



CDISC India Day

Biomedical Concepts: The Barcode for Clinical Data

Ramya Gangadi, Efficacy Lifesciences
Ayushi Agarwal, Efficacy Lifesciences



Speaker



Ramya Gangadi is a Senior Manager of Biostatistics and Programming at **Ephicity Lifesciences**, with over 14+ years of clinical research experience specializing in SDTM programming, study submissions, standards development, metadata management, and automation. Her expertise spans oncology, vaccines, immunology, medical devices, and other therapeutic areas.

She holds an M.Pharm in Pharmacology from Rajiv Gandhi University of Health Sciences and has previously worked with Accenture and IQVIA. Ramya actively contributes to the **CDISC community** through the SDS, CORE, NSV, and CDISC 360i initiatives, with a focus on standards, metadata-driven processes, and automation.

Agenda

1. Need for Biomedical Concepts
2. Understanding Biomedical Concepts
3. Biomedical Concepts in Practice
4. Oncology Biomedical Concepts: Use Case



1. Need for Biomedical Concepts

Why Change?



The Need for Semantic Consistency

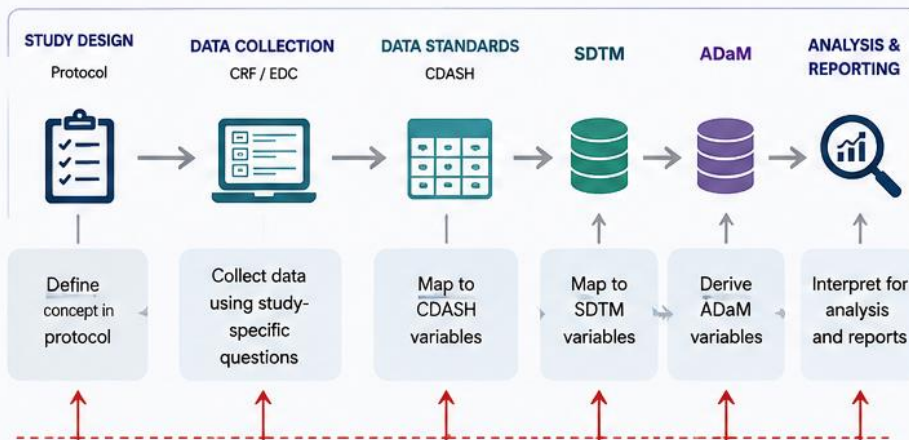
CDISC STANDARDS: BEFORE AND AFTER BIOMEDICAL CONCEPTS (BCs)

BEFORE BCs

DATA STANDARDS – STRUCTURE FOCUSED

Meaning is interpreted and re-created at every step.

More effort, more variability, more risk.



MEANING RE-INTERPETED AT MULTIPLE POINTS

- ❗ Concept defined in silos
- ❗ Different terminology, mappings and rules
- ❗ Inconsistent interpretation across datasets and studies
- ❗ More manual effort and reconciliation
- ❗ Higher risk of inconsistencies and errors

OUTCOME

Same clinical concept, different representations.
Harder to reuse, automate and ensure consistency.

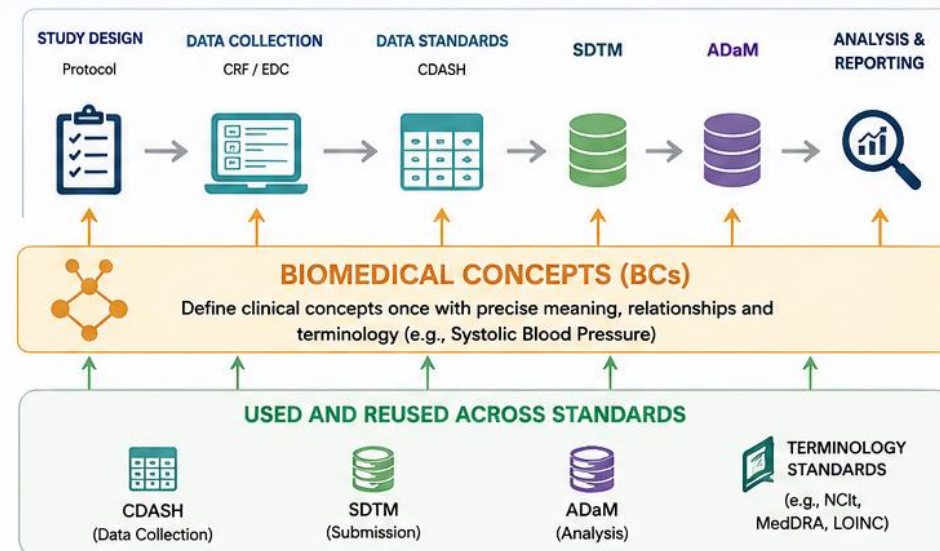


AFTER BCs

SEMANTIC STANDARDS – MEANING DRIVEN

Meaning is defined once and reused everywhere.

Less effort, consistent, reliable, automation-ready.



- ✓ Common, unambiguous meaning across the entire data lifecycle
- ✓ Consistent terminology, mappings and relationships
- ✓ Reusable across studies, platforms and therapeutic areas
- ✓ Enables automation, traceability and semantic interoperability
- ✓ Better data quality, efficiency and regulatory confidence



OUTCOME

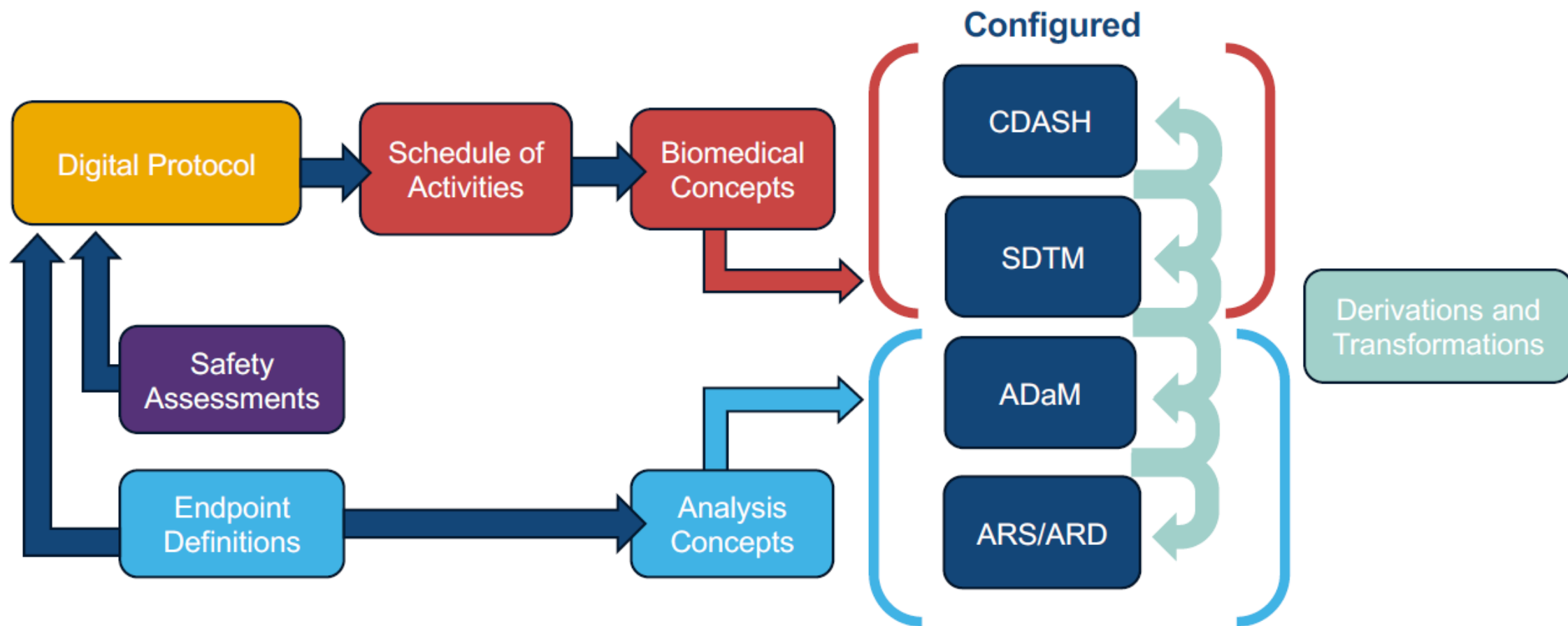
Same clinical concept, same meaning, everywhere.
Easier to reuse, automate and ensure consistency.



THE SHIFT

From structure (what data is) to semantics (what it means).
BCs bring the “meaning layer” to CDISC standards and power the CDISC 360i vision.

CDISC BC Vision



2. Understanding Biomedical Concepts

What are Biomedical Concepts?



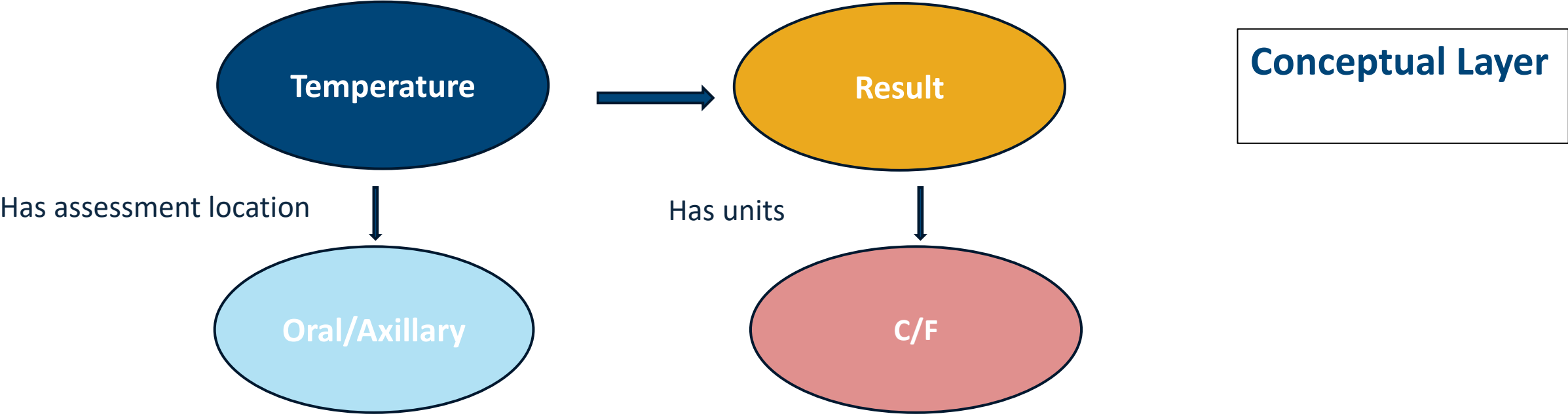


What Are Biomedical Concepts?

- 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



