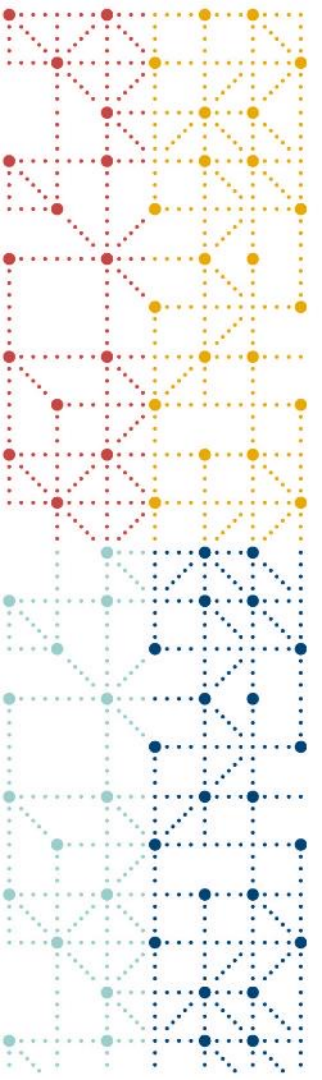




The Development of CDISC Biomedical Concepts: Update and Next Steps

Bess LeRoy, Head of Standards Innovation, CDISC

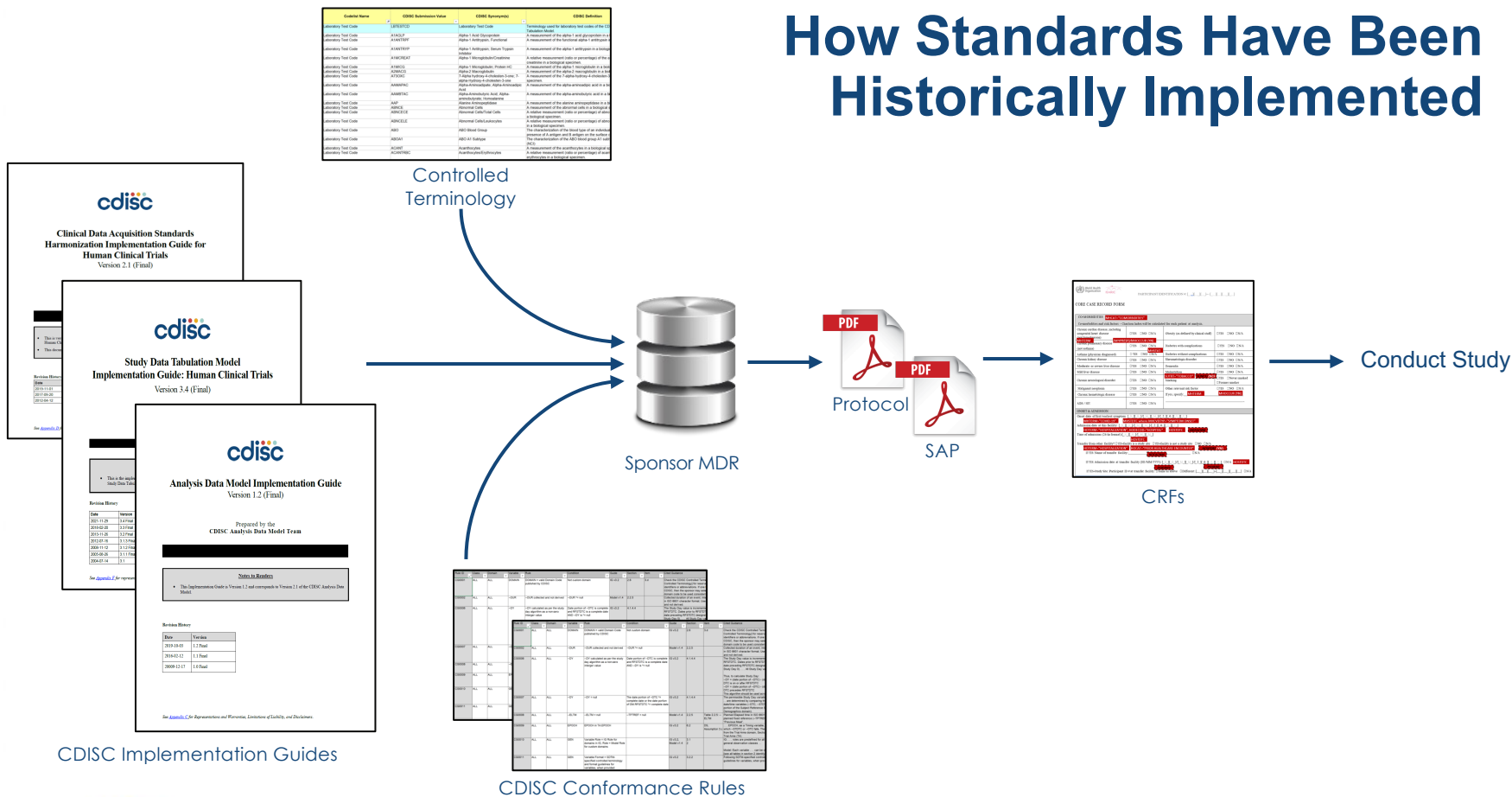




Agenda

1. Background
2. CDISC COSMoS: Conceptual & Operational Standards Metadata Services
3. Looking Towards the Future

How Standards Have Been Historically Implemented





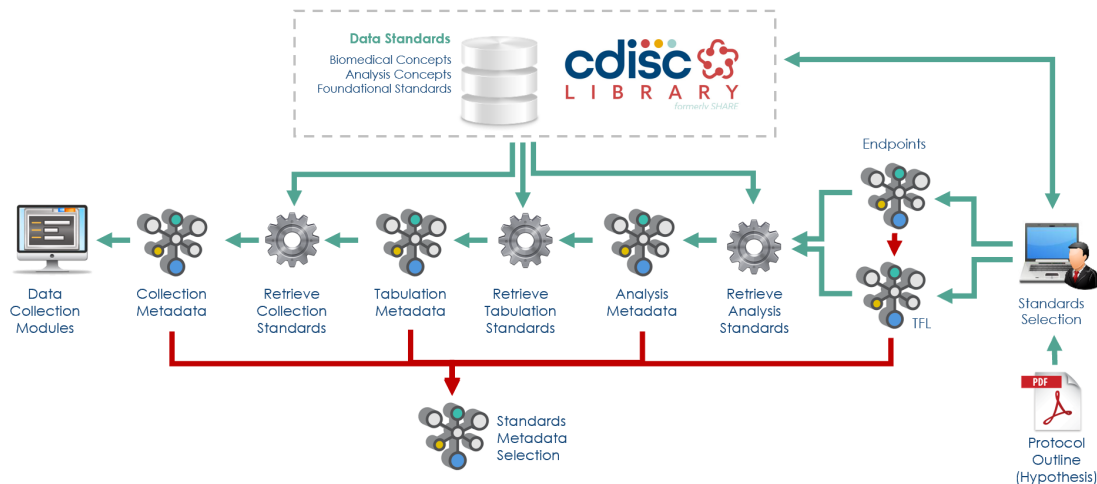
The Problem with This Approach

- Labor-intensive; requires extensive knowledge of standards documents
- Subject to interpretation (and therefore, *misinterpretation*)
