



CDISC Biomedical Concepts for Breast Cancer: A CDISC 360i Perspective DS 17

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1. Biomedical Concepts
2. Oncology and Breast Cancer Biomedical Concepts
3. Leveraging Biomedical Concepts in CDISC 360i

Background

- Biomedical concepts serve as the essential semantic framework that connects and aligns various foundational standards in clinical research
- These concepts provide a common language for representing critical clinical trial data, ensuring consistency, accuracy, and interoperability across systems
- By linking key standards such as SDTM, ADaM, ARS ,and CDISC's Unified Study Definitions Model (USDM), biomedical concepts enable seamless data flow and support regulatory compliance across platforms
- Up until recently, the sourcing for biomedical concepts has primarily focused on common safety concepts; CDISC 360i provides an opportunity to explore using therapeutic area concepts to illustrate end to end connectivity

Moving Toward Biomedical Concepts



Part of the overarching CDISC vision enabling **connected standards**



Facilitates **accurate** and **more consistent implementation** by reducing unnecessary variability



Facilitates **metadata-driven automation**

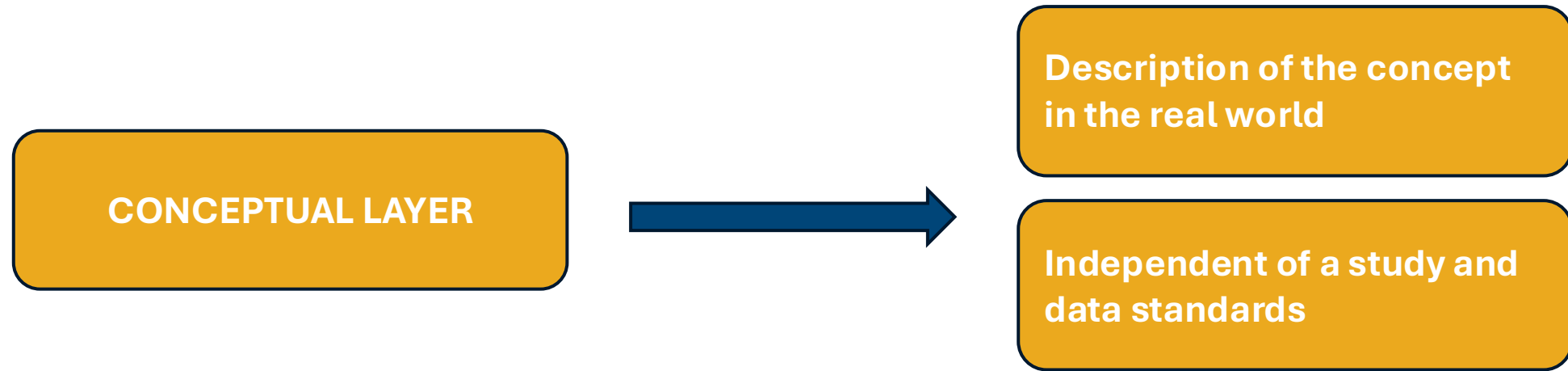


Increases **quality and efficiency** throughout end-to-end study delivery process

