CDISC 360i: Lessons Learned and Road Ahead

Peter Van Reusel
Chief Standards Officer
CDISC

Meet the Speaker

Peter Van Reusel

Title: Chief Standards Officer
Organization: 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.

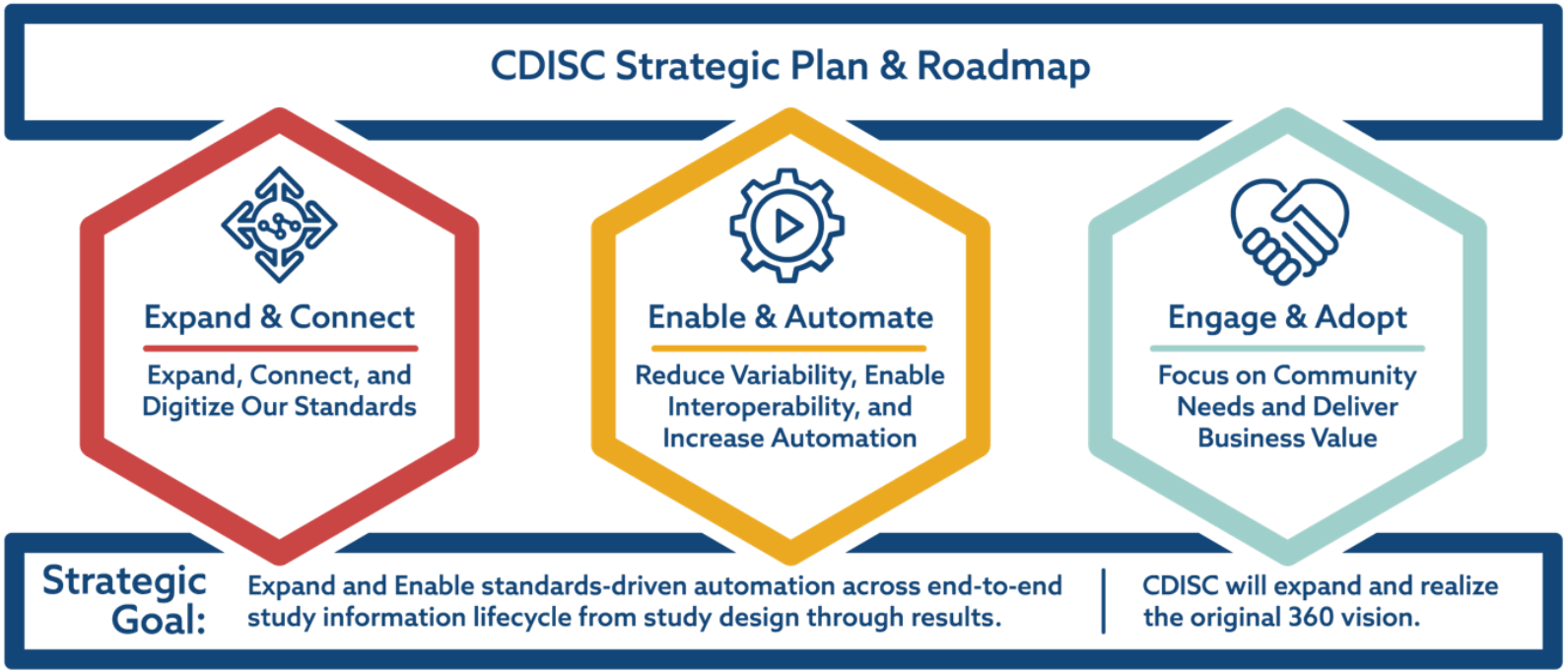
Agenda

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



