CDISC 360i

Lessons Learned and Road Ahead

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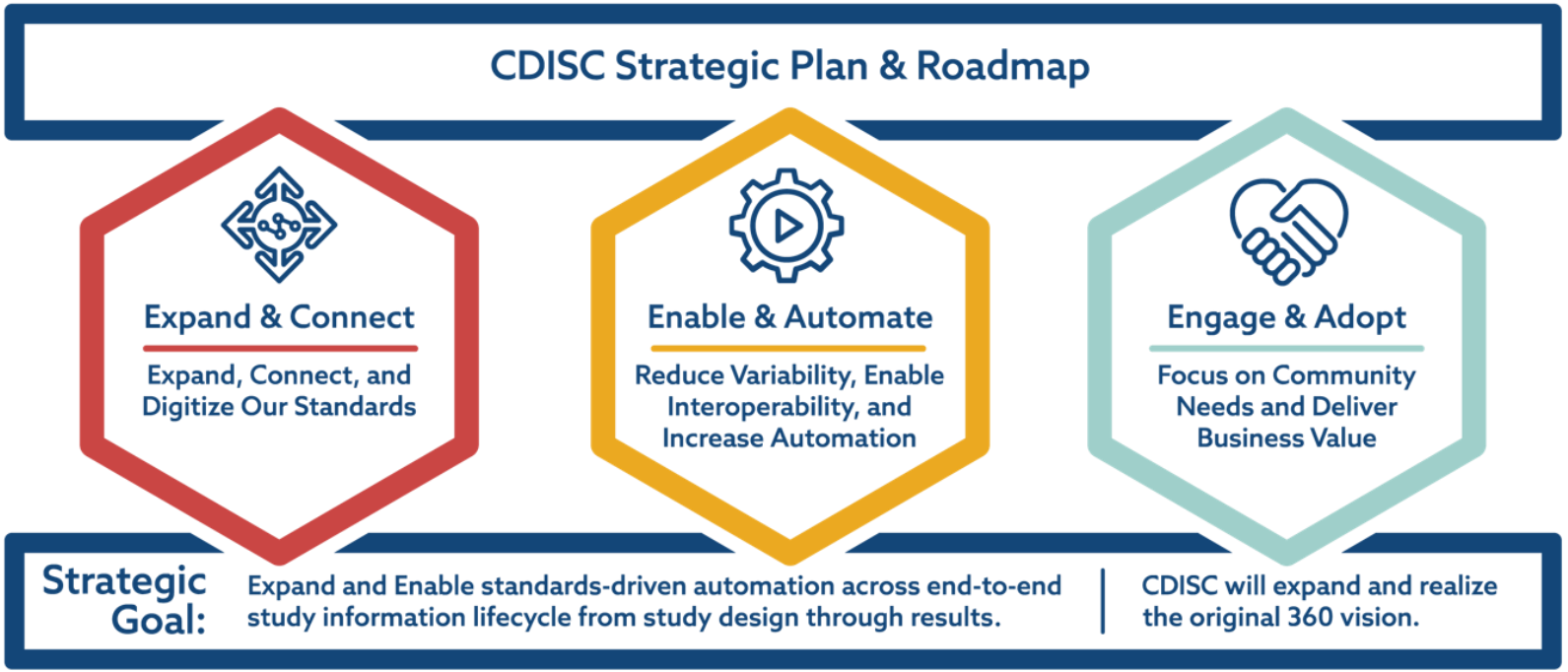
Agenda

