



DS05: Enable and Automate: A Technical Roadmap Defining CDISC's Path to End-to-End Automation

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2025 PHUSE US Connect



Meet the Speaker

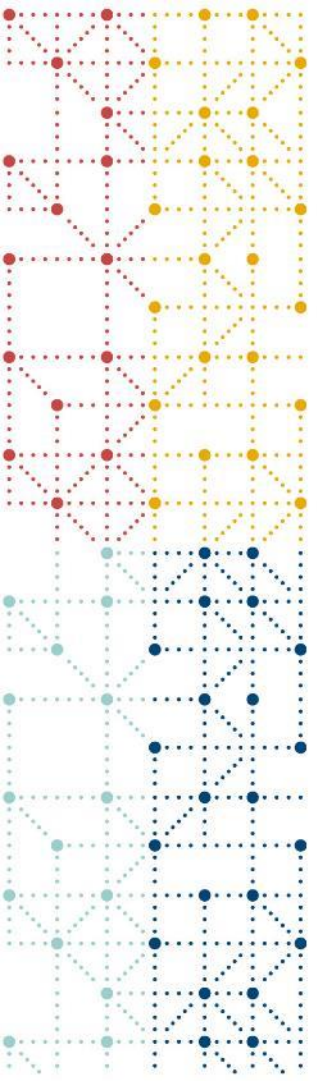
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Organization: CDISC

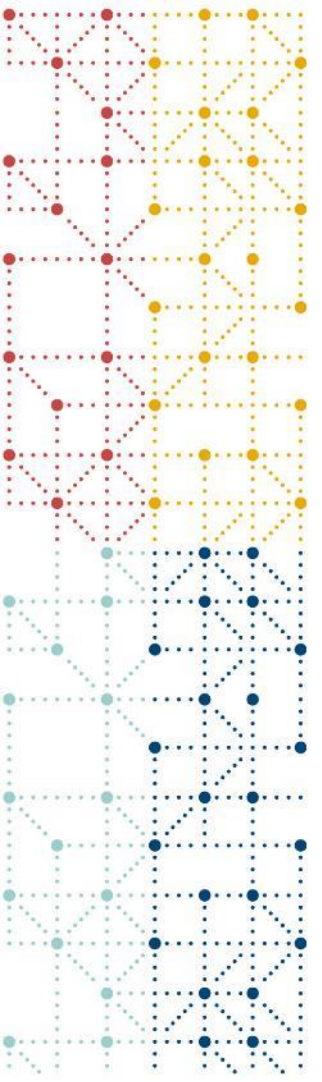


Sam Hume co-leads the CDISC Data Exchange Standards team, advises CDISC leadership on strategy, and contributes technical leadership to 360i, COSA, CORE, and CDISC Library. Sam formerly served as the CDISC VP of Data Science. During his 30 years in the biopharmaceutical industry, he has held several senior-level technology positions. Sam is an active PHUSE contributor. He holds a doctorate in Information Systems.



Agenda

- 1) 360i and the Enable and Automate Strategic Pillar
- 2) 360i Technical Roadmap
- 3) Rules of the Road



360i and the Enable and Automate Strategic Pillar

A quick introduction to the CDISC 360i Program and the Enable and Automate Strategic Pillar.

Realizing the CDISC Mission

CDISC Strategic Plan & Roadmap



Expand & Connect

Expand, Connect, and
Digitize Our Standards



Enable & Automate

Reduce Variability, Enable
Interoperability, and
Increase Automation



Engage & Adopt

Focus on Community
Needs and Deliver
Business Value

Strategic Goal:

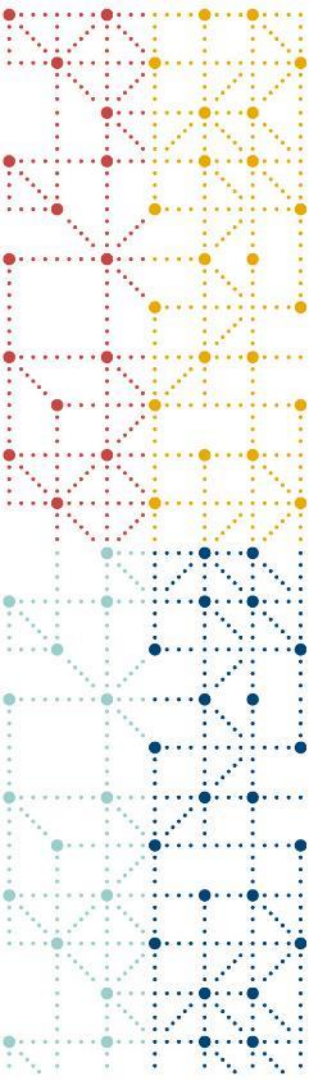
Expand and Enable standards-driven automation across end-to-end study information lifecycle from study design through results.

CDISC will expand and realize the original 360 vision.

360i Definition of Done



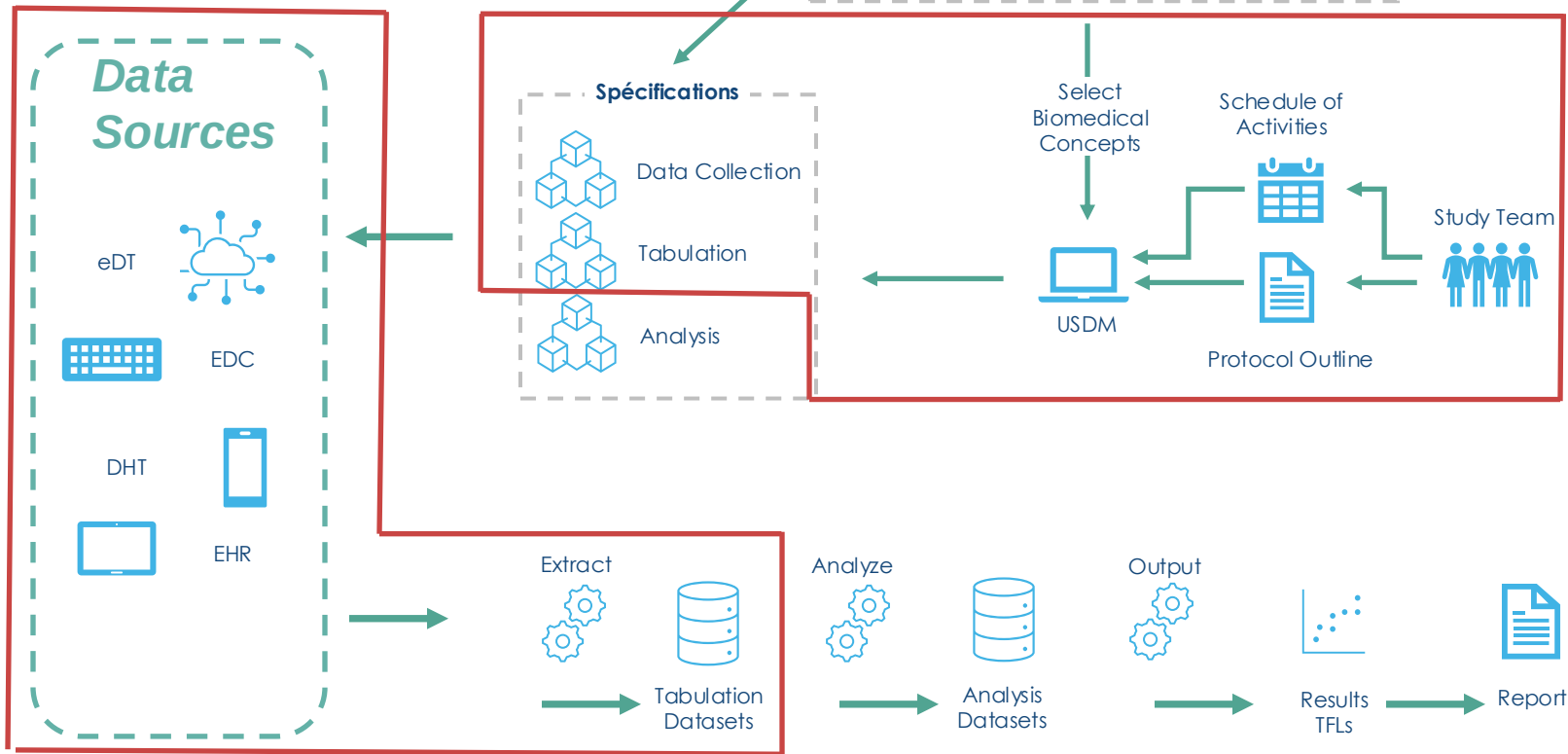
360i has published a complete pre-configured study package with all the components defined in metadata from study design to submission, test data for the study, and open-source software to run the study data pipeline to generate analysis results



