

CDISC 360i: Lessons Learned and Road Ahead

Peter Van Reusel, CDISC
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Paper DS15





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

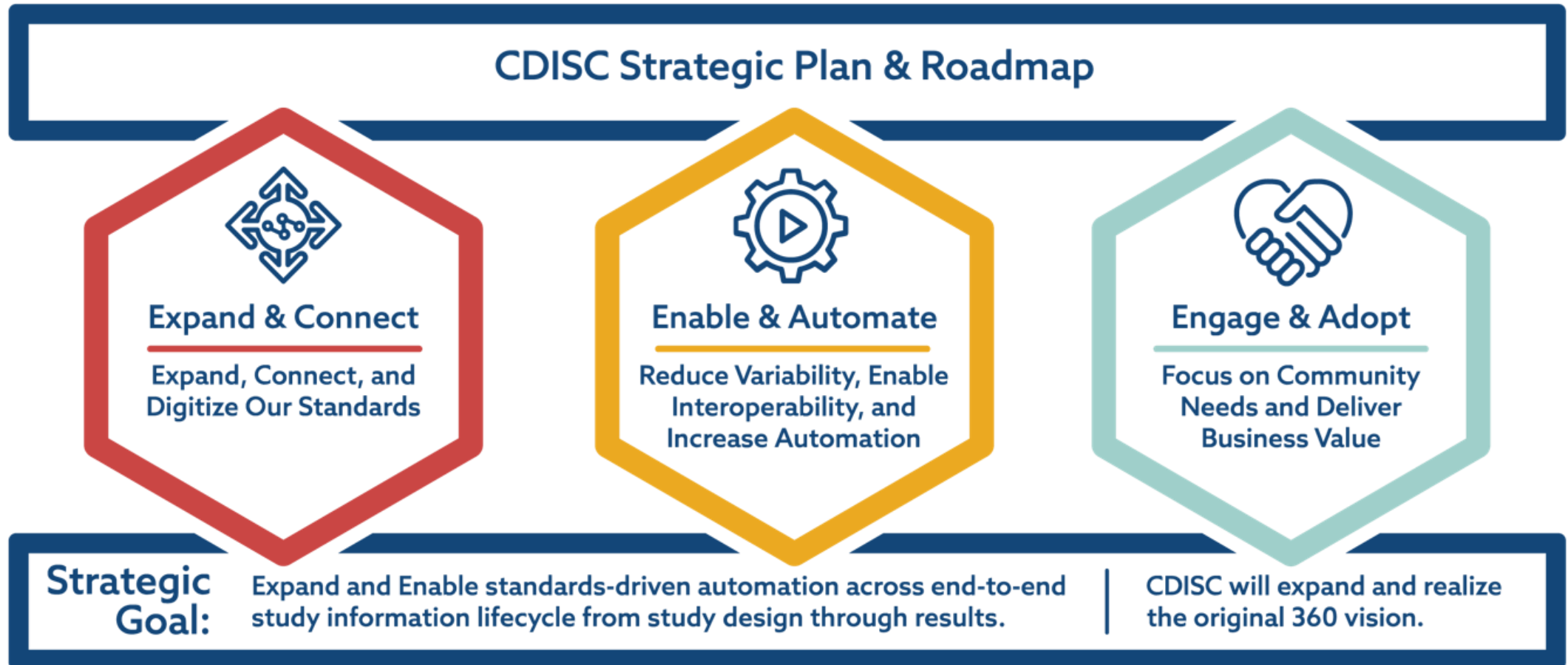
1. Purpose & Approach
2. Achievements, Challenges & Insights
3. Looking forward: Art of the Possible



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 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 (SoA)
 - 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 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



