SCDM Live EMEA Conference
9-11 April, 2025 | Brussels, Belgium

# CDISC 360i Roadmap to Enable Standards Driven Automation from Study Design Through Results and the Intersection with Clinical Data Management

**Chris Decker**
CEO, CDISC

**Patrick Nadolny**
SCDM & CDISC Board
Head CDM, Sanofi

**Ward Lemaire**
SCDM Board
Head of CDM & CM
Janssen

**Manny Vazquez**
SCDM Board
Sr Director, Clinical Data Strategy, Veeva Systems


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# CDISC 360i Roadmap to Enable Standards Driven Automation from Study Design Through Results and the Intersection with Clinical Data Management

CDISC 360i Overview, Chris Decker

Can CDISC 360i enabling Clinical Data Management?, Patrick Nadolny

Panel Discussion

Q & A

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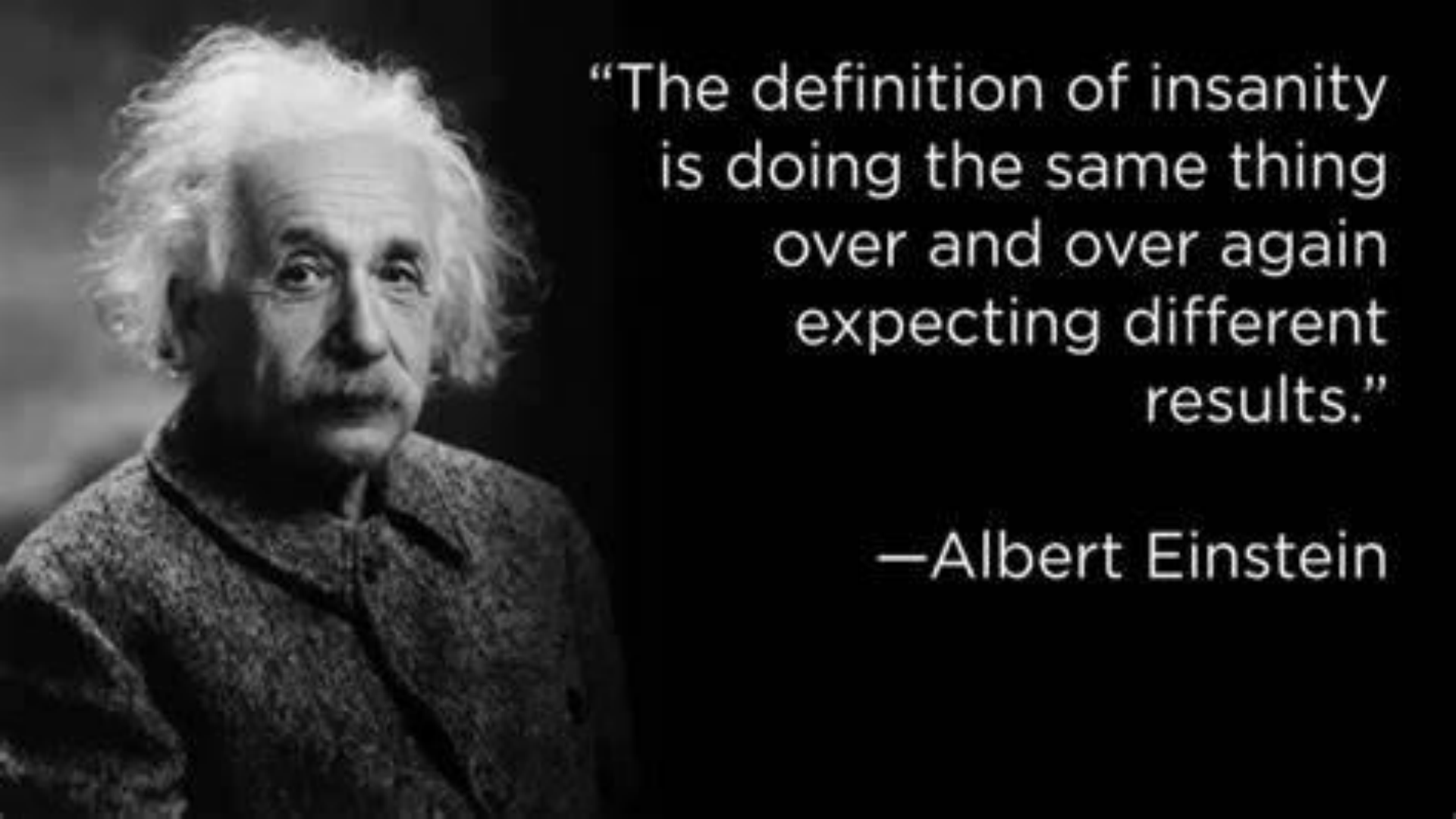
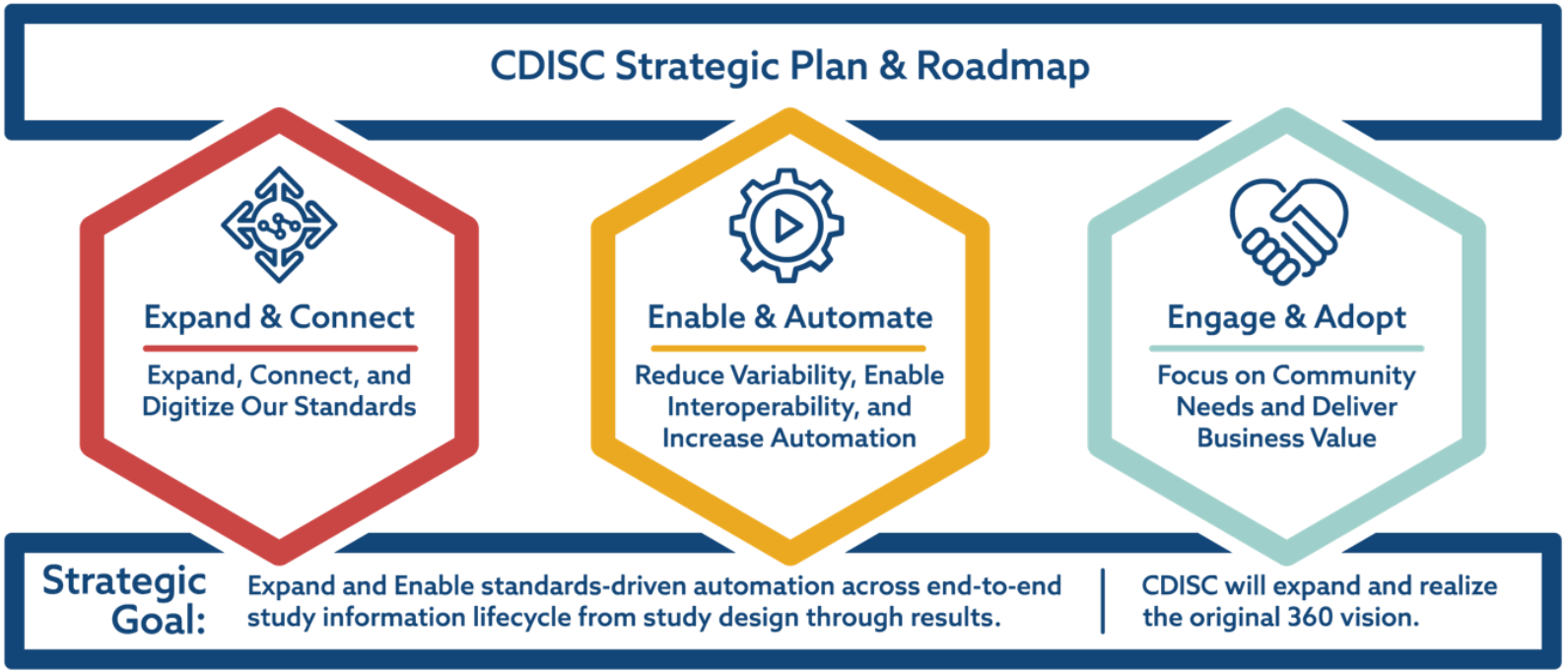
# 360i Program Overview
# Enabling Standards Driven Automation from Study Design Through Results