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



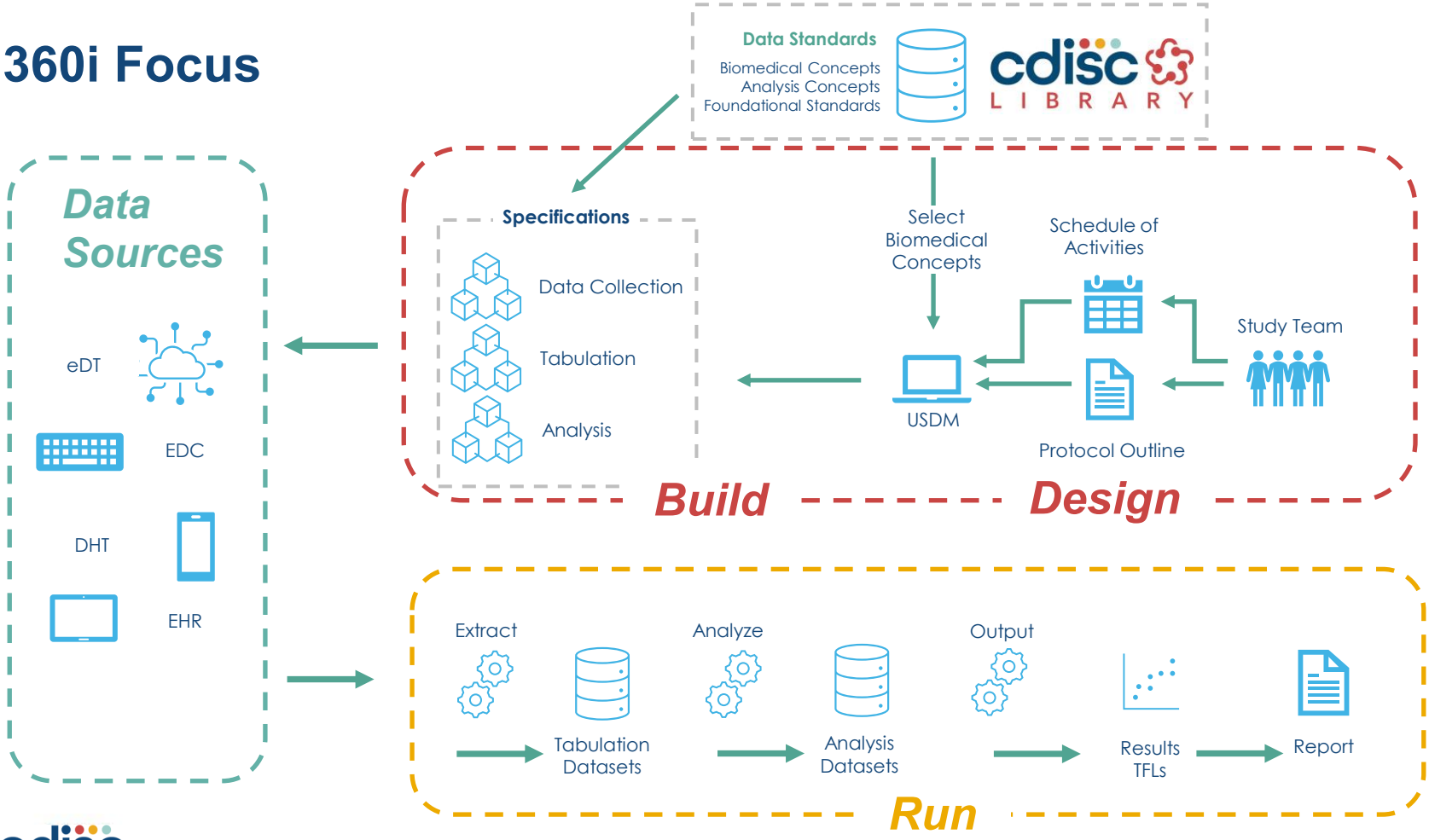
360i Goals

- 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

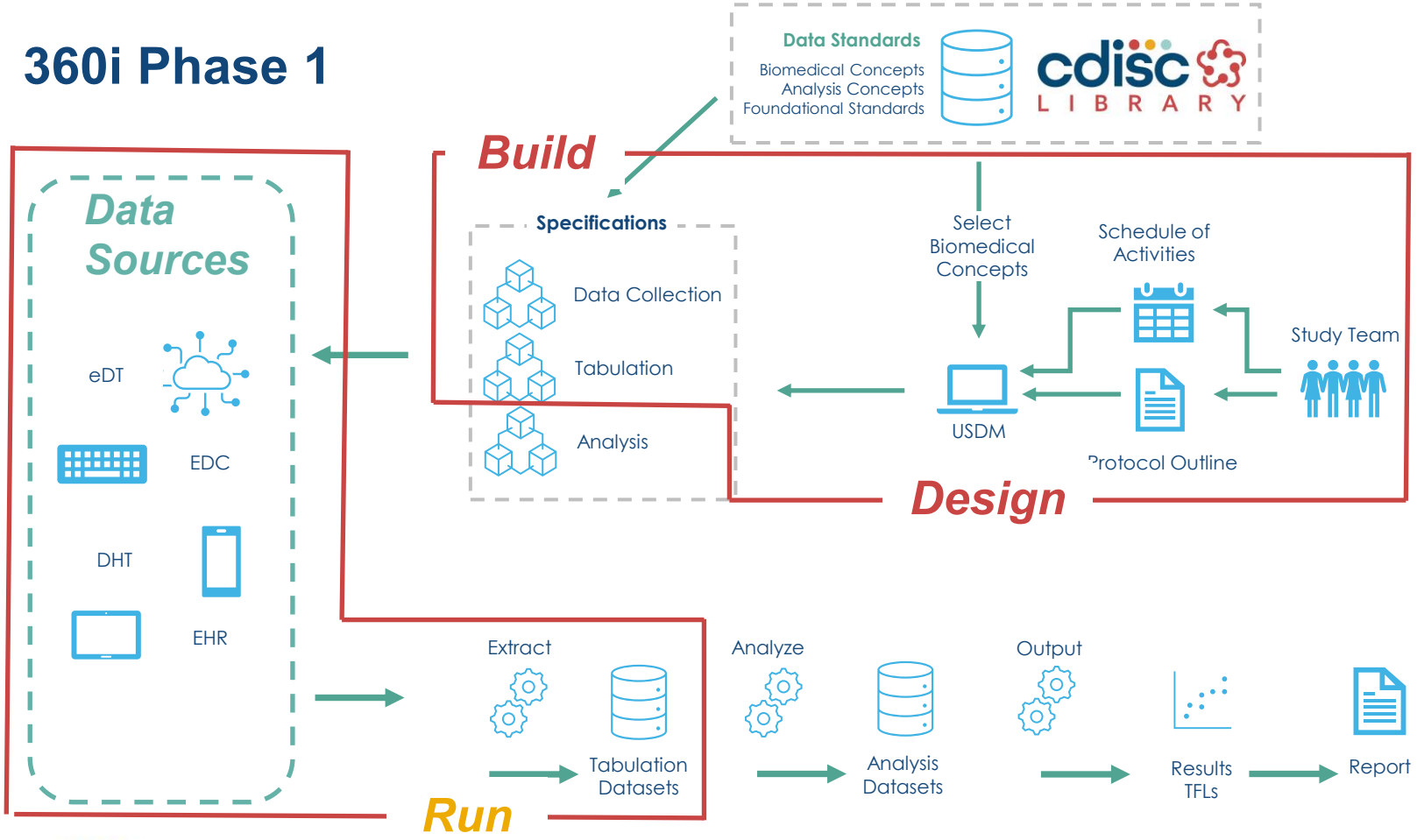
- Study design & build
  - Select concept and concept groups in digital Schedule of Activities
  - Automates study build
    - Forms definition, SDTM specs, ADaM specs, TFL specs, …

- 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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360i Operational Team

88

Operational Steering Committee

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

12

Design

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

23

Build

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

16

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)
- Lacking time to demonstrate protocol amendment impact assessment