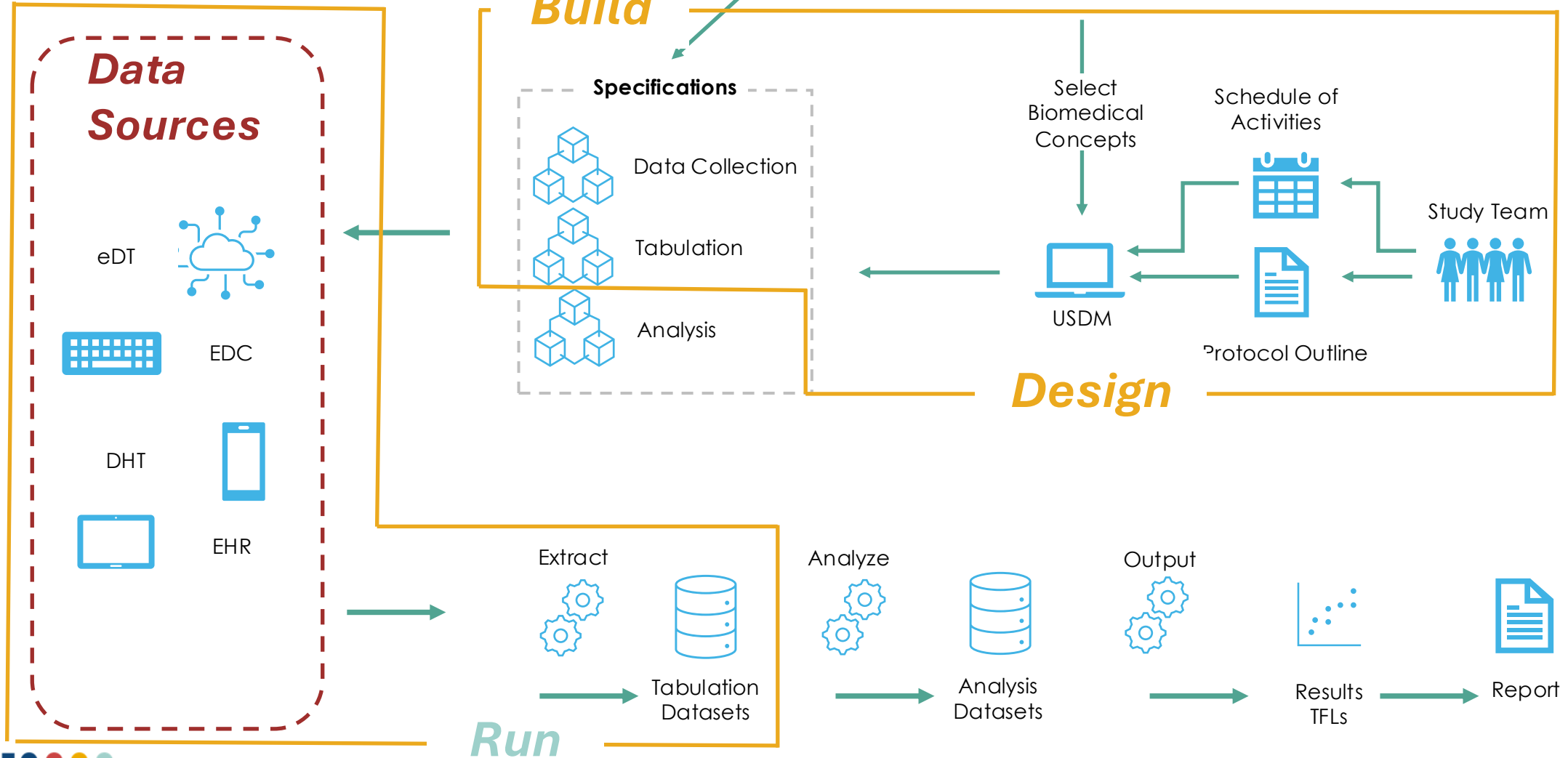
Results
TFLs



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
 - Christine Connolly
 - Anthony Chow
- **Sub-teams**
 - Data
 - sdtm.oak
 - Conformance

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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

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 LZTZ 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