- Can result in inconsistent implementation

The intense effort required is a barrier to standards adoption

How We Evolve: CDISC Library

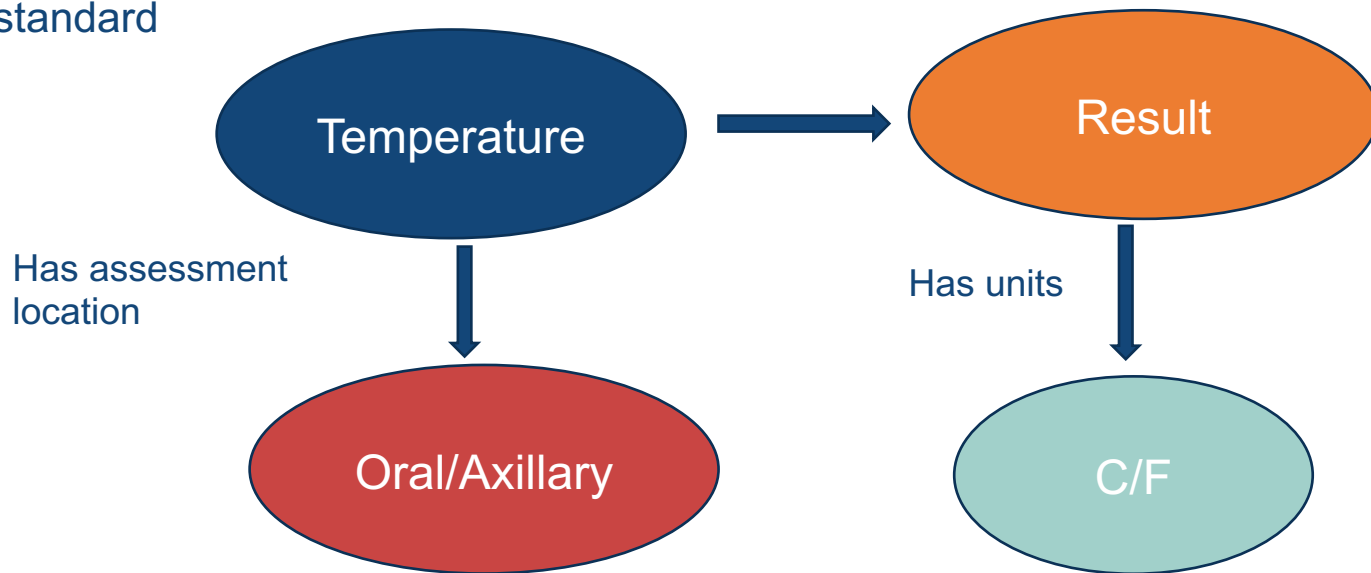
- Electronically publish data standards as groups of linked metadata
- Define relationships between variables, associated terminology codelists, and linkages across standards
- ***CDISC 360 Piloted development of linked biomedical concept metadata to enable end to end automation***



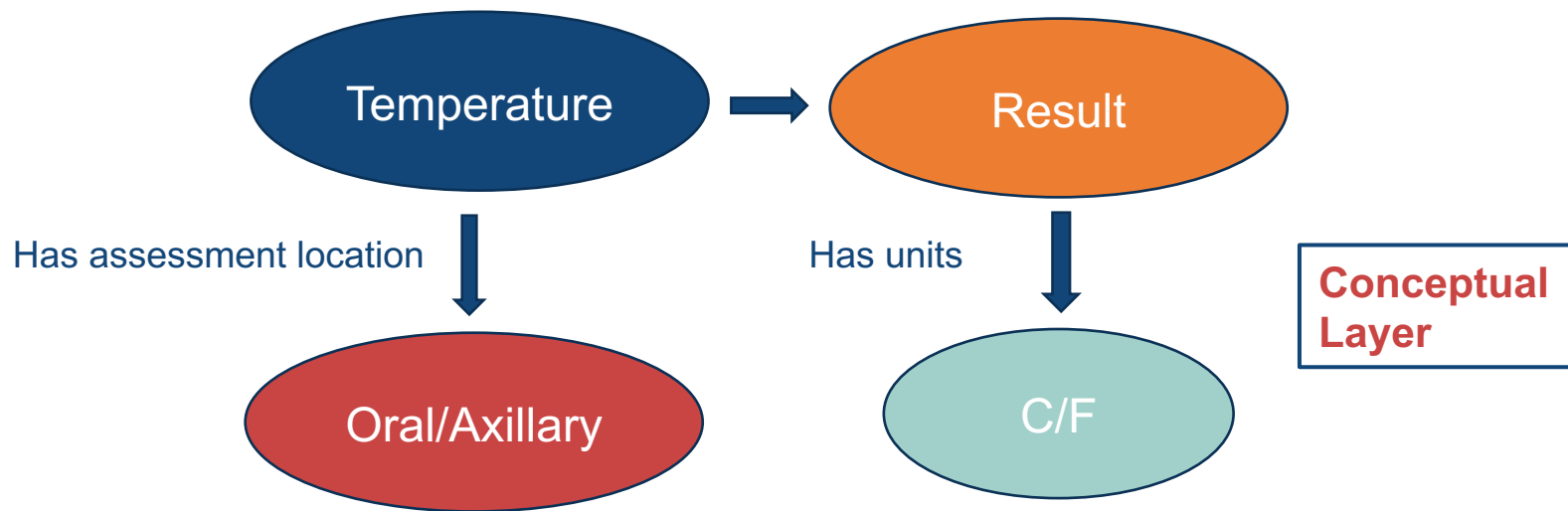
What Is a Biomedical Concept (BC)?