“The definition of insanity is doing the same thing over and over again expecting different results.”
—Albert Einstein

# Realizing the CDISC Vision & Mission

# 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*



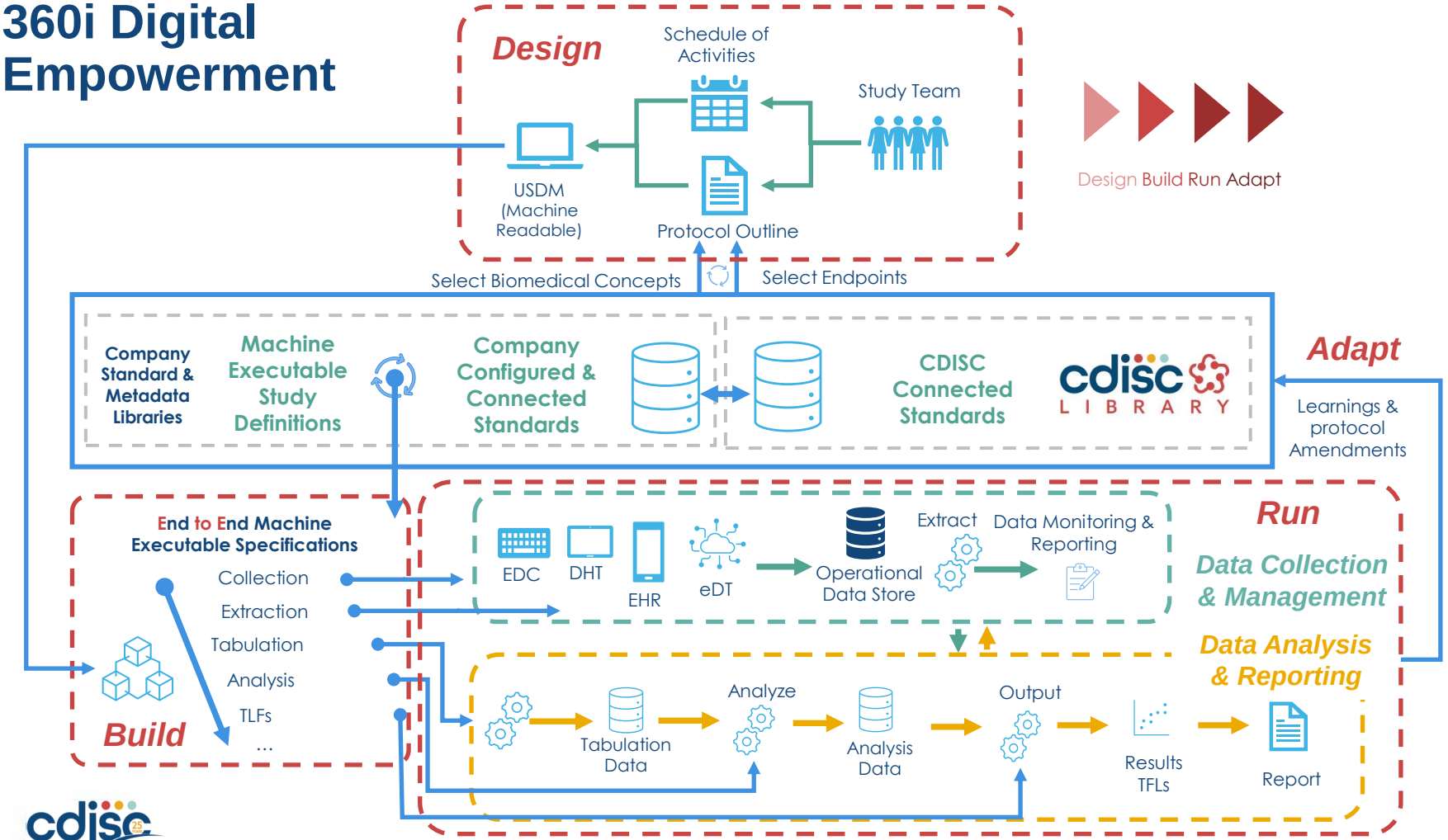
# Value Of A Connected World

## Transition standards use from necessary requirement to valuable enabler through connected and ready to use implementable standards

| | |
|---|---|
| Patients | Data that is easier to understand and extract making it more accessible to patients |
| Sponsors | Protocol driven research automating the metadata & data pipeline reducing time to study results & increasing quality |
| Regulators | Reduced variability & clickable traceability from analysis to the collected data increasing confidence in decisions |
| Researchers | Reduce barrier to entry and cost for standards through ready to use implementable standards & open source tools |
| Technologists | Provide machine readable and interoperable inputs and outputs for easier adoption by software solutions |

# 360i Vision and Overview

# 360i Digital Empowerment



# Use Cases 360i Can Enable

Potential AI Use Cases | Initial 360i Focus | Potential future uses

| Protocol Design & Study Planning | Study Conduct & Data Collection | Data Aggregation & Standardization | Analysis and Reporting | Regulatory Submission |
|---|---|---|---|---|
| Protocol Authoring | Study Build | SDTM Generation | ADaM Generation | Clinical Report Generation |
| Past Protocols | Electronic Data Transfers | Study Pooling | Digital Analysis Plan | Narrative Generation |
| Digital SOA | Patient Recruitment | Tabulation & Analysis Specs | | Clickable Submission |
| Data Transfer Specifications | Data Cleaning | | | eTMF |
| Protocol Feasibility | Safety Monitoring | | | |

