



cdisc® 2026 Europe Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



MILAN, ITALY | MAIN CONFERENCE: 20-21 MAY | TRAININGS & WORKSHOPS: 18, 19, & 22 MAY

Digital Therapeutic Area User Guides: A Modern Approach to Developing CDISC Standards

Bess LeRoy, Principal Director, CDISC

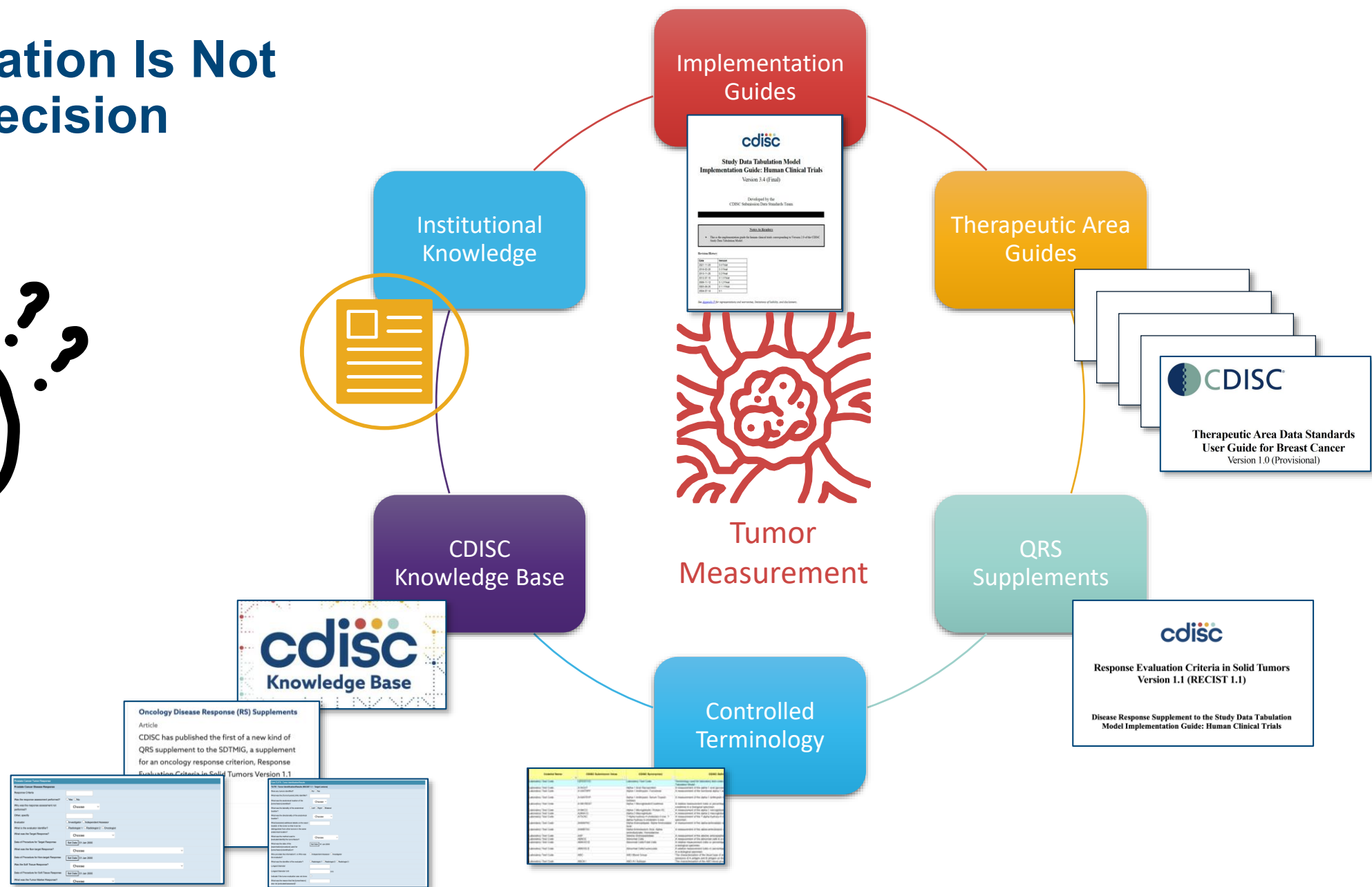
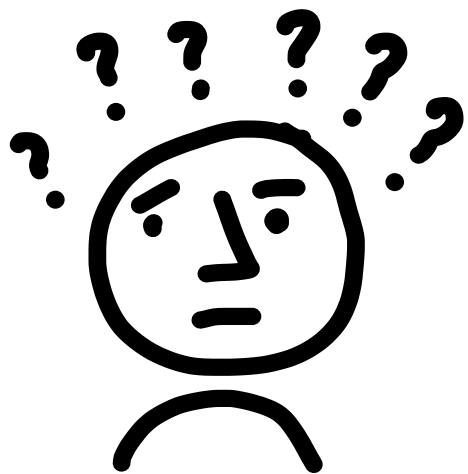


