Breaking Down the Silos with 360i: A Technical Roadmap

Presented by Julie Smiley, Vice President, Data Sciences, CDISC

Meet the Speaker

Julie Smiley, MS

Title: Vice President, Data Sciences

Organization: CDISC

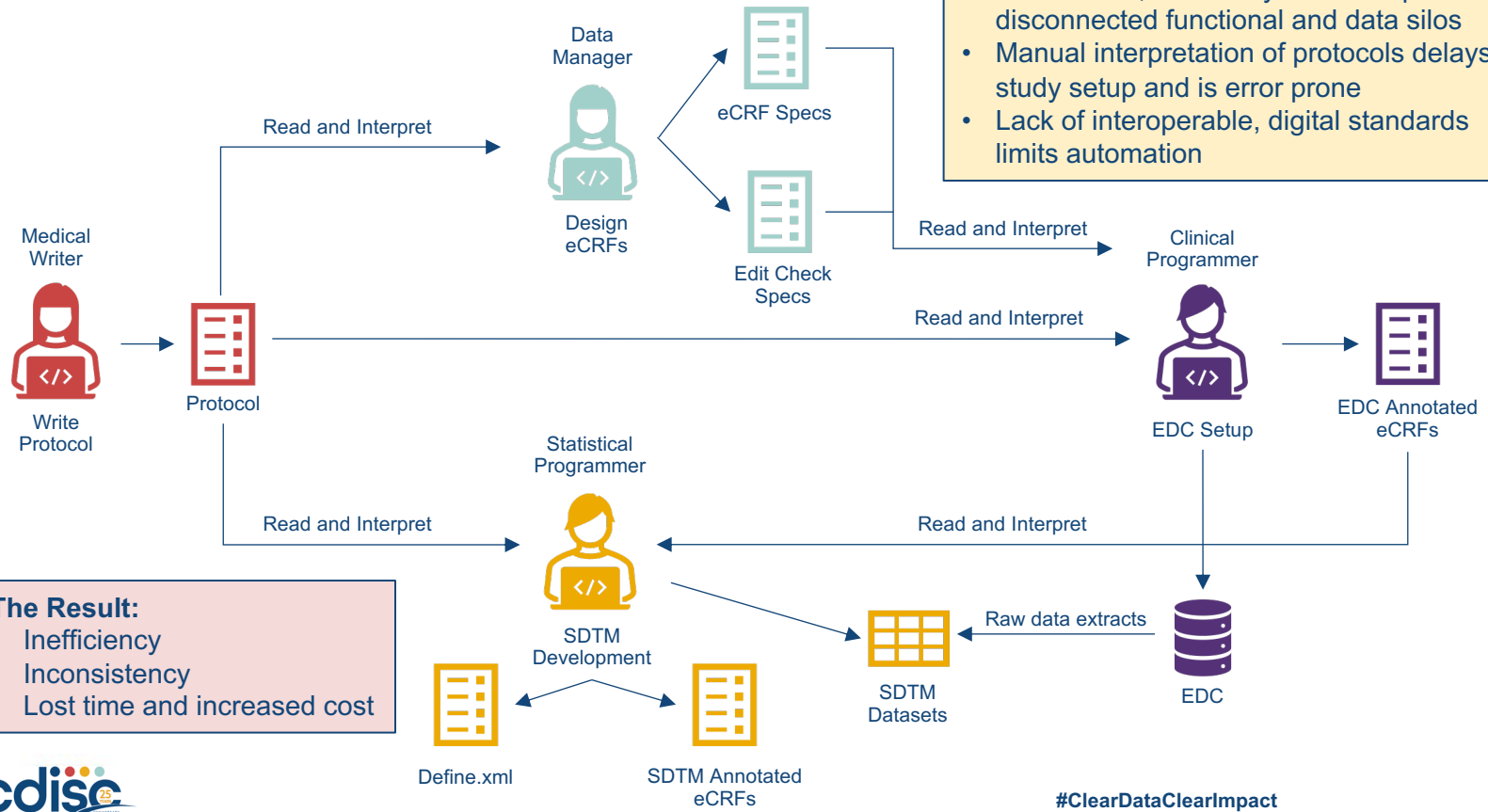
Julie Smiley has over 25 years of experience in the pharmaceutical industry and extensive expertise with data standards and data flow automation. Throughout her career, she has led data management and database programming organizations, later shifting her focus to standards, metadata governance, and end-to-end data flow automation. As Vice President of Data Sciences at CDISC, Julie is dedicated to driving innovation in data standards, enhancing interoperability, and supporting the industry's evolving data needs. She holds a Master of Science in Computer Information Systems from Boston University, specializing in database and knowledge management.