**And many more use cases exist…**

Governance & Reusability

Artifact Recommendations | Semantic Interoperability | Built In Traceability | Standards Conformance

# What Will 360i Deliver?

- Linked and executable metadata from study endpoint through analysis
- Includes concepts, rules, & sample data

**Standards Packages**

- Instructions to build standards packages
- Recipes to implement packages within your processes

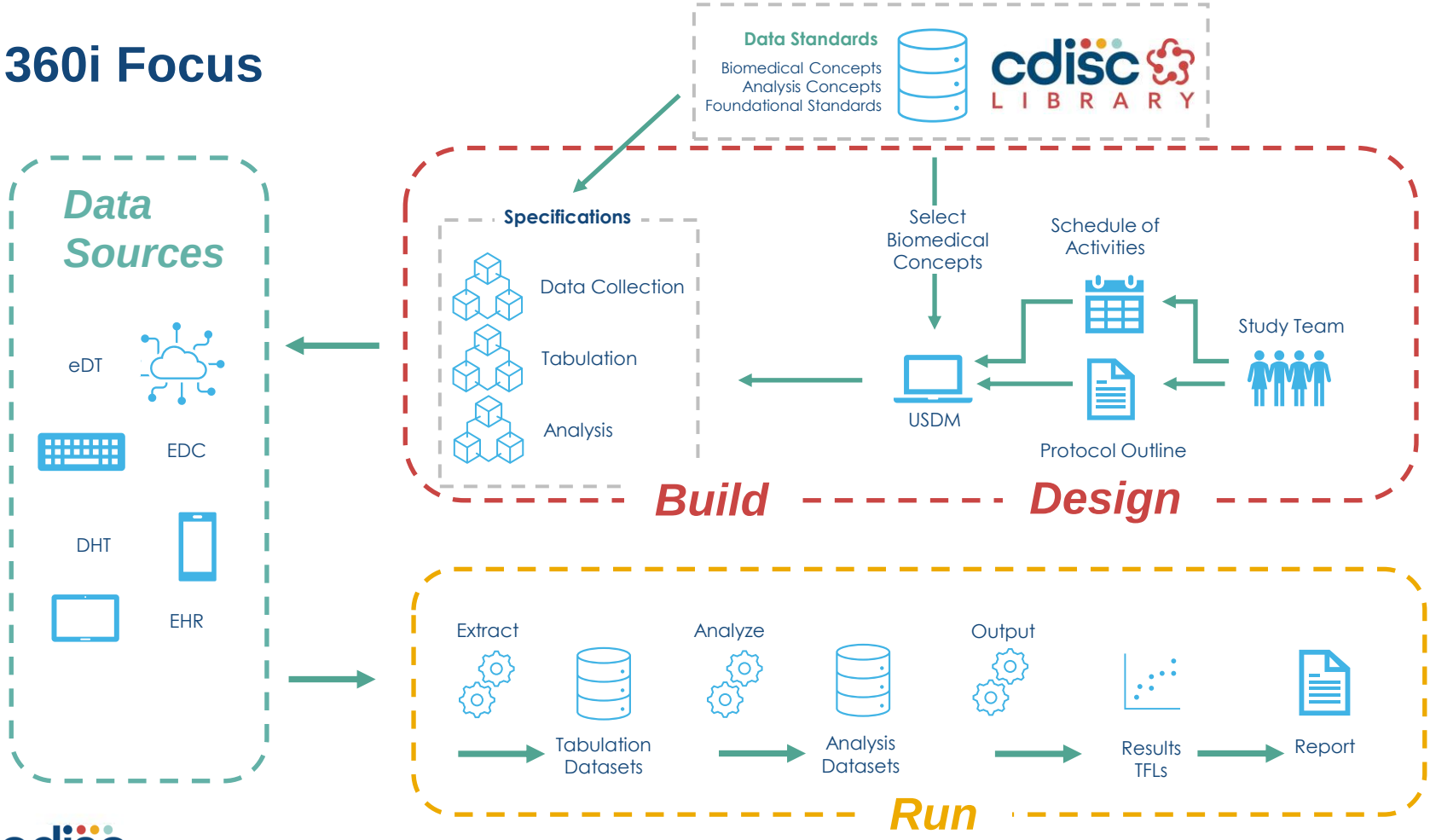
**Implementation Cookbooks**

- Technology enabled example leveraging packages & recipes
- Library of community based open-source tools