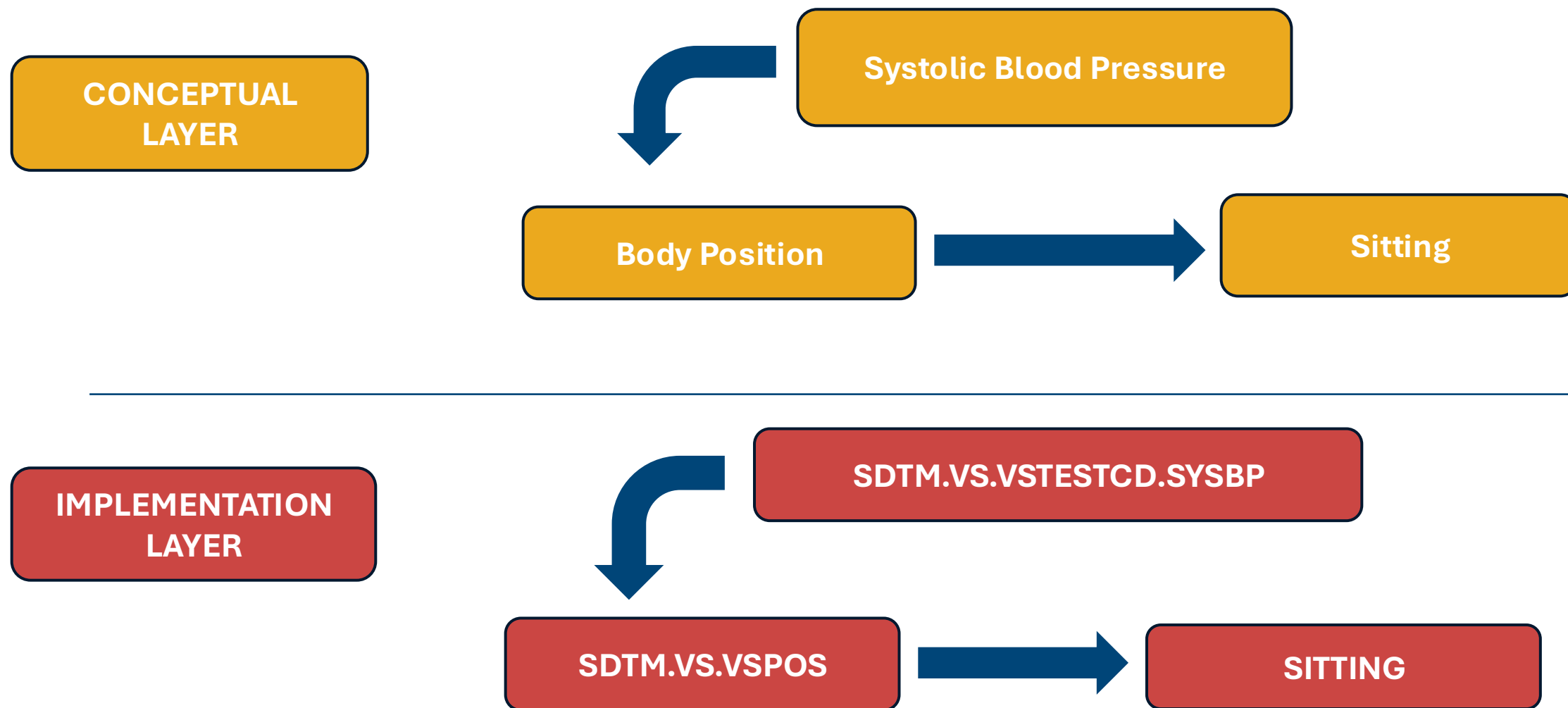


Enables **data reuse**

CDISC Biomedical Concept Structure



CDISC Biomedical Concept Example Illustrated



Accessing CDISC Biomedical Concepts

[About](#)[Standards](#)[Tools](#)[Partnerships](#)[Education](#)[Events](#)[Membership](#)[Members Only](#)

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CDISC Biomedical Concepts

[Overview](#)[Resources](#)[Exports](#)[BC Browser](#)