Agenda

1) Setting the Stage
2) Vision for 360i
3) 360i Technical Roadmap

Setting the Stage: The Problem

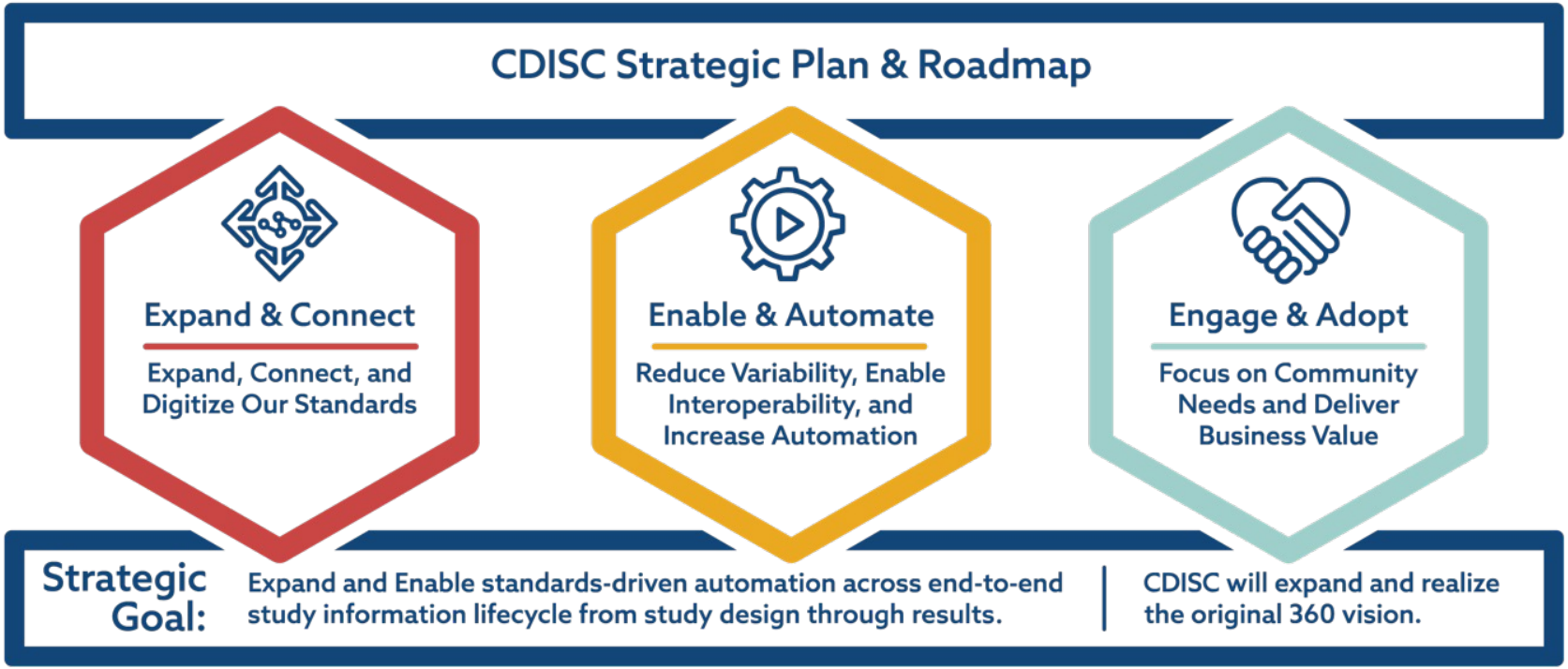
Today's Clinical Research Landscape:
- Study Design, Data Collection, Tabulations, and Analysis often operate in disconnected functional and data silos
- Manual interpretation of protocols delays study setup and is error prone
- Lack of interoperable, digital standards limits automation



