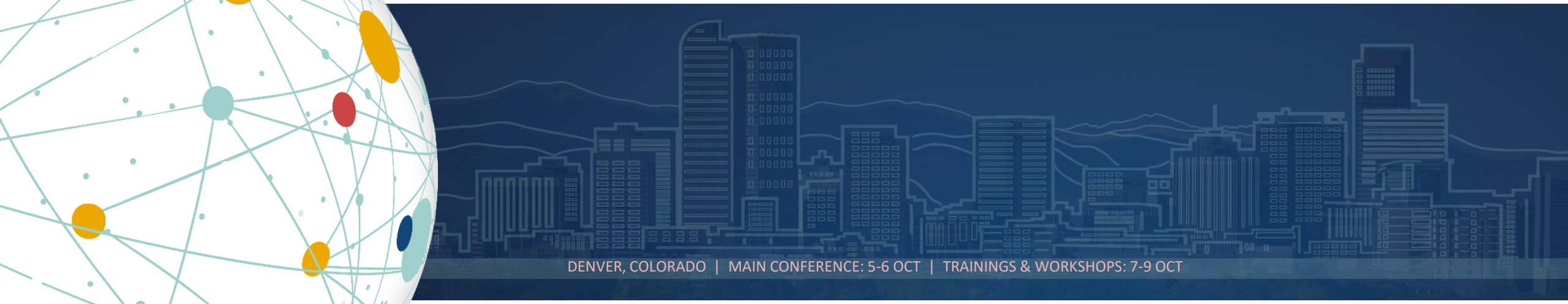


2026 US Interchange

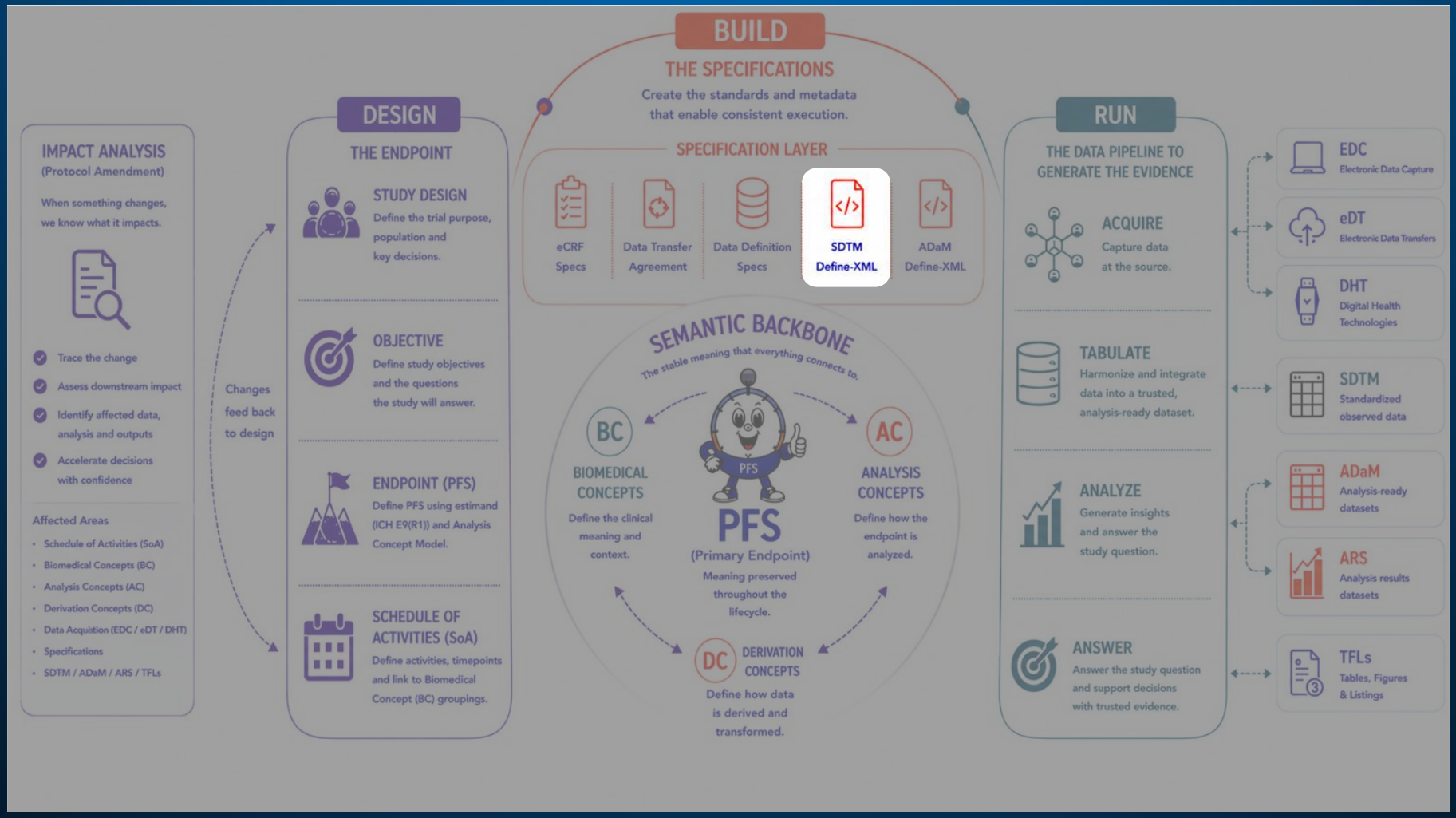
THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