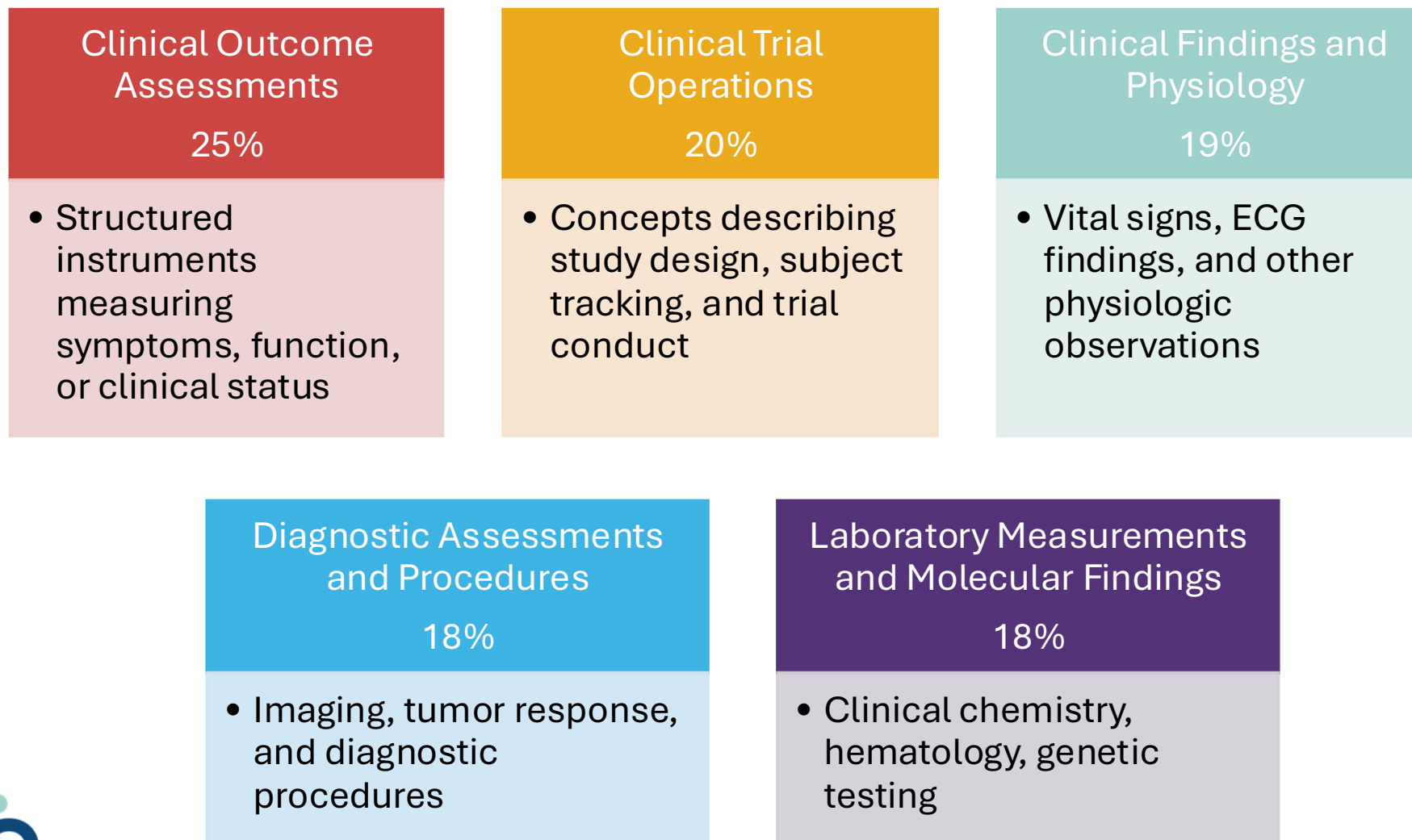
CDISC kicked off the Conceptual and Operational Standards Metadata Services (COSMoS) project in 2022, taking a pragmatic, iterative approach to creating biomedical concepts and representing them in the [Foundational Standards](#) as dataset specializations with Value Level Metadata definitions. Biomedical Concepts fill gaps in the current standards by adding semantics, variable relationships, and the detailed metadata needed to generate CRFs or [Define-XML](#).

CDISC Biomedical Concepts (BCs) include a two-layered approach.

- Conceptual/abstract layer that provides standards-agnostic, unambiguous semantic definition largely based on [NCIt](#) concepts.
- An implementation layer consisting of SDTM Dataset Specializations provides value level definition that facilitates metadata-driven automation.

The data model is flexible and can accommodate other standards (e.g., HL7 FHIR, etc.).

What Do CDISC BCs Currently Cover?