Agenda

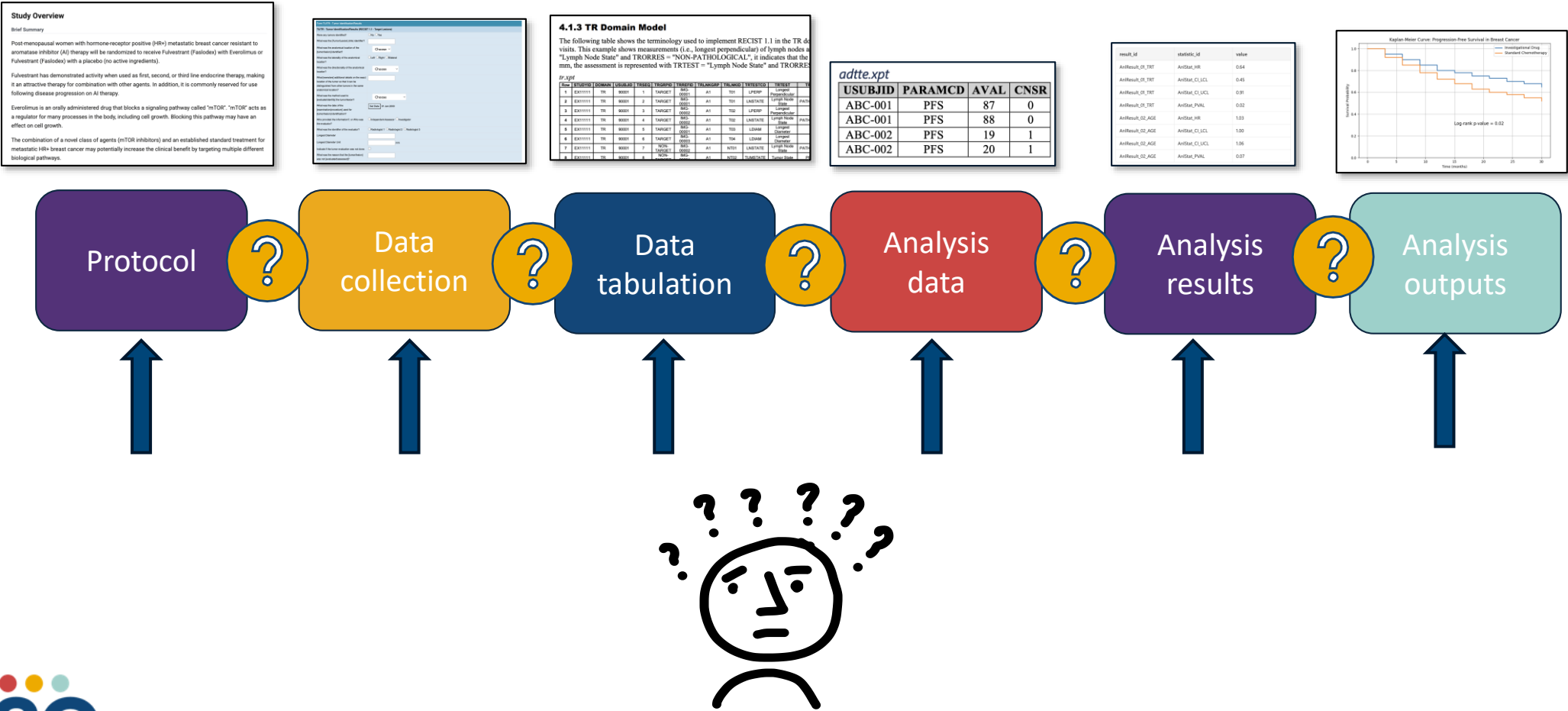
1. Why Meaning Matters
2. What Therapeutic Areas User Guides Were Designed to Solve
3. Putting Meaning First
4. Art of the Possible



Representation vs Meaning



Meaning Does Not Explicitly Flow Across the Data Lifecycle



Consequences of Focusing on Representation First

Heavy reliance on expert interpretation at each stage with a focus on mapping

- Increases unnecessary variability
- Increases barriers to adoption

Context and intent are not explicitly linked from protocol through analysis

- Limits automation despite standards at each stage
- Challenges in establishing traceability
- Limits tool development



What Therapeutic Areas User Guides Were Designed to Solve



Therapeutic Areas User Guides (TAUGs)

Autoimmune

Psoriasis
Rheumatoid Arthritis

Cardiovascular

Cardiovascular
Heart Failure
QT Studies
Traditional Chinese Medicine - Coronary Artery Disease-
Angina

Endocrine

Acute Kidney Injury
Diabetes
Diabetes Type 1 - Exercise and Nutrition
Diabetes Type 1 - Pediatrics and Devices
Diabetes Type 1 - Screening, Staging and Monitoring of
Pre-clinical Type 1 Diabetes
Diabetic Kidney Disease
Dyslipidemia
Kidney Transplant
Polycystic Kidney Disease

Gastrointestinal

CDAD
Crohn's Disease

Infectious

COVID-19
Ebola
Hepatitis C
HIV
Influenza
Malaria
Tuberculosis
Virology

Mental Health

Major Depressive Disorder
Post Traumatic Stress Disorder
Schizophrenia

Neurology

Alzheimer's
Huntington's Disease
Multiple Sclerosis
Parkinson's Disease
Traumatic Brain Injury