360i Phase 1 Technical Roadmap

An overview of the current 360i Enable and Automate Technical Roadmap focused on Phase 1.

360i Phase 1 of 2



High-level Roadmap

Phase 1

Roadmap does not need to be completed sequentially in all cases

1. Study Design

2. CRFs & eDTs

3. SDTM Define-XML

4. aCRFs

5. Shell Datasets

7. ODS

6. Populate CRFs

9. SDTM Datasets

8. oak.sdtm Algorithms

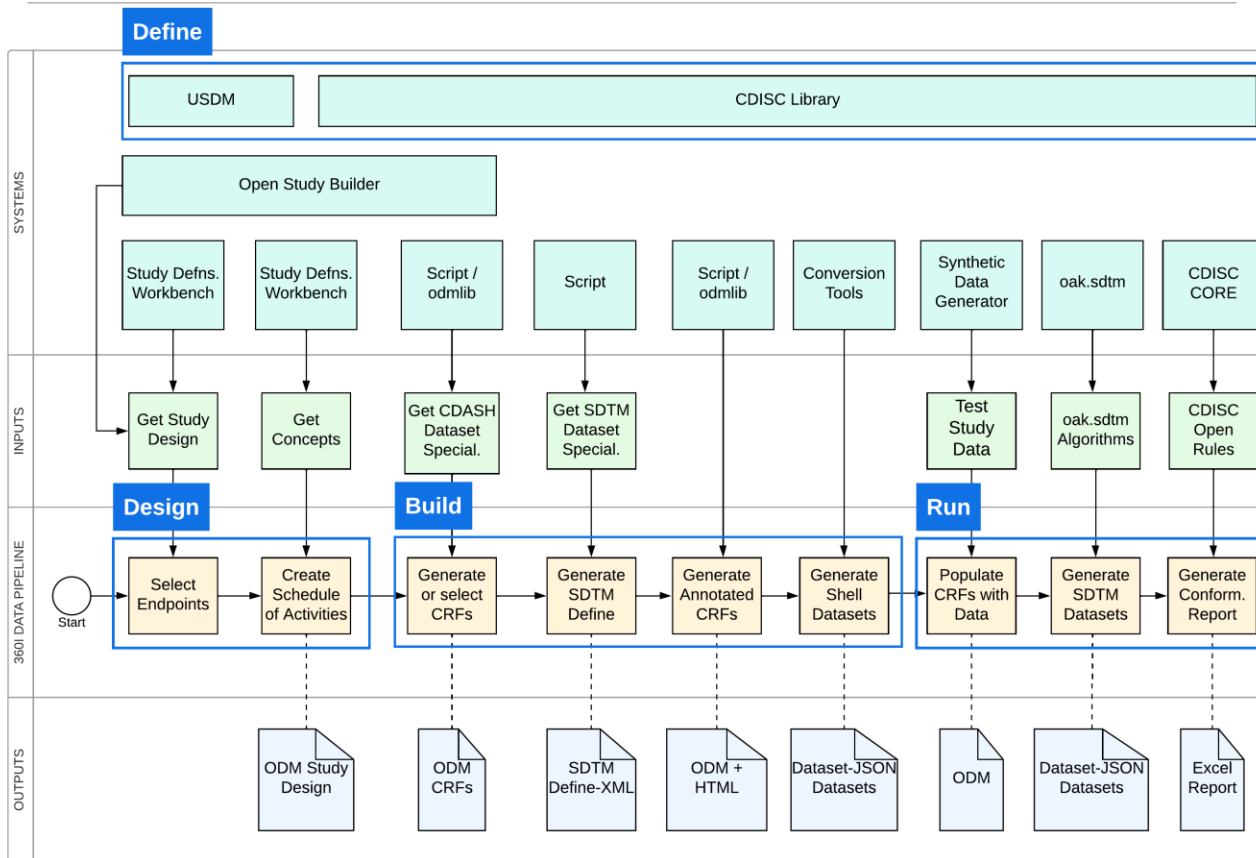
10. Open Rule Set

11. Conformance Report

CDISC 360i Phase 1: Generating SDTM

CDISC 360i TECHNICAL PROCESS - GENERATING SDTM - 2025.02

Sam Hume | February 11, 2025



1. Create Study Design

Inputs

- LZZT study design XLS
- Biomedical Concepts

Tools

- Open Study Builder
- Study Definitions Workbench
- CDISC Library

Outputs

- USDM JSON export
- ODM Study Design

Description:

- Use existing LZZT artifacts to generate the study design using OSB and SDW
- Export the study design as JSON or ODM
- If ODM is not supported, generate it from a JSON export
- Other artifacts may also be generated if supported, such as ODM-based CRFs
- The SOA will be included in the exported study design.

2. Generate CRFs & eDTs



Description:

- Use OSB to generate CRFs & eDTs based on the study design
- Create a script to generate CRFs & eDTs from the study design and CDISC Library
- A similar ODM-based approach will be used for CRFs and eDT data

3. Generate SDTM Define-XML



Description:

Software tools:

- read the BCs
- find the associated Dataset Specializations
- generate a complete Define-XML with VLM
- generate an HTML version for viewing

4. Generate aCRFs



Description:

- Using the ODM-based CRFs & eDTs and Define-XML, add annotations to the ODM
- Generate an HTML version of the aCRF for visualization
- Using the Define-XML add Origins values