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

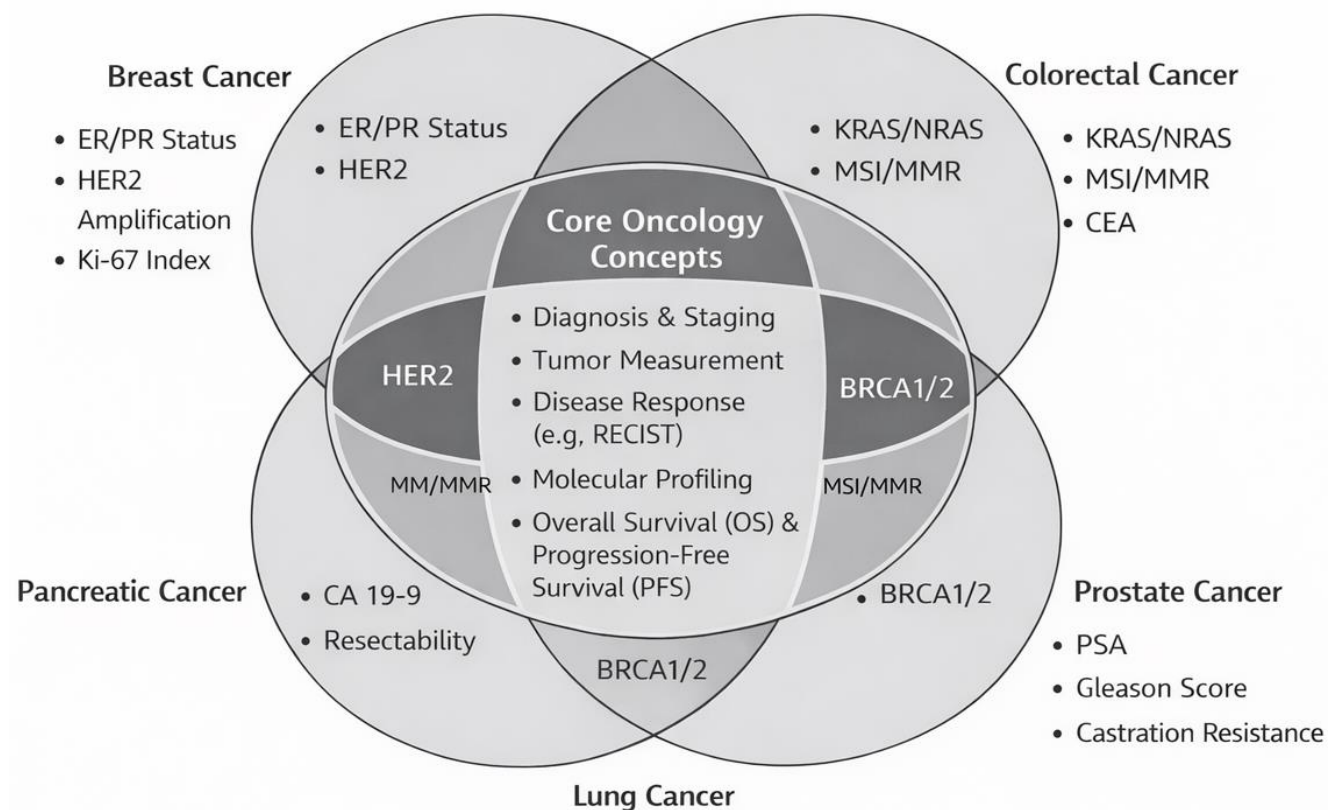
Pain
Vaccines

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

CDISC Oncology Therapeutic Area User Guides



Shared and Indication-Specific Oncology Concepts Across CDISC TAUGs



*Approximately 70–85% of **oncology** concepts in TAUGs are reusable across cancers, either universally or across solid tumors*

*Approximately 15–30% are **cancer-specific***

CDISC 360i



Design

- Define and digitalize end to end standards from study design endpoints through the analyses

Build

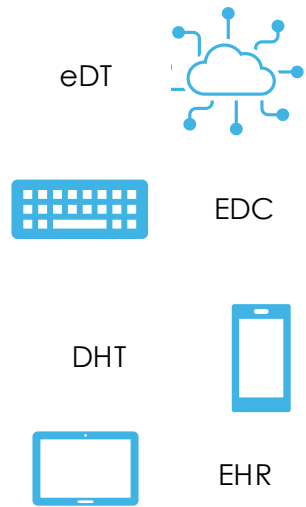
- Leverage those standards to accelerate the study design and build phase of the trial