Oncology

Breast Cancer
Colorectal Cancer
Lung Cancer
Pancreatic Cancer
Prostate Cancer

Other

Nutrition
Pediatrics
Traditional Chinese Medicine - Acupuncture

Rare Diseases

Duchenne Muscular Dystrophy
Rare Diseases

Respiratory

Asthma
COPD
COVID-19

Treatments

Pain
Vaccines

TAUGs extend the CDISC Foundational Standards to represent data that pertains to specific disease areas

Increased focus on concepts

How TAUGs Evolved

2009-2010

- Concept Maps (*Cmaps)
- SDTM Examples
- Controlled Terminology

2011-2014

- Addition of CDASH CRF Examples

2015-2018

- Addition of ADaM Examples

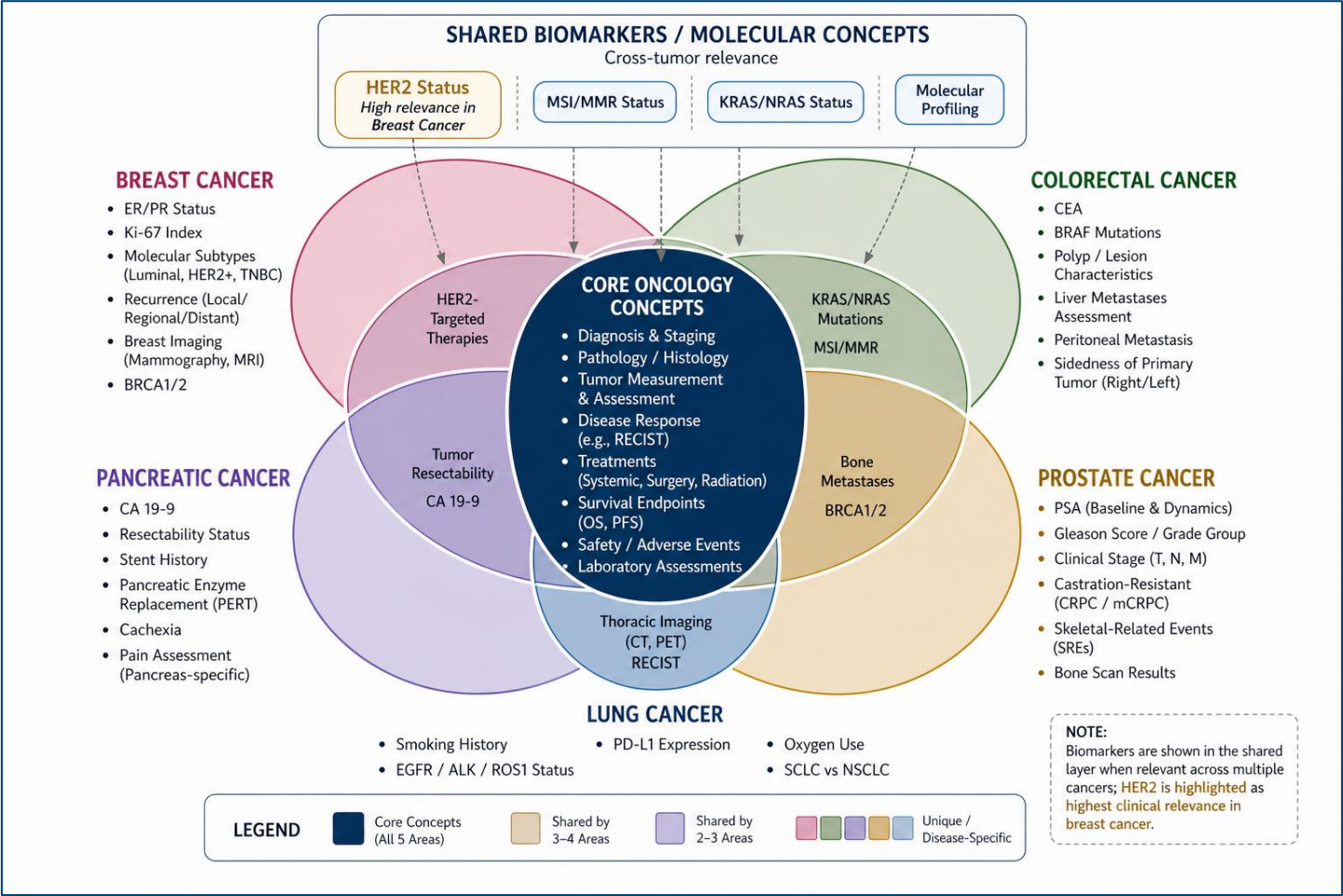
