



In Partnership with



INDIA CDISC DAY

PHUSE APAC Connect Hyderabad India 20 February 2026

CDISC 360i: Lessons Learned and Road Ahead

Peter Van Reusel, Chief Standards Officers, CDISC.



Meet the Speaker



Peter Van Reusel

Chief Standards Officer
CDISC

Peter Van Reusel provides executive leadership to the development and implementation of clinical standards in line with CDISC's strategy and operational plans, working closely with the President and CEO, as well as CDISC staff and stakeholders.

He has over 20 years' experience in senior roles in pharma and at CROs, providing standards expertise and carrying out other standards work in various organizational settings. A long-time, CDISC-authorized instructor, Peter has helped significantly in developing CDISC training courses.

He previously served as CDISC's European Liaison, fostering relationships with key European regulatory, academic, and biopharma stakeholders. Peter is also an active PHUSE collaborator.

Agenda

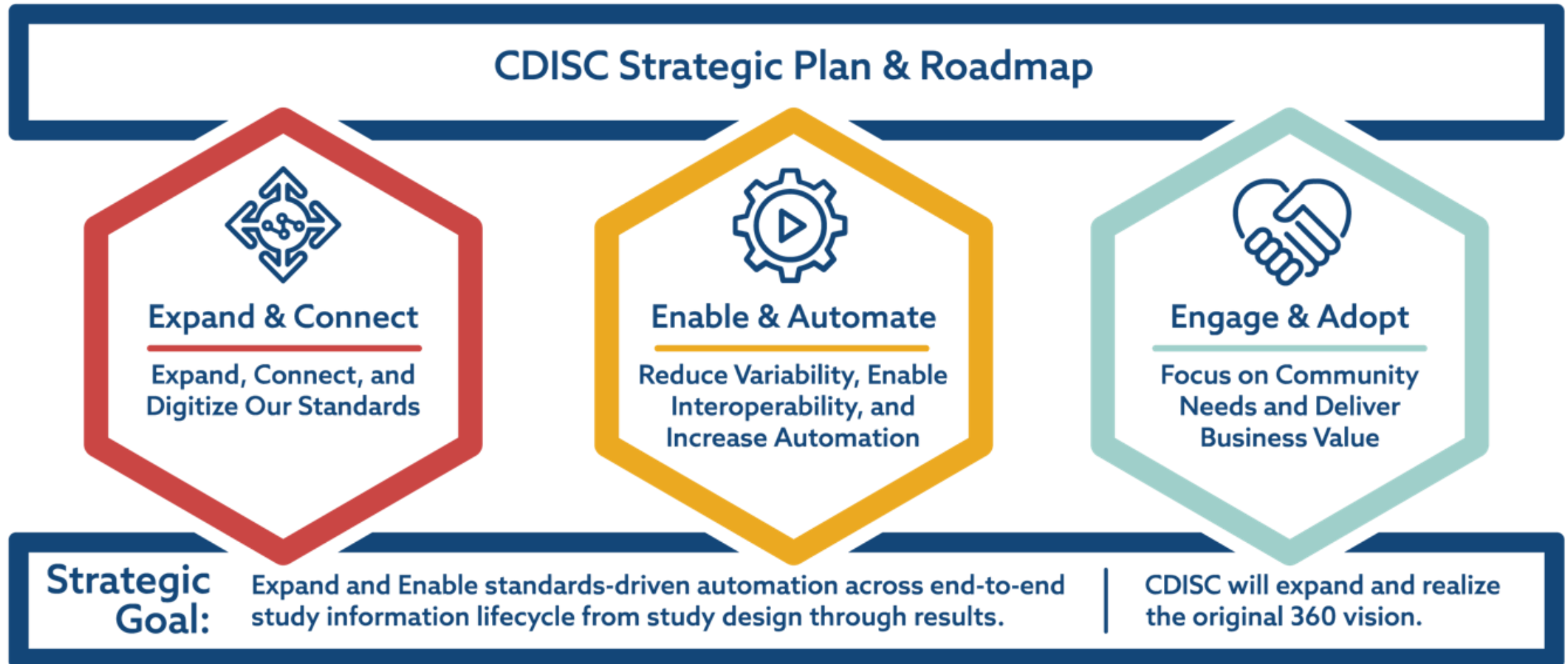
1. Purpose & Approach
2. Achievements, Challenges & Insights
3. Looking forward: Art of the Possible



Purpose & Approach

Realizing CDISC's Mission

*CDISC's **vision** is to amplify data's impact to advance research by...
creating connected standards across the study information lifecycle to enable accessible,
interoperable, and reusable data for more meaningful and effective research*