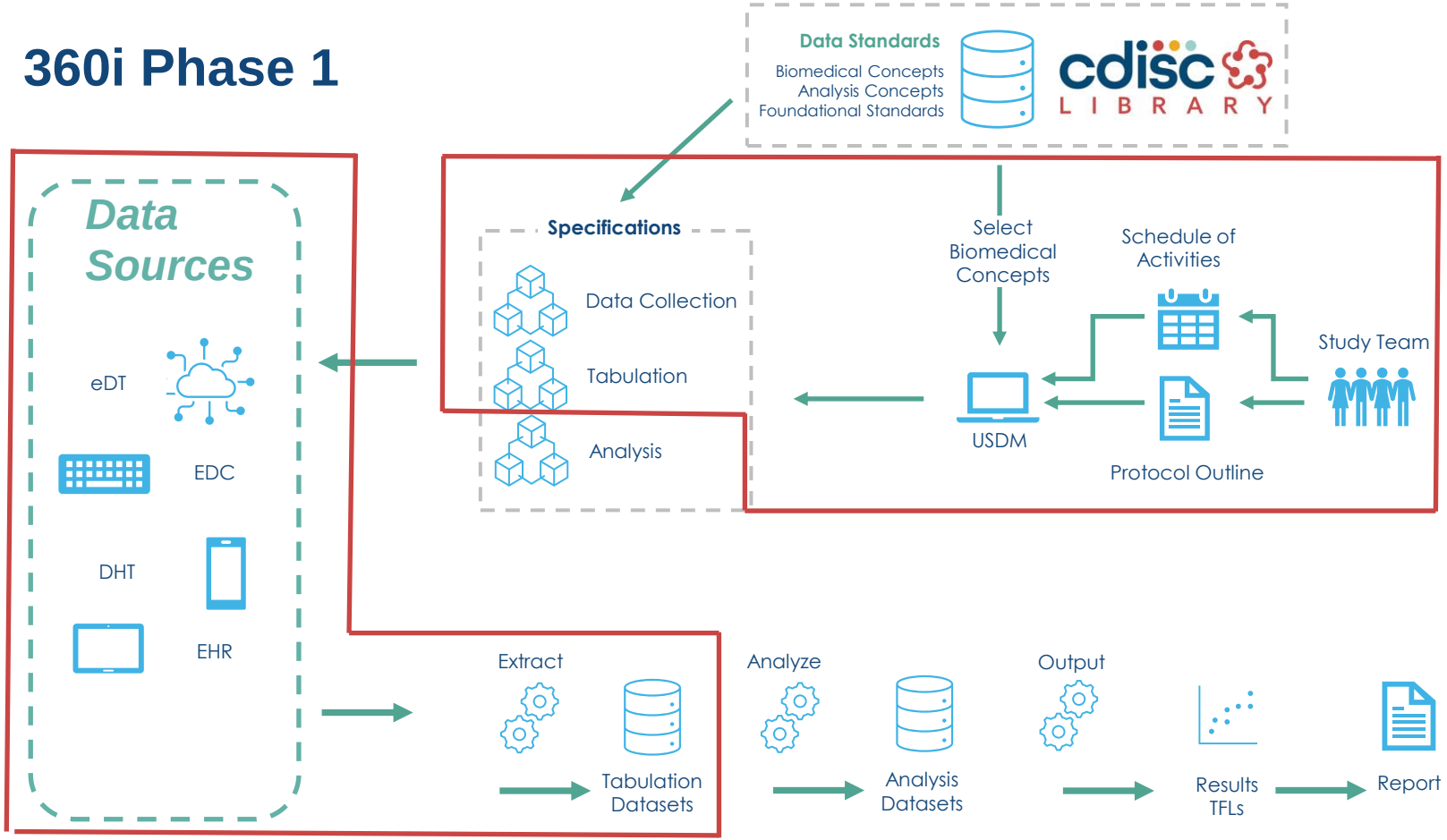
**Example Implementations**

# 360i Phase 1: First Step in Realizing End to End Connected Standards

# 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
Analyze
Output
Tabulation Datasets
Analysis Datasets
Results TFLs
Report
Run

# 360i Phase 1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# Content Scope: Implementing Breadth/Depth of Endpoints

**Safety Assessments**

- ✓ Demography
- ✓ Death Details
- ✓ Adverse Events
- ✓ Disposition
- ✓ Change from Baseline Labs
- ✓ Vital Signs
- ✓ Drug Induced Liver Injury (DILI)