2019-Present

- Full end-to-end standards alignment

TAUGs In Practice



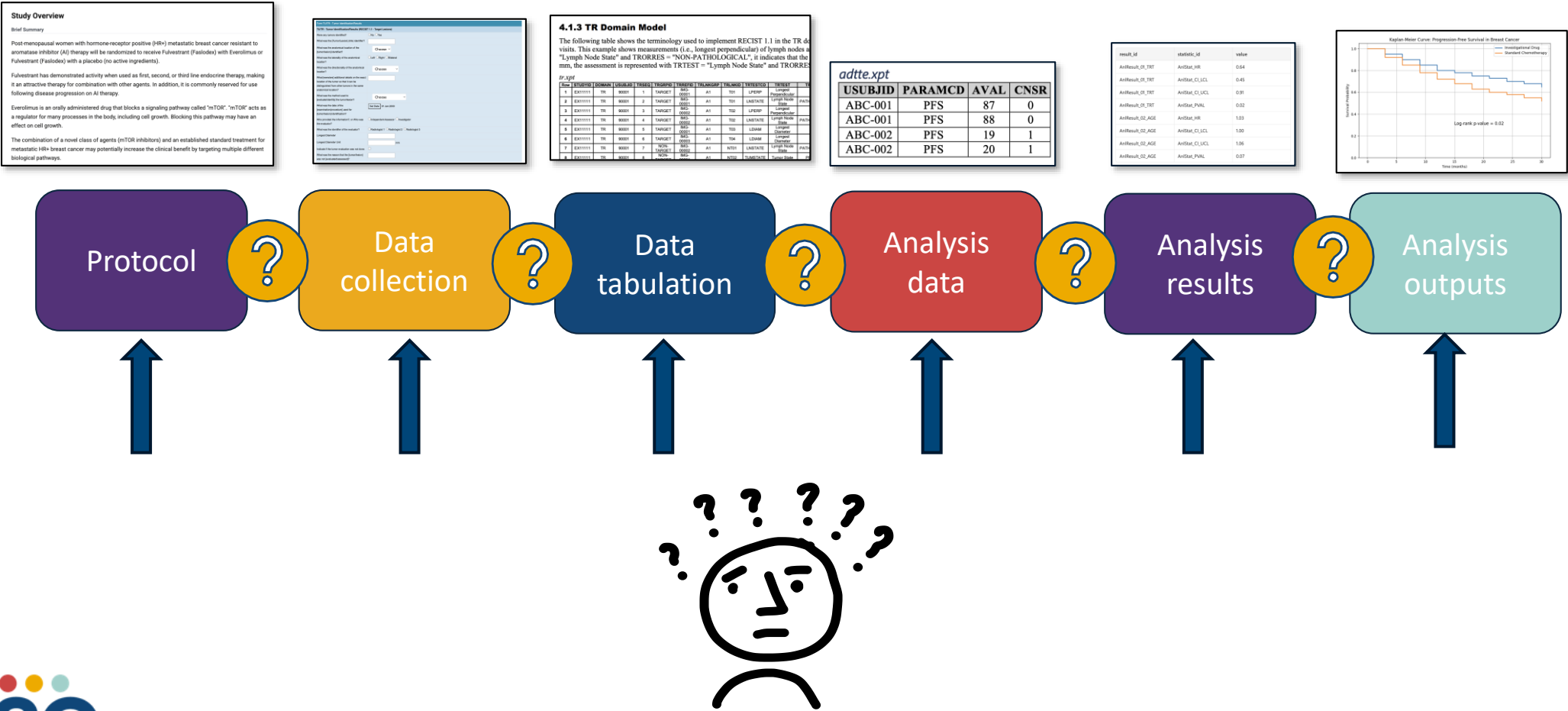
Shared and Indication-Specific Oncology Concepts Across CDISC TAUGs



Approximately 75% of oncology concepts in TAUGs are reusable across at least two areas

Approximately 25% are cancer-specific

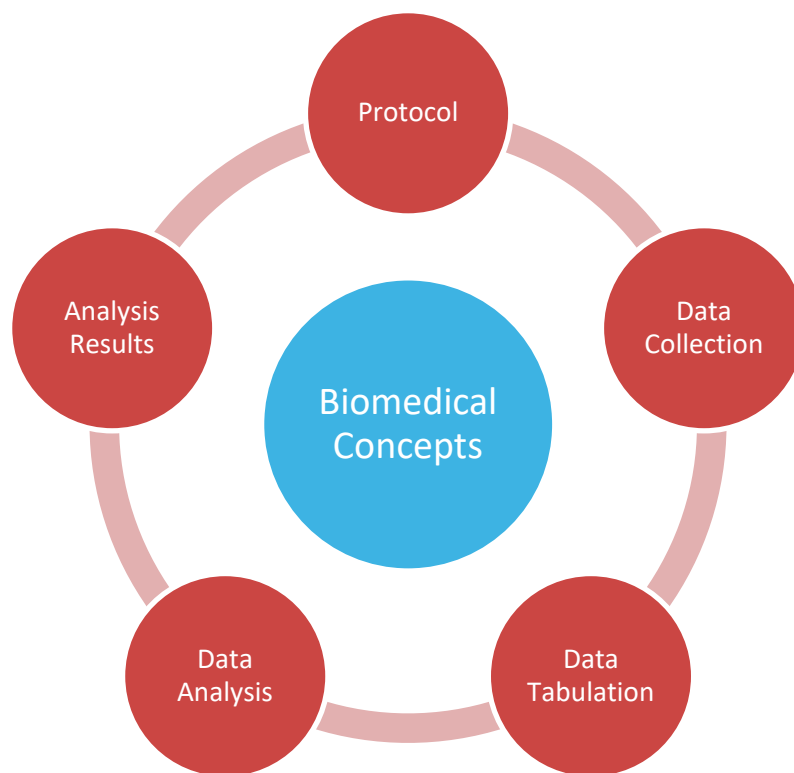
TAUGs Did Not Solve Meaning Flow





Shifting to Meaning First

Biomedical Concepts Anchor Clinical Meaning



Biomedical Concepts define clinical meaning once, and that meaning flows consistently into protocol design, data collection, data tabulation, analysis datasets, and analysis results