360i Goals

- Define and digitalize end to end standards from study design endpoints through the analyses
- Leverage those standards to accelerate the study design and build phase of the trial
- Demonstrate the automated data flow from raw data source to the generation of the targeted result



360i Focus

Data Sources



eDT



EDC

DHT



EHR



Specifications



Data Collection

Tabulation

Analysis

Data Standards
Biomedical Concepts
Analysis Concepts
Foundational Standards



cdisc
LIBRARY

Select
Biomedical
Concepts

Schedule of
Activities



Study Team



USDM



Protocol Outline

Build

Design

Extract



Tabulation
Datasets

Analyze



Analysis
Datasets

Output



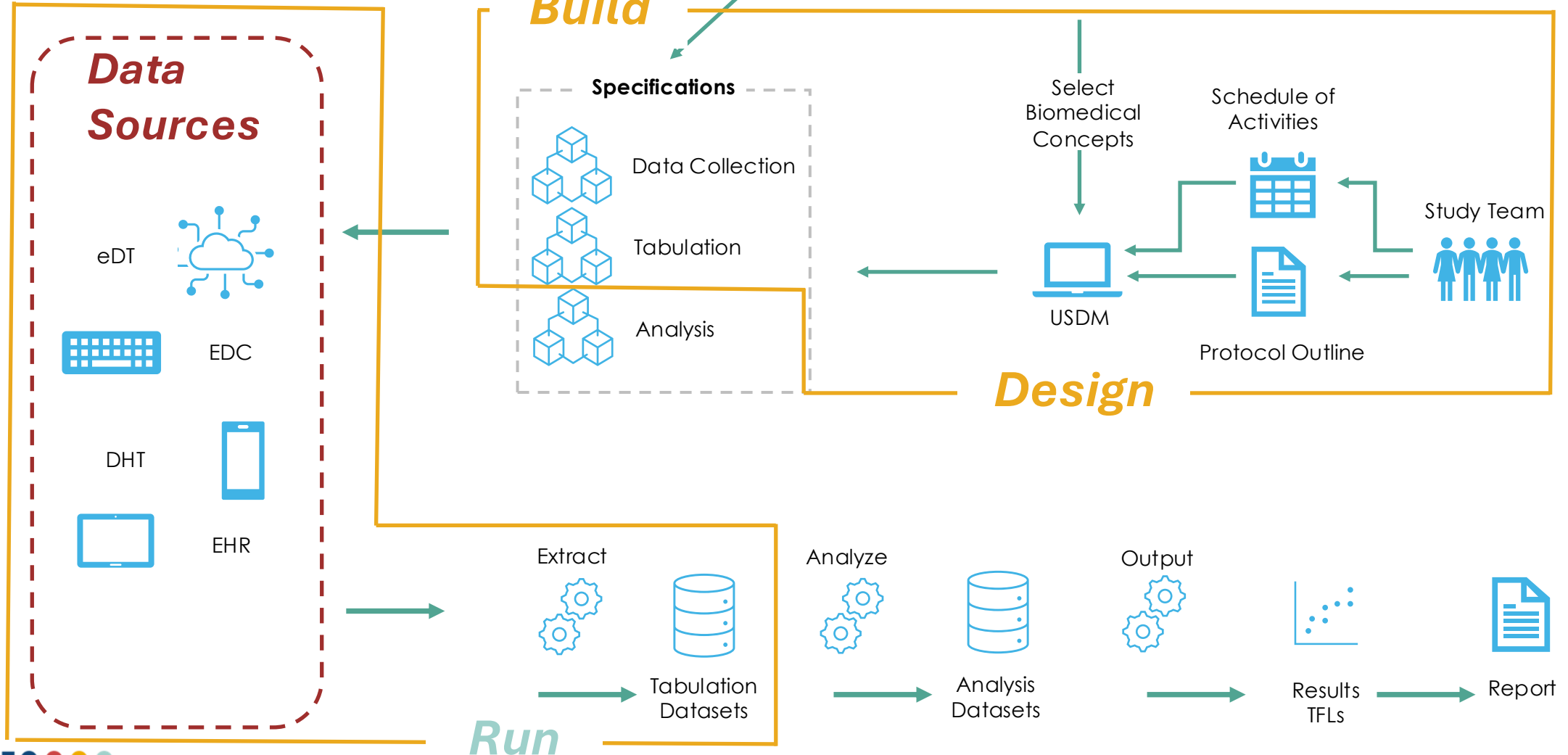
Results
TFLs



Report

Run

360i Phase 1



360i Operational Team

88



Operational Steering Committee

12

Design

- **Co-Leads**
 - Mikkel Traun
 - Valerie Sheft
- **Sub-teams**
 - Study Design Team