Insights

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

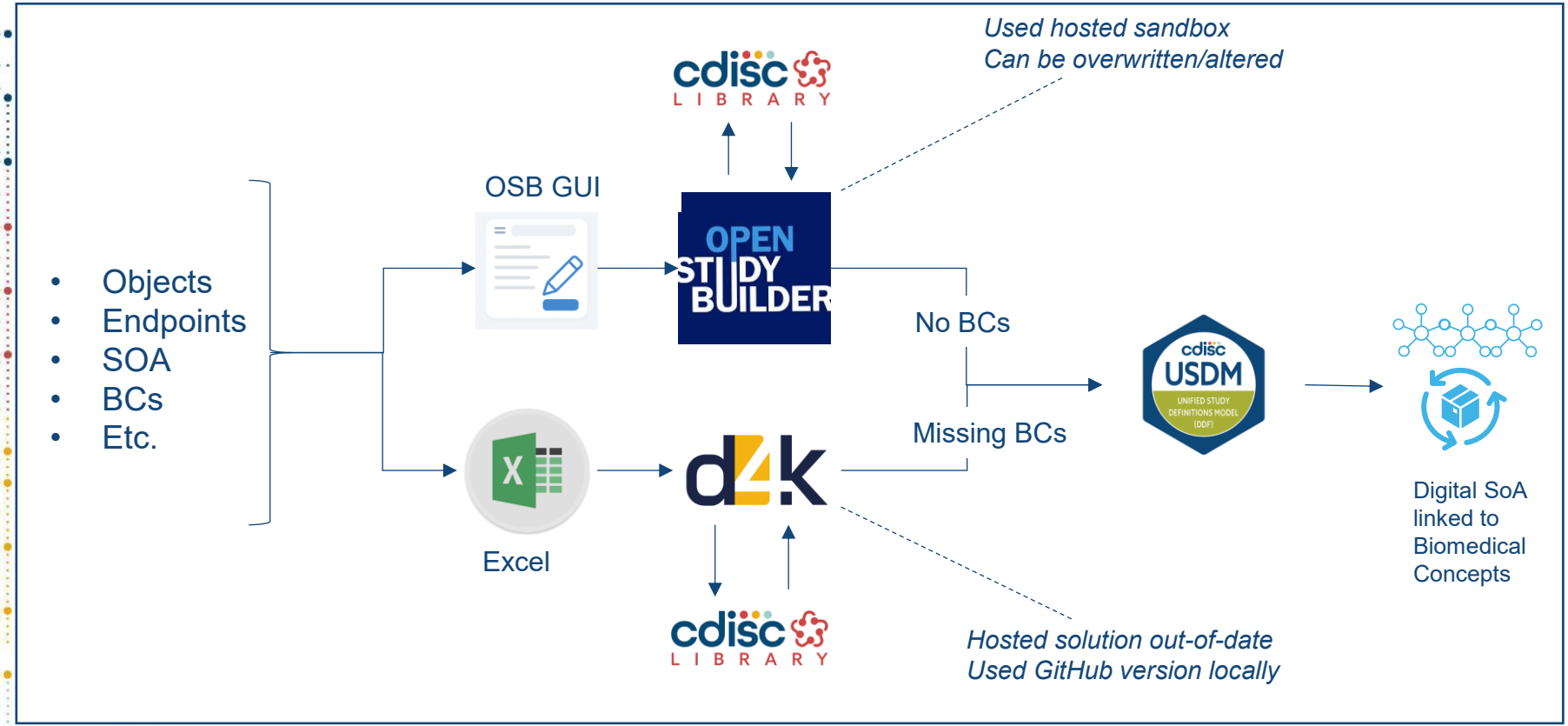
Collection method
CRFs, Data Transfers, …

Data type
Questionnaires, Clinical Measures, Procedures

Category
Demographics, Digital Health Technologies, …

Analysis
Safety profile, defined endpoints, …

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

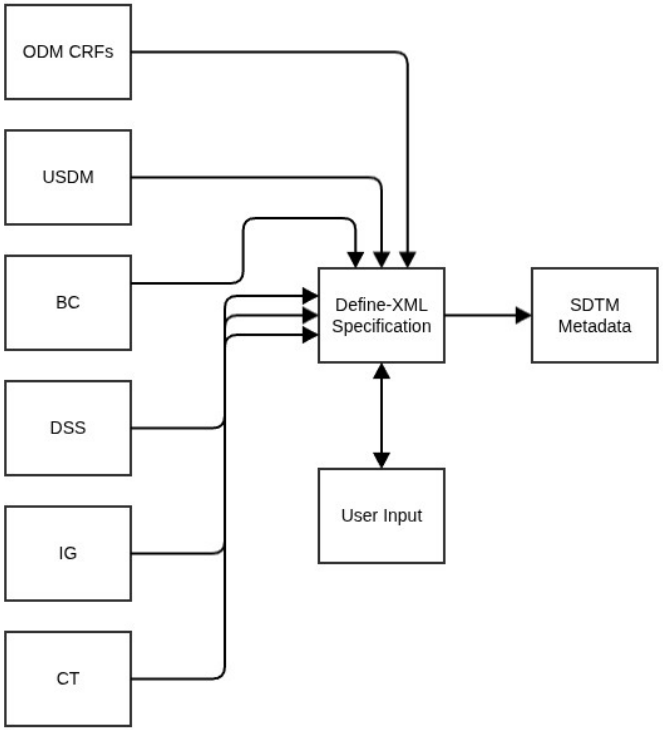
Challenges

- Large process flow to achieve full automation (next slide)
- Work-arounds needed to obtain all needed metadata