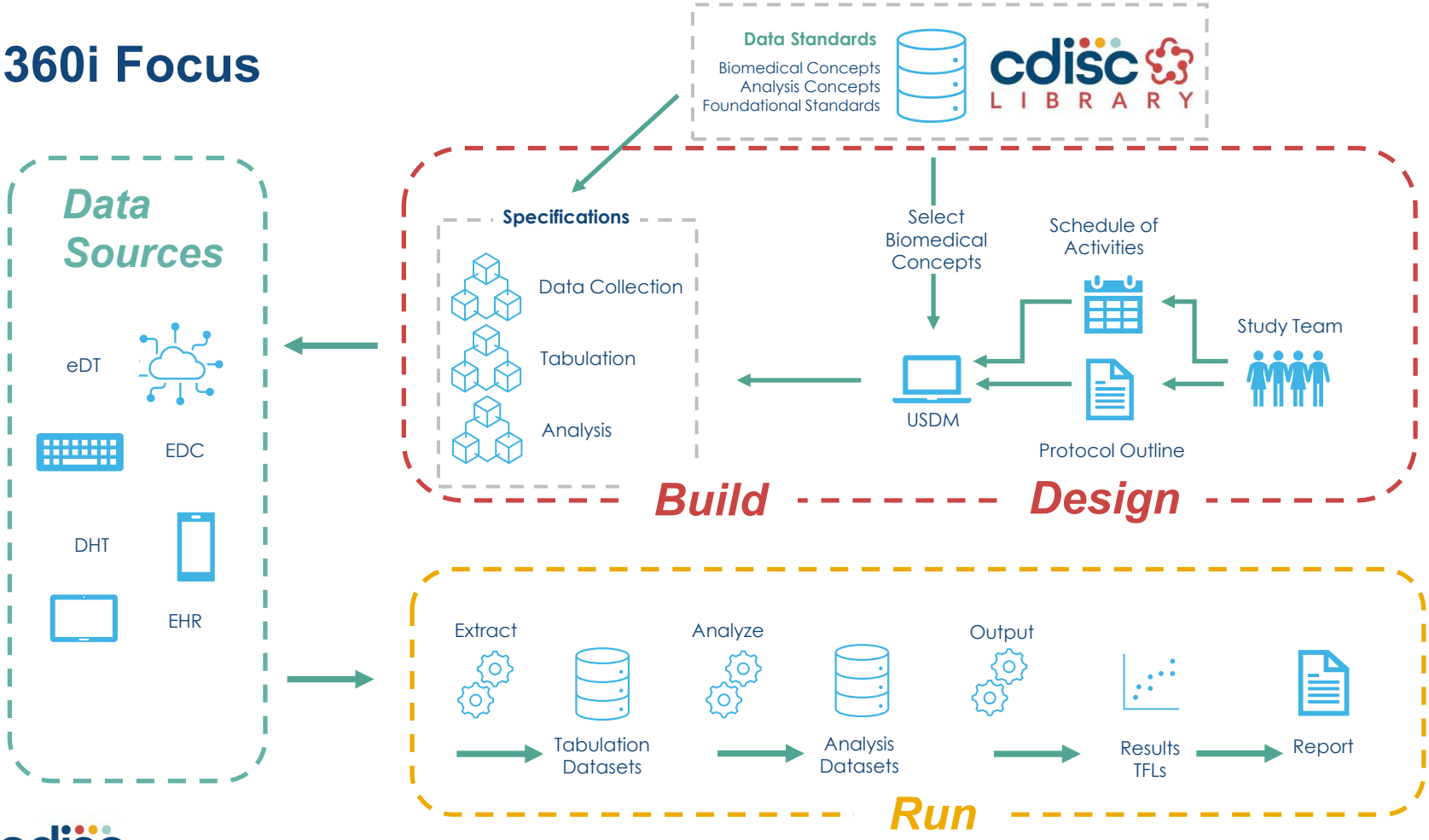
360i Goals

- Define end to end standards
  - Digitalize information from protocol to reporting
  - Link concepts to representation standards
    - Forms definition, eDTs, DHT, SDTM specs, ADaM specs, TFL specs, …
  - Enrich with transformation & derivation logic