23

Build

- **Co-Leads**
 - Lex Jansen
 - Nicolas de Saint Jorre
- **Sub-teams**
 - Sam Hume
 - Jeremy Teoh
- **Sub-teams**
 - ODM/CRF/aCRF
 - Define-XML/Shell Dataset

16

Run

- **Co-Leads**
 - Bess Le Roy
 - Dianna Di Russo
- **Sub-teams**
 - Christine Connolly
 - Anthony Chow
- **Sub-teams**
 - Data
 - sdtm.oak
 - Conformance

15

Program Manager

• Charles Shadle

CDISC Executive Team

• Chris Decker
• Peter Van Reusel
• Nicole Harmon
• Julie Smiley

Co-Leads

• Sam Hume
• Bess LeRoy
• Anthony Chow
• Dianna Di Russo
• Christine Connolly
• Mikkel Traun
• Nicolas De Saint Jorre
• Valerie Mildred Sheft
• Jeremy Teoh
• Lex Jansen

Parallel Focus Teams

BC Curation

CDISC
Open Rules

Analysis
Concepts

TMF Digital
Model

26

Reviewers

> 40



Achievements, Challenges & Insights

Design

Achievements



- Detailed user stories for Study Design and Study Amendment
- Digital Schedule of Activities linked to biomedical concepts

Challenges



- Interpreting LZZT protocol information to identify what data is needed
- Fit for purpose Study Design software