Run

- Demonstrate the automated data flow from raw data source to the generation of the targeted result

360i Focus

Data Sources

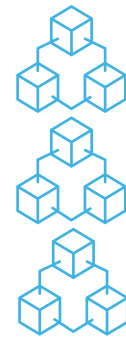


Data Standards
Biomedical Concepts
Analysis Concepts
Foundational Standards



cdisc
LIBRARY

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

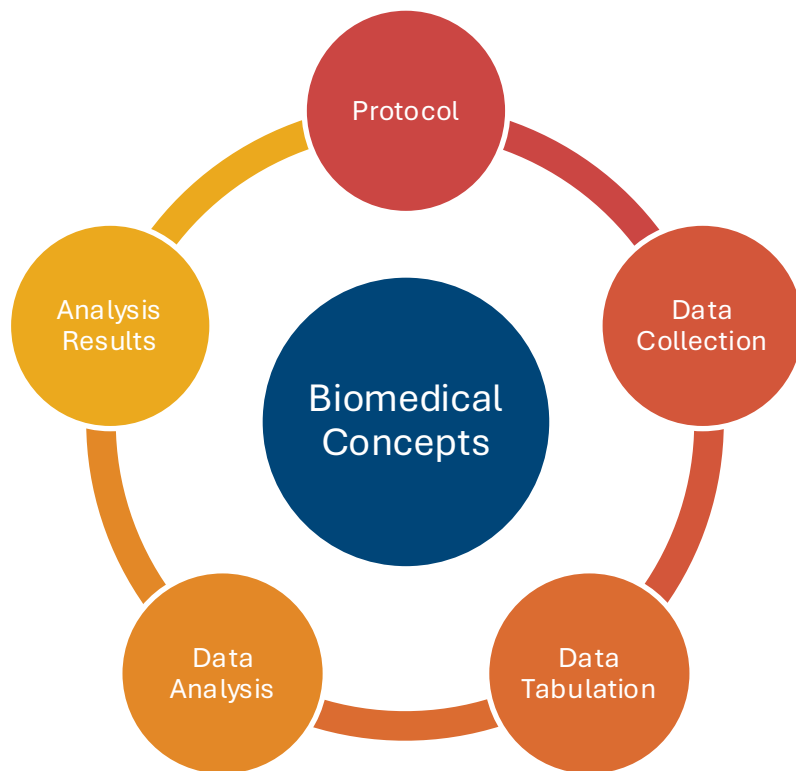


Results
TFLs



Report

Run



Biomedical Concepts Anchor CDISC 360i

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

Breast Cancer TAUG v2.0

✓ 3 Subject and Disease Characteristics

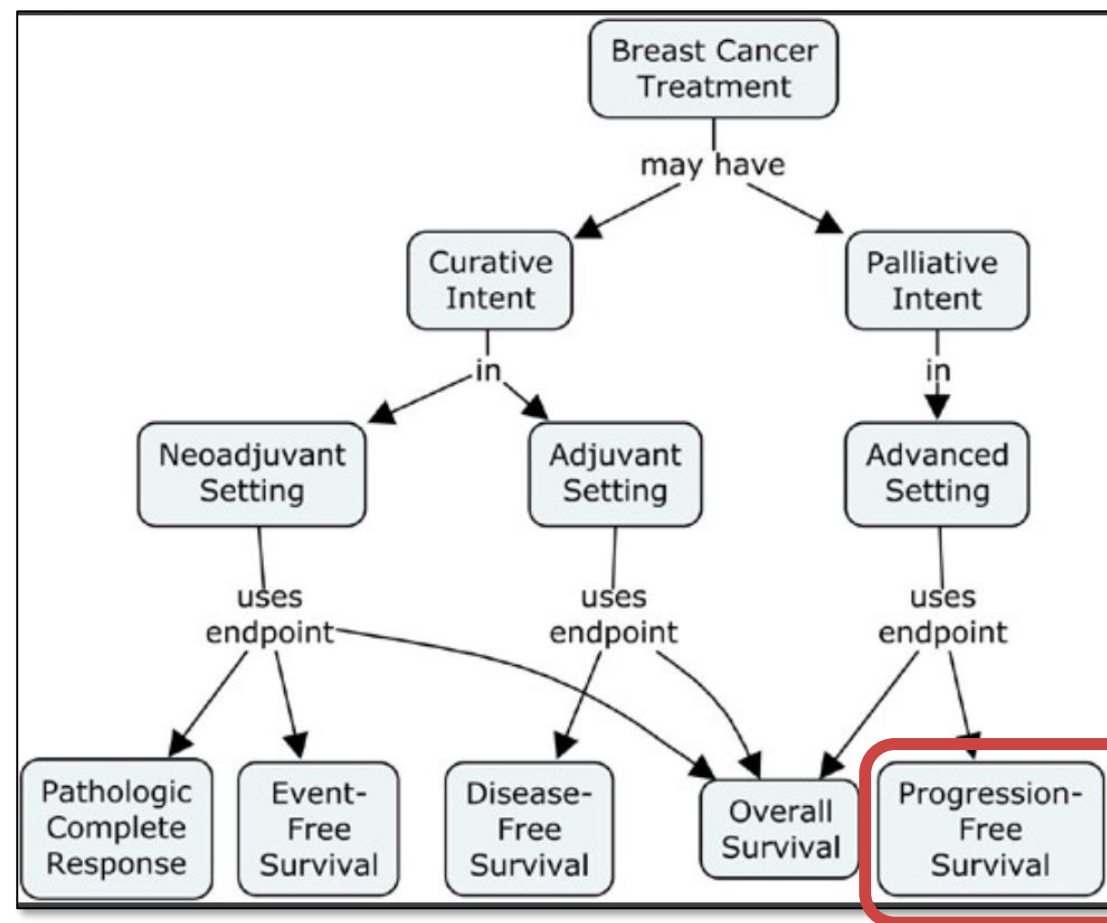
- 3.1 Diagnosis
- 3.2 Staging
- › 3.3 Pathology
- › 3.4 Prior Treatments
- 3.5 Risk and Prognostic Factors

✓ 4 Disease Management

- › 4.1 Treatments
- 4.2 Tumor Identification, Assessment, and Disease Response
- › 4.3 Disease Recurrence

✓ 5 Analysis Data

- › 5.1 Analysis Endpoints



BCs to Support Study Design

Study in advanced breast cancer that evaluates progression-free survival



ClinicalTrials.gov

VISITNUM	Visits	Study Day	Cycle	Treatment	AEs	Prior BrCa Treatments	Con Meds	Radiological Assessment	Randomization	Receptor Status, Stage
1	Baseline					x		x		x
2	Week 1	1	1	x	x		x		x	
