstration
• Publish a complete study metadata package that covers the full study data pipeline from study design through TLFs.	• Publish the complete set of raw datasets for the test study to execute the automated study data pipeline.	• Publish a pre-configured set of open-source software tools that consume the study metadata and data to execute the study design using the test data.	• Execute the study build and data pipeline automation in a Connectathon event to demonstrate generating analysis results from a study design.

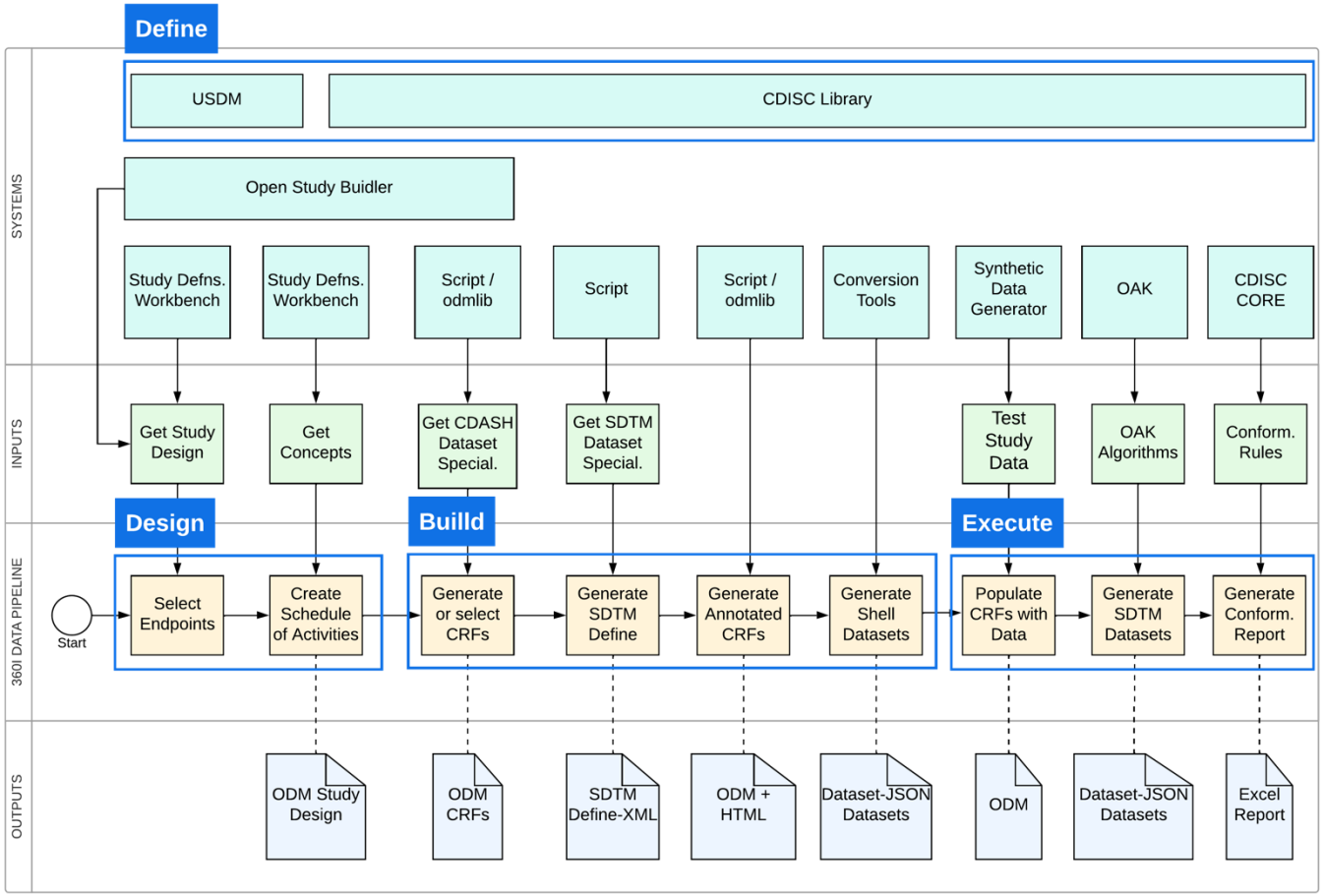


Enable and Automate in Practice

Moving beyond a POC towards developing standards and software tools that drive end-to-end automation