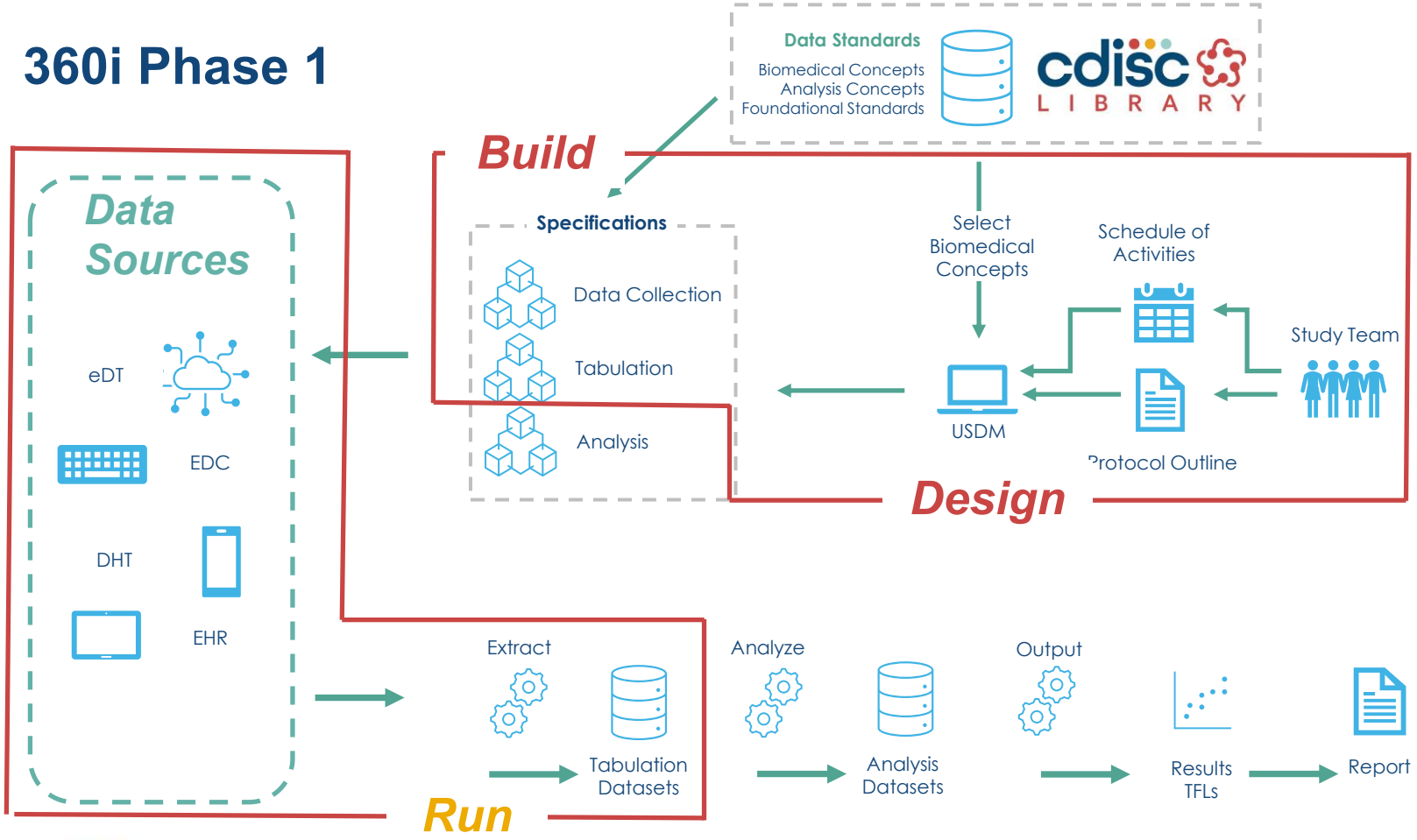
- Study design & build
  - Select concept and concept groups in digital Schedule of Activities
  - Automates study build
    - Forms definition, SDTM specs, ADaM specs, TFL specs, …

- Automate data flow
  - Demonstrate end to end automation
    - Starts with linking Schedule of Activities to Concepts (and Concept Groups)
  - Automate transformations & derivation between data states
    - Collection, tabulation, analysis, results

360i Focus


Data Standards
Biomedical Concepts
Analysis Concepts
Foundational Standards
cdisc LIBRARY
Data Sources
eDT
EDC
DHT
EHR
Specifications
Data Collection
Tabulation
Analysis
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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Analysis Datasets
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360i Operational Team

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Operational Steering Committee

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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