3	Week 3	15	2	x	x		x			
4	Week 5	29	3	x	x		x			

Build a schedule of activities



Study Build: Define-XML

Define-XML is the machine-readable metadata file submitted with SDTM and ADaM datasets to regulators

SDTM Specialization

short_name	subject	data_type	length	format	significant_digits	m
Temperature	VSTESTCD					
Temperature	VSTEST					
Temperature	VSORRES	float	8	8.3		3

Define-XML

VS (Vital Signs) - [STDTMIG 3.3]

Variable	Where Condition	Label / Description	Type	Role	Length or Display Format
VSORRES VLM		Result or Finding in Original Units	text	Result Qualifier	8
	VSTESTCD = "TEMP" (Temperature)	Temperature	float		8

Study Build: Case Report Forms



short_name	bc_id	ncit_cod	bc_categories
Best Overall Response	C94536	C94536	Oncology Standards;Disease Response;Disease Response Criteria;Disease Response and Clinical Classification;RS;RECIST 1.1;iRECIST
New Lesion Indicator	C142362	C142362	Oncology Standards;Disease Response;Disease Response Criteria;Disease Response and Clinical Classification;RS;iRECIST;LUGANO CLASSIFICATION;RANO;IRANO 2015
Overall Response	C96613	C96613	Oncology Standards;Disease Response;Disease Response
Response in Non-Target Lesion	C94535	C94535	



