



In Partnership with



INDIA CDISC DAY

PHUSE APAC Connect Hyderabad India 20 February 2026

CDISC 360i in Action: Demonstrating the Shift to Fully Digital Standards

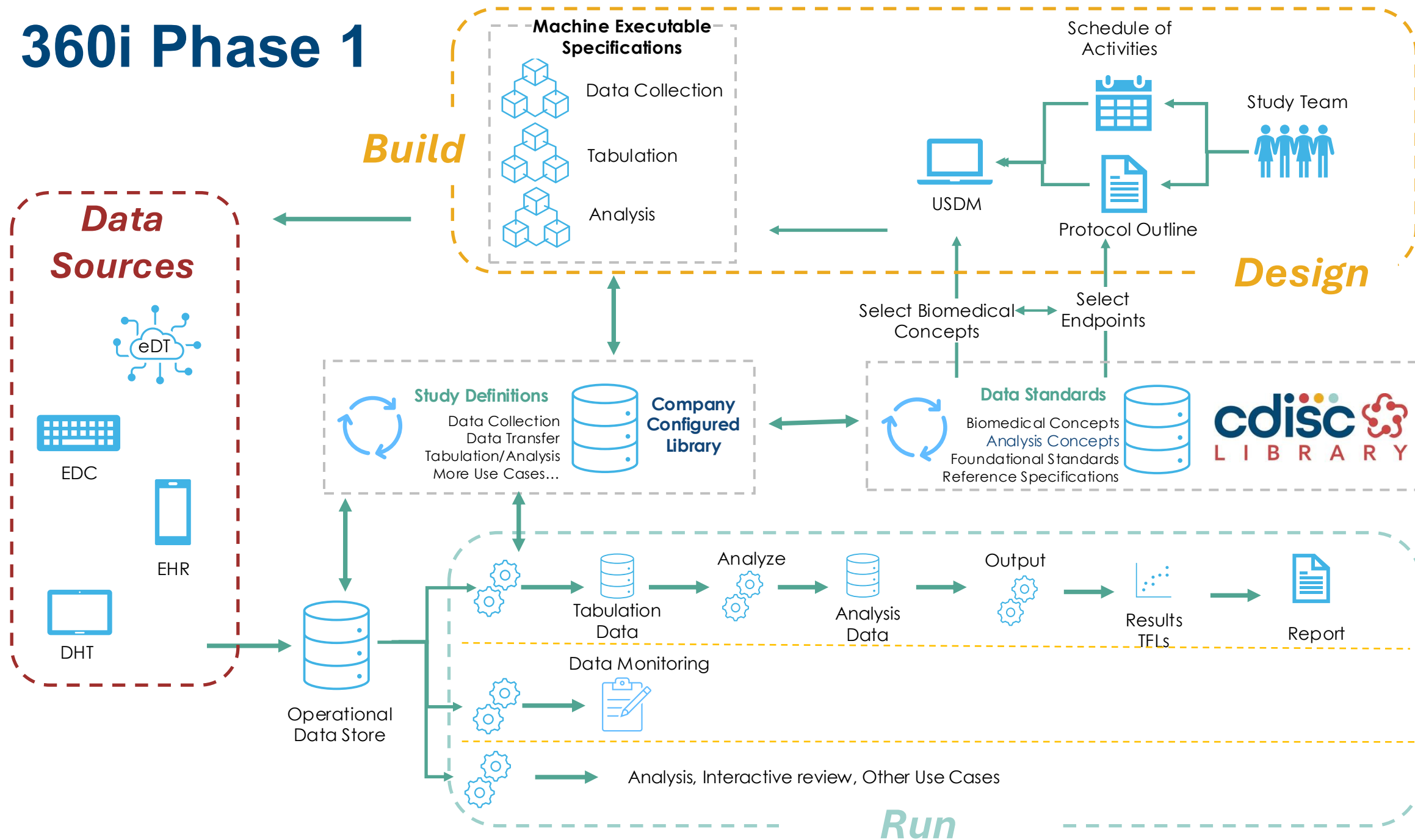
Darren Moreland, CDISC

Julie Smiley, CDISC

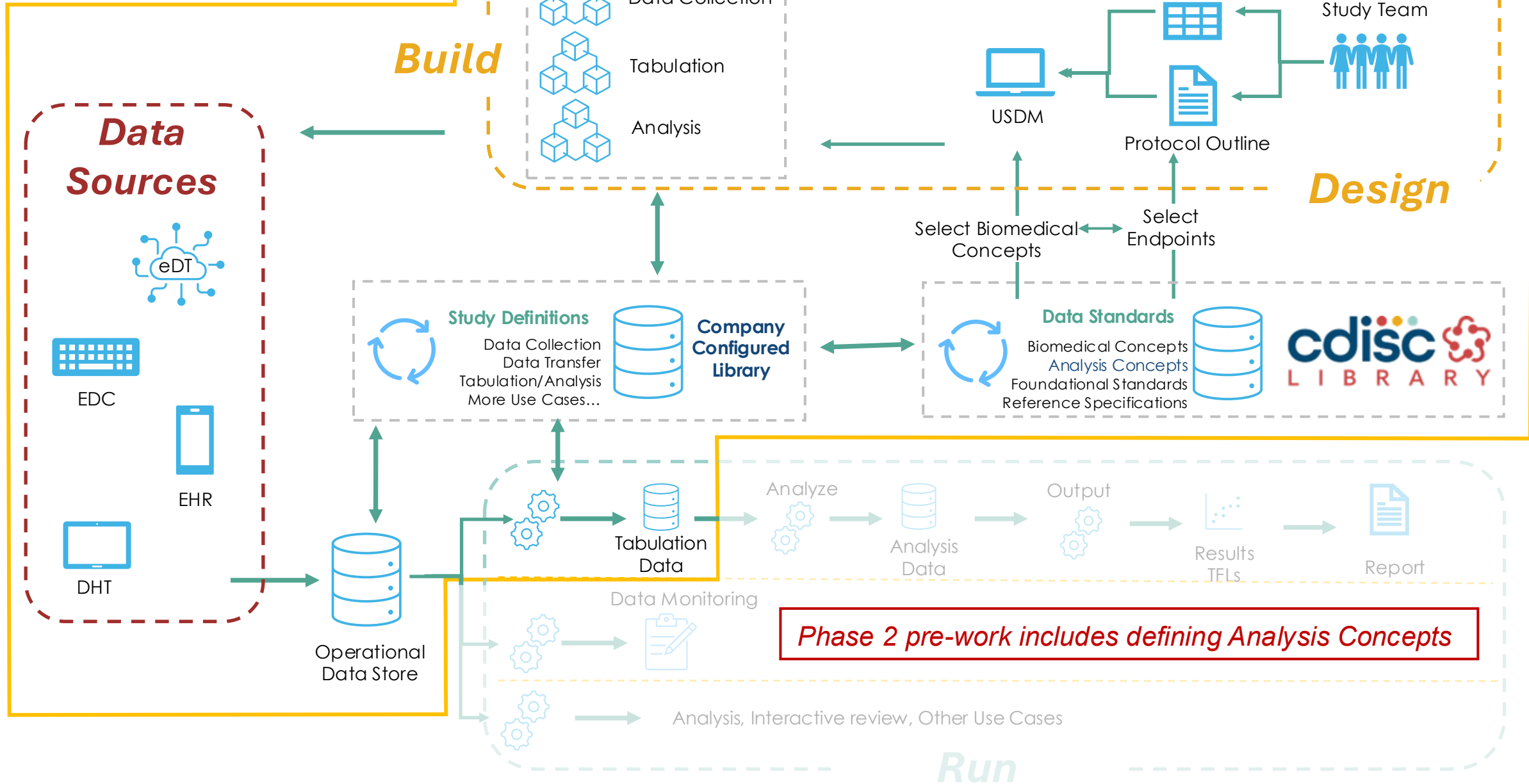
Bhavin Busa, Clymb Clinical

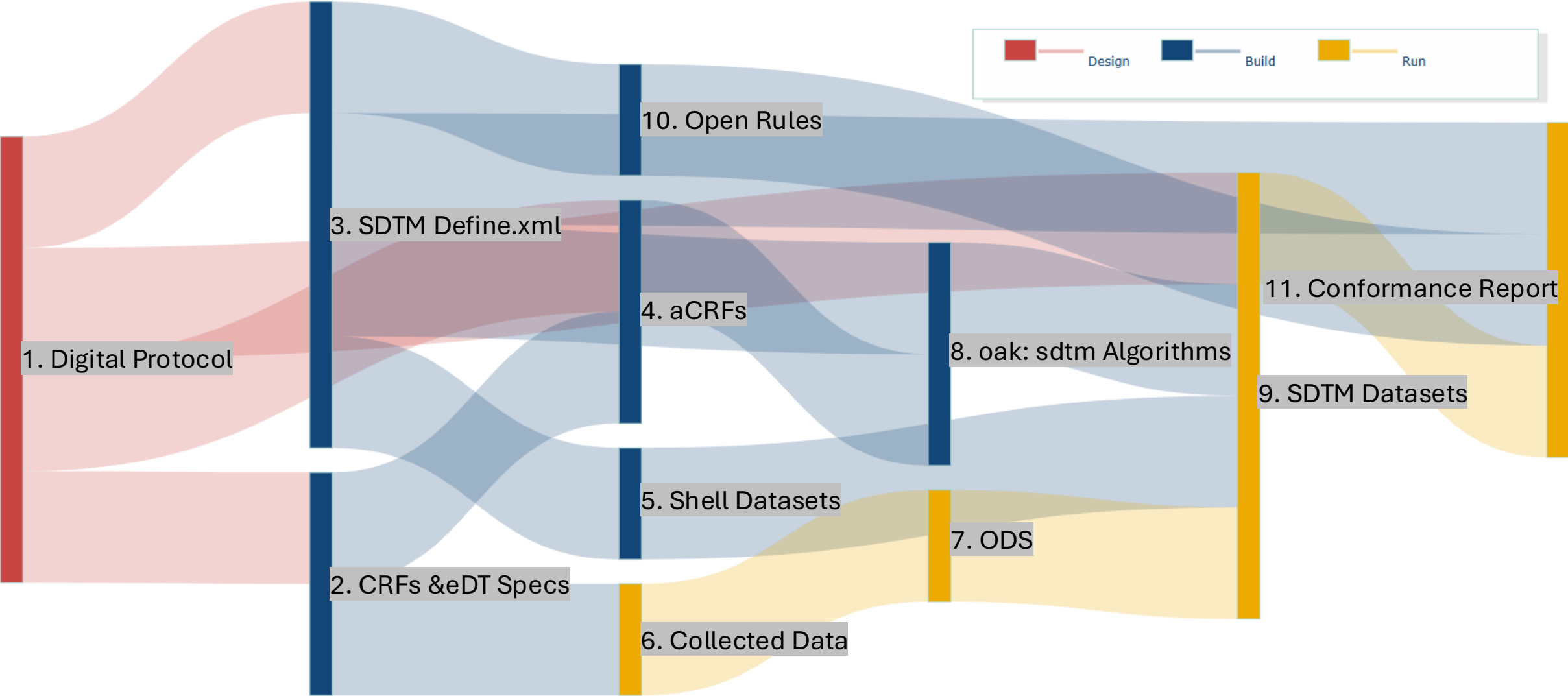
Peter Van Reusel, CDISC

360i Phase 1



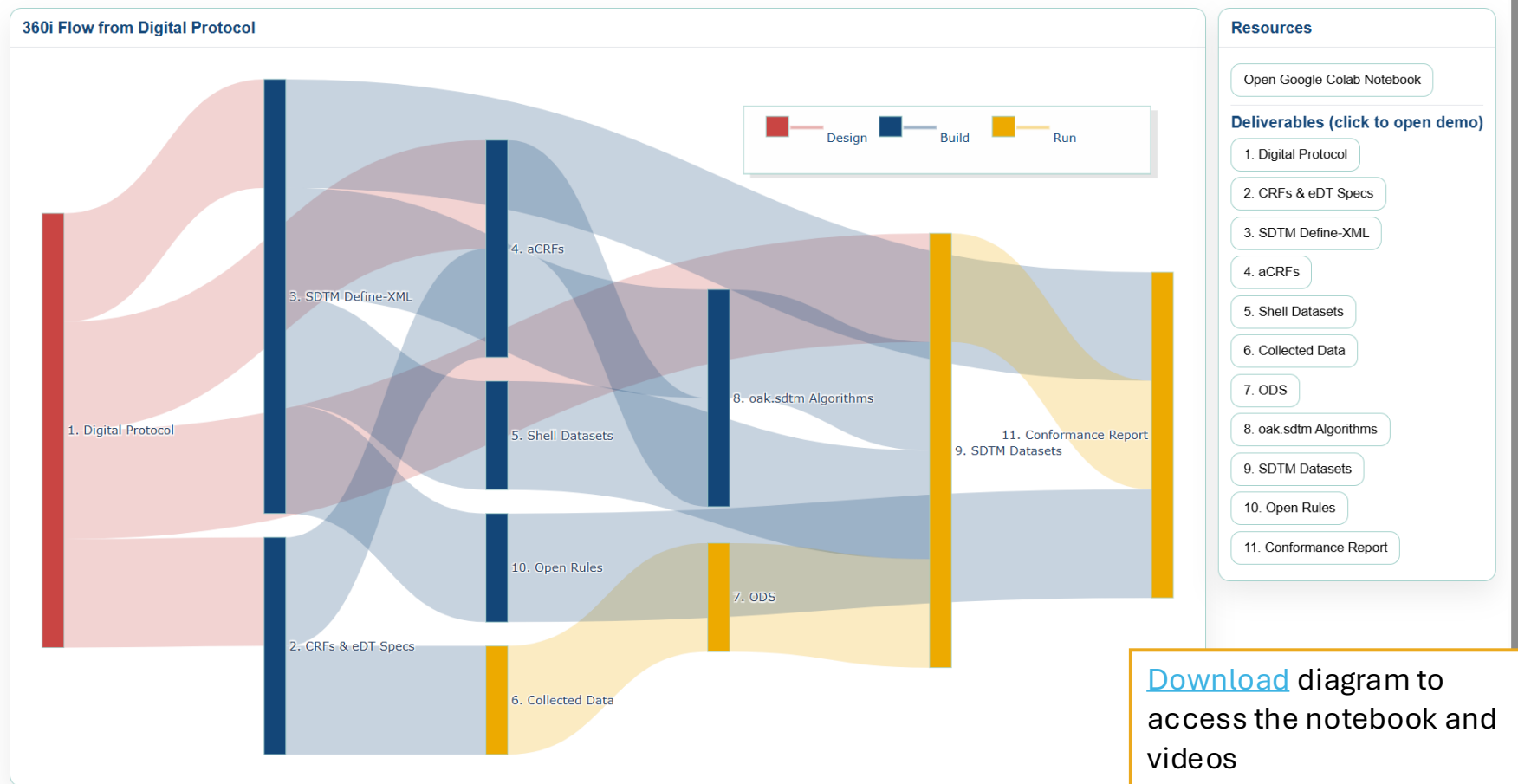
360i Phase 1





CDISC 360i Demos

cdisc CDISC 360i — Design / Build / Run



Direct Video Links:

1. [Digital Protocol](#)
2. [CRFs & eDT Specs](#)
3. [SDTM Define-XML](#)
4. [aCRFs](#)
5. [Shell Datasets](#)
6. [Collected Data](#)
7. [ODS](#)
8. [oak.sdtm Algorithms](#)
9. [SDTM Datasets](#)
10. [Open Rules](#)
11. [Conformance Report](#)

[Download](#) diagram to
access the notebook and
videos

- Click the link
- File > Download



Demonstration Video



Google Colab Notebook

CO

CDISC_360i_Protocol_to_Submission.ipynb

File Edit View Insert Runtime Tools Help

Q Commands + Code + Text ▶ Run all Copy to Drive

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Digital Protocol USDM

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OpenStudyBuilder (OSB)

USDM JSON

Creating and Validating...

OpenStudyBuilder (OSB)

Case Report Forms and For...

Electronic Case Report F...

Annotated Case Report F...

SDTM Resources

SDTM Define-xml

SDTM Shell Datasets

SDTM Trial Design Domai...

360i Approach

Create the Trial Design D...

Create Define-XML

Create the Required SDT...

CDISC 360i: Implementing Standards-Driven Automation Across the Clinical Research Data Lifecycle

CDISC Strategic Plan & Roadmap



Expand & Connect

Expand, Connect, and Digitize Our Standards



Enable & Automate

Reduce Variability, Enable Interoperability, and Increase Automation



Engage & Adopt

Focus on Community Needs and Deliver Business Value

Strategic Goal:

Expand and Enable standards-driven automation across end-to-end study information lifecycle from study design through results.

CDISC will expand and realize the original 360 vision.

Abstract

CDISC 360i defines a vision and roadmap to enable standards-driven automation across the clinical research data life cycle - from study design to analysis. The purpose of this paper is to demonstrate the 360i Technical Roadmap by showcasing a strategy for research data pipeline automation using end-to-end, machine-readable standards metadata

Accessing the 360i Notebook

The notebook displayed during this demonstration can be found here:
<https://github.com/cdisc-org/cdisc-360i-notebooks>

- The repository is under continued development; follow repository for latest releases
- There are multiple notebooks
- Raise any issues encountered while using notebooks
- To contribute to the CDISC project:
 - Fork the repo and create a new branch
 - Once changes are made and tested, raise a Pull Request

GitHub Repositories Used in the Demo

Purpose	Location
Study Definition Workbench	https://github.com/data4knowledge/study_definitions_workbench
Open Study Builder	https://gitlab.com/Novo-Nordisk/nn-public/openstudybuilder/OpenStudyBuilder-Solution
Study USDM documents	https://github.com/cdisc-org/360i/tree/main/data/protocol/LZZT/usdm
USDM validation utility	https://github.com/pendingintent/cdisc-json-validation
CDISC CORE Rules Engine	https://github.com/cdisc-org/cdisc-rules-engine
CRF creation	https://github.com/lexjansen/cdisc360i-pocs
Trial Design Dataset creation	https://github.com/pendingintent/cdisc-usdm-utils
Define-XML template creation	https://github.com/dostiep/360i
Define-XML creation	https://github.com/swhume/template2define
Raw subject data	https://github.com/alidootson/UpdatedCDISCPilotData/tree/main/UpdatedCDISCPilotData/CDASH

Using GitHub

The GitHub repositories used in the demo are public and use open-source libraries

The process for using these libraries is consistent:

- Fork the original public repository into personal GitHub repository
- Create new branch in personal GitHub repository
- Edit code to meet individual requirements, add features or fix issues
- Commit changes to personal branch
- If proposing change to parent (original) branch to share with wider community:
 - Raise a Pull Request with original repository owner
 - Original repository owner will review the Pull Request and work with requestor to evaluate and test Pull Request
 - Merge new code in Pull Request with original parent branch



Thank You!