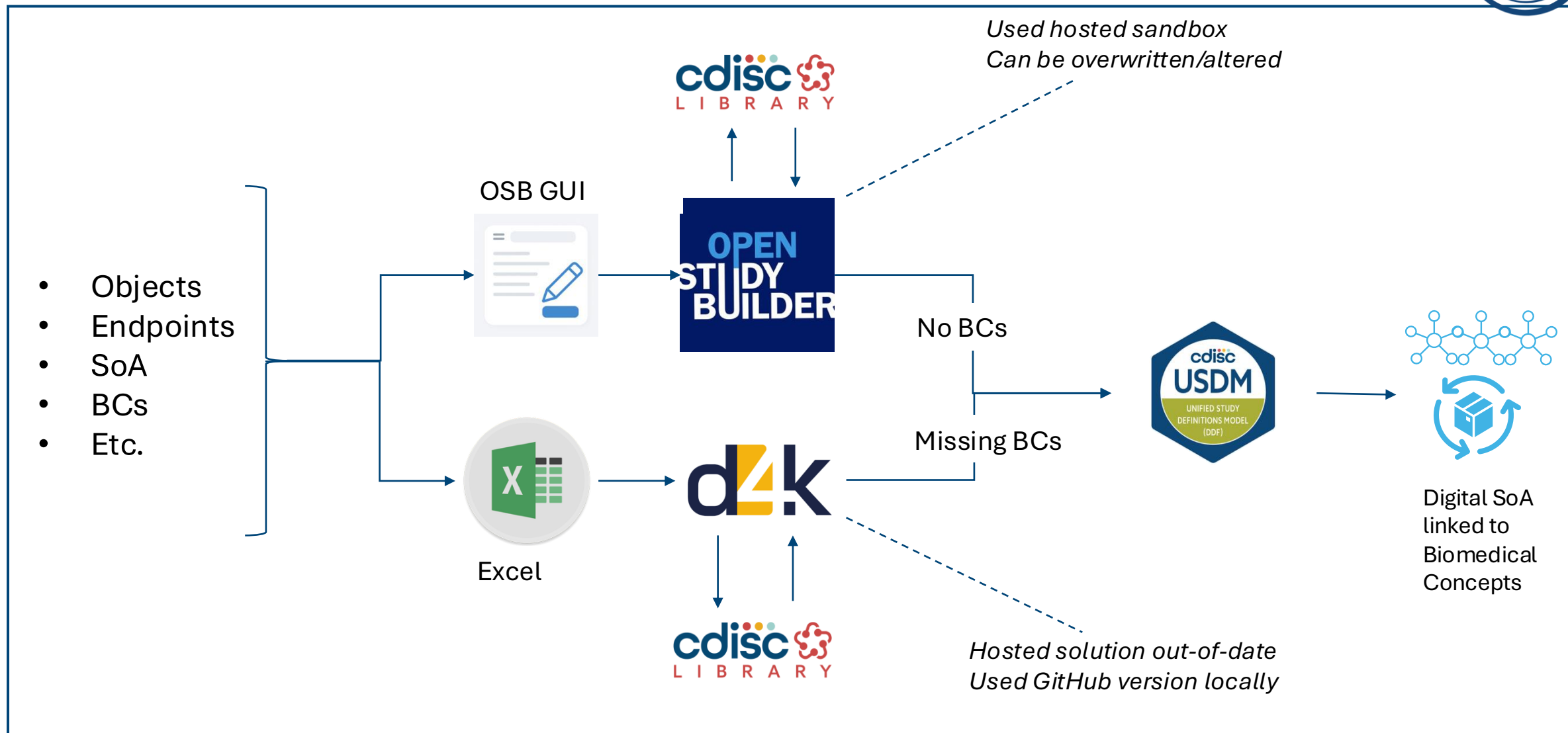
Insights

Linking concepts works, but **concept groupings** are needed for usability

- Collection method
- Data type
- Category
- Analysis

Open-Source USDM SoA **authoring tool** is needed

Study Design Applications Used



Build Define.xml and Shell Datasets

Achievements



- Used BCs from USDM JSON and query CDISC library for dataset specializations
- Identified all metadata for automation

Challenges



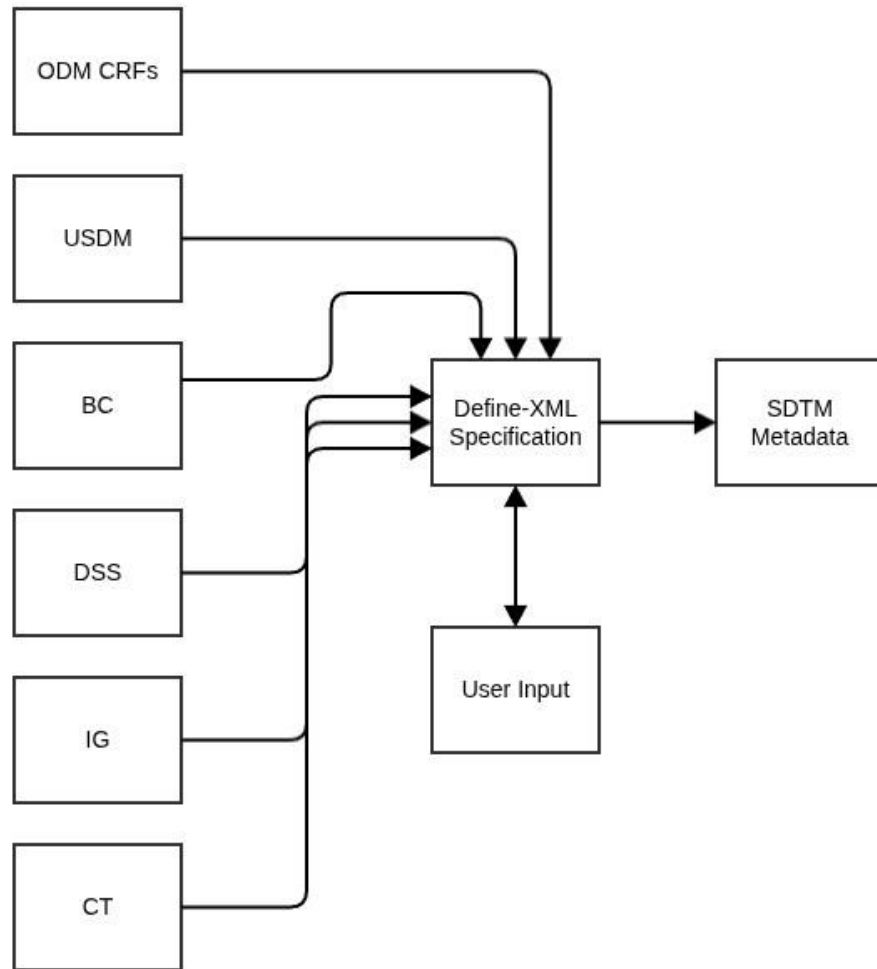
- Large process flow to achieve full automation
- Work-arounds needed to obtain all needed operational metadata