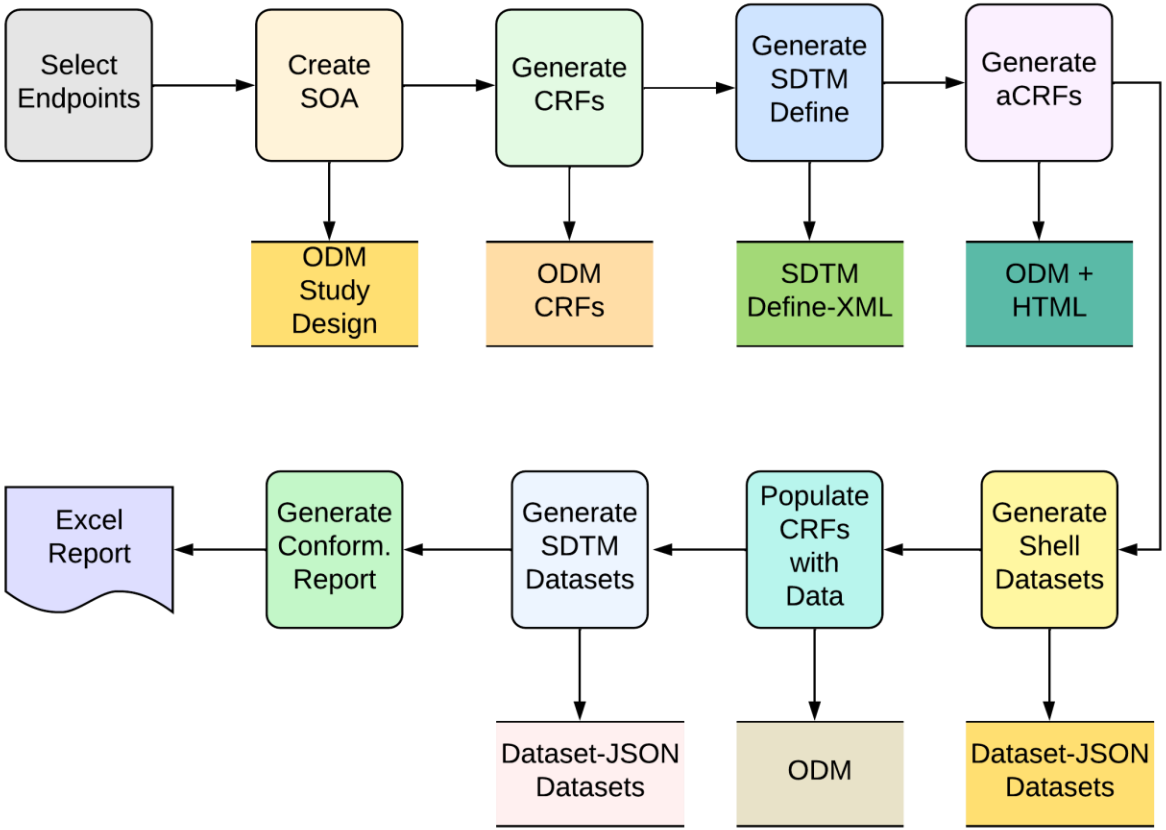
CDISC 360i Phase 1: Generating SDTM

Technical Process

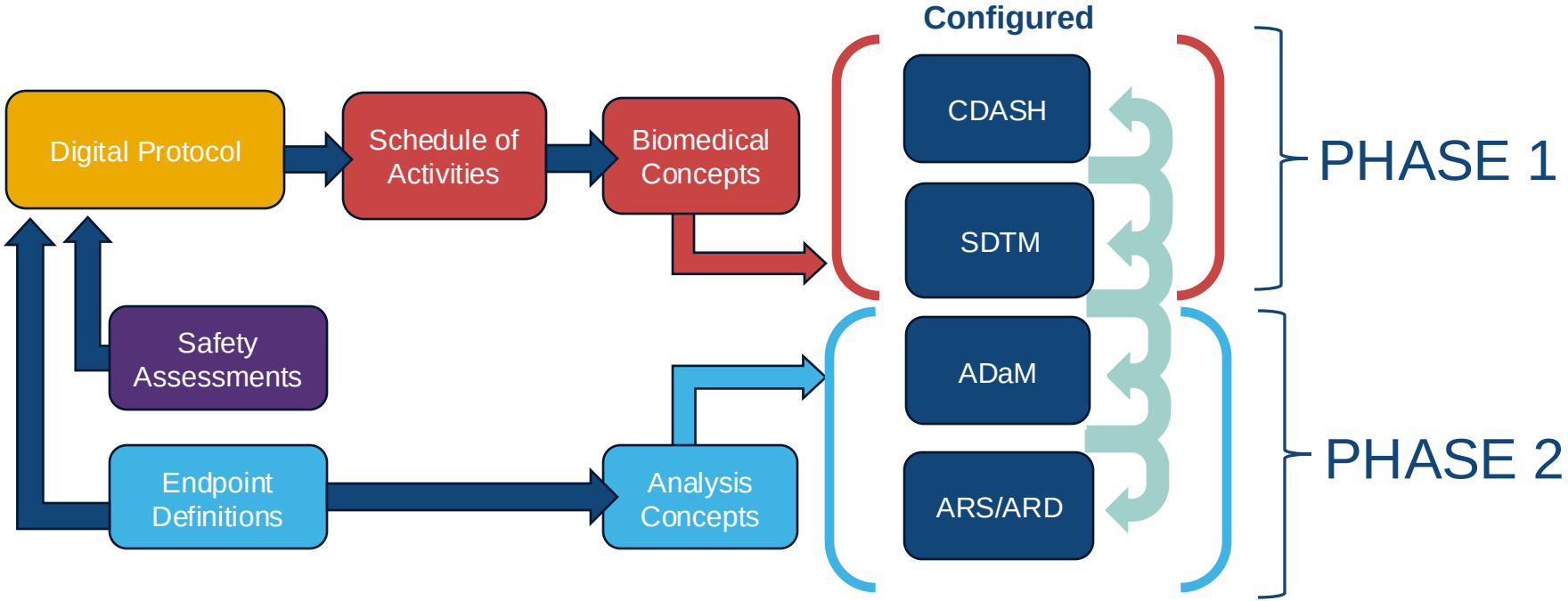


360i Phase 1: Generating SDTM

Process and Outputs



360i Phase 2: Generating Analysis Results



Phase 2 pre-work includes defining Analysis Concepts

What's Changed since the CDISC 360 POC?

New standards:

- DDF USDM
- Analysis Results Standard
- Biomedical Concepts and Dataset Specializations
- sdtm.oak transformations
- Dataset-JSON for dataset exchange
- Open conformance rules

New software tools:

- Open Study Builder
- TLF Designer
- admiral
- CORE
- sdtm.oak
- Dataset-JSON conversion tools
- Other COSA tools
- Other Pharmaverse tools

These lists are examples and not intended to be comprehensive

Software Tools*

Study Design	Data Collection	SDTM	ADaM	Define-XML	ARS
Open Study Builder	odmlib	sdtm.oak	admiral	OpenCST	TLF Designer**
Study Definitions Workbench	ODM XML Stylesheet	Dataset-JSON Tools	Dataset-JSON Tools	defineR	cards
BC Browser		CORE	carver	odmlib	gtsummary
DDF SDR		Smart Dataset Viewer		Define XSL Stylesheet	JMP Clinical**

* Examples listed – not a comprehensive listing
** Open-source components expected to be available

More Practical Benefits of Enable and Automate

What additional practical benefits are expected from the CDISC Enable and Automate strategy?

Practical Benefit: Faster Innovation at Reduced Costs

Collaborative development yields reduced development and maintenance costs

- This applies to data standards and open-source software
- Continuous development and maintenance spread across a team of volunteers
- Reduced Total Cost of Ownership - free as in puppy, not as in beer

Faster innovation

- Standards reduce risk for those developing software tools
- Open-source software projects often have a higher tolerance for risk
- Open-source software can support sustained development and innovation

Open-source software and open standards support commercial software

- Planning Connectathons that include open-source and commercial software tools

Enable and Automate: Benefits for Large and Small Organizations

Scalability for large organizations

- Scale-up research data processes using standards-driven end-to-end automation
- Improved efficiencies, lower TCO, and reduced risk

Path of least resistance for small organizations and academics

- Path of least resistance – easier and cheaper than using a proprietary approach
- Easy on ramps – make it easier for researchers to get started with CDISC
- Lower barriers to entry for smaller organizations and budgets

Thank You!

Questions?

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We Want Your Feedback!

Opportunities:

- Survey with QR Code
- Contact CDISC leadership team
- Social post to share message with broader CDISC community