**Questionnaire**

- ✓ ADAS-Cog

**Digital Measure (DHT)**

- ✓ Glucose Monitoring
- ✓ Steps / Movement / Sleep

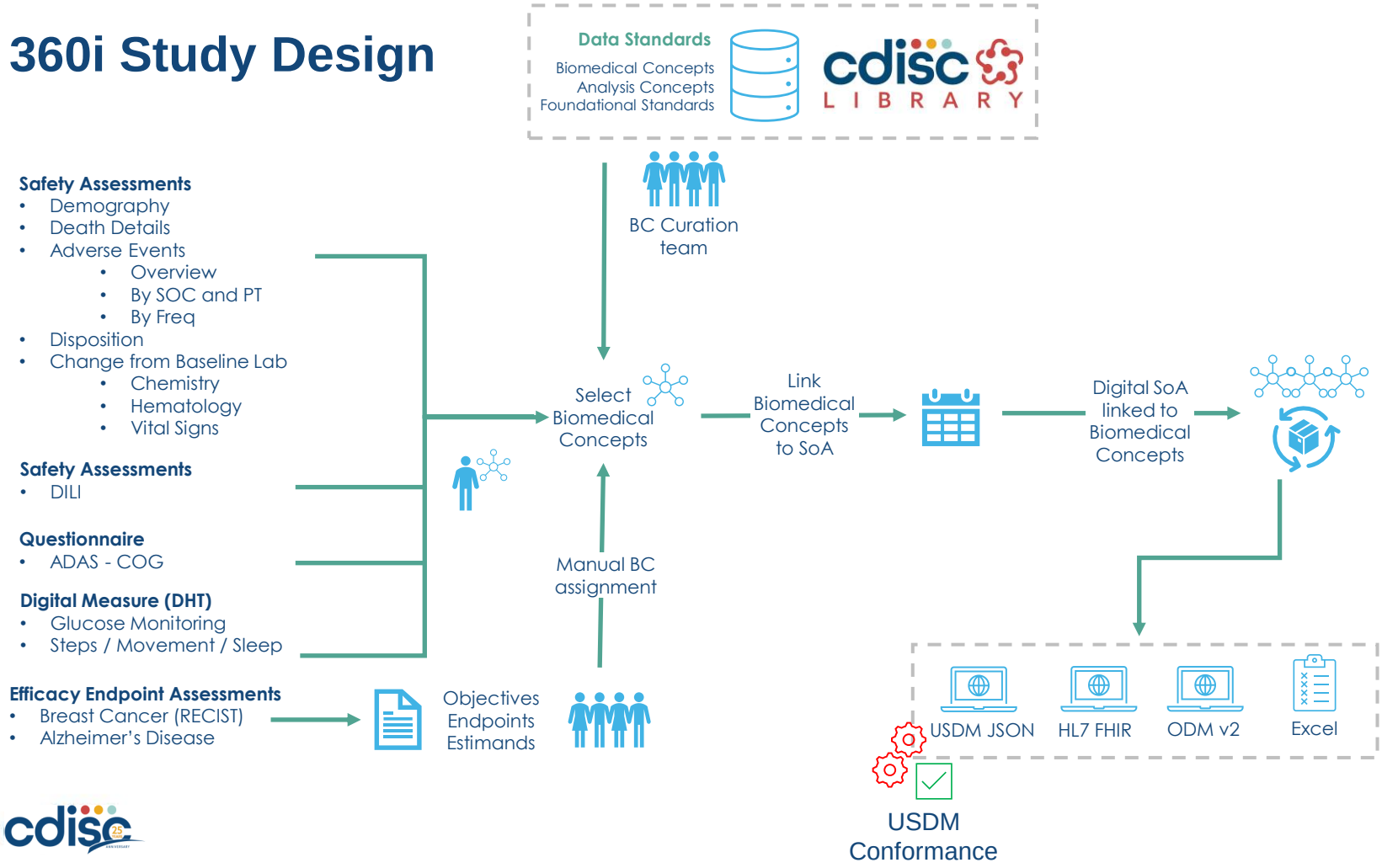
**Efficacy Endpoint Assessments**

- ✓ Breast Cancer (RECIST)
- ✓ Alzheimer's Disease

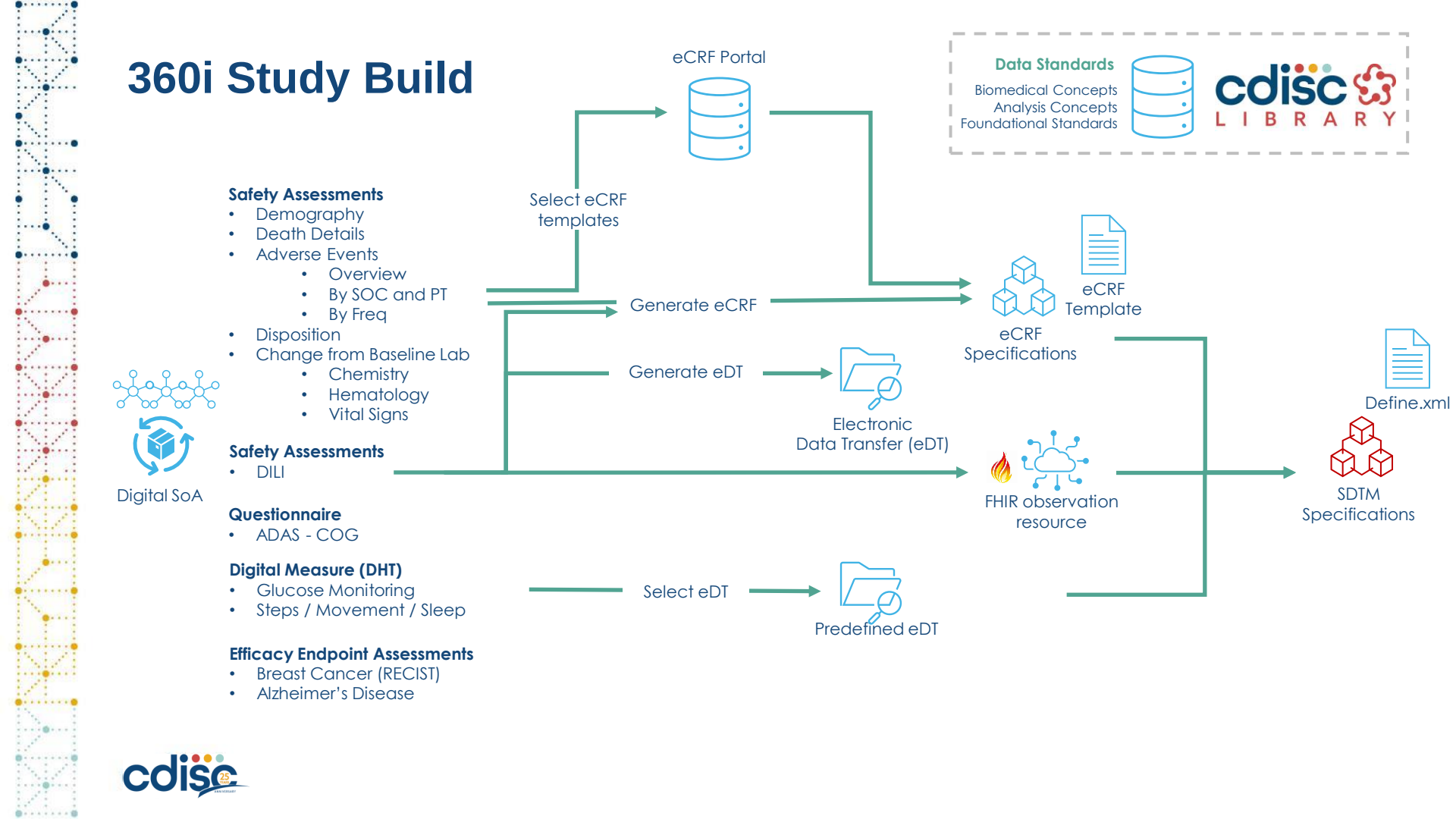
Why This Scope?

- ➢ *Leverage what is well known and a set of artifacts already available*
- ➢ *Use diverse set of data sources to demonstrate different data pipeline flows*
- ➢ *Focused and doable – need to get it right and build the playbook*