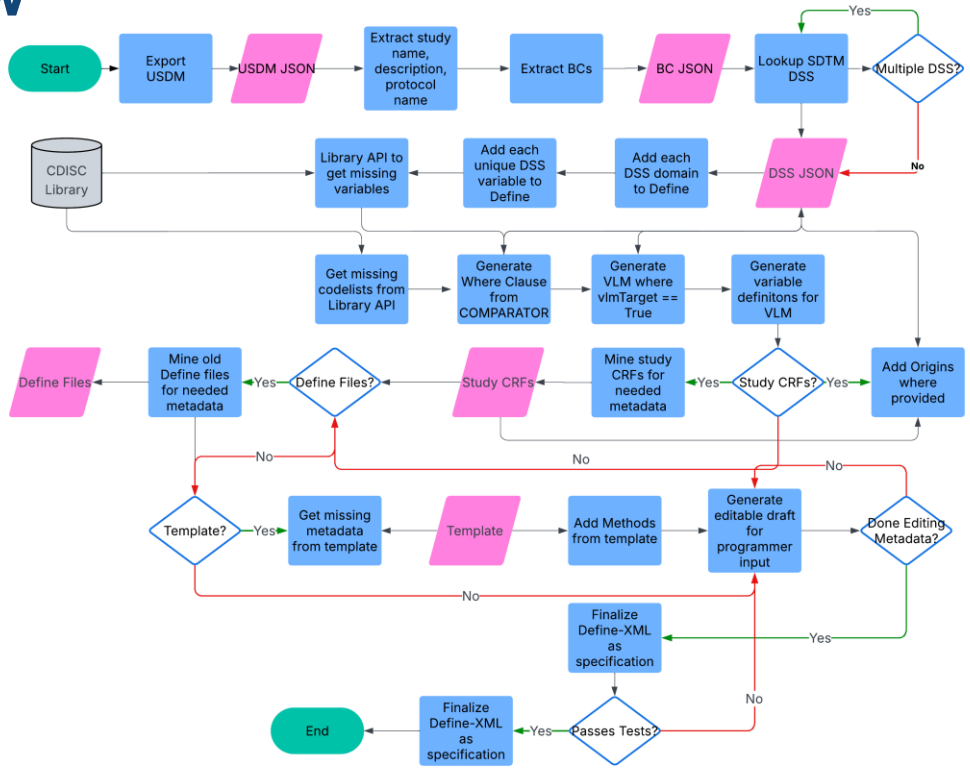
Insights

- 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 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