360i Phase 2: Define-XML Generation

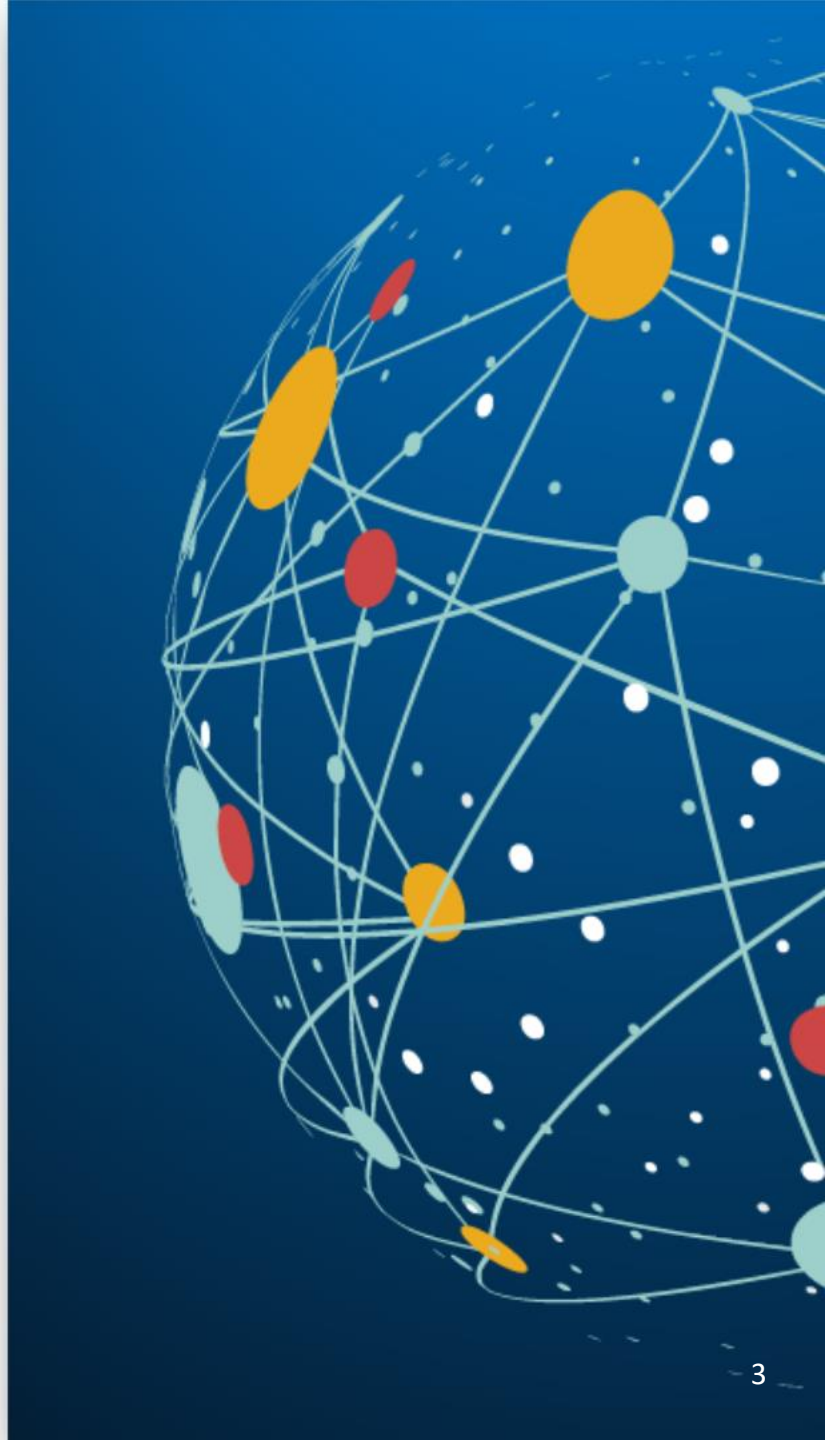
Darren Moreland
Director, Digital Transformation
CDISC