The Result:
- Inefficiency
- Inconsistency
- Lost time and increased cost

Vision for 360i

Realizing the CDISC Mission



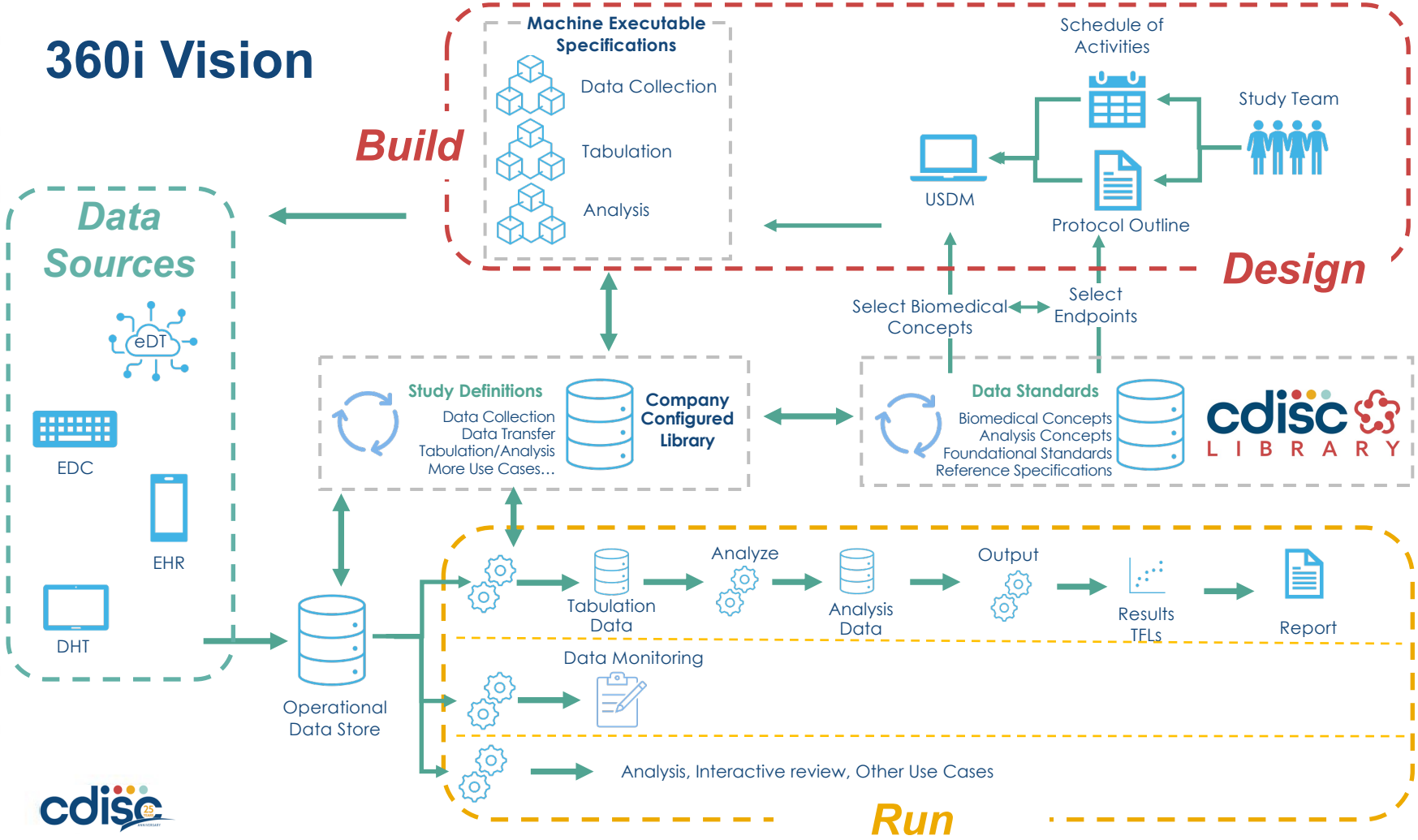
360i Vision

Creating a Digital Ecosystem:

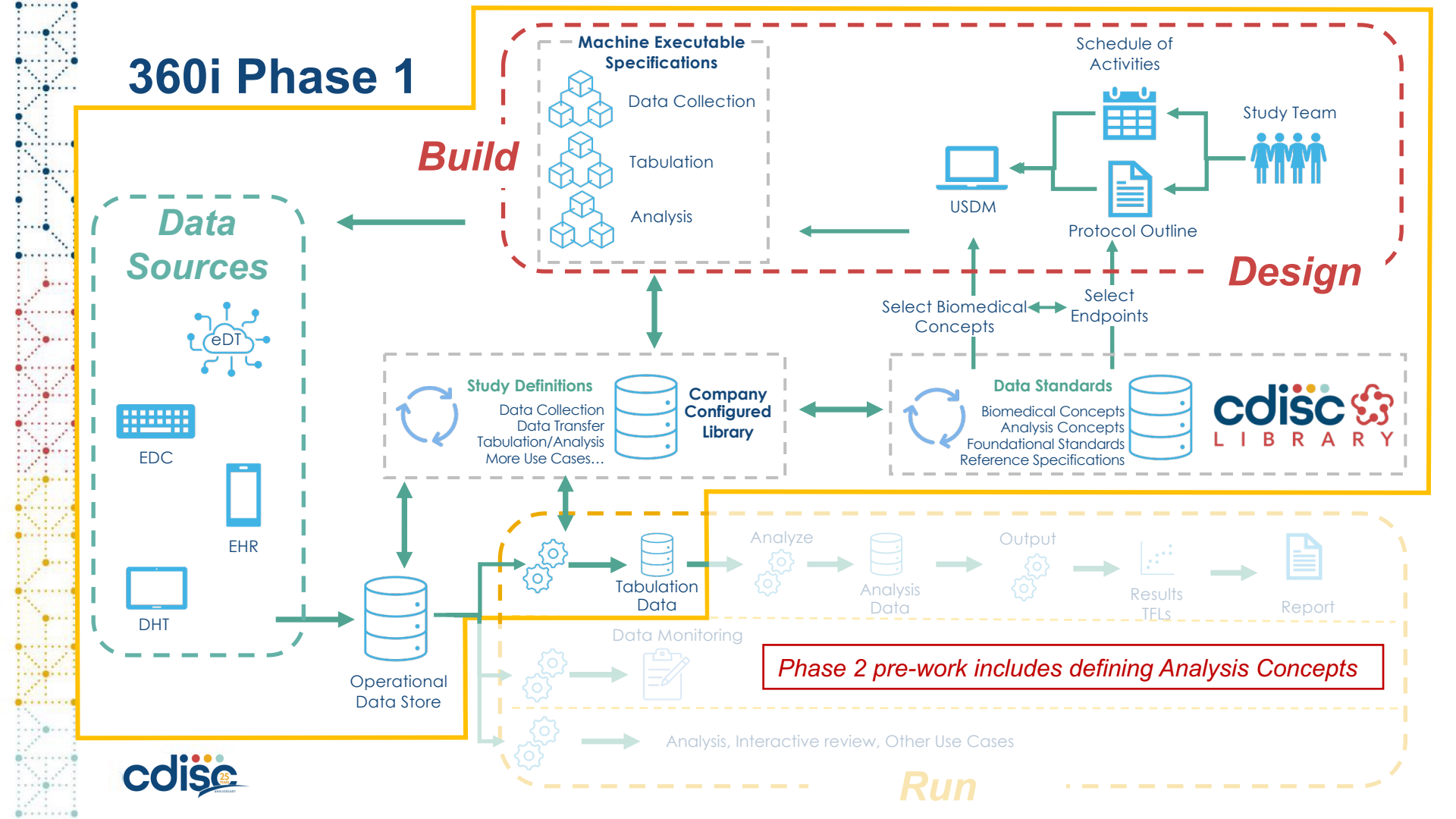
- Unified Study Definitions Model (USDM) as the foundation
- Digital Protocol feed downstream artifacts
- Linked Biomedical Concepts enrich meaning
- Machine-readable, interoperable data flows
- Open-source tools to support transparency and adoption