Tumor Identification (RECIST 1.1 Classification) Normalized

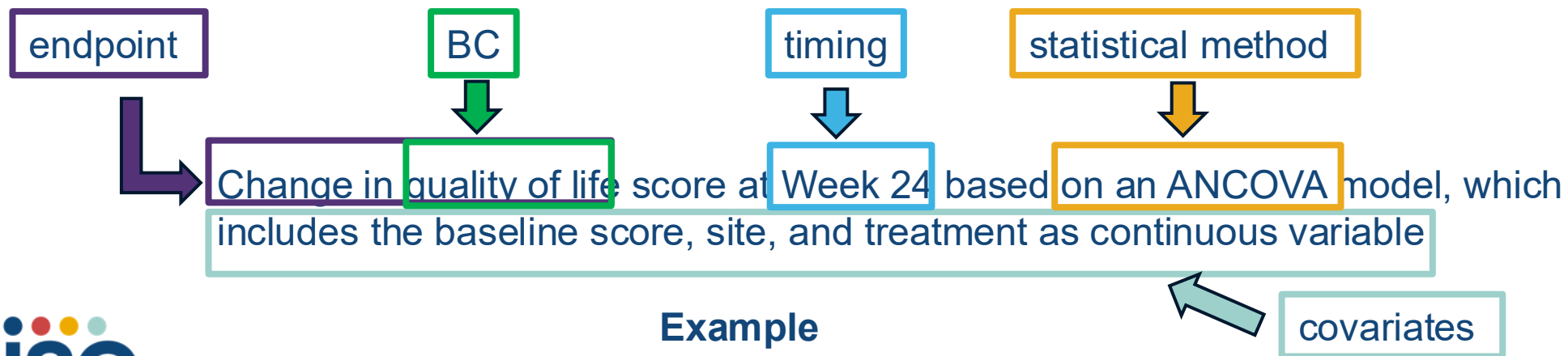
Tumor Identification (RECIST 1.1 Classification) Normalized
CDISC Biomedical Concept: C94523 (/mdr/bc/biomedicalconcepts/C94523)
CDISC SDTM Dataset Specialization: TUMIDENT_RECIST1_1 (/mdr/specializations/sdtm/datasetsspecializations/TUMIDENT_RECIST1_1)

* Date of Assessment	03/02/2026	TUDTC
* Tumor ID		TULNKID
* Tumor Identification Result	-- Select --	TUORRES;TUSTRESC <i>CodeList: TUIDRS (C123650)</i>
Anatomical Location	-- Select --	TULOC <i>CodeList: LOC (C74456)</i>
Laterality	-- Select --	TULAT <i>CodeList: LAT (C99073)</i>
Directionality	-- Select --	TUDIR <i>CodeList: DIR (C99074)</i>

Run: BCs Support Analysis Concepts



- Analysis Concepts
 - 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



Moving Toward Digital TAUGs

Text to provide context

Biomedical Concepts

- Conceptual BCs
- SDTM Specializations
- CRF Specializations
- Data Transfer Agreements