In Focus: Define-XML Generation



Problem Statement

- Manual and Inefficient Workflow
- Error-Prone Processes
- Limited Maintainability and Reuse
- Generated at the End of a Study



Solution & Benefits

Generating Define-XML from the Study Design

What Are We Trying to Accomplish?

- Create the new Data Definition Specification (DDS) model to support metadata-driven automation
- Generate Define-XML: USDM → Biomedical Concepts → SDTM Dataset Specializations
- Automate Define-XML generation
- Identify and resolve metadata/standards gaps

Why This Matters

- Higher quality Define-XMLs generated earlier and more efficiently
- Define-XML generated as a specification
- Demonstrate a new DDS model
- Maximizes the use of CDISC published metadata resulting in less maintenance for sponsors

360i Define-XML Generation Workflow

1 LOAD

Creates the DDS template

- Builds DDS from the USDM SOA
- BCs & Dataset Specializations supply most content
- Missing metadata pulled from the CDISC Library
- Gaps flagged as PLACEHOLDERs

2 REFINE

Finalizes the DDS file

- Fills metadata gaps by substituting PLACEHOLDER content
- Adds study-specific additions & updates
- **Produces the final DDS file**

3 GENERATE

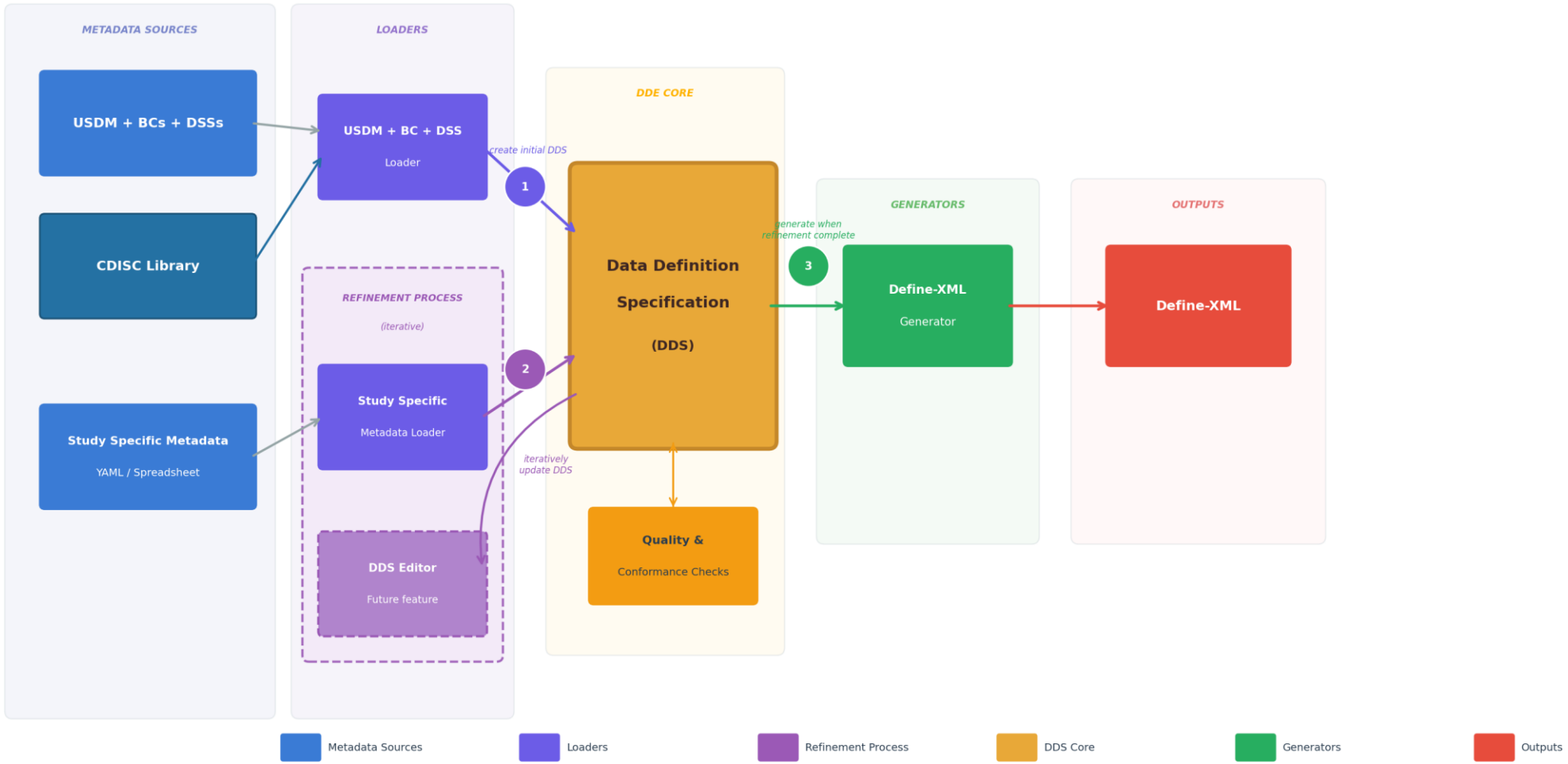
Outputs the Define-XML

- A generator reads the final DDS file
- **Generates the final, valid Define-XML v2.1 specification output**