- **Goal:** Fully digital, standards-driven clinical development lifecycle

360i Vision


Machine Executable Specifications
Data Collection
Tabulation
Analysis
Build
Schedule of Activities
Study Team
USDM
Protocol Outline
Design
Data Sources
eDT
EDC
EHR
DHT
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
cdisc LIBRARY
Operational Data Store
Tabulation Data
Analyze
Analysis Data
Output
Results TFLs
Report
Data Monitoring
Analysis, Interactive review, Other Use Cases
Run

360i Phase 1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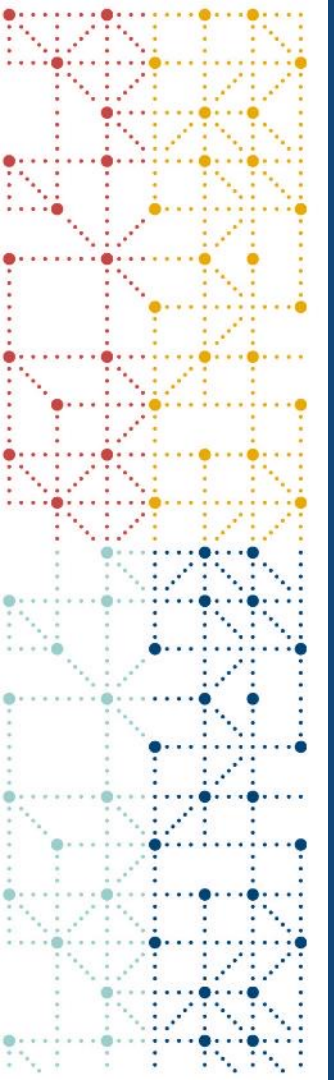
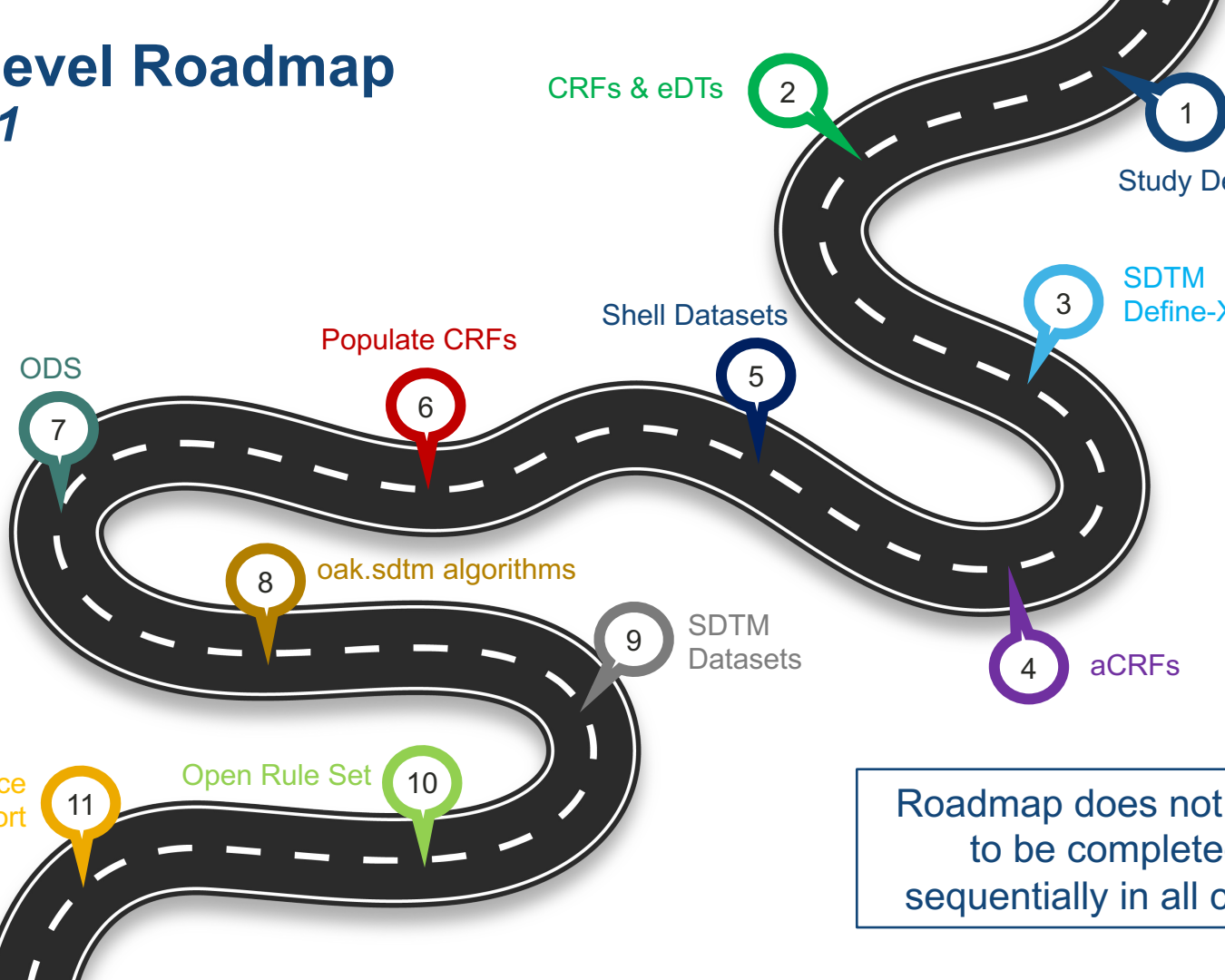
Analysis Concepts
Foundational Standards
Reference Specifications
cdisc LIBRARY
Tabulation Data
Analyze
Analysis Data
Output
Results TFLs
Report
Data Monitoring
Operational Data Store
Phase 2 pre-work includes defining Analysis Concepts
Analysis, Interactive review, Other Use Cases
Run