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Design

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

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Build

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

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Run

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

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

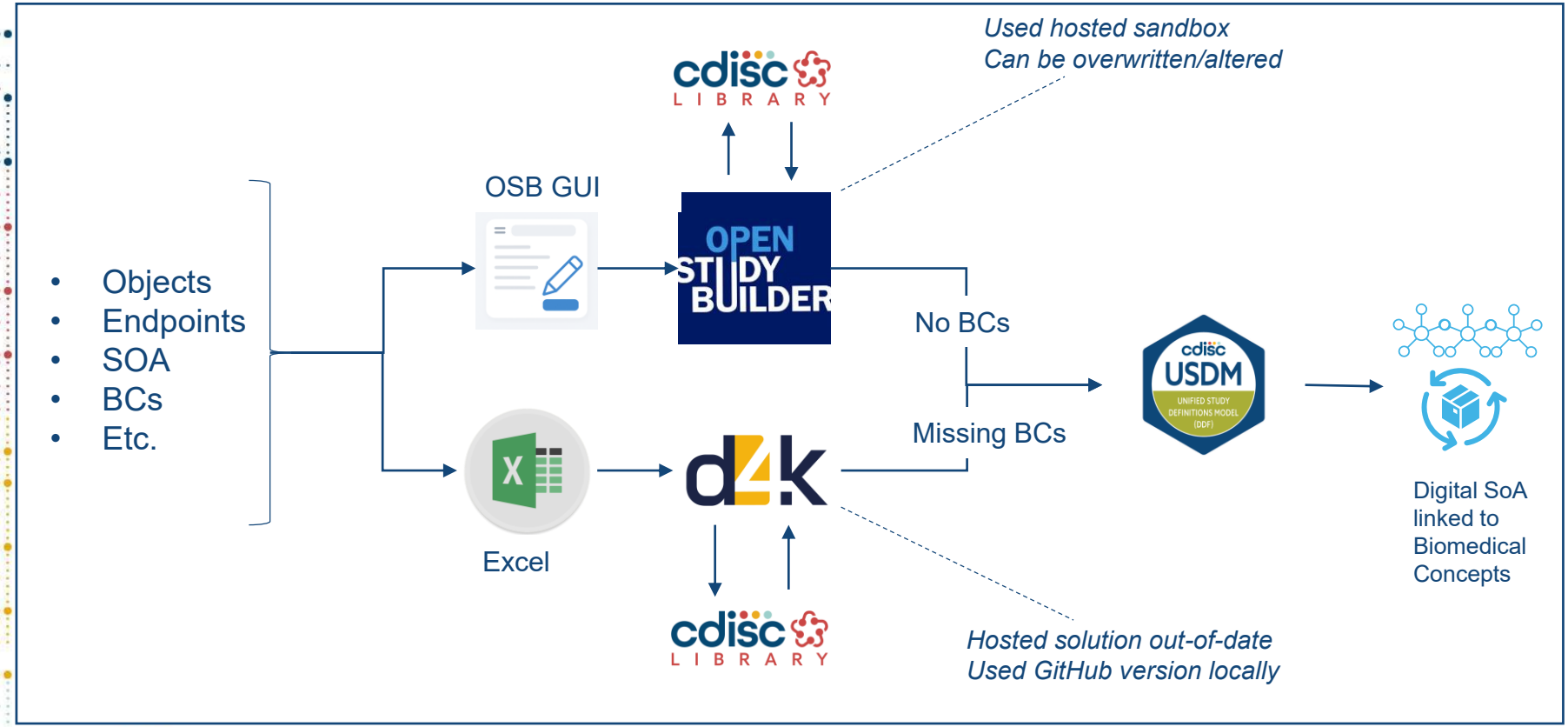
Challenges

- Interpreting LZZT protocol information to identify what data is needed
- 2 Study Design software tools (next slide)
- Not enough time to demonstrate protocol amendment impact assessment

Insights

- Linking concepts works, but concept groupings are needed for usability
  - collection method (CRFs, Data Transfers, …)
  - data type (Questionnaires, Clinical Measures, Procedures, …)
  - category (Demographics, Digital Health Technologies, …)