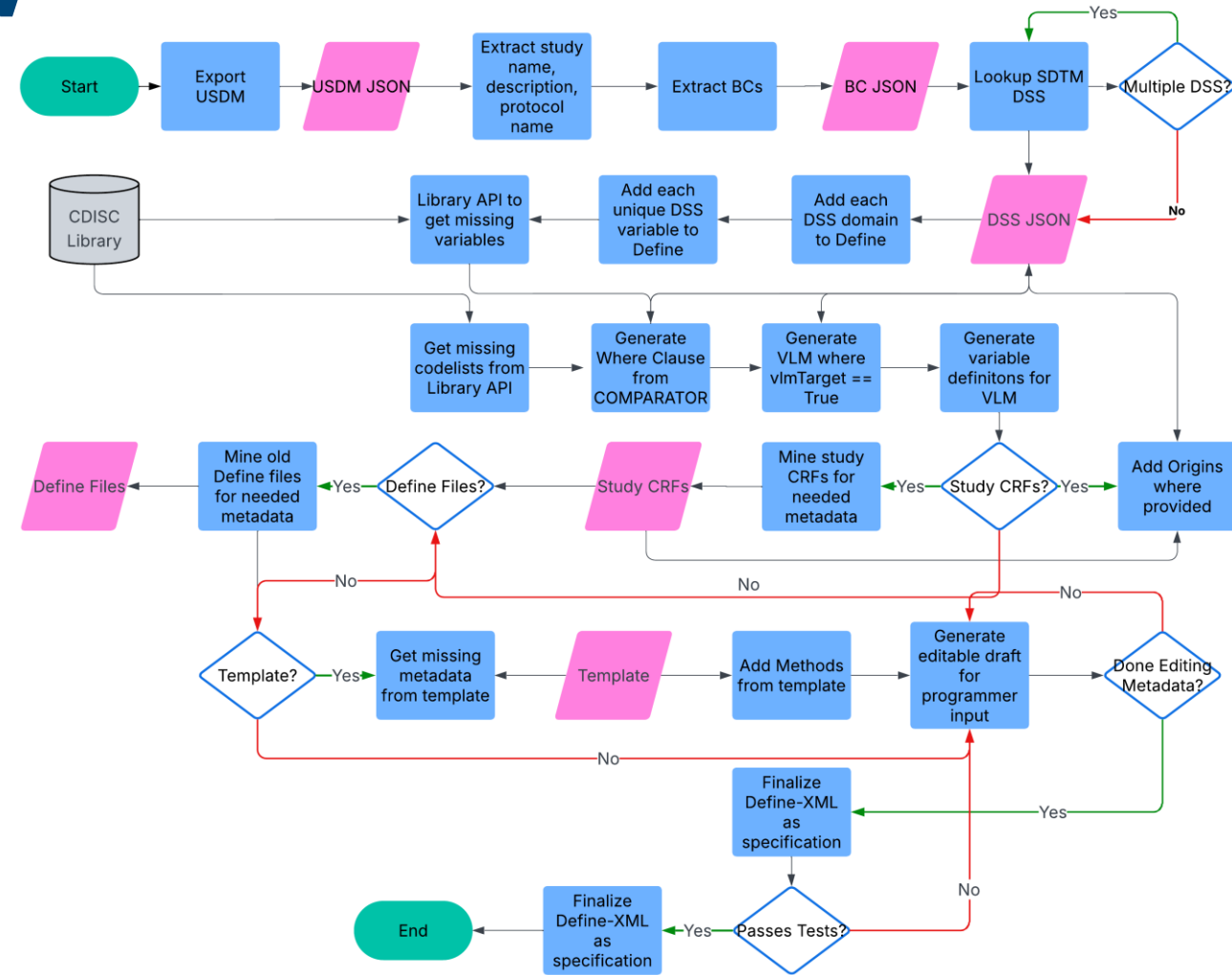
Insights

- To fully automate, we need to add study specific **operational metadata**
- Develop an updated Data Definition Specification (DDS) standard (Define.JSON)

Define-XML Metadata flow



High-level Data Flow



Detailed Data Flow

Build CRFs and Annotated CRFs

Achievements



- Generation of ODM file of the necessary structures
- Generation HTML rendition of CRFs and annotated CRFs

Challenges



- CRF specializations under development and not available in CDISC Library
- USDM does not provide forms metadata
- Need to use a workaround (xlsx spreadsheet)



Insights

- Biomedical Concept **groupings** and CRF specializations are needed
- Additional forms metadata are needed
- To fully automate, we need to add study specific **operational metadata**

Annotated CRF Generated from Biomedical Concept

EQ-5D-5L Questionnaire

DOMAIN = QS; QSCAT = EQ-5D-5L

EQ-5D-5L Questionnaire - Lead Question

Field	Value	Details
* Category of Questionnaire	-- Select --	QSCAT = EQ-5D-5L <i>CodeList: QSCAT</i>
Was the EQ-5D-5L questionnaire performed?	-- Select --	[NOT SUBMITTED]; QSSTAT = NOT DONE <i>CodeList: NY</i>
* Date of Assessment	mm / dd / yyyy	QSDTC
* Collected Evaluation Interval		QSEVINTX = TODAY

* Mandatory field

EQ-5D-5L Questionnaire - Question 1-5

Under each heading, please check the ONE box that best describes your health TODAY.