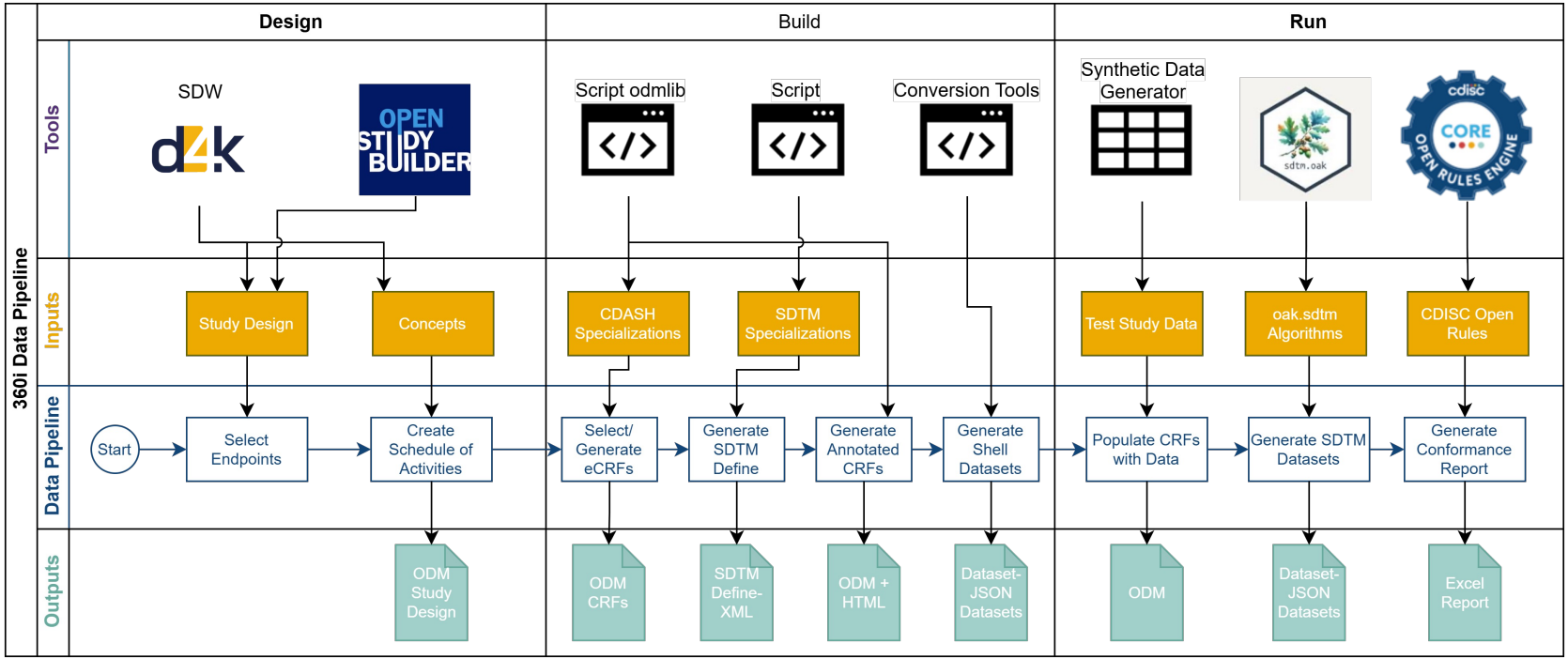
360i Technical Roadmap

High-level Roadmap
Phase 1



Roadmap does not need to be completed sequentially in all cases

Phase 1: Generating SDTM



1. Create Study Design

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

Build