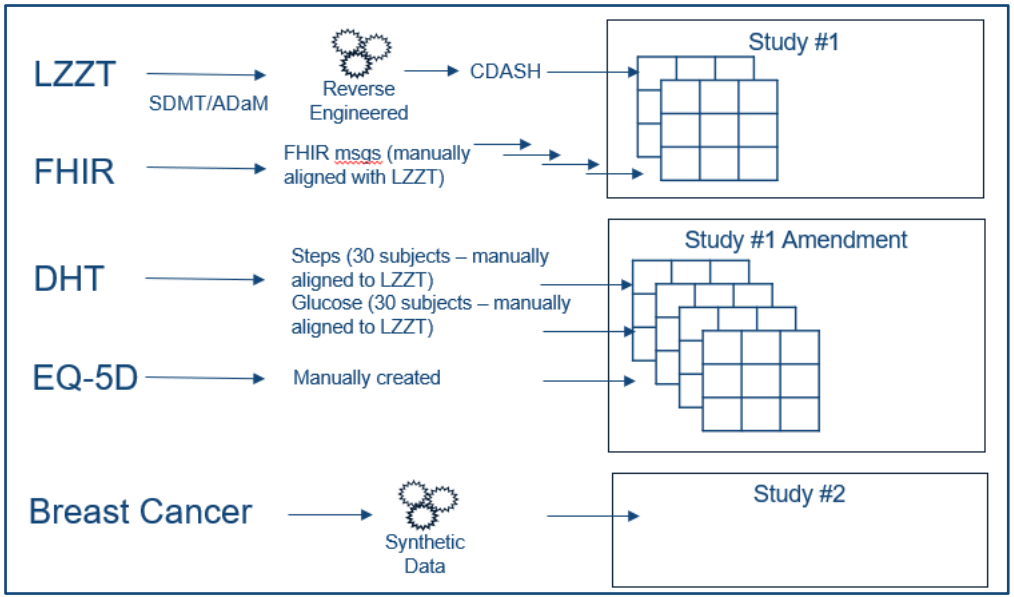
EQ-5D-5L Questionnaire - Question 1-5

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

Achievements

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

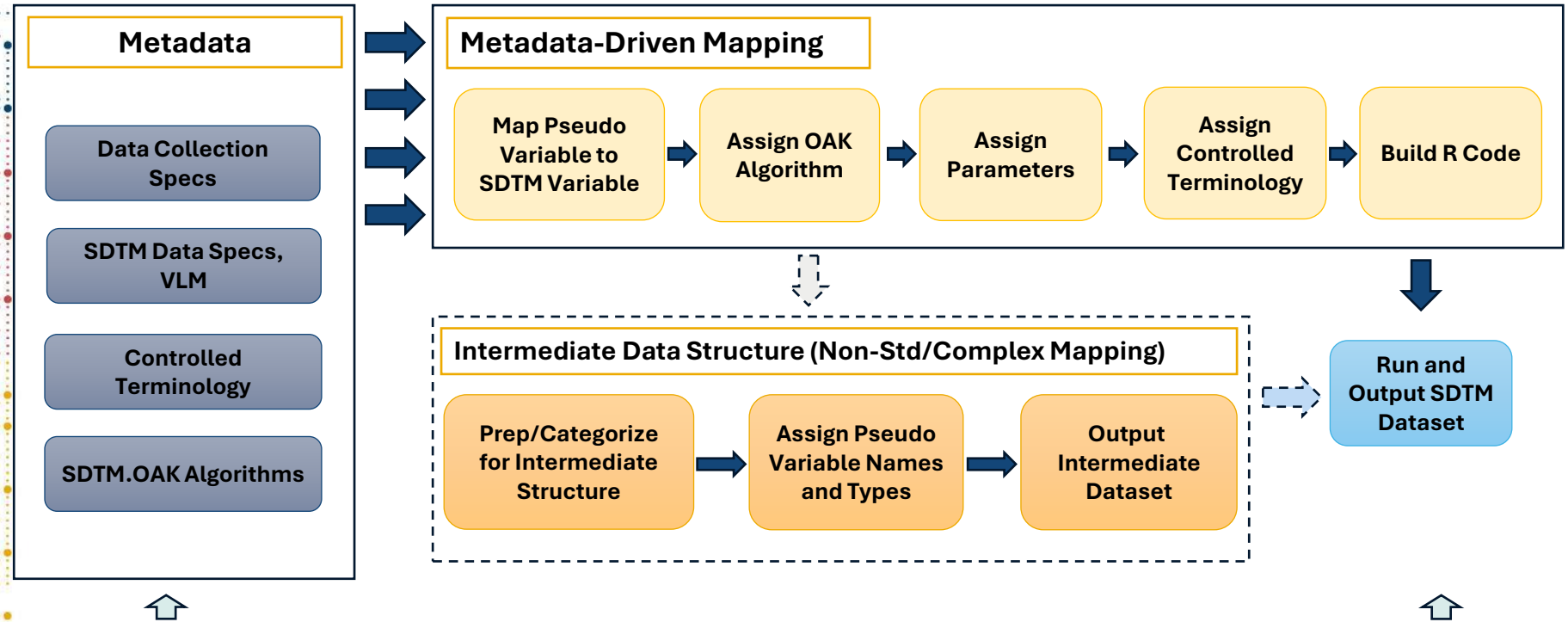
Challenges

- 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



CDISC 360i Demonstration

Looking Forward: Art of the Possible

Welcome Back!