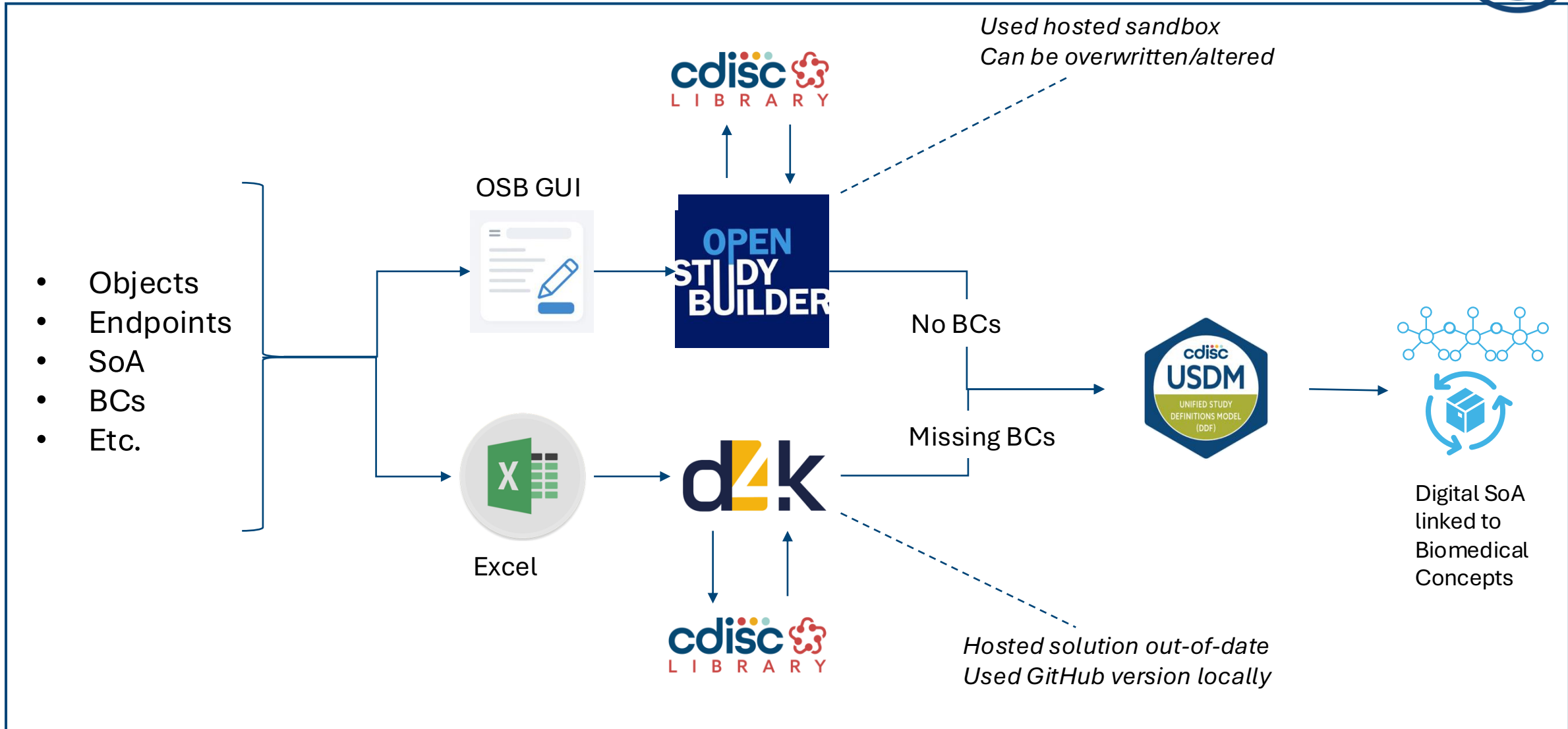
Category

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



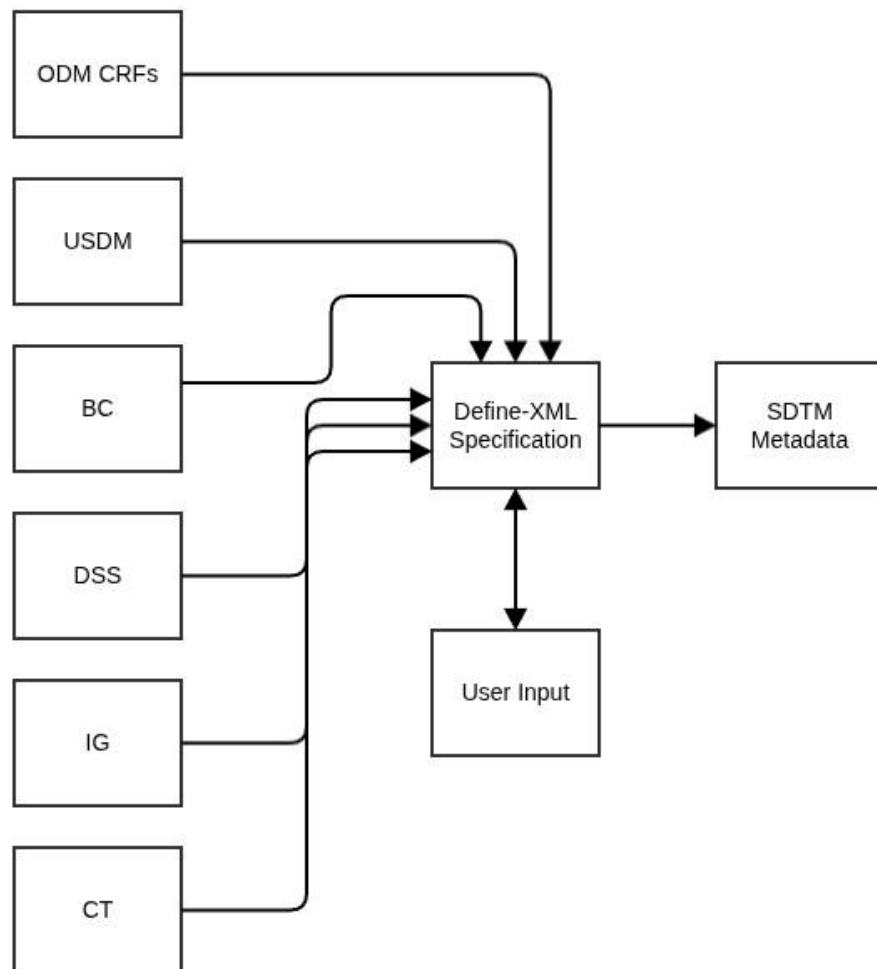
- Large process flow to achieve full automation (next slide)
- Work-arounds needed to obtain all needed metadata