CDISC Biomedical Concepts

Conceptual Layer

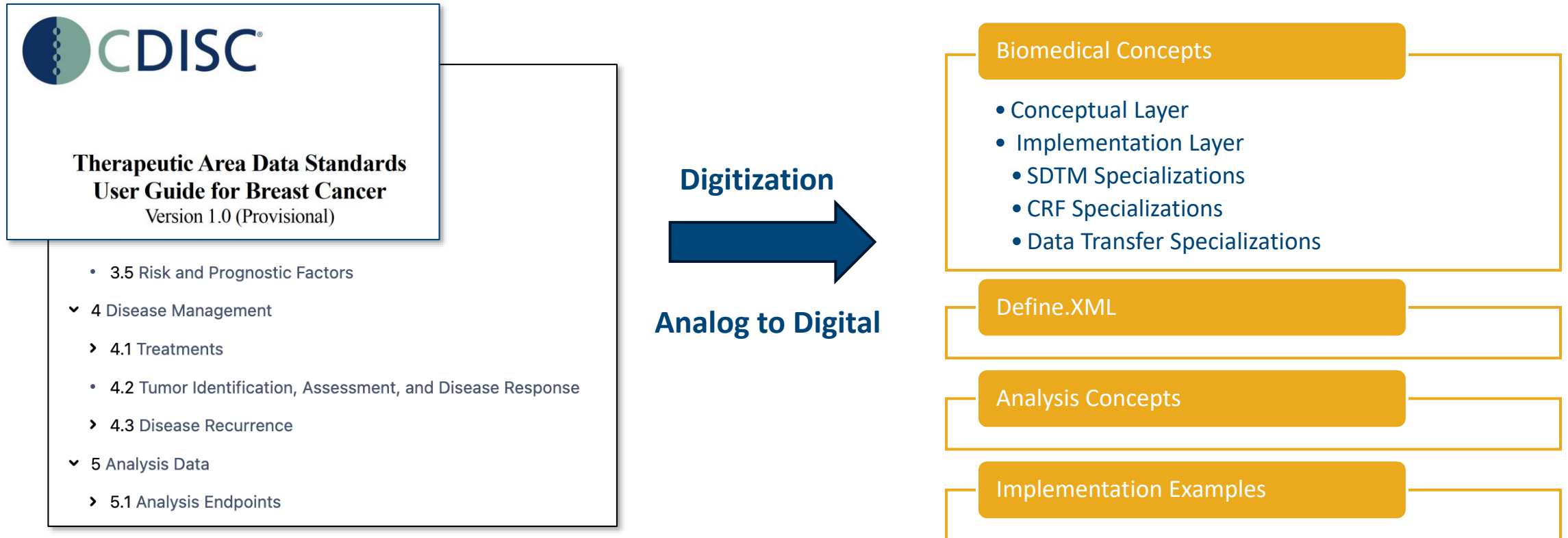
- Clinical meaning
- Description of the concept in the real world
- Independent of a study and data standards

Implementation Layer

- Representation of the concept in a specific a Data Standard (e.g., CDASH, SDTM, FHIR, OMOP, etc.)