ISO 11179 Definition: *A unit of knowledge created by a unique combination of characteristics*

- Independent of study
- Independent of a representation in any standard, but can be tethered to a standard



What Is a Biomedical Concept (BC)?



VSTEST	VSTESTCD	VSORRES	VSUNIT	VSLOC
Temperature	TEMP	101.3	F	ORAL

**Implementation
Layer**

Why Develop BCs?

- Representation of CDISC standards as metadata (CDISC Library) helps promote automation of CDISC standards
- Developing BCs allows accurate and **more consistent implementation** of the ***conceptual content*** being implemented

Focus On Your Data. Let the Standards Come To YOU



Your data
“shopping list”



CDISC
Library



Retrieve your BCs as
machine-readable files



vs.xpt

Row	STUDYID	DOMAIN	USUBJID	VSSEQ	VSTESTCD	VSTEST	VSPOS	VSORRES	VSORRESU	VSTSTRES	VSTSTRESN	VSTSTRESU	VSSTAT	VSREASND	VSLOC	VSLOBXFL	VISITNUM	VISIT	VISITDY	VSDTC	VSDY
			ABC-001-			Systolic Blood									BRACHIAL					2022-06-	

vs.xpt

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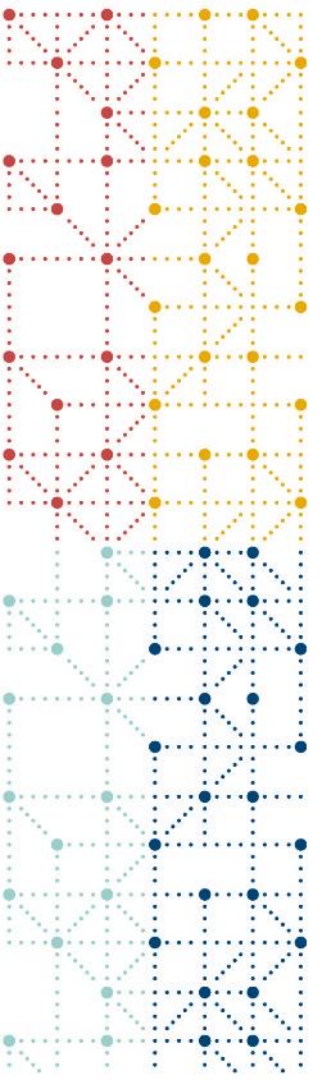
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You're most of the way there towards
implementing CDISC for your data!



CDISC COSMoS

Conceptual & Operational Standards Metadata Services



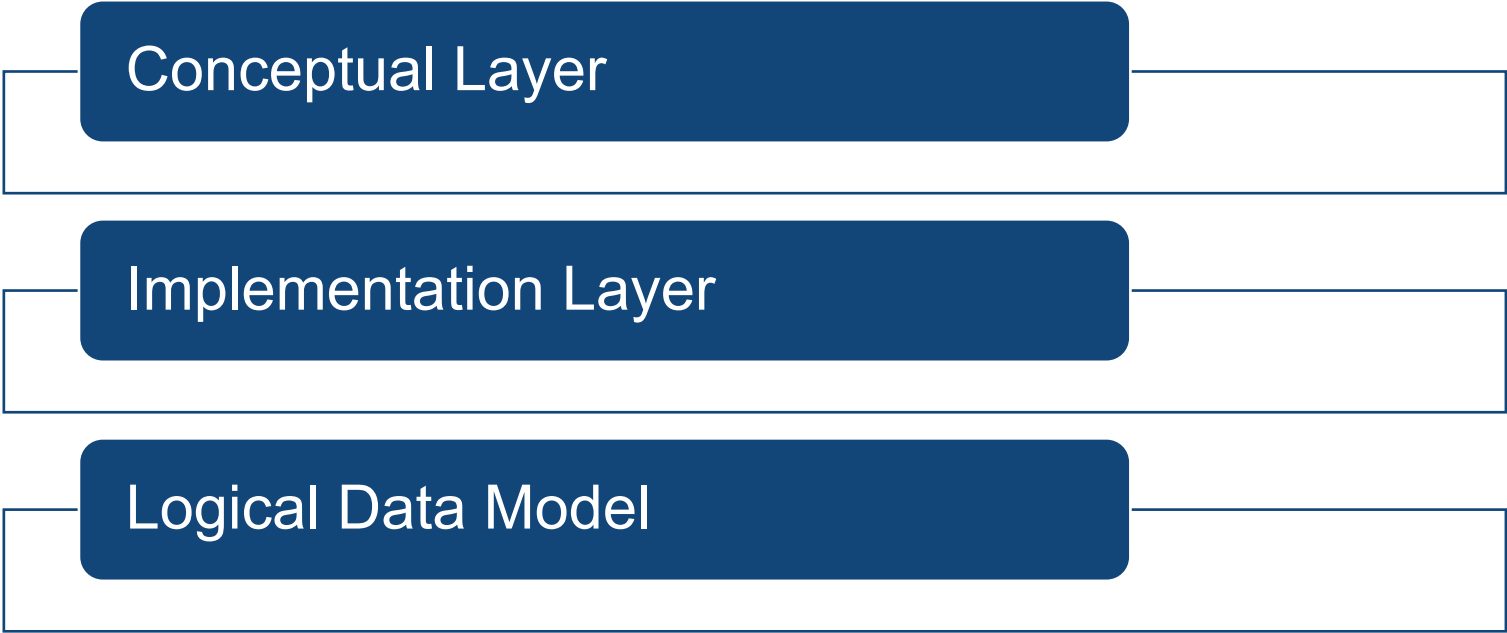
What Is COSMoS?