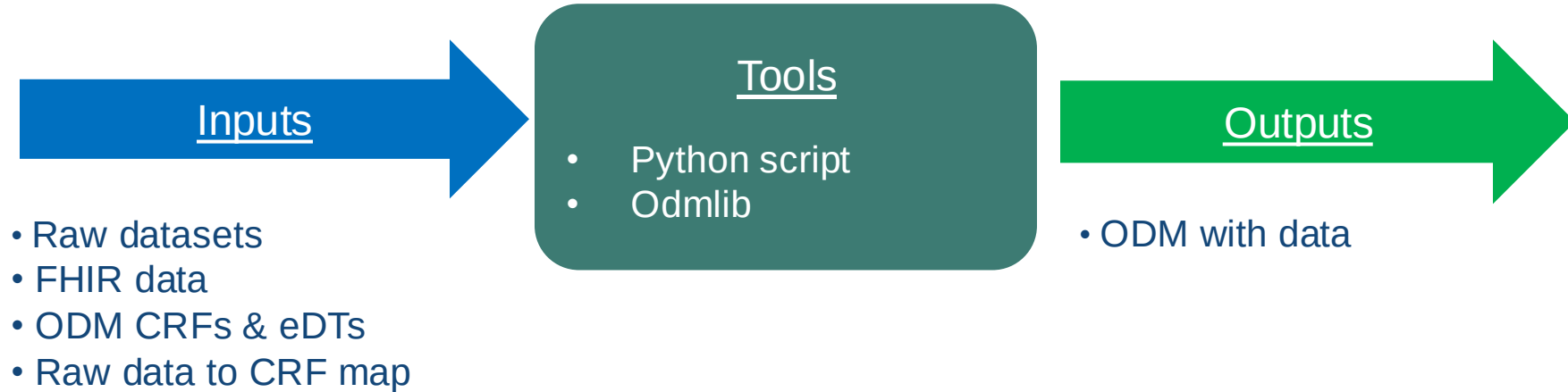
5. Generate Shell Datasets



Description:

- Use Dataset-JSON conversion tools to read Define-XML and generate shell datasets
- The shells can also be generated using the Dataset-JSON API

6. Populate CRFs & eDTs with Raw Data



Description:

- Develop a Python script to load the raw data into the ODM CRFs & eDTs
- FHIR data will be included in the raw data after the LZZT data has been loaded

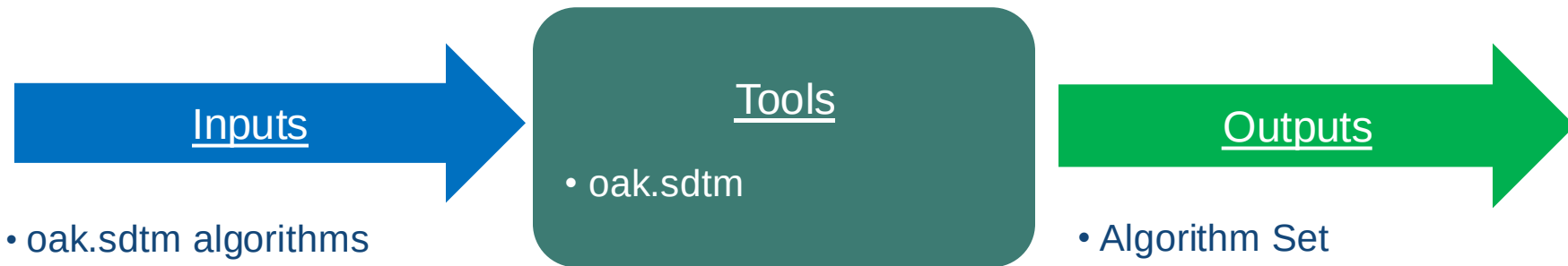
7. Load Operational Data Store*



Description:

- The Operational Data Store (ODS) is an abstract repository/interface
- The exact tools used for the 360i ODS have not yet been determined
- A data store may be a graph database, a relational database, a document database, datasets, any other data store, or some combination of data stores
- The ODS can accommodate different use cases beyond the SDTM and ADaM generation we will target in 360i.

8. Create oak.sdtm Algorithm Set



Description:

- Select the existing oak.sdtm algorithms needed to convert the raw data into SDTM
- New algorithms may be created to meet the needs of the LZZT study