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

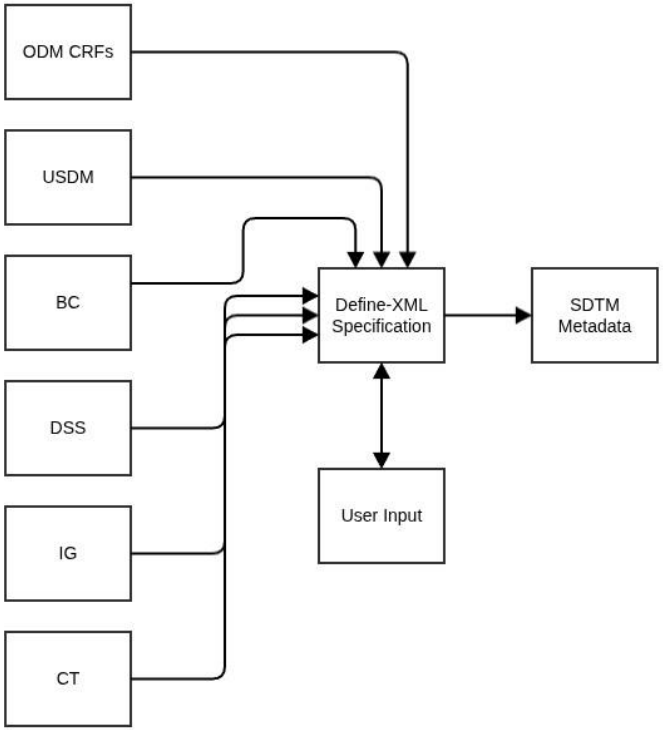
Challenges

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

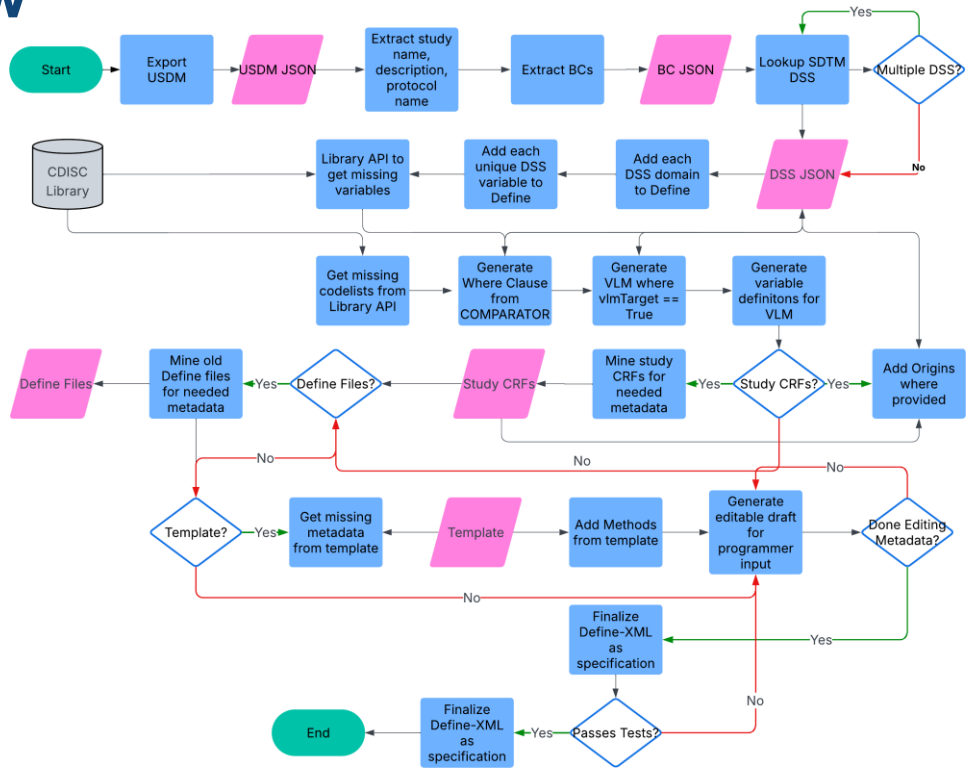
Insights

- To fully automate, we need to add operational metadata
- The process can benefit from existing (historic) define.xmls
- New standard opportunity (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