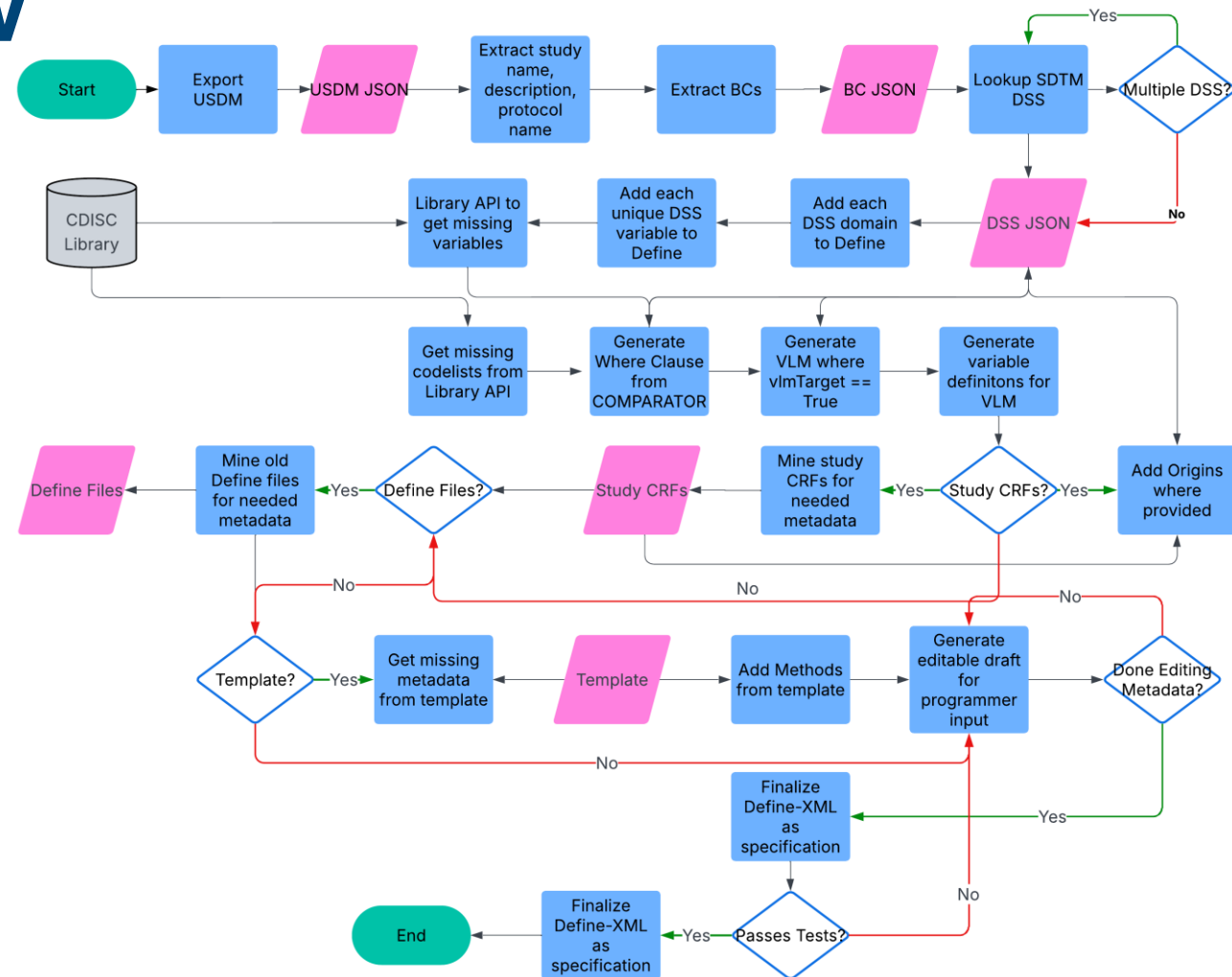
Insights

- 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 <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>