- Study design exports
- Biomedical Concepts
- Dataset Specializations

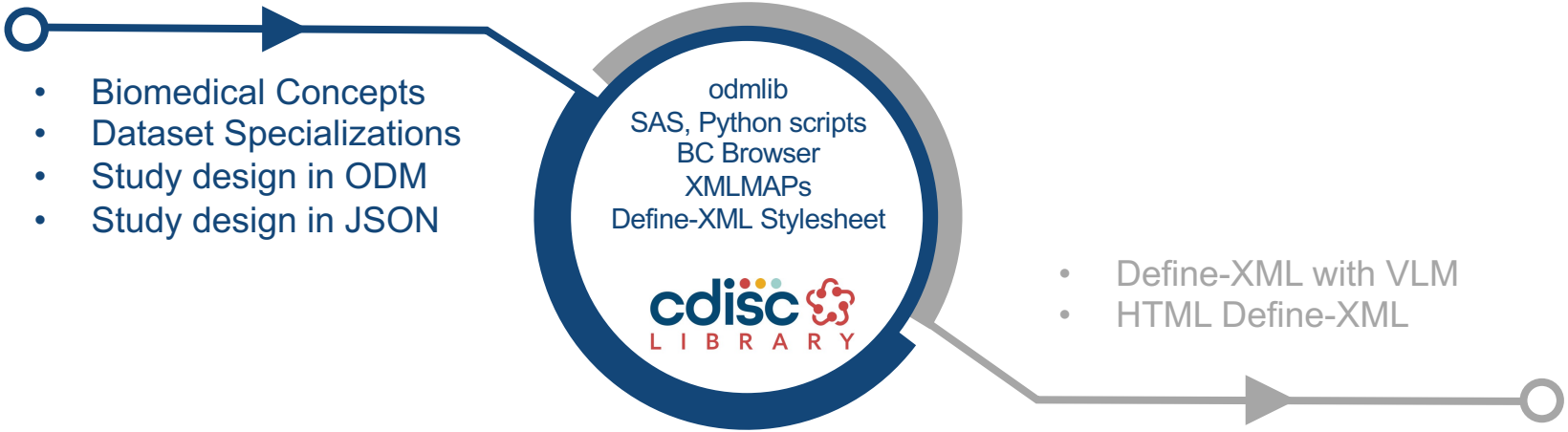
- ODM-based CRFs
- ODM-based eDTs
- HTML CRFs

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

Build



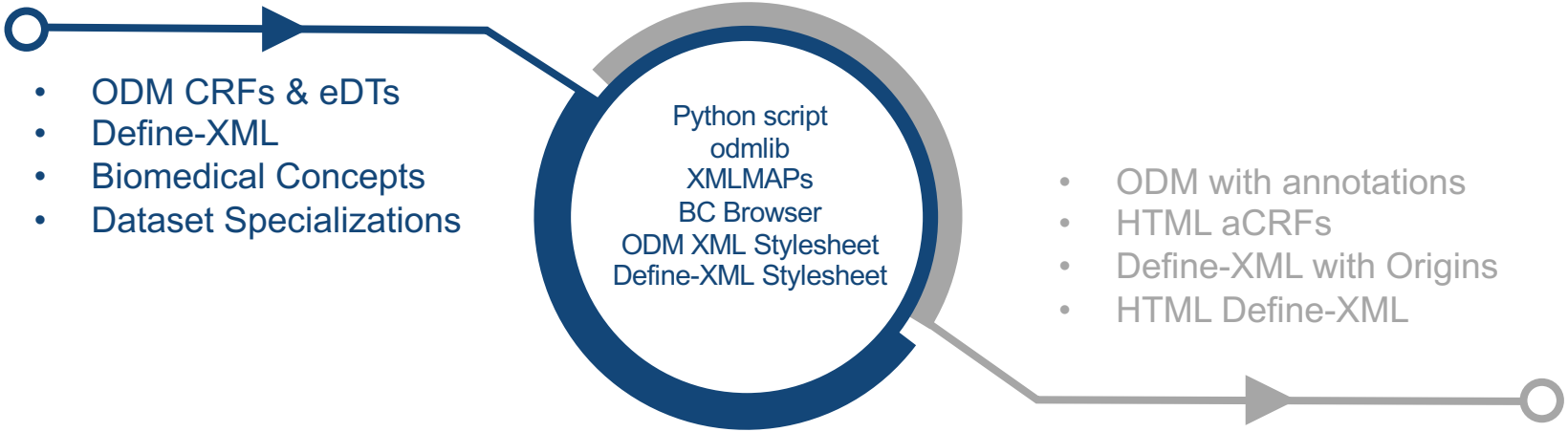
Description:

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

Build

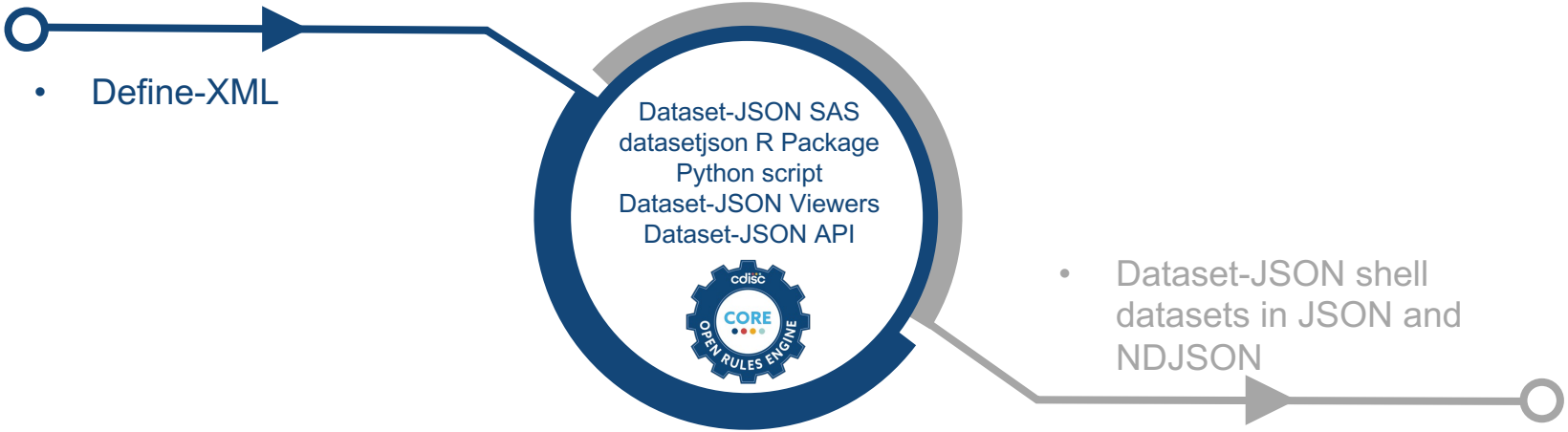


Description:

- 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

Build

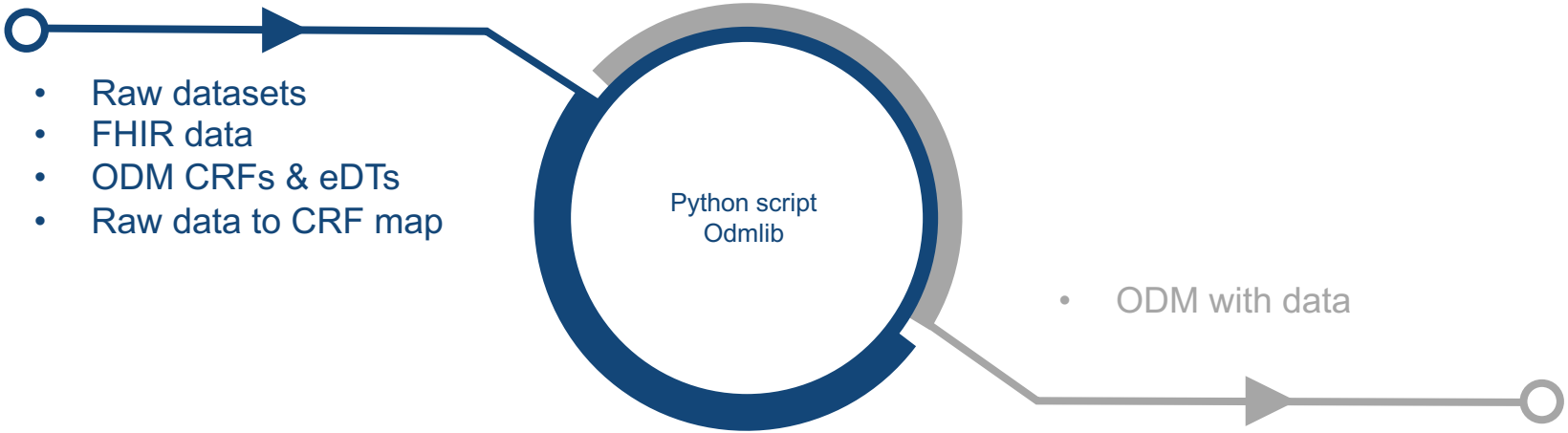


Description:

- 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

Run



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 (ODS)

Run

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 support different use cases beyond SDTM and ADaM generation