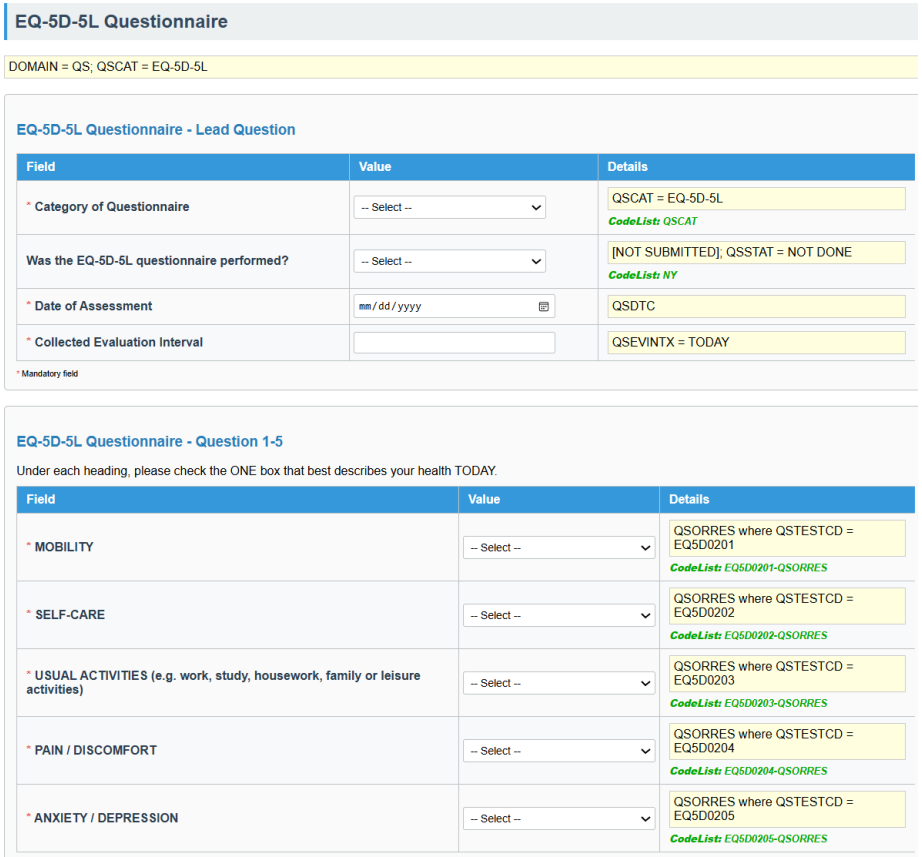
Challenges

- Collection dataset specializations under development and not available in the CDISC Library
- USDM does not provide forms metadata
- Need to use a workaround (xls spreadsheet)

Insights

- Biomedical Concept groupings and collection specializations are needed
- Additional forms metadata are needed

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 *CodeList: QSCAT*
Was the EQ-5D-5L questionnaire performed?	-- Select --	[NOT SUBMITTED], QSSTAT = NOT DONE *CodeList: NY*
* Date of Assessment	mm/dd/yyyy	QSDTC
* Collected Evaluation Interval		QSEVINTX = TODAY