Creating Digital Assets Lays the Groundwork for Digitalization



Digitalization uses Digital Assets to Improve How We Work

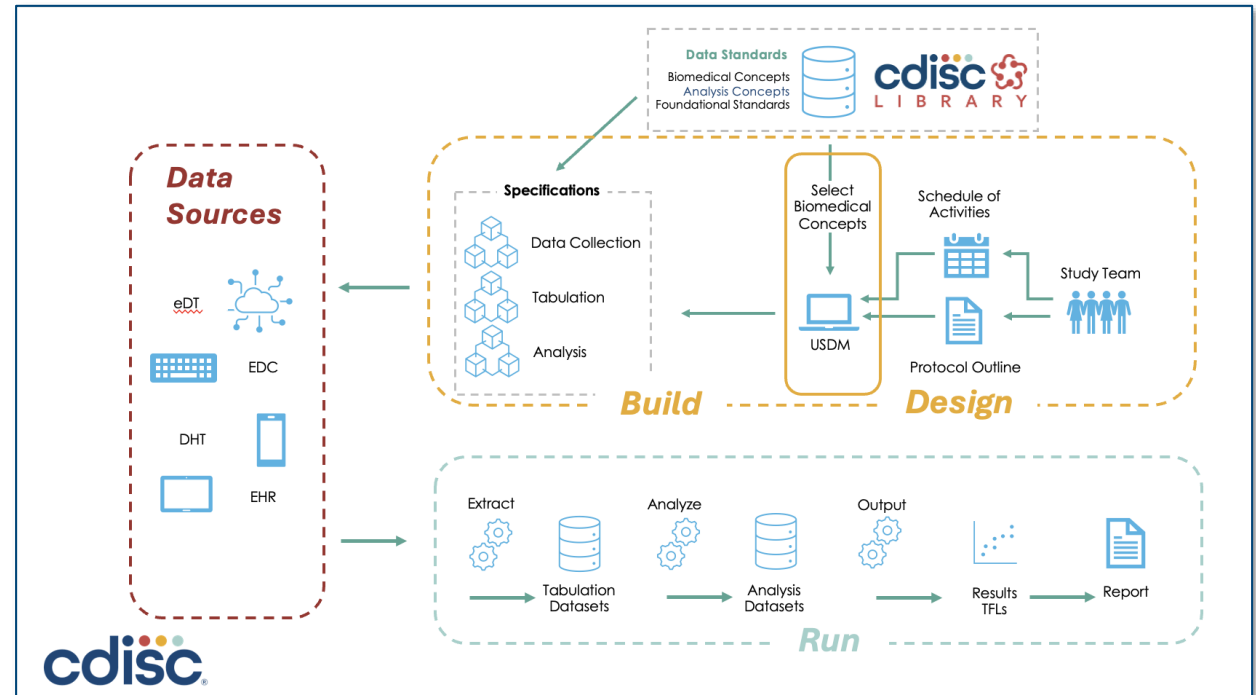
Biomedical Concepts

- Conceptual Layer
- Implementation Layer
 - SDTM Specializations
 - CRF Specializations
 - Data Transfer Specializations

Define.XML

Analysis Concepts

Implementation Examples



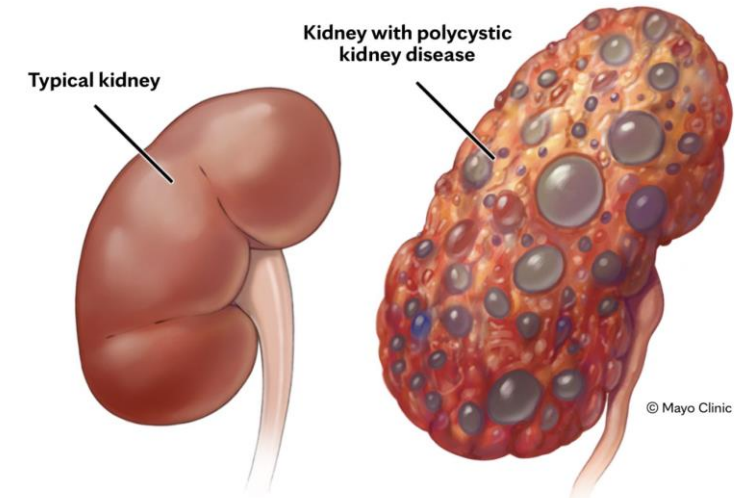




Art of the Possible for Digital TAUGs

Configuring Analysis-Informed Standards for a PKD Registry

- I am a researcher studying Polycystic Kidney Disease (PKD), a genetic disorder affecting kidney function that currently has no cure
- My goal is to set up a disease registry to collect data in an observational setting to understand disease characteristics, disease progression, treatment patterns, and outcomes over time
- My data collection plan is flexible and evolving and while I have hypotheses I would like to test, my analysis plan is not fixed
- I am interested in using CDISC Standards but as an academic researcher, I don't have the same years of experience with data standards as someone working in the pharmaceutical industry



Source: <https://mcpress.mayoclinic.org/polycystic-kidney-disease>



DIGITAL TAUGS

Study Standards Configuration

1 Select Therapeutic Area

2 Select Disease

3 Select Concepts

4 Configure Concepts

5 Schedule of Activities

6 Analyses

7 Analysis Readiness

8 Outputs

Study Snapshot

TA: —

Disease: —

Concepts: 0

Analyses: 0



CDISC DIGITAL TAUGS

Study Standards Configuration

Step 1 of 8

Select Therapeutic Area

Choose a therapeutic area to scope the study standards flow.

Oncology

Neurology

Cardiovascular

Renal/Nephrology

Infectious Diseases

Gastroenterology

← Back

Next →



Thank You!





CDISC
Digital TAUG Prototype

DIGITAL TAUGS

Study Standards Configuration

1 Select Therapeutic Area

2 Select Disease

3 Select Concepts

4 Configure Concepts

5 Schedule of Activities

6 Analyses

7 Analysis Readiness

8 Outputs

Study Snapshot

TA: Renal/Nephrology

Disease: Polycystic Kidney Disease

Concepts: 0

Analyses: 0

Study Standards Package Configuration



CDISC DIGITAL TAUGS

Study Standards Configuration

Step 1 of 8

Select Therapeutic Area

Choose a therapeutic area to scope the study standards flow.