Field	Value	Details
* MOBILITY	-- Select --	QSORRES where QSTESTCD = EQ5D0201 <i>CodeList: EQ5D0201-QSORRES</i>
* SELF-CARE	-- Select --	QSORRES where QSTESTCD = EQ5D0202 <i>CodeList: EQ5D0202-QSORRES</i>
* USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)	-- Select --	QSORRES where QSTESTCD = EQ5D0203 <i>CodeList: EQ5D0203-QSORRES</i>
* PAIN / DISCOMFORT	-- Select --	QSORRES where QSTESTCD = EQ5D0204 <i>CodeList: EQ5D0204-QSORRES</i>
* ANXIETY / DEPRESSION	-- Select --	QSORRES where QSTESTCD = EQ5D0205 <i>CodeList: EQ5D0205-QSORRES</i>

Run – Generate SDTM datasets from source

Achievements



- Generation of multiple SDTM datasets using the SDTM.OAK open-source R package

Challenges



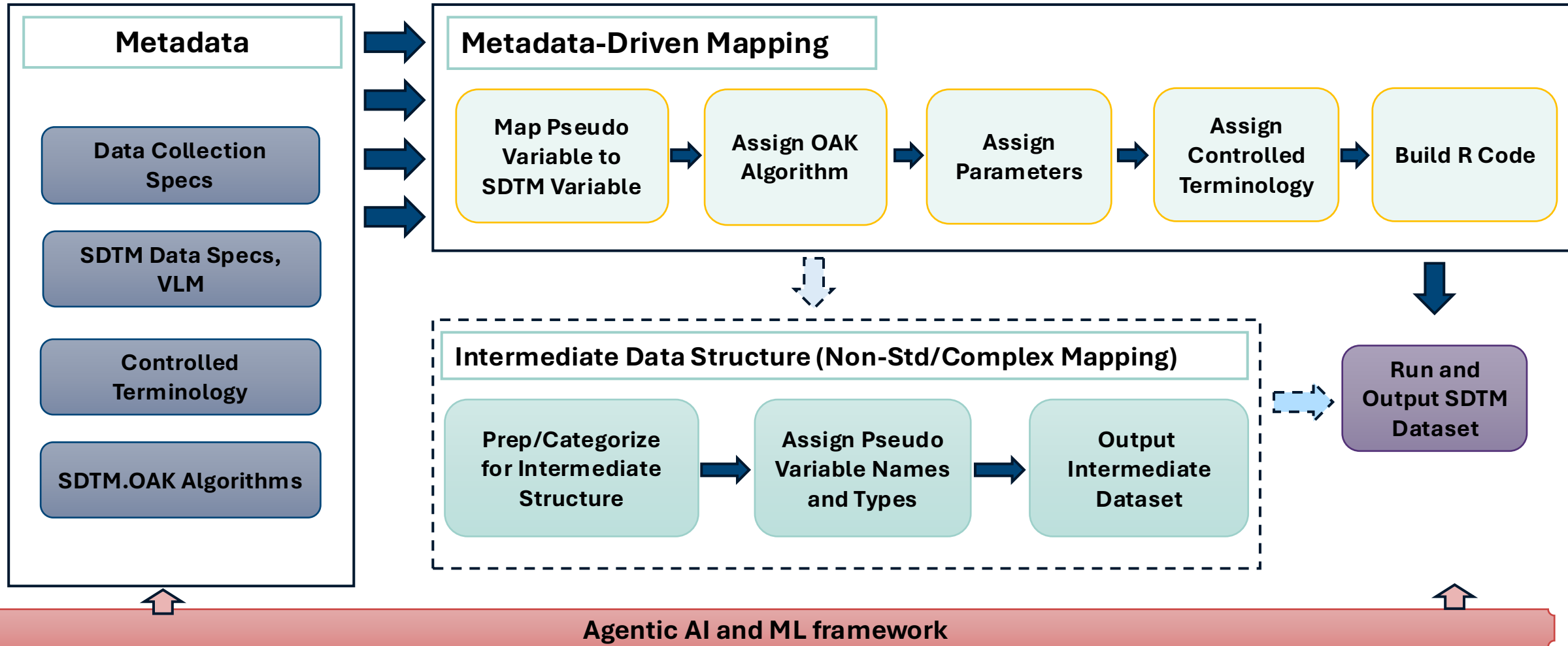
- Dealing with non-standard , non-tabular data
- Limited source data



Insights

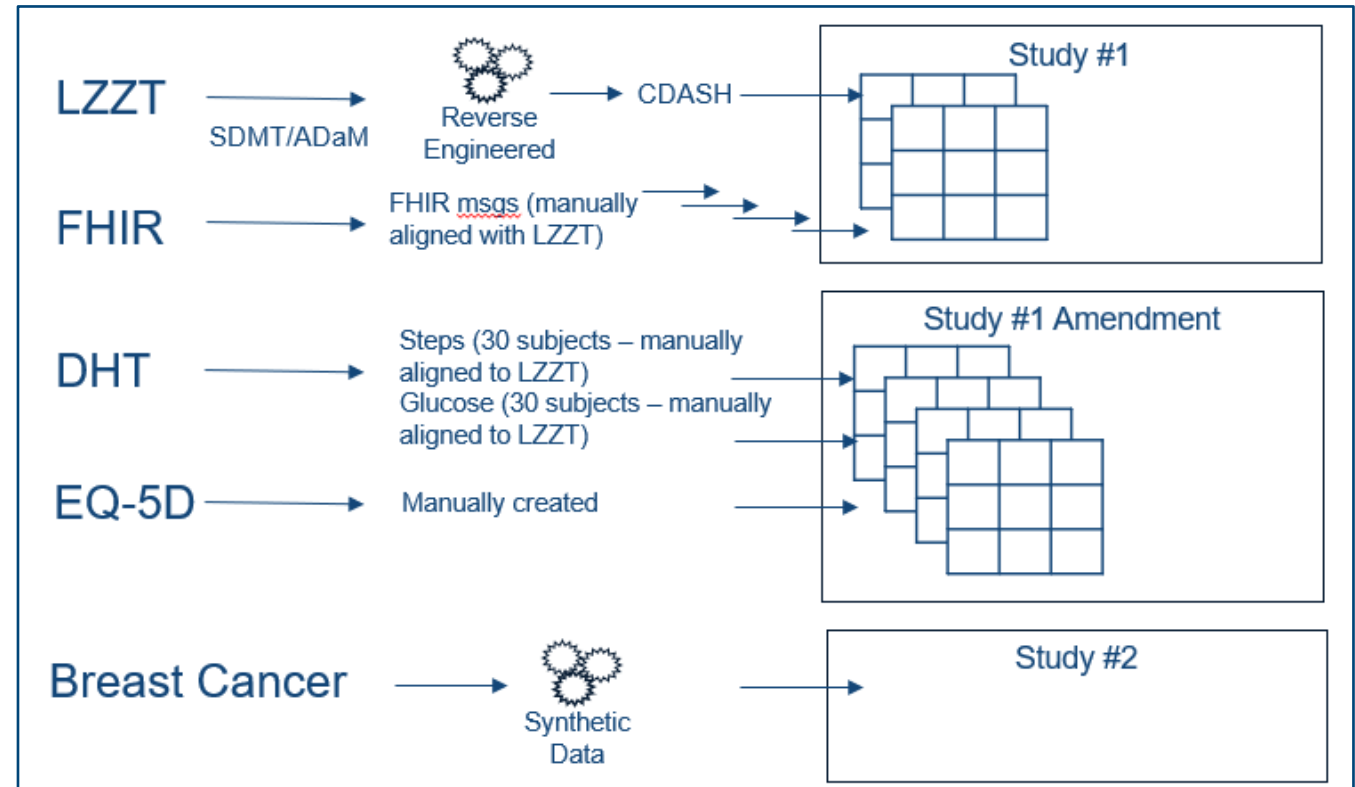
- Need for tool-agnostic transformation logic between data collection and tabulation
- Need to develop an ingestion filter for non-standard source data
- Need to demonstrate the data flow through the entire pipeline

Run - SDTM Datasets with SDTM.OAK



Run – preparing source data

- Started with CDISC pilot data
- Reverse engineered source data
- Manual aligning with LZZT data
- Created aligned FHIR messages
- Lots of help from the Community





Looking Forward: Art of the Possible



Welcome Back!

Enter your credentials to access your account

User Name

Password

[Forgot password?](#)

[Sign In](#)

[Don't have an account? Sign up](#)



Art of the Possible

- Purpose of this Prototype
 - This is a **conceptual UX Design**
 - It illustrates **how CDISC Standards could be experienced** in an integrated environment
 - Not functional software, but a **visual representation**
- Helps **visualize the potential** of standards-driven end-to-end automation
- [CDISC_Final – Prototype](#)
- Prototype password: CDISC2025



CDISC 360i Phase 2: What's next

360i Phase 2: Operationalizing the Vision

Key Deliverables

Digital Protocol & Impact Analysis Reporting: Machine-readable protocol model with automated amendment and impact analysis

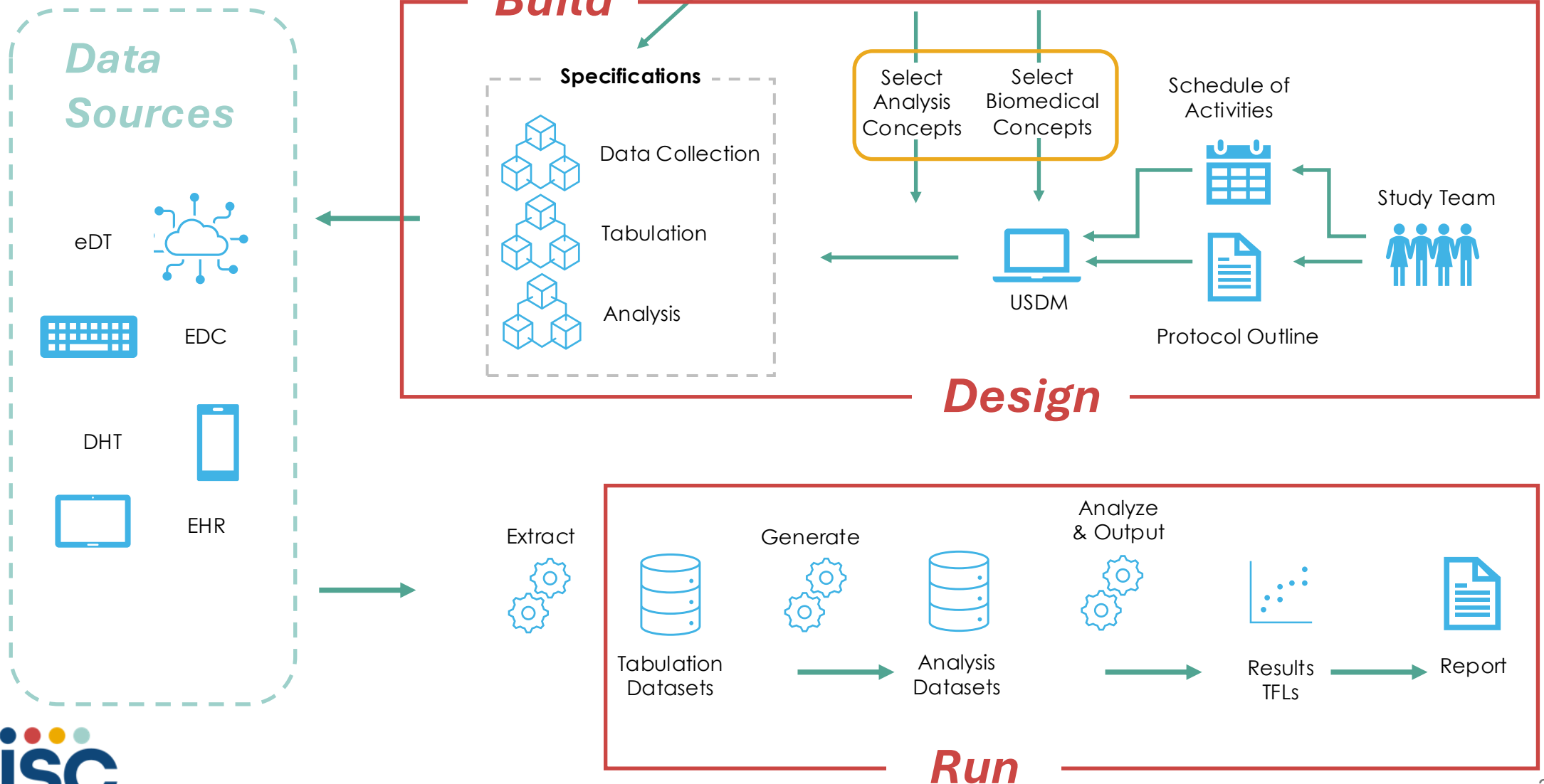
Automated eCRFs, Define & Dataset Generation: Generation of eCRFs, Define.xml and datasets integrated with study workflows

Digital Data Transfer Agreement Model: Technical DTA model and standardized template aligned with the digital protocol

Standardized Analysis Concept Model: Configurable, machine-readable analysis concepts driving automated analysis artifacts



360i Phase 2 Focus





Thank You!

Peter Van Reusel
pvanreusel@cdisc.org