* Mandatory field

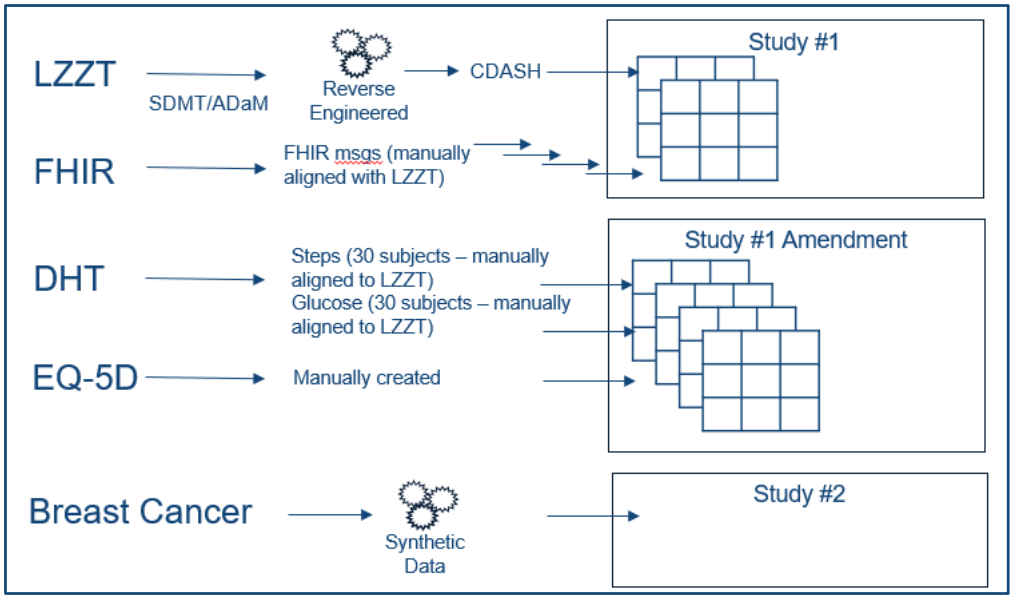
EQ-5D-5L Questionnaire - Question 1-5

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

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

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



Run – Generate SDTM datasets from source data

Achievements

- Generation of multiple SDTM datasets using the SDTM.OAK open-source R package
- Automated controlled terminology mapping

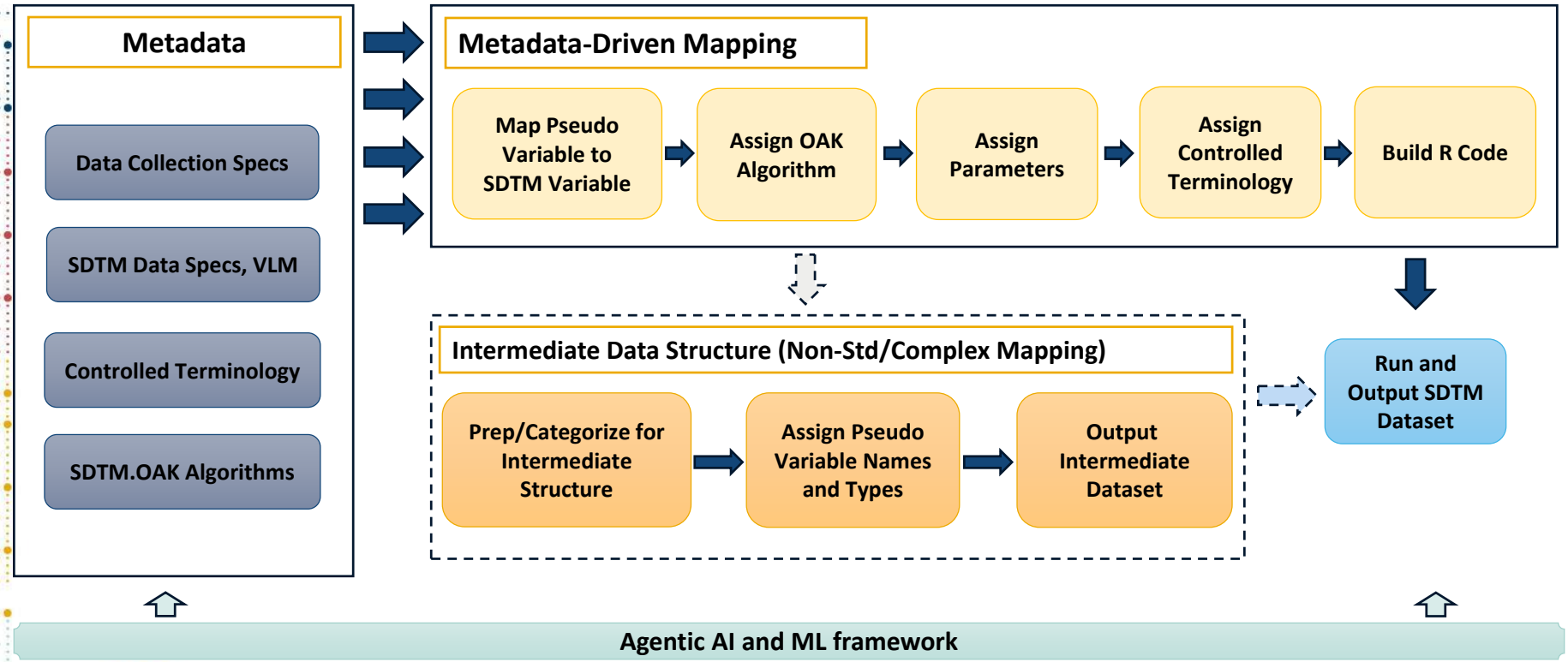
Challenges

- Dealing with non-standard data
- Limited source data

Insights

- Knowledgeable and active R programmer community
- Expanding approach with agentic AI and ML framework