Oncology

Neurology

Cardiovascular

Renal/Nephrology ✓

Infectious Diseases

Gastroenterology

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DIGITAL TAUGS

Study Standards Configuration

☒ Select Therapeutic Area

2 Select Disease

3 Select Concepts

4 Configure Concepts

5 Schedule of Activities

6 Analyses

7 Analysis Readiness

8 Outputs

Study Snapshot

TA: **Renal/Nephrology**

Disease: **Polycystic Kidney Disease**

Concepts: **0**

Analyses: **0**

CDISC DIGITAL TAUGS

Study Standards Configuration

Step 2 of 8

Select Disease

Filtered by the selected therapeutic area.

Therapeutic Area: **Renal/Nephrology**

Chronic Kidney Disease

Acute Kidney Injury

Polycystic Kidney Disease

Kidney Transplant

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Next →

DIGITAL TAUGS

Study Standards Configuration

☒ Select Therapeutic Area

☒ Select Disease

3 Select Concepts

4 Configure Concepts

5 Schedule of Activities

6 Analyses

7 Analysis Readiness

8 Outputs

Study Snapshot

TA: Renal/Nephrology

Disease: Polycystic Kidney Disease

Concepts: 2

Analyses: 0

CDISC DIGITAL TAUGS

Study Standards Configuration

Step 3 of 8

Select Concepts

Select the study assessment concepts relevant to this protocol.

Path: Renal/Nephrology / Polycystic Kidney Disease

Search concepts

IMAGING CONCEPTS

☒ Kidney Volume

☐ Cyst Volume

☐ Cyst Size

KIDNEY FUNCTION CONCEPTS

☒ eGFR

☐ Serum Creatinine

☐ Urine Protein

CORE STUDY CONCEPTS

☐ Demographics

☐ Vital Signs

☐ Medical History



CDISC
Digital TAUG Prototype

DIGITAL TAUGS

Study Standards Configuration

☒ Select Therapeutic Area

☒ Select Disease

☒ Select Concepts

4 Configure Concepts

5 Schedule of Activities

6 Analyses

7 Analysis Readiness

8 Outputs

Study Snapshot

TA: Renal/Nephrology

Disease: Polycystic Kidney Disease

Concepts: 2

Analyses: 0

Study Standards Package Configuration • Polycystic Kidney Disease • Renal/Nephrology

CDISC DIGITAL TAUGS

Study Standards Configuration

Step 4 of 8

CRF Preview

Kidney Volume

Blank CDASH-style CRF preview — choices visible, none selected

Visit: Baseline

Mode: Read-only

[Reset](#)

Laterality

Allowed values shown (unchecked).

[unchecked choices]

- ☐ Bilateral
- ☐ Right
- ☐ Left

Imaging Modality

Allowed values shown (unchecked).

[unchecked choices]

- ☐ MRI
- ☐ CT
- ☐ Ultrasound

Calculation Method

Allowed values shown (unchecked).

[unchecked choices]

- ☐ Ellipsoid
- ☐ Stereology

Units

Dropdown shown even if only one unit is available.

mL (fixed)

Result

Numeric value to be entered later.

[data entry field]

This preview intentionally shows no selections.

DIGITAL TAUGS

Study Standards
Configuration

- ☒ Select Therapeutic Area
- ☒ Select Disease
- ☒ Select Concepts
- ☒ Configure Concepts

- 5 Schedule of Activities
- 6 Analyses
- 7 Analysis Readiness
- 8 Outputs

Study Snapshot

TA: Renal/Nephrology
Disease: Polycystic Kidney Disease
Concepts: 2
Analyses: 0

CDISC DIGITAL TAUGS
Study Standards Configuration

Step 5 of 8

Schedule of Activities

Fixed visit structure with checkbox scheduling per concept.

CONCEPT	SCREENING	BASELINE	MONTH 3	MONTH 6
Kidney Volume	☐	☐	☐	☐
eGFR	☐	☐	☐	☐

← Back

Next →

DIGITAL TAUGS

Study Standards Configuration

- ☒ Select Therapeutic Area
- ☒ Select Disease
- ☒ Select Concepts
- ☒ Configure Concepts
- ☒ Schedule of Activities

6 Analyses

7 Analysis Readiness

8 Outputs

Study Snapshot

TA: Renal/Nephrology

Disease: Polycystic Kidney Disease

Concepts: 2

Analyses: 2

CDISC DIGITAL TAUGS

Study Standards Configuration

Step 6 of 8

Analyses

Choose the planned analyses for this study.

Imaging-Based Analyses

☒ Change from baseline in total kidney volume

☐ Annualized growth rate

☐ Slope analysis

Kidney Function Analyses

☐ eGFR decline over time

☐ Time to 30% decline in eGFR

☒ Time to ESRD

☐ Change in blood pressure

DIGITAL TAUGS

Study Standards Configuration

- ☒ Select Therapeutic Area
- ☒ Select Disease
- ☒ Select Concepts
- ☒ Configure Concepts
- ☒ Schedule of Activities
- ☒ Analyses

7 Analysis Readiness

8 Outputs

Study Snapshot

TA: Renal/Nephrology

Disease: Polycystic Kidney Disease

Concepts: 2

Analyses: 2

CDISC DIGITAL TAUGS

Study Standards Configuration

Step 7 of 8

Analysis Readiness

Rule-based readiness results for the selected analyses.