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- A woman with blonde hair, wearing a grey business suit jacket over a white collared shirt, is shown from the chest up. She has her eyes squeezed shut and a pained or distressed expression on her face, with her mouth open in a grimace. Her hands are pressed against her ears, with her fingers buried in her hair. The background is plain white.



Run – Generate SDTM datasets from source

Achievements



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

Challenges



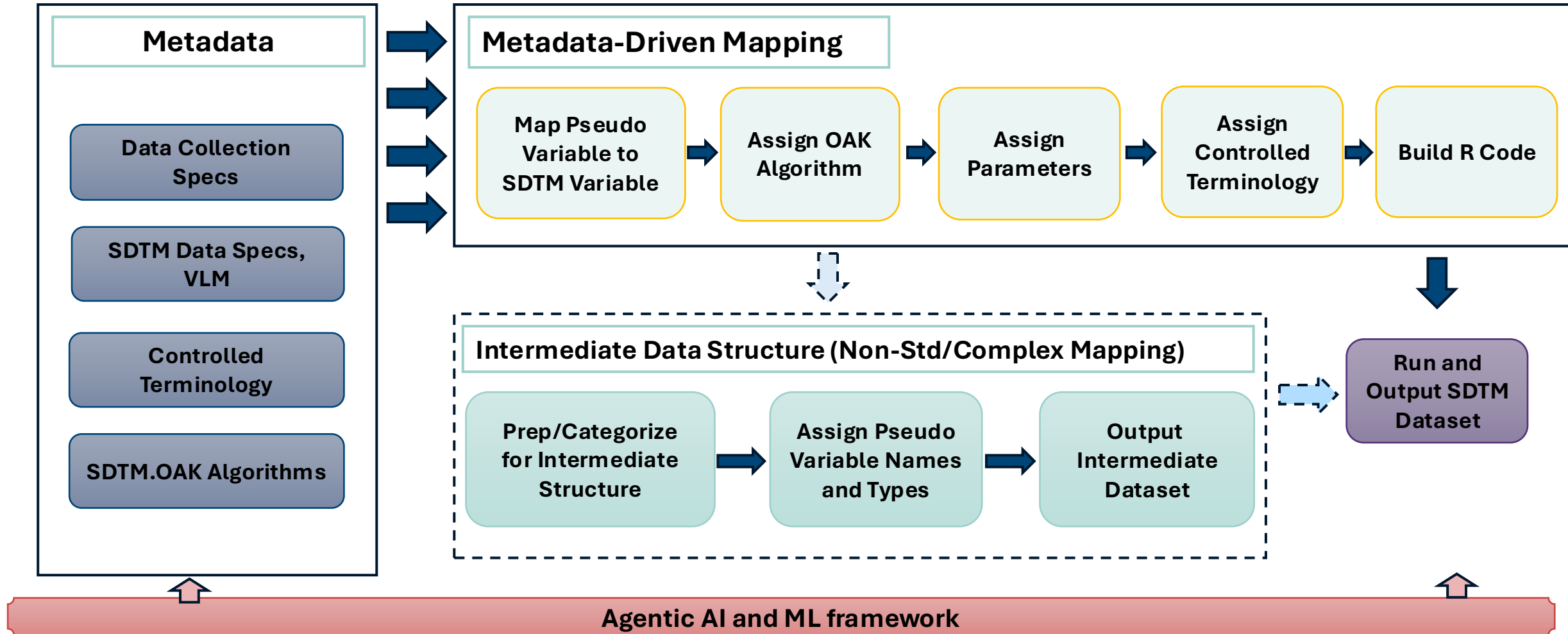
- Dealing with non-standard data
- Limited source data



Insights

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

Run - SDTM Datasets with SDTM.OAK





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](#)



The Future of the Clinical Study Design is Digital

Is Your Organization Ready?

[Get Started with USDM Onboarding](#) 

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



Thank You!

Peter Van Reusel
pvanreusel@cdisc.org