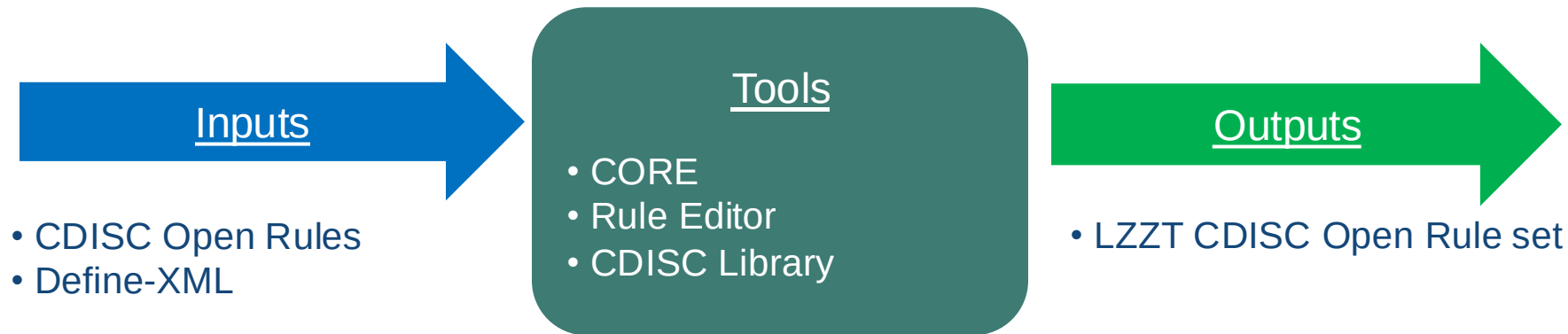
9. Generate SDTM Datasets



Description:

- Convert the ODM / ODS raw data into oak.sdtm raw datasets
- Run oak.sdtm with the algorithm set to generate the SDTM Dataset-JSON datasets
- If oak.sdtm does not yet support Dataset-JSON, generate datasets and convert them to Dataset-JSON

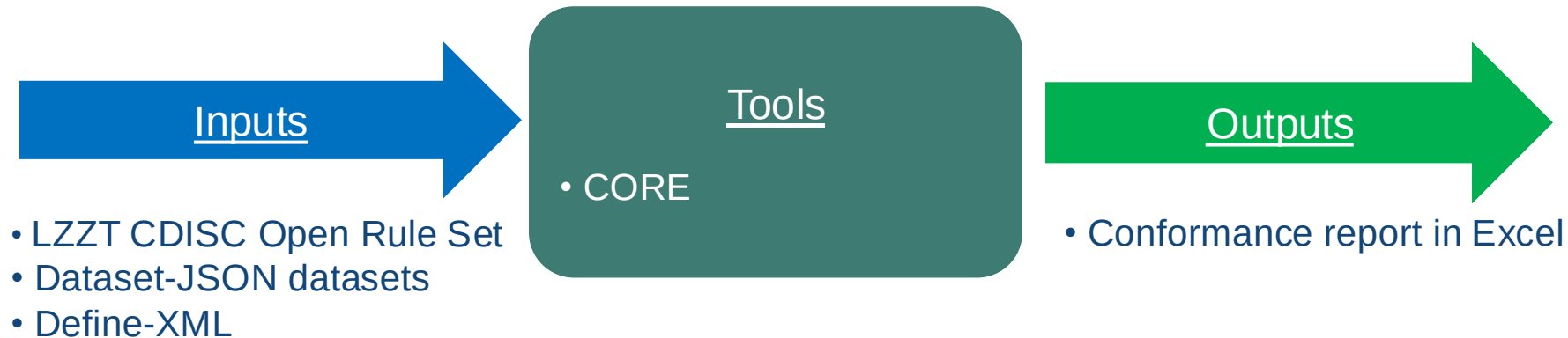
10. Create Open Rule Set



Description:

- Select the SDTMIG conformance rules from the CDISC Library
- Use the Rule Editor to generate study specific or data quality rules for the LZZT study

11. Generate Conformance Report

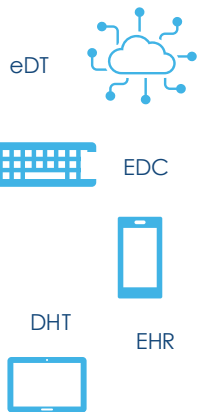


Description:

- Run CORE using the Open Rule Set against the LZZT study SDTM datasets to generate an Excel-based report of the findings

360i Vision

Data Sources



Build

Machine Executable Specifications



Design



Select Biomedical Concepts

Select Endpoints

Study Definitions

Data Collection
Data Transfer
Tabulation/Analysis
More Use Cases...