8. Create oak.sdtm Algorithm Set

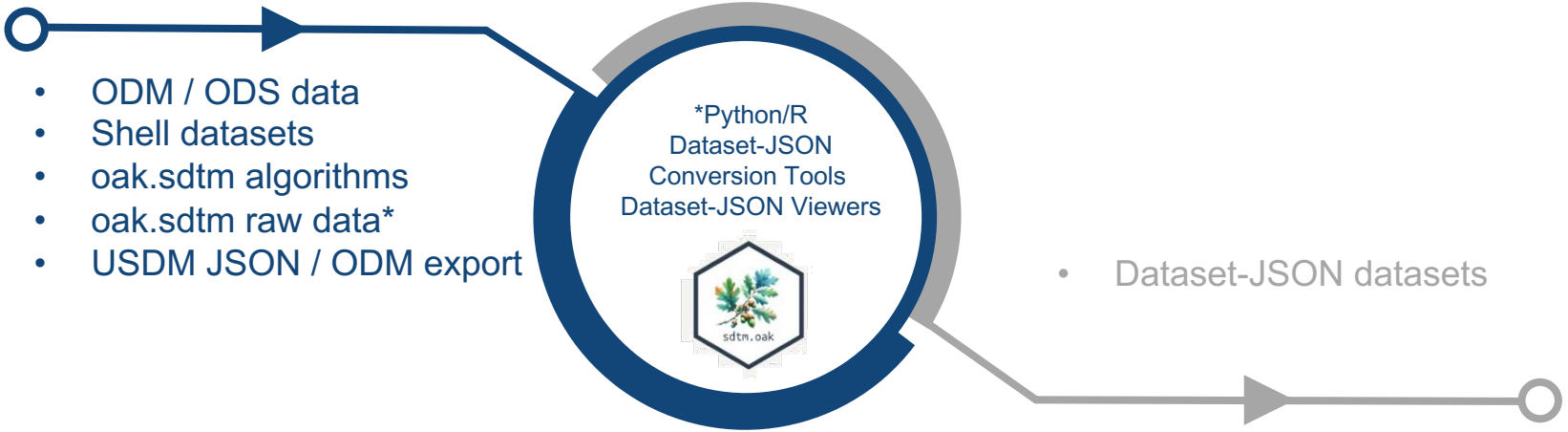
Build

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

Run



Description:

- Convert the ODM / ODS raw data into oak.sdtm raw datasets using Python/R
- 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

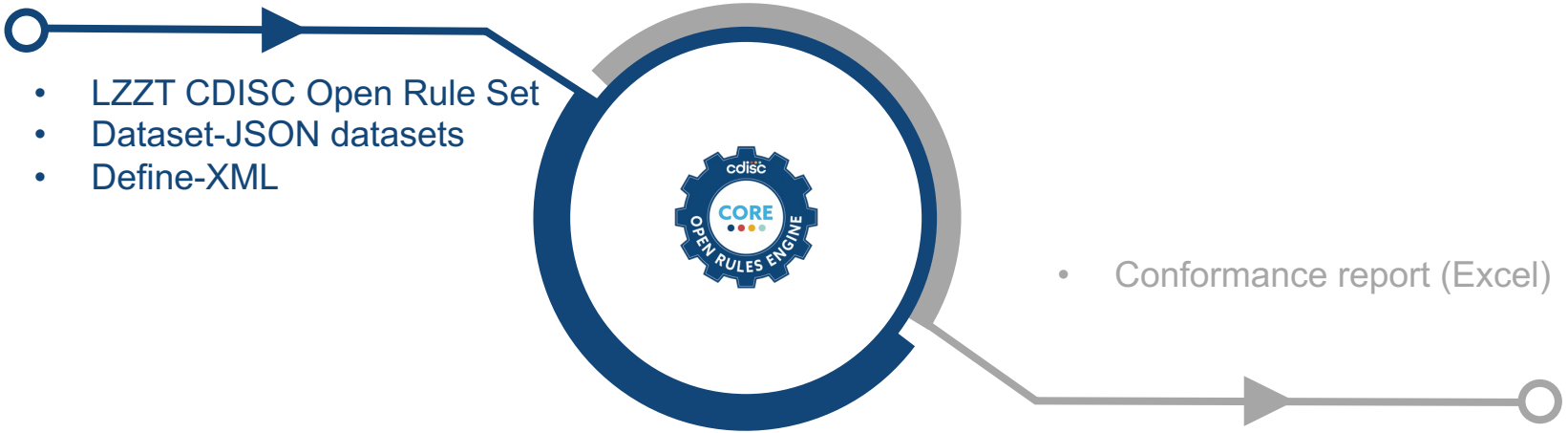
Build

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

Run



Description:

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

Technical Roadmap Rules of the Road

Implementation focus is a new way of working that transcends 360i.

Implementation Focus

We'll implement 360i in small iterative increments and learn as we go.

Empirical, Iterative Process

Make it work, make it right, make it fast.

Make it Work

There's more Than One Way To Do It – alternative software tools are welcome.

TMTOWTDI

Make it testable. Continuous Integration / Continuous Deployment.

CI/CD

Pull Requests > Suggestions. What gets worked on gets done.

Just Do It

Benefit from network effects and transparency. Collaborate on GitHub.

Build Publicly

Example Roadmap Infrastructure Needs

Technical Environments

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

Synthetic Data Generator

- Generate raw test data

APIs

- OSB API
- CDISC Library API
- Dataset-JSON API

Early Progress

Logistics

- Initiative kicked off
- Team leads assigned
- Volunteers assigned
- Team meetings
- Tasks in Jira
- Project organization
- Team training

Deliverables/PoCs

- GitHub repo
- Code to load LZZT data
- Code to run pipeline
- CRF in ODM
- ODM-XML validation
- HTML version of CRF
- USDM Rules
- Synthetic data
- SDTM TDM datasets

Community engagement

- Tech vendor roundtable
- 360i Advisory Council
- TransCelerate DDF
- Call-to-vendors

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

Thank You!

Join Us in Building the Future:

- Engage with CDISC 360i working groups
- Test, pilot, and provide feedback on new models and tools
- Support the adoption of open digital standards

Together, we are breaking down silos to deliver faster, smarter, more connected clinical research.