Define.xml

Analysis Concepts/TFL

Implementation Examples

TAUG-Breast Cancer v2.0 - Compiled

Created by Alana St. Clair, last modified on Mar 04, 2025

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1 INTRODUCTION

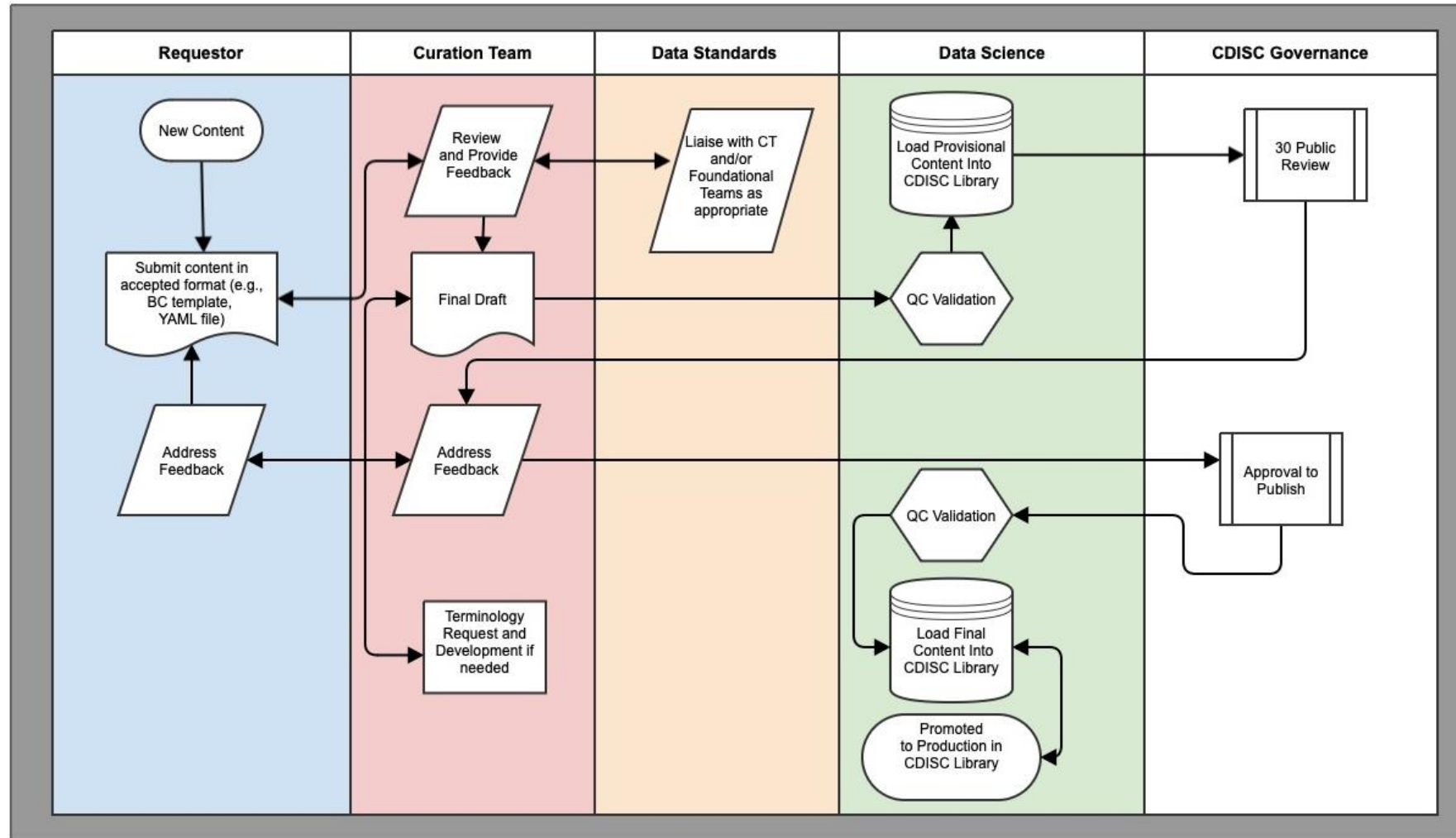
- 1.1 How to Read this Document (TBD)
- 1.2 Organization of this Document
- 1.3 Known Issues

2 OVERVIEW OF BREAST CANCER

3 SUBJECT AND DISEASE CHARACTERISTICS

- 3.1 Diagnosis
- 3.2 Staging
- 3.3 Pathology
 - 3.3.1 Examples for Pathology
- 3.4 Prior Treatments
 - 3.4.1 Examples for Prior Treatments
- 3.5 Risk and Prognostic Factors

BC Development Process and Addendum to COP-001



Summary

Biomedical concepts act as semantic glue

360i depends on a computable concept layer

Breast cancer provides a scalable model and will help to inform the framework for future TAUGs

The future is model-driven, not document-driven