A pragmatic, iterative approach to creating biomedical concepts with a focus on providing tangible value for the CDISC community

Key Objectives:

- Reduce variability in standards implementations
- Increase metadata-driven automation
- Reduce barriers to operational implementation

Key Components of COSMoS



The diagram illustrates the three key components of COSMoS in a vertical stack. Each component is represented by a dark blue rounded rectangle with white text. To the left of each rectangle is a vertical line with a bracket-like shape at the bottom, and to the right is a horizontal line. These lines are connected by a long horizontal line at the bottom, suggesting a sequential or interconnected flow. The top component is the Conceptual Layer, the middle is the Implementation Layer, and the bottom is the Logical Data Model.

Conceptual Layer

Implementation Layer

Logical Data Model

- 



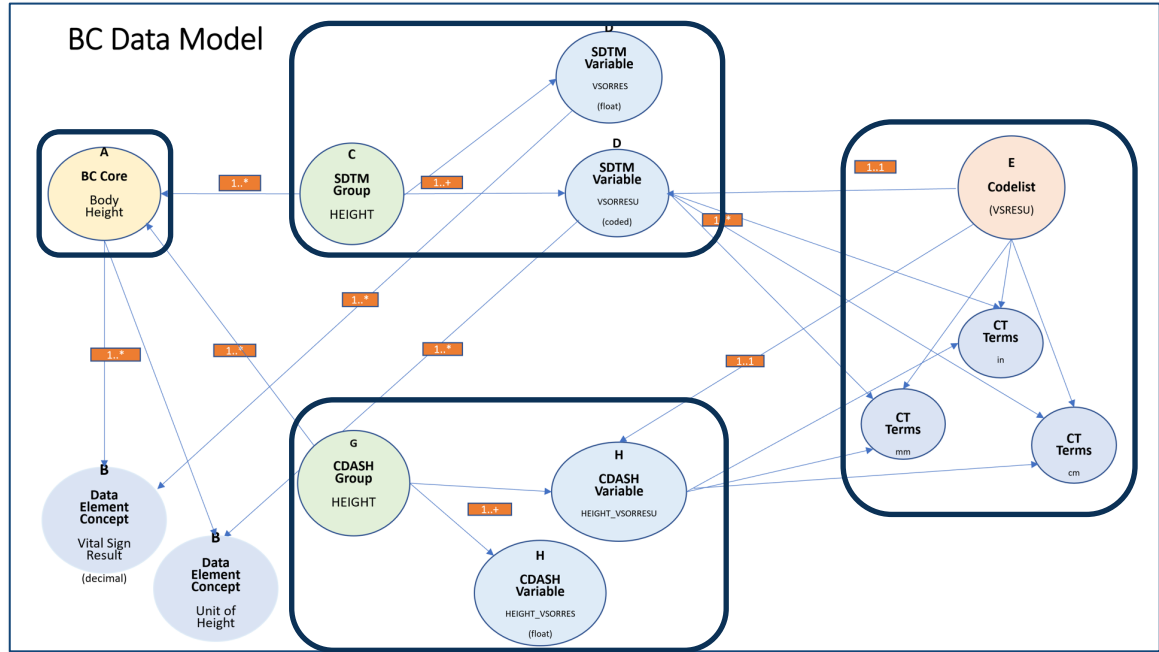
Implementation Layer

- Representation of a BC in a specific standard with implementation details such as value level metadata, formats, terminology



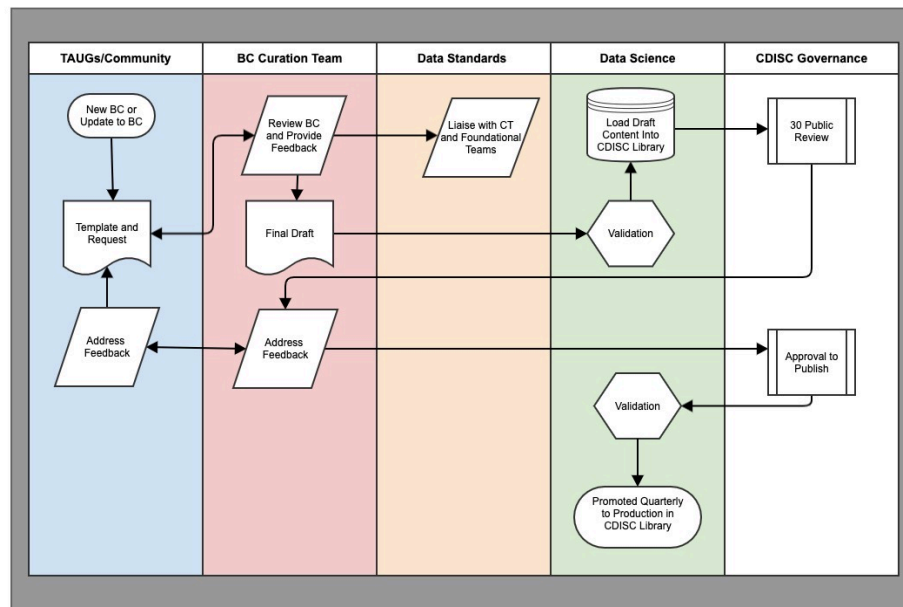
Logical Data Model

- Concept specific value level metadata
- Add explicit relationships between variables
- Additional operational metadata, e.g., data type, format, etc.
- Creation of structured machine-readable YAML files validated with conformance rules
- Searchable and retrievable via CDISC Library APIs



BC Governance

- Light-weight CDISC curation and governance process
- 30-day Public Review
- Published quarterly
- Mechanism for community change requests



Draft governance process



Initial COSMoS Use Cases

*Retrieve a list of
assessments for a study*

*Publish BC content as
Define-XML document
including value level
metadata*

Use Case 1: Support Study Design – Schedule of Assessments

BC Conceptual Layer

- Accurate and consistent implementation of conceptual content
- Retrievable standards agnostic assessments for a study SOA
- Includes pointers to pre-configured SDTM and CDASH dataset specializations

[illegible]

Use Case 2: Define-XML – Value Level Metadata

Pre-configured Define-XML Building Blocks

- Practical implementation of BCs at the SDTM implementation layer
- Pre-configured and ready to go value level metadata
- Templates to support consistent curation
- Fully opinionated and out of the box – allows for tweaks as needed
- Immediate benefit to data management and programming producing SDTM

VS (Vital Signs) - [SDTMIG 3.1.2]

Related Supplemental Qualifiers Dataset: SUPPVS (Supplemental Qualifiers for VS)					
Variable	Where Condition	Label / Description	Type	Length or Display Format	Controlled Terms or ISO Format
VSORRES VLM		Result or Finding in Original Units	text	30	
	VSTESTCD = "DIABP" (Diastolic Blood Pressure)	Diastolic Blood Pressure in Orig U	integer	2	
	VSTESTCD = "FRMSIZE" (Body Frame Size)	Body Frame Size - Orig	text	6	Size • "SMALL" • "MEDIUM" • "LARGE"
	VSTESTCD = "HEIGHT" (Height)	Height in Orig U	float	5.1	

```
{
  "name": "VSTESTCD",
  "isNonStandard": false,
  "codelist": { ...
},
  "assignedTerm": {
    "conceptId": "C25347",
    "value": "HEIGHT"
  },
  "role": "Topic",
  "relationship": {
    "subject": "VSTESTCD",
    "linkingPhrase": "is decoded by the value in",
    "predicateTerm": "IS_DECODED_BY",
    "object": "VSTEST"
  },
  "comparator": "EQ",
```

API Endpoints in CDISC Library

Biomedical Concepts (BC)

GET /mdr/bc/packages

GET /mdr/bc/packages/{package}/biomedicalconcepts

GET /mdr/bc/packages/{package}/biomedicalconcepts/{biomedicalconcept}

GET /mdr/bc/packages/{package}/biomedicalconcepts/{biomedicalconcept}/dataelementconcepts

GET /mdr/bc/packages/{package}/biomedicalconcepts/{biomedicalconcept}/dataelementconcepts/{dataelementconcept}

Study Data Tabulation Model Dataset Specializations (SDTM)

GET /mdr/specializations/sdtm/packages

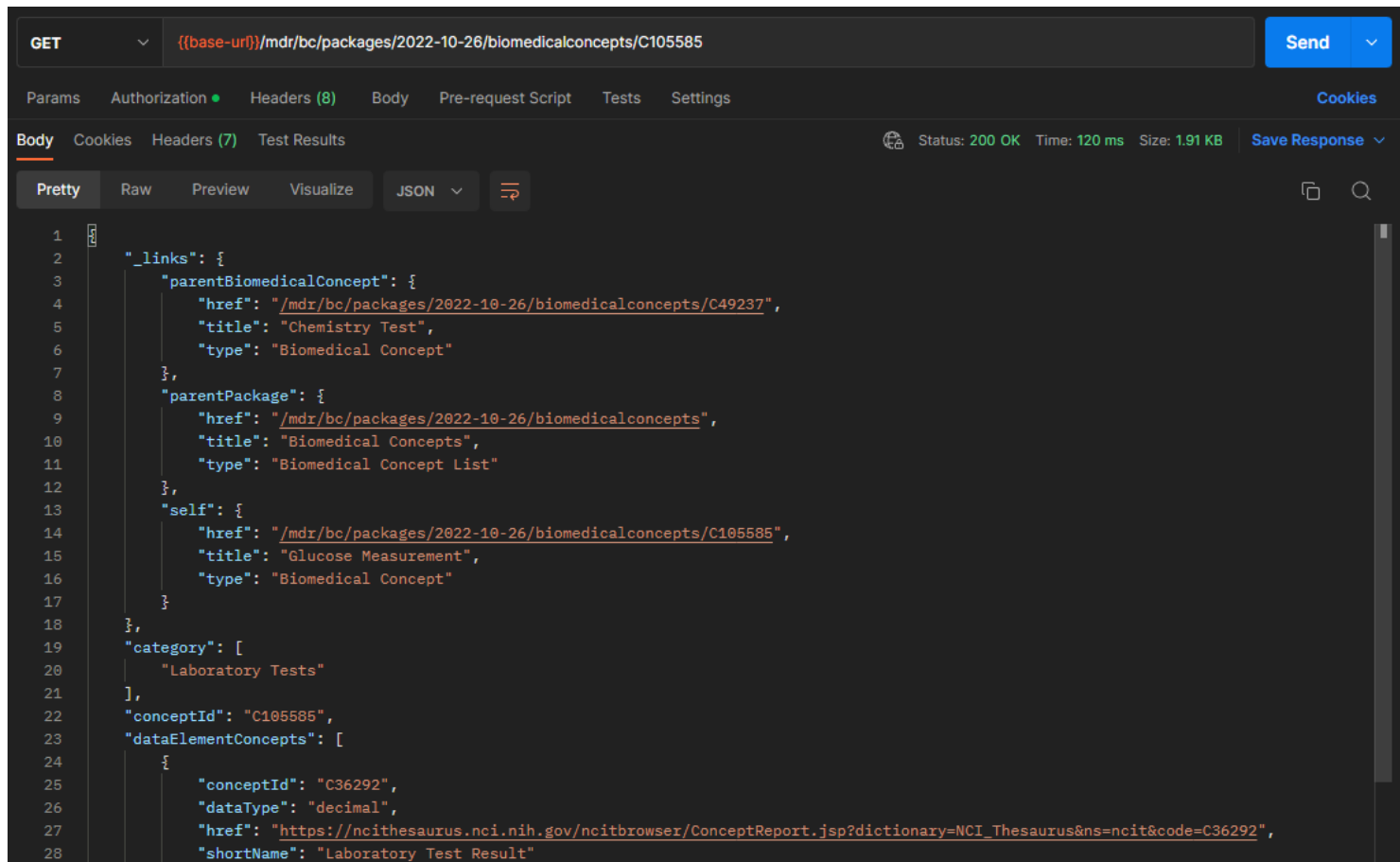
GET /mdr/specializations/sdtm/packages/{package}/datasetspecializations

GET /mdr/specializations/sdtm/packages/{package}/datasetspecializations/{datasetspecialization}

GET /mdr/specializations/sdtm/packages/{package}/datasetspecializations/{datasetspecialization}/variables

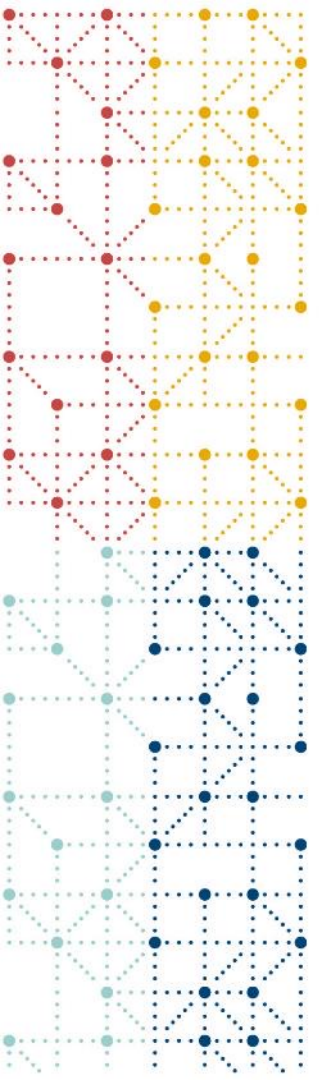
GET /mdr/specializations/sdtm/packages/{package}/datasetspecializations/{datasetspecialization}/variables/{variable}

API Endpoints in CDISC Library



The screenshot displays a REST client interface with a GET request to the endpoint `{{base-url}}/mdr/bc/packages/2022-10-26/biomedicalconcepts/C105585`. The response is shown in the 'Body' tab, formatted as JSON. The status is 200 OK, with a response time of 120 ms and a size of 1.91 KB. The JSON response contains hierarchical information about a Biomedical Concept, including links to parent concepts and packages, and a list of data element concepts.

```
1  {
2    "_links": {
3      "parentBiomedicalConcept": {
4        "href": "/mdr/bc/packages/2022-10-26/biomedicalconcepts/C49237",
5        "title": "Chemistry Test",
6        "type": "Biomedical Concept"
7      },
8      "parentPackage": {
9        "href": "/mdr/bc/packages/2022-10-26/biomedicalconcepts",
10       "title": "Biomedical Concepts",
11       "type": "Biomedical Concept List"
12     },
13     "self": {
14       "href": "/mdr/bc/packages/2022-10-26/biomedicalconcepts/C105585",
15       "title": "Glucose Measurement",
16       "type": "Biomedical Concept"
17     }
18   },
19   "category": [
20     "Laboratory Tests"
21   ],
22   "conceptId": "C105585",
23   "dataElementConcepts": [
24     {
25       "conceptId": "C36292",
26       "dataType": "decimal",
27       "href": "https://ncithesaurus.nci.nih.gov/ncitbrowser/ConceptReport.jsp?dictionary=NCI_Thesaurus&ncit=ncit&code=C36292",
28       "shortName": "Laboratory Test Result"
29     }
30   ]
31 }
```



Looking Towards the Future

- Adding CDISC Library functionality
- Adding to conceptual and implementation layers

Adding Functionality to CDISC Library



BCs and Implementations Accessible Through the Data Standards Browser



BC Authoring Tool

Searchable and Retrievable BCs via CDISC Library APIs and Data Standards Browser



Data Standards Browser

SDTM v2.0

Status Effective Date Implemented By
Final 2021-11-29 SDTMIG v3.4

 Export 

Classes

General Observations

Interventions

Events

Findings

Findings About

Special-Purpose

Associated Persons

Trial Design

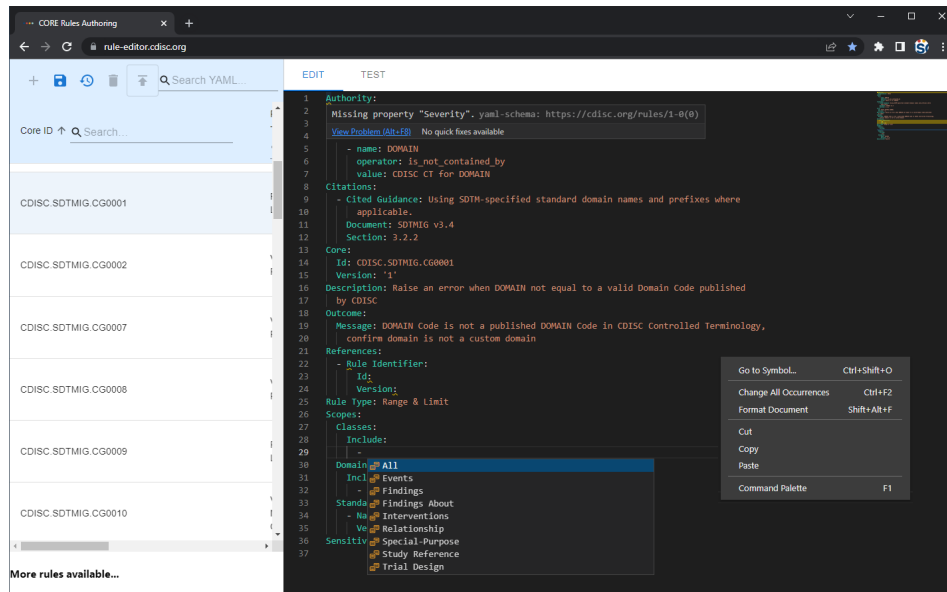
Study Reference

Relationship

BC Authoring Tool

Web-based editor

- YAML specification
- Conversion to JSON machine-executable code+
- Similar to CORE Rules Editor



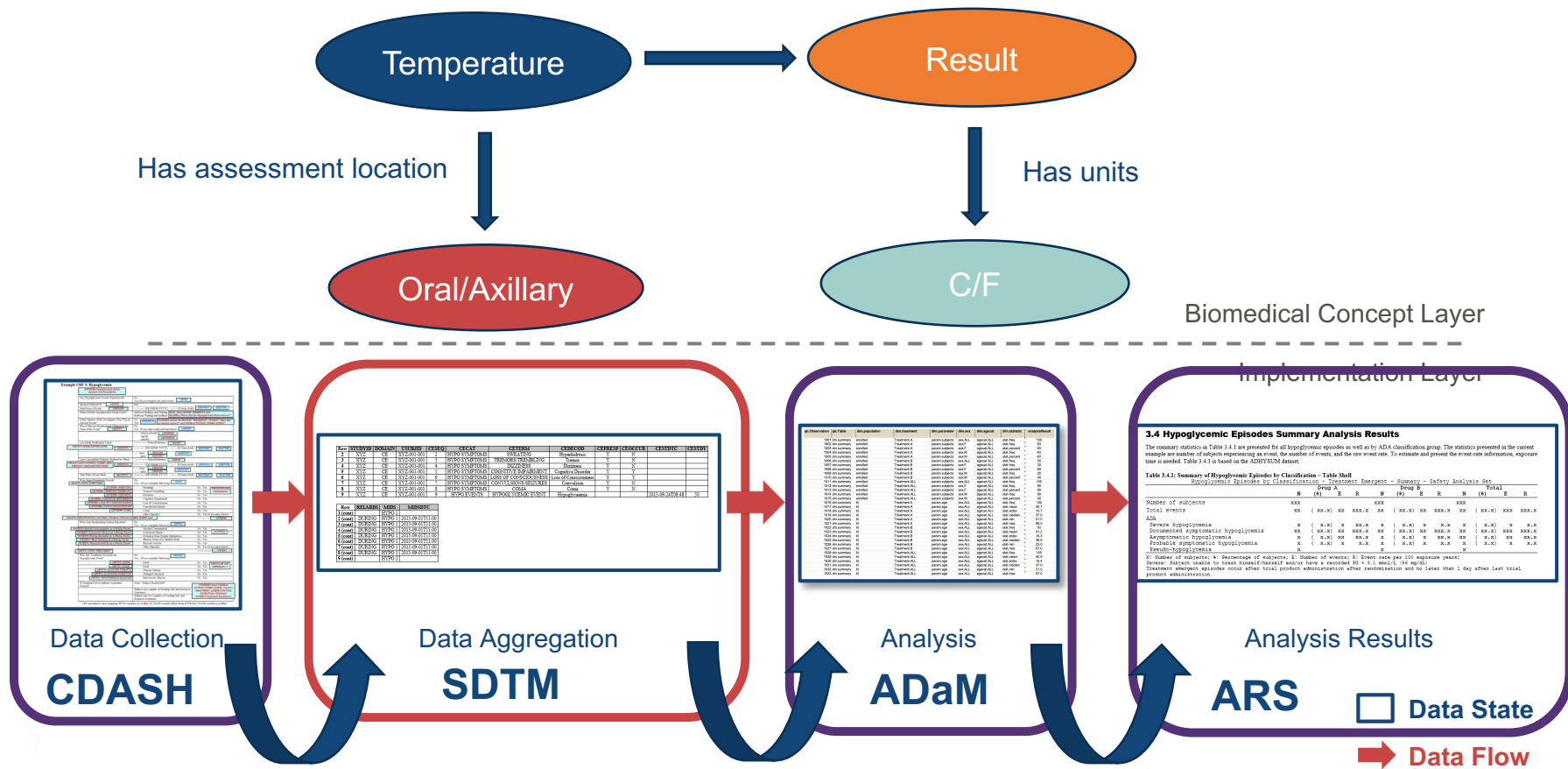
Example: CORE Rule Editor



Adding to Conceptual and Implementation Layers

- End to end standardization
 - Addition of Collection and Analysis Concepts
 - Derivations and transformations
- Connecting to real-world data
- Community collaboration through the donation and curation of BCs

End to End Standardization: Expanding the Implementation Layer



Connecting to Real-World Data

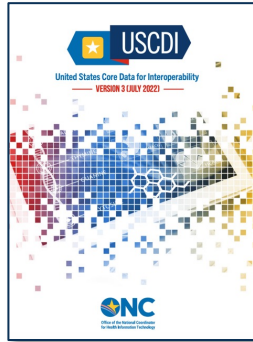
- FDA assessing the use of RWD to support regulatory decisions
- Office of the National Coordinator for Health IT (ONC) promotes the use of standards in health care
- The United States Core Data for Interoperability (USCDI) is a standardized set of data elements for nationwide, interoperable health information exchange
- Electronic health care record (EHR) systems will be required support the USCDI



Vital Signs

- Systolic Blood Pressure
- Diastolic Blood Pressure
- Heart Rate
- Respiratory Rate
- Body Temperature
- Body Height
- Body Weight
- Pulse Oximetry
- Inhaled Oxygen Concentration
- BMI Percentile (2 - 20 years)
- Weight-for-length Percentile (Birth - 24 Months)
- Head Occipital-frontal Circumference Percentile (Birth- 36 Months)

Linking Across Implementation Layers



US Core Implementation Guide
5.0.1 - STU5 Release US



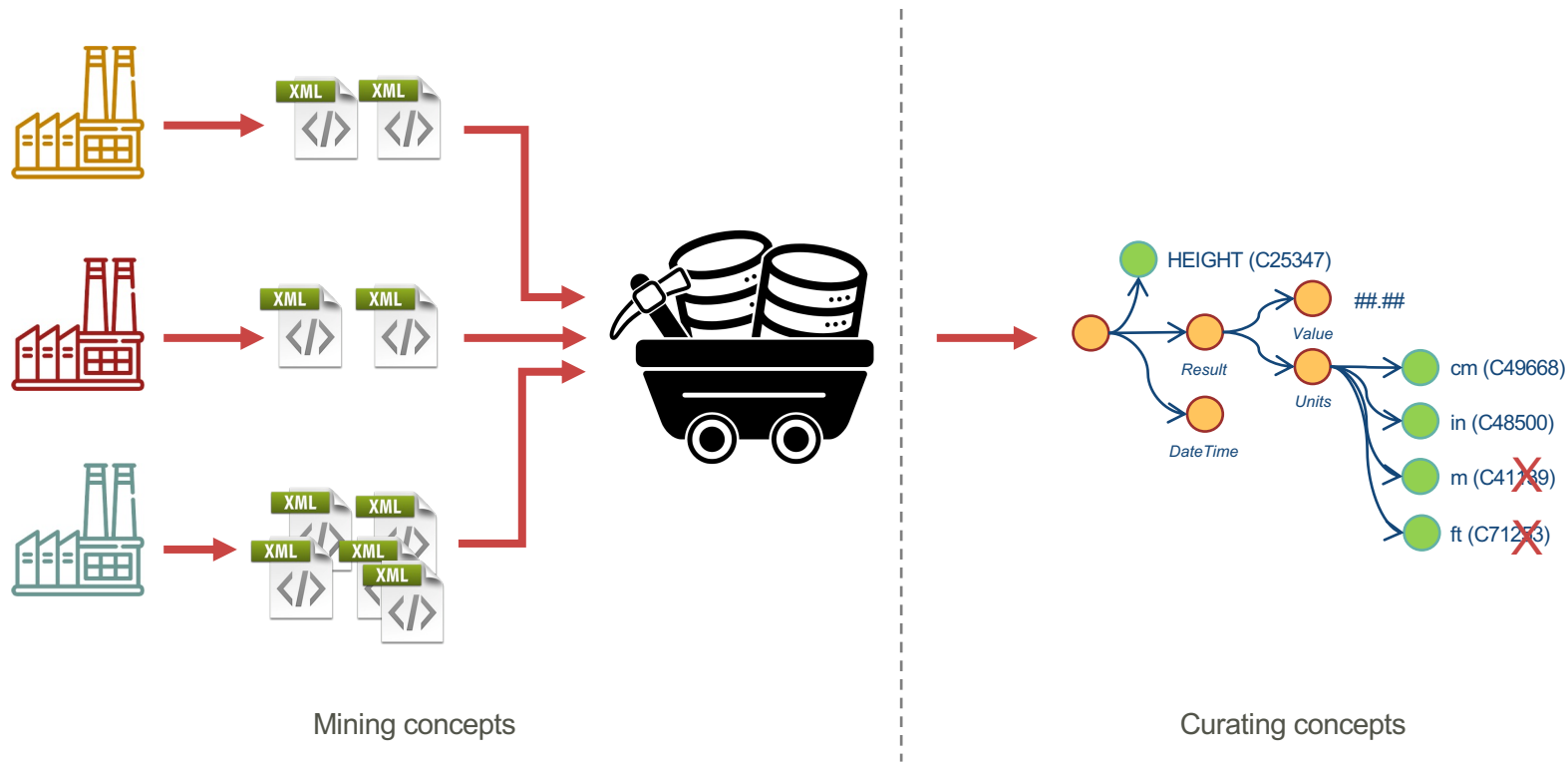
Representation of USCDI in HL7 FHIR and CDISC SDTM

USCDI Data Element: Ethnicity			
US Core v5.0.1 based on HL7 FHIR 4.0.1 Value Set: OMB Ethnicity Categories		CDISC STD MIG v3.2 Value Set: Ethnic Group	
Display	Code	Submission Value	Code
Hispanic or Latino	2135-2	HISPANIC OR LATINO	C17459
Not Hispanic or Latino	2186-5	NO HISPANIC OR LATINO	C222
Asked but Unknown	ASKU	NOT REPORTED	C43234
Unknown	UNK	UNKNOWN	C17998

Community Collaboration

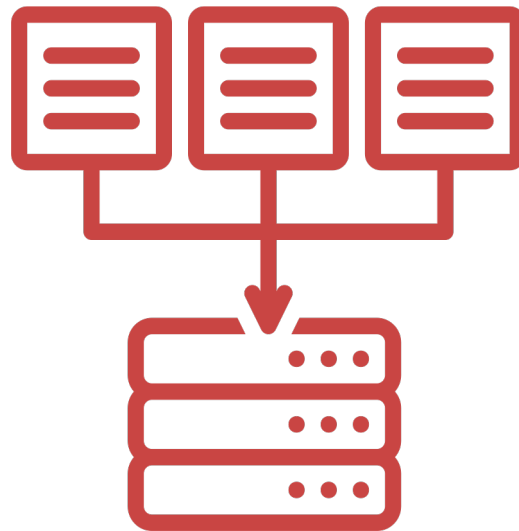


Mining and Curation Collaboration



Additional Sources of BCs

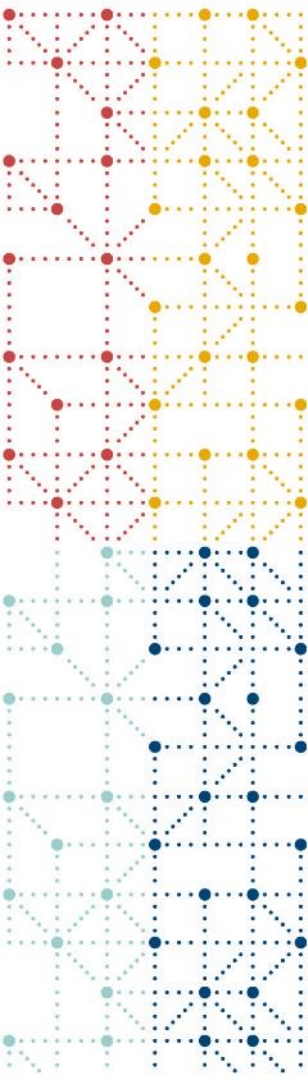
- Mining datasets
- Donation of company created BCs
- Code Table mapping files
- LOINC to LB mapping
- NCI Thesaurus





Summary/Conclusions

- BCs provide consistent meaning around collected concepts
 - Everyone is speaking the same language
 - Conceptual layer details provide for easily browsable catalog to drill down into the data you need to collect
- BCs have the power to significantly lower barriers to implementation of standards
 - Start with the concepts, the standards implementation details come along with them
 - Sponsors no longer need to spend as much effort poring over documentation to match their data with implementation details
- BCs provide consistent implementation of standards



Thank You!