↻ **Subsequent DDS refinements may be needed as the study proceeds**

CDISC 360i Define-XML Automation Architecture

Generating Define-XML from the Study Design

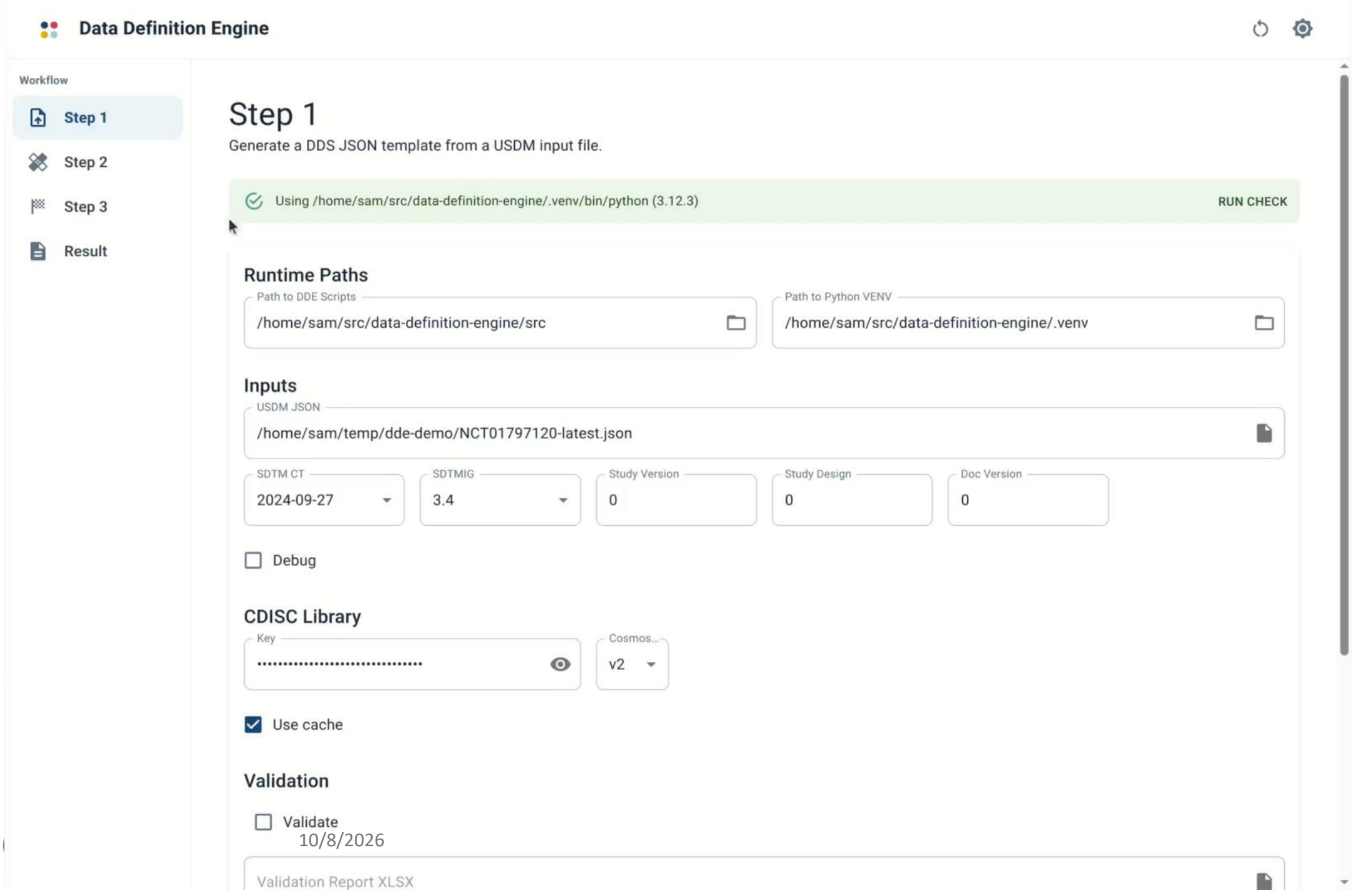


Participant Engagement: Data Definition Specification (DDS)

- If you'd like to explore the technical details of the Data Definition Specification (DDS) model or profiles, scan the QR code to view the repository GitHub.

Participant Engagement: Data Definition Engine (DDE)

- If you'd like to explore the technical details of the Data Definition Engine (DDE) proof-of-concept, scan the QR code to view the repository GitHub.


Data Definition Engine
Workflow
Step 1
Step 2
Step 3
Result
Step 1
Generate a DDS JSON template from a USDM input file.
Using /home/sam/src/data-definition-engine/.venv/bin/python (3.12.3)
RUN CHECK
Runtime Paths
Path to DDE Scripts
/home/sam/src/data-definition-engine/src
Path to Python VENV
/home/sam/src/data-definition-engine/.venv
Inputs
USDM JSON
/home/sam/temp/dde-demo/NCT01797120-latest.json
SDTM CT
2024-09-27
SDTMIG
3.4
Study Version
0
Study Design
0
Doc Version
0
Debug
CDISC Library
Key
Cosmos...
v2
Use cache
Validation
Validate
Validation Report XLSX

Demo Takeaway: Define-XML Generation Phases 1-2

Data Definition Engine (DDE) Proof-of-concept

- Demonstrates a process for automating the generation of a complete, valid Define-XML v2.1 using USDM + BCs + DSSs
- Uses the DDS operational model to represent the metadata that drives the automation
- Pulls standards metadata from the CDISC Library
- Demonstrates one possible approach to adding study specific metadata
- Provides graphical and command-line interfaces

Data Definition Specification (DDS) Model

- Demonstrates the application of DDS as an operational model that supports process automation
- Uses DDS to represent the Define-XML study metadata
- DDS JSON schema is used to validate the generated model

Looking Ahead

- Update DDE to implement DDS Define-XML Profiles
- Update DDE to accommodate USDM updates
- Update the UI and Patch Editor to simplify running the proof-of-concept

Thank You!