# 360i Study Design

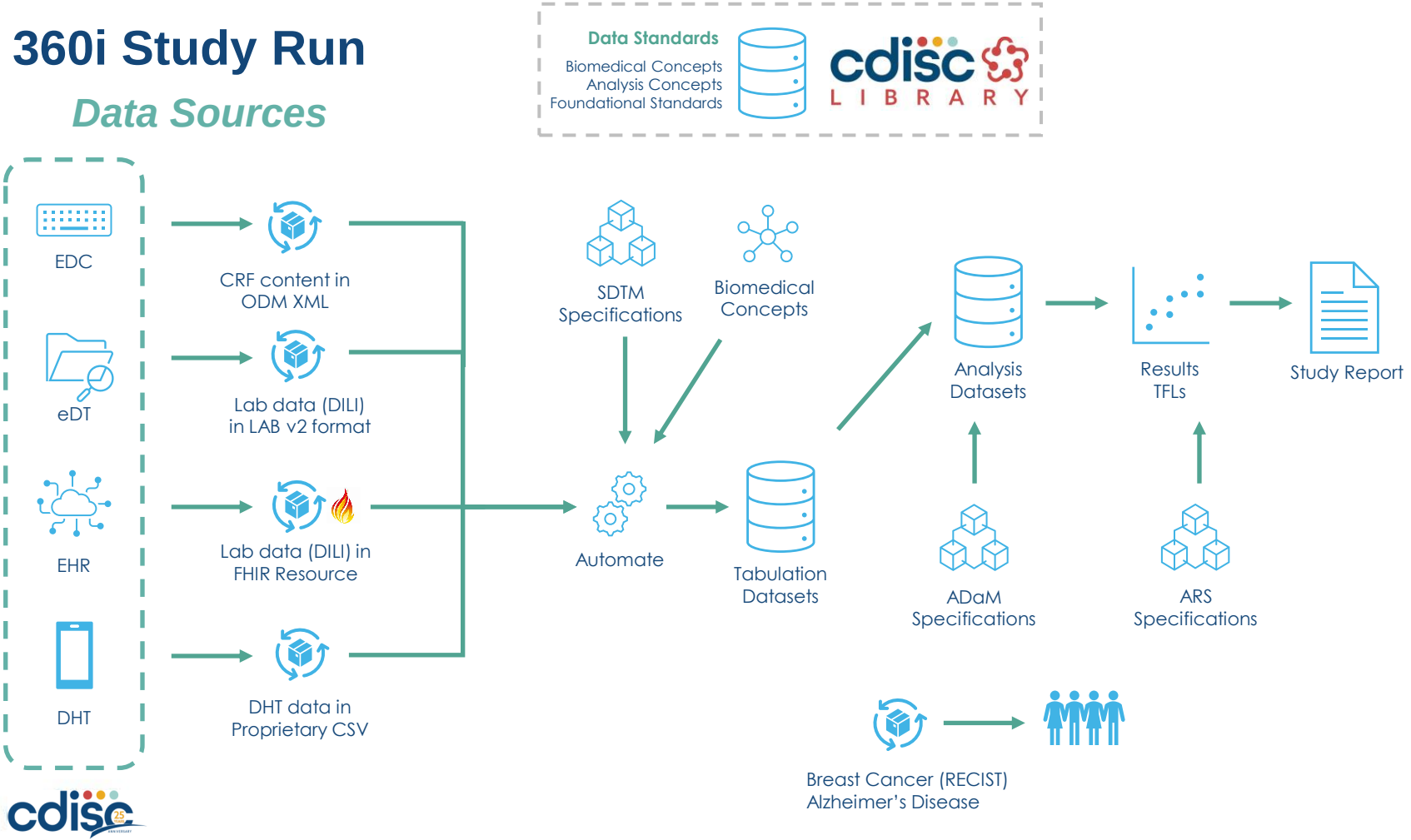


# 360i Study Build



# 360i Study Run

## *Data Sources*



# Open Rules

**Data Standards**
Biomedical Concepts
Analysis Concepts
Foundational Standards

cdisc LIBRARY

## Data Sources

- eDT
- EDC
- DHT
- EHR

**Specifications**
- Data Collection
- Tabulation
- Analysis

Verify specifications

Select Biomedical Concepts

Schedule of Activities

Study Team

USDM

Protocol Outline

USDM Conformance

Extract → Tabulation Datasets

SDTM Conformance

Analyze → Analysis Datasets

ADaM Conformance

Output → Results TFLs → Report

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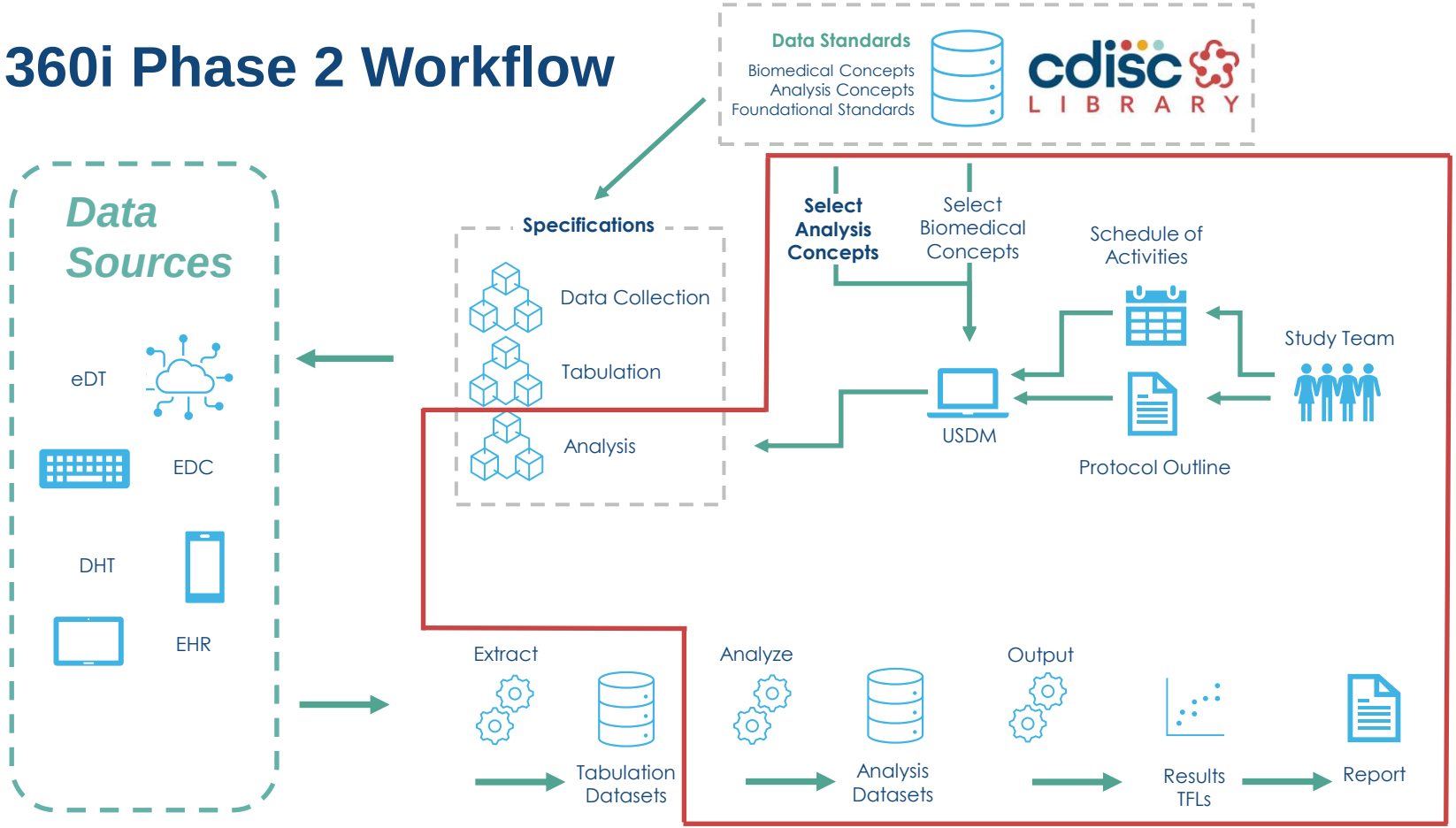
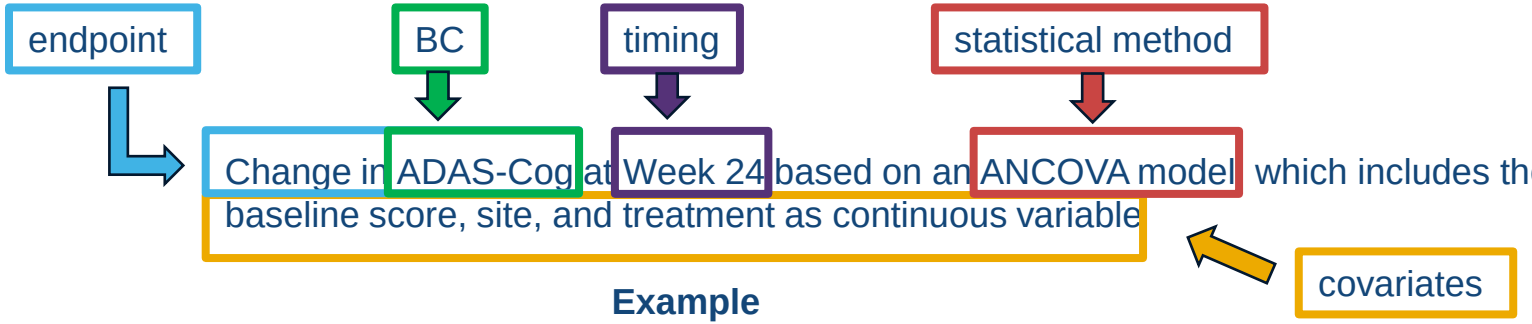
# 360i Phase 2 Workflow