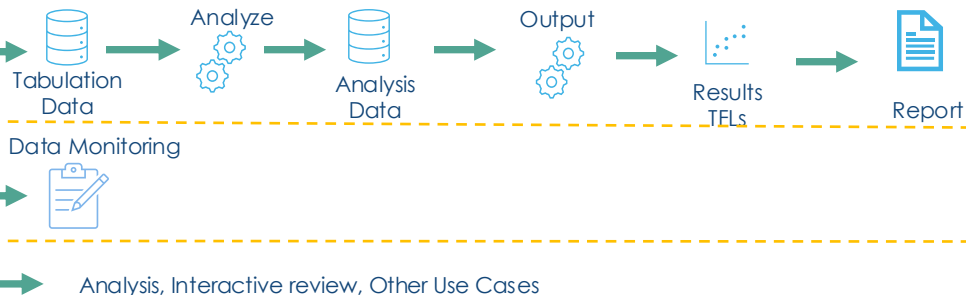
Company
Configured
Library

Data Standards

Biomedical Concepts
Analysis Concepts
Foundational Standards
Reference Specifications

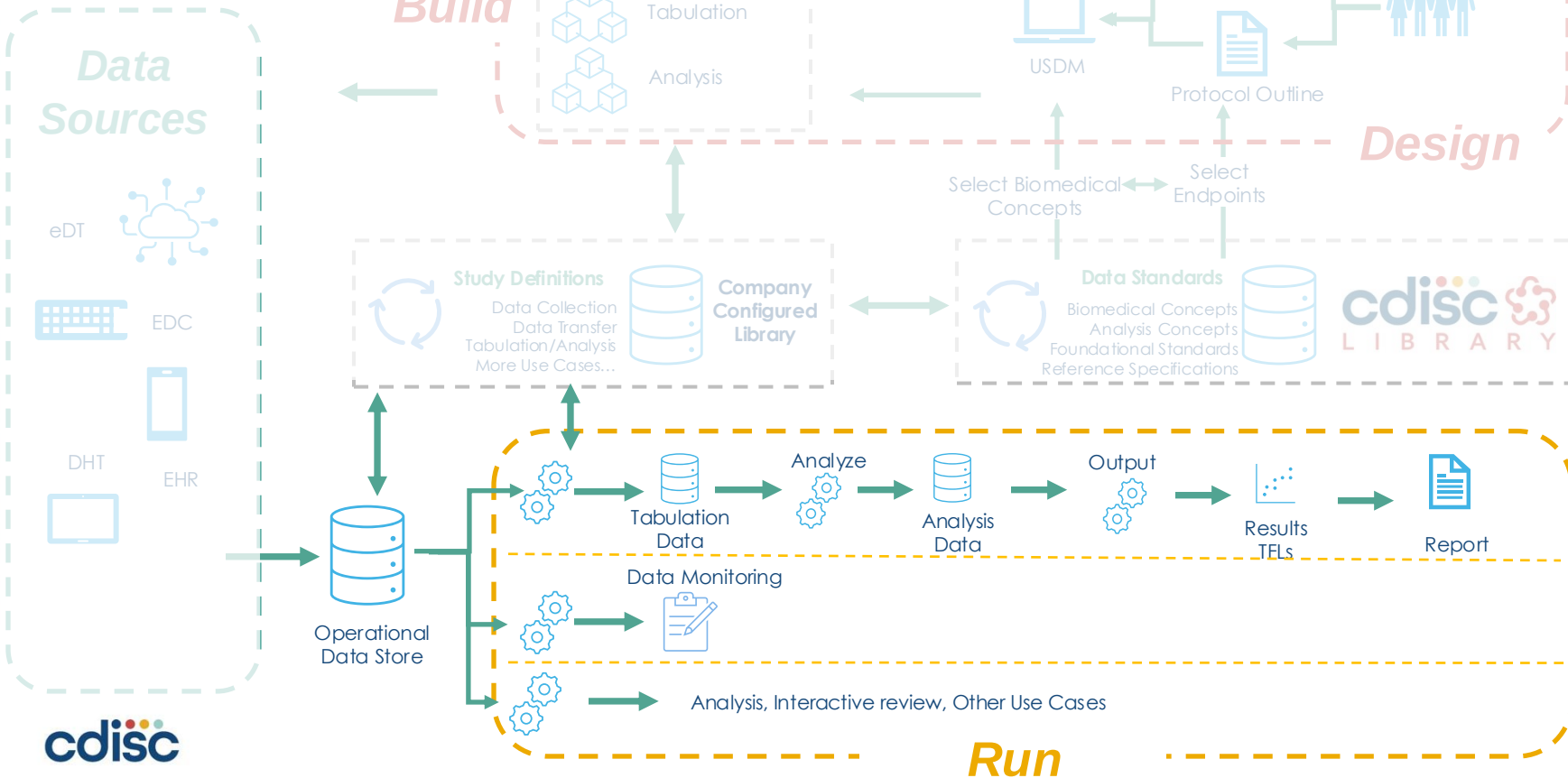


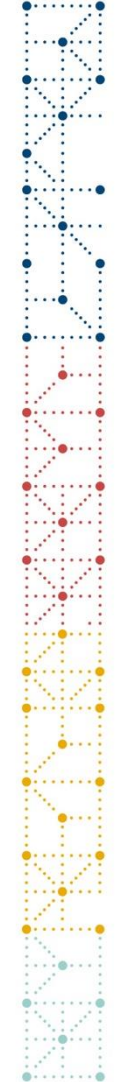
Operational
Data Store



Run

360i Vision





Example Roadmap Infrastructure Needs

Synthetic Data Generator

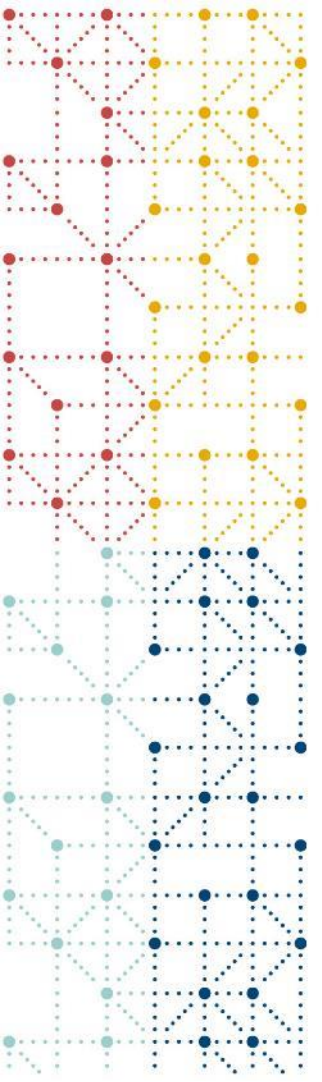
- Generate raw test data

APIs

- Open Study Builder API
- CDISC Library API
- Dataset-JSON API

Technical Environments

- Open Study Builder
- GitHub
- R and SAS execution environments
- Cloud processing and storage



Rules of the Road

A set of principles and insights into how we plan to navigate the 360i Enable & Automate Technical Roadmap

Technical Roadmap Rules of the Road

Principle	Description
Implementation Focus	Implementation focus is a new way of working that transcends 360i.
Empirical, Iterative Process	We'll implement 360i in small increments and learn as we go.
Make it Work	Make it work, make it right, make it fast.
More Than One Way To Do It	TMTOWTDI, alternative software tools are welcome.
CI/CD	Make it testable. Continuous Integration / Continuous Deployment.
Just Do It	Pull Requests > Suggestions. What gets worked on gets done.
Build Publicly	Benefit from network effects and transparency. Collaborate on GitHub.

Thank You!

Questions?

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