Enter your credentials to access your account

User Name

JSmith@company.com

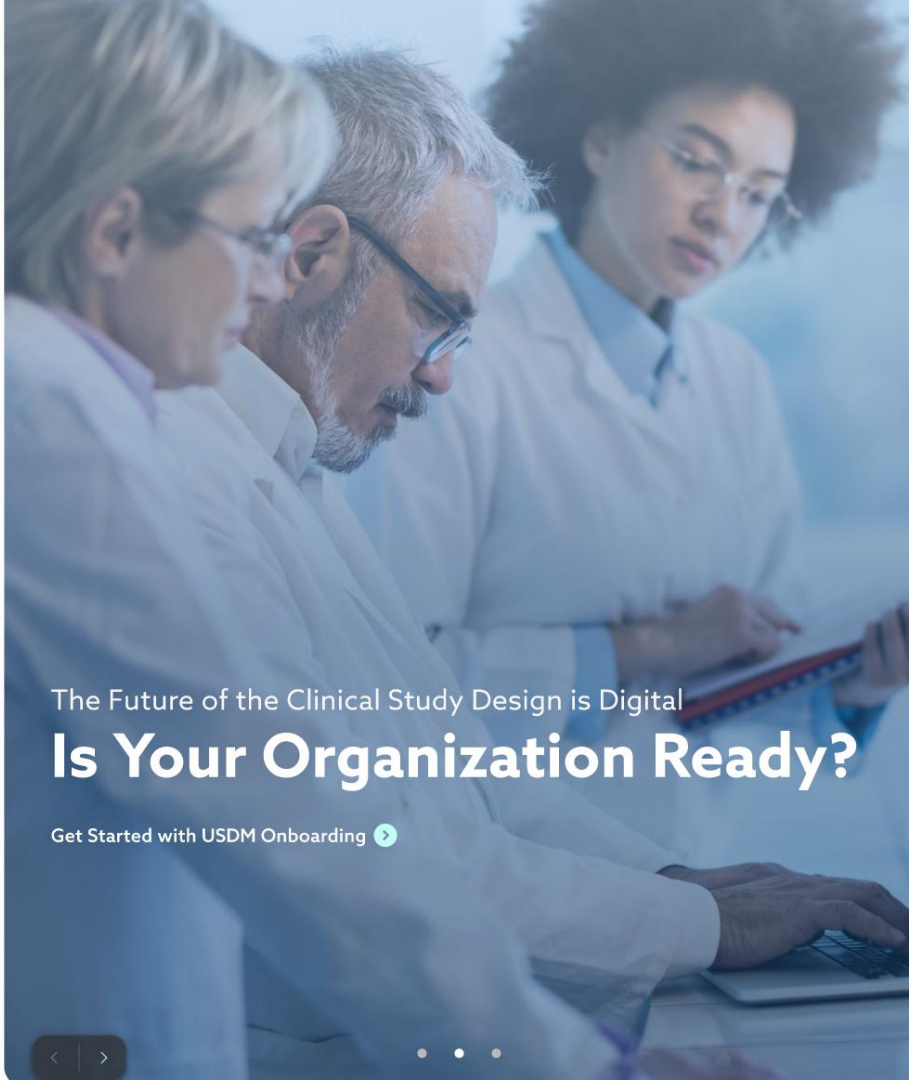
Password

****

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**

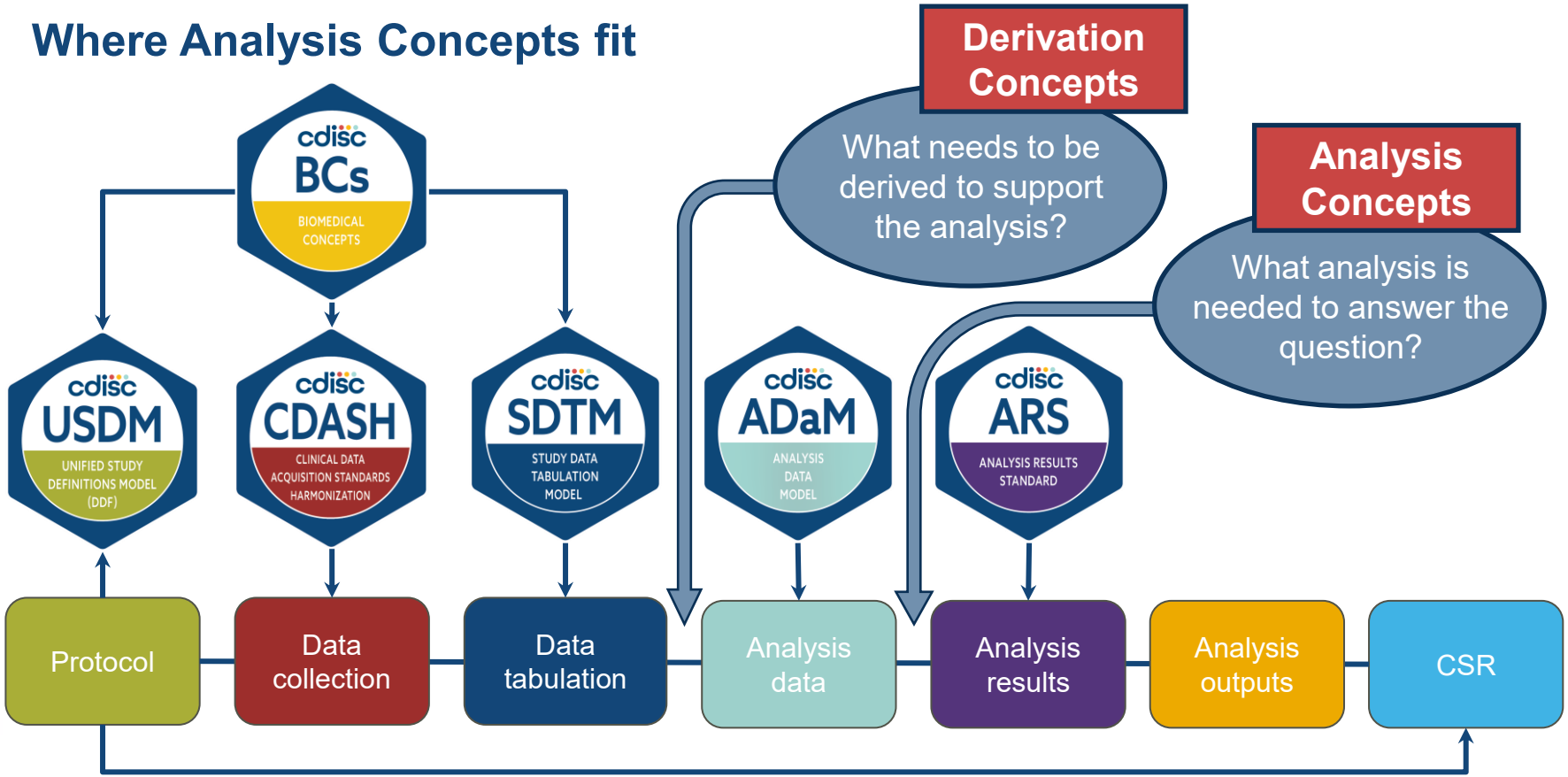
- Helps **visualize the potential** of standards-driven end-to-end automation

- CDISC_Final - Prototype

CDISC 360i Phase 2

Draft Plan

Where Analysis Concepts fit



360i Phase 2 draft plan

- Define and ***pilot analysis concepts*** to generate analysis artifacts
  - ADaM datasets, TFLs, eSAP, …
- Address ***gaps*** identified in Phase 1 to connect Biomedical concepts to ***operational artifacts***
  - Decide how and where to handle operational metadata
  - Identify requirements for the next generation CDISC Library
- Establish ***digital data transfer agreements*** 'standard' and ***pilot*** the generation from USDM
- Create a basic open-source ***tool to author the digital Schedule of Activities*** and linking to ***Biomedical Concepts*** from the CDISC Library
  - Partner with vendors and the Open Source community
- Create and publish all content for an ***end-to-end digital TAUG*** and playbook on how to implement
- Partner with community to define an operational model for ***BC collaborative curation***
- ***Accelerate development*** of concepts (BCs, ACs, end to end TAUGs,…)
- Develop the TMF Standards Model to evolve towards a ***digital TMF***

Questions?