✓ Change from baseline in total kidney volume

- ☒ Baseline visit defined
- ☒ Longitudinal timepoints available
- ☒ Image modality specified
- ☒ Units standardized (mL)

⚠ Time to ESRD

- ☐ ESRD event definition not selected
- ☐ Event data not scheduled
- ☐ Disposition tracking not included

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DIGITAL TAUGS

Study Standards Configuration

- ☒ Select Therapeutic Area
- ☒ Select Disease
- ☒ Select Concepts
- ☒ Configure Concepts
- ☒ Schedule of Activities
- ☒ Analyses
- ☒ Analysis Readiness

8 Outputs

Study Snapshot

TA: **Renal/Nephrology**
Disease: **Polycystic Kidney Disease**
Concepts: 2
Analyses: 2



CDISC DIGITAL TAUGS

Study Standards Configuration

Step 8 of 8

Outputs

Users choose which artifacts and standards to include in the generated package.

Summary

Concepts	2
Analyses	2
Readiness	Rule-based

Generated Artifacts

- ☒ Biomedical Concept Set
- ☒ Annotated CRFs



Package Generated

Your selected outputs are ready for download.

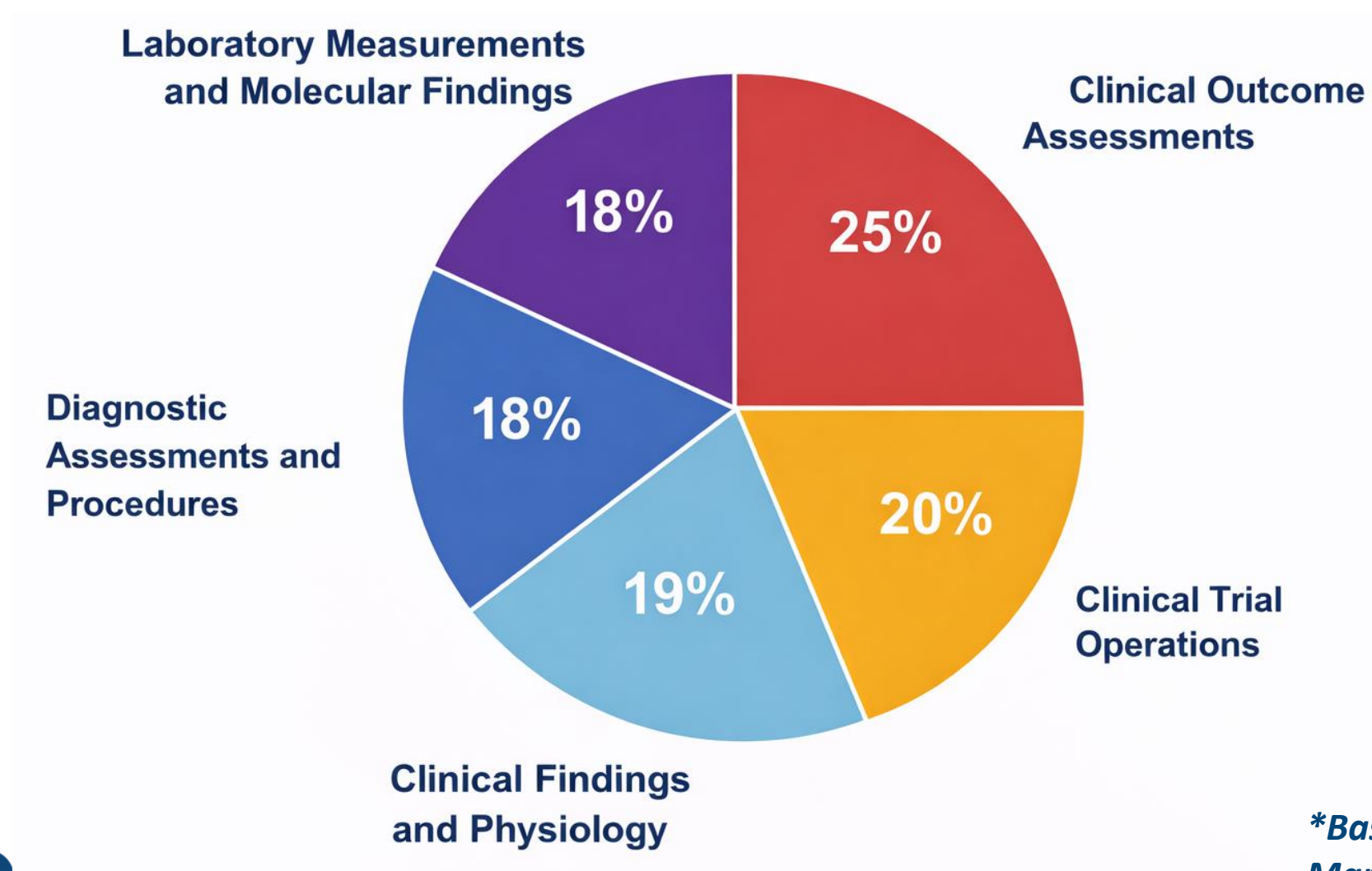
Close

- ☒ ADaM

- ☒ ARS

↓ Download Package

Current BC Content in the CDISC Library



**Based on ~1300 BCs
March 31st, 2026*