Run - SDTM Datasets with SDTM.OAK



Looking Forward: Art of the Possible

Welcome Back!

Enter your credentials to access your account

User Name

JSmith@company.com

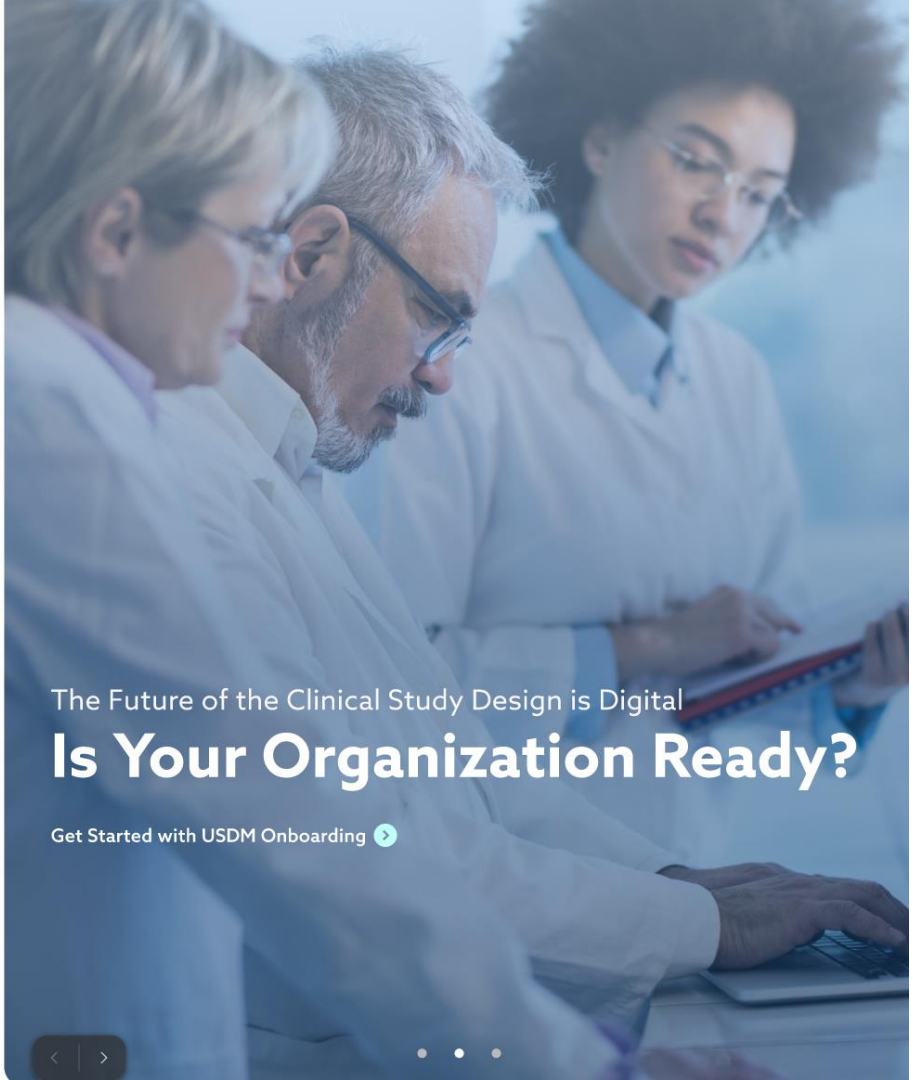
Password

****

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 softwared, but a **visual representation**

- Helps **visualize the potential** of standards-driven end-to-end automation

- CDISC_Final - Prototype

Thank You!