# Analysis Concepts

- What is an Analysis Concept?
  - Collection of standardized configurable elements & methods that are needed to describe a final output or answer a clinical question
  - Standard definitions in a digital statistical analysis plan

- What is the purpose of an Analysis Concept?
  - Supports configuration and automation of analysis
  - Informs what needs to be collected to answer the clinical question



# Next Steps and How You Can Support 360i!

# Next Steps

## Webinar

- Share the 360i Roadmap
- Call for Action for team contributors

## Kickoff: March

- Assemble contributors
- Define detailed charters
- Kickoff meeting with contributors

## CDISC Interchange: May

- First Milestone: SOA to Specifications for targeted content
- F2F 360i Working meeting to define next Iteration

# We Need You!

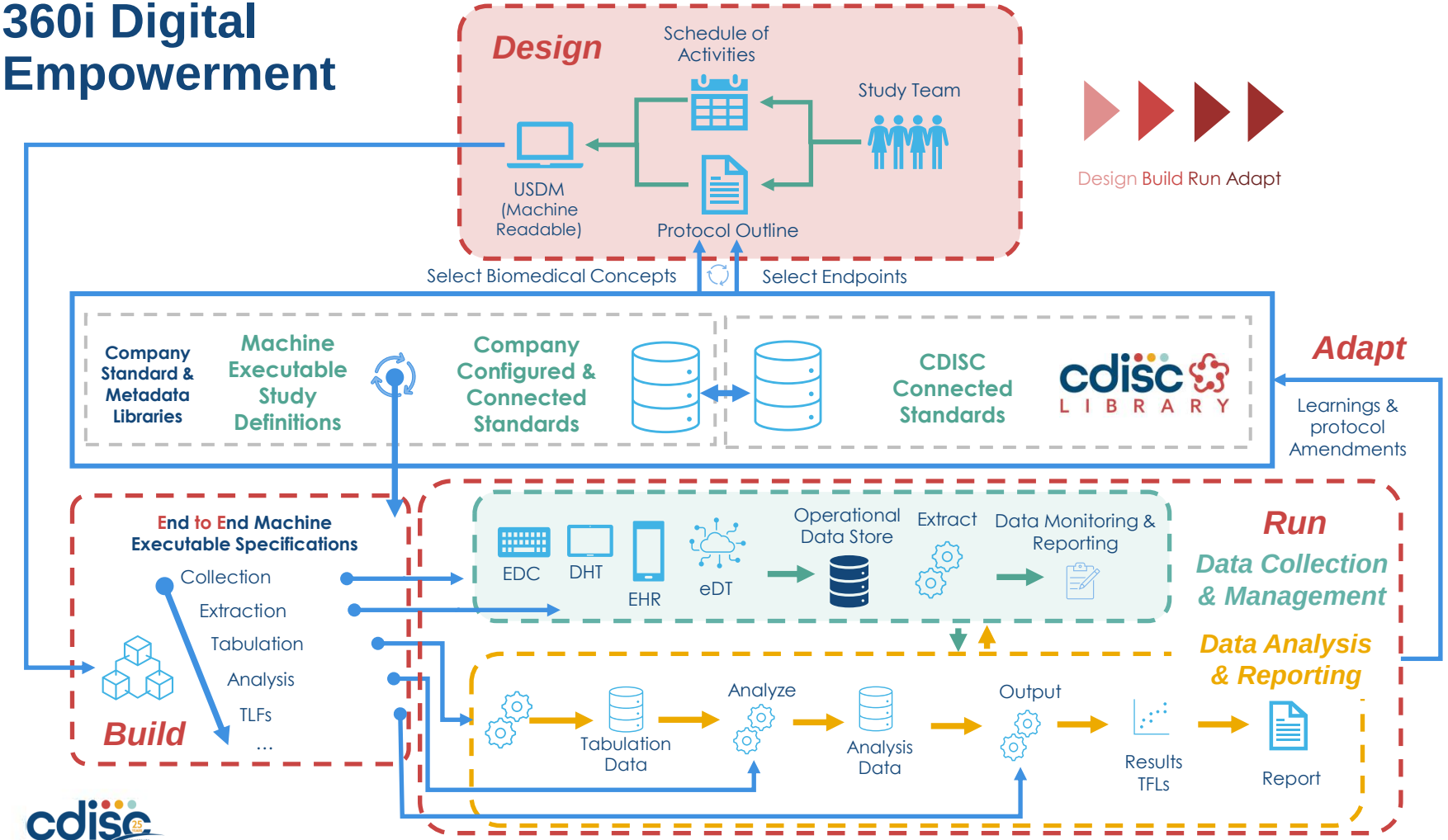
- Be part of the team to drive this forward
- We need committed contributors AND…companies that support the goal
- QR Code below to volunteer
- Make sure to select 360i from the list!

https://www.cdisc.org/volunteer

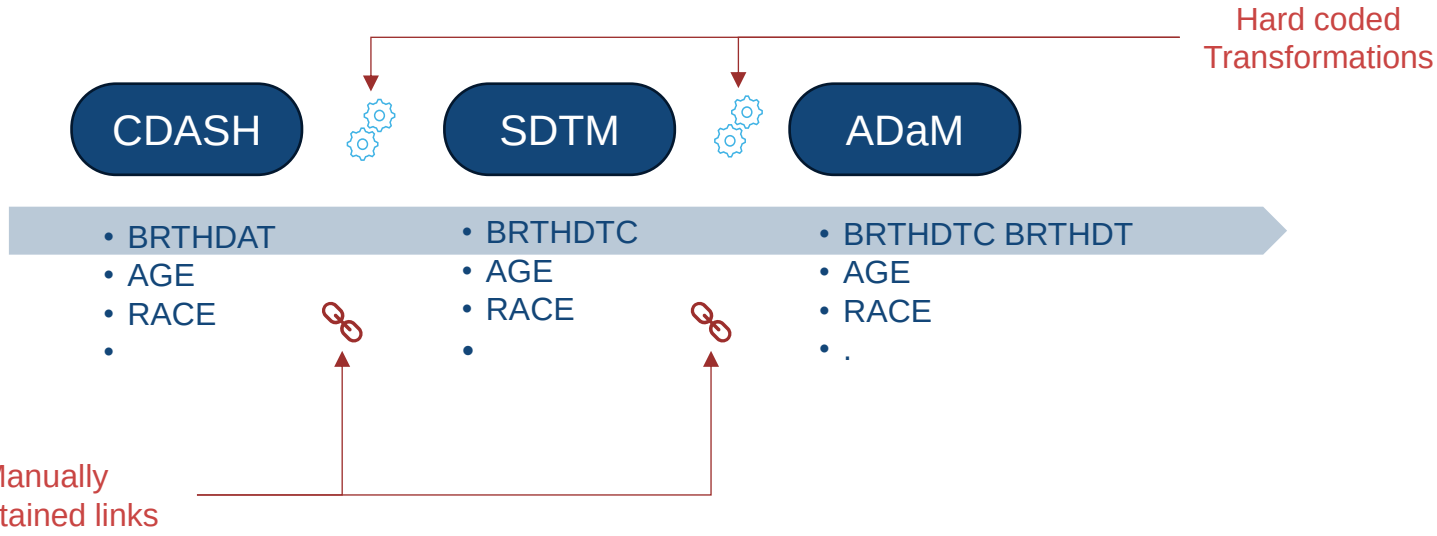
- ✓ Complete CDISC Volunteer Form
- ✓ Complete 360i Contributor Survey

Change is the only constant in life.
One's ability to adapt to those changes
will determine your success in life.
Benjamin Franklin
quotefancy

# 360i Digital Empowerment



# Standards Mapping - TODAYS



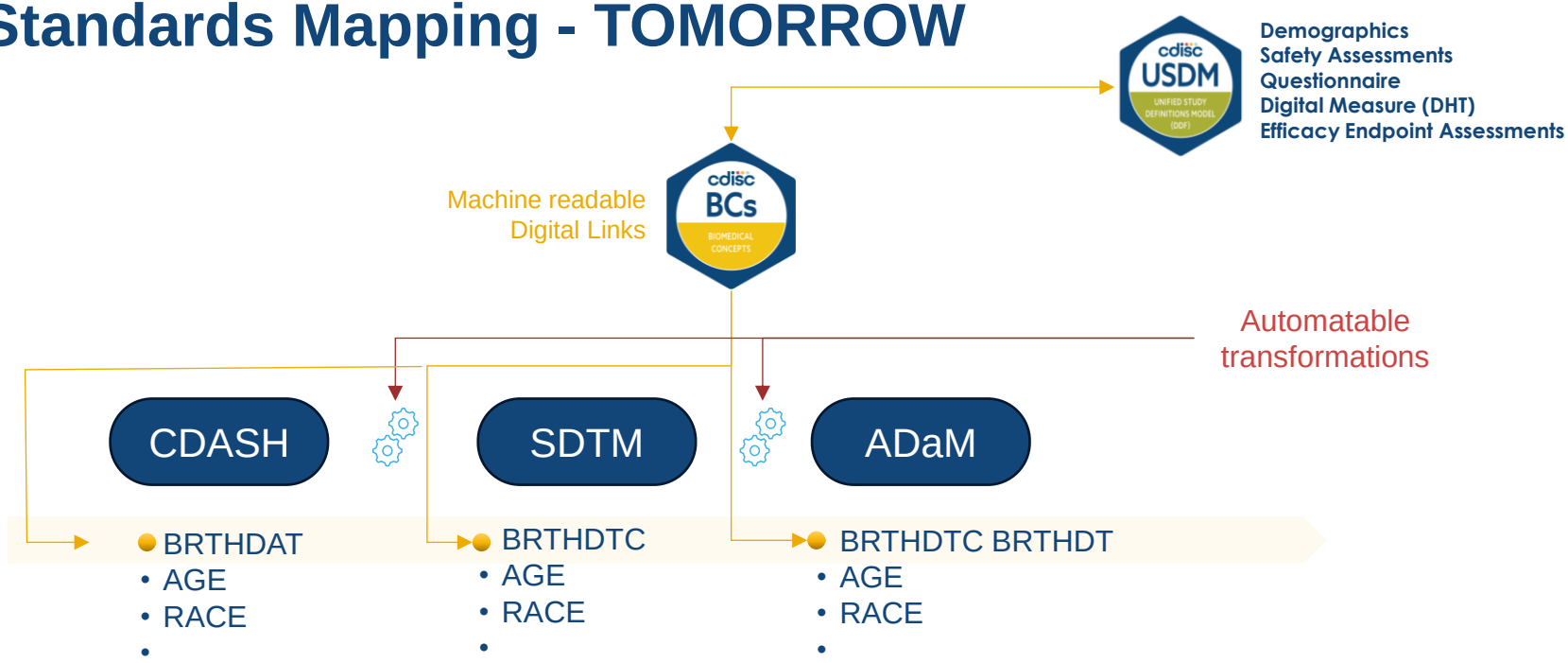

**Non**
machine-readable
References & Guides

CDASH Model v1.3

SDTMIG v3.4

ADaMIG v1.3

# Standards Mapping - TOMORROW



# Standards Mapping – VISION

Demographics
Safety Assessments
Questionnaire
Digital Measure (DHT)
Efficacy Endpoint Assessments

Hepatic BC Query

DATA

- Date Of Birth
- Age
- AE Verbatim
- AE Start Date
- AE End Date
- AE Severity
- Medications
- Labs Values
- ..

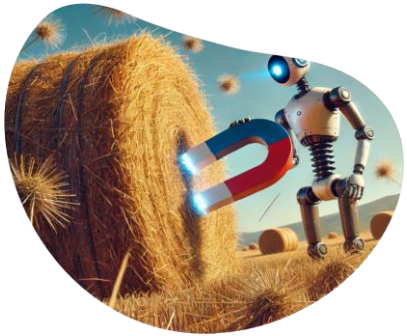
Filters & Triggers

- > Over 50 (T)
- SMQ (Hepatic Disorders) (F & T)
- Moderate & Severe (F)
- Who DD Query (Hepatic) (F)
- LOINC Codes (Hepatic) (F)

Auto Generated
Data Reviews Solutions

CDASH
SDTM
ADaM

# Standards Mapping – VISION



PROTOCOL

cdisc USDM UNIFIED STUDY DEFINITIONS MODEL (DDF)

DATA DRIVEN ACTIONS

DATA

cdisc BCs BIOMEDICAL CONCEPTS

Hepatic Alerts

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# PANEL DISCUSSION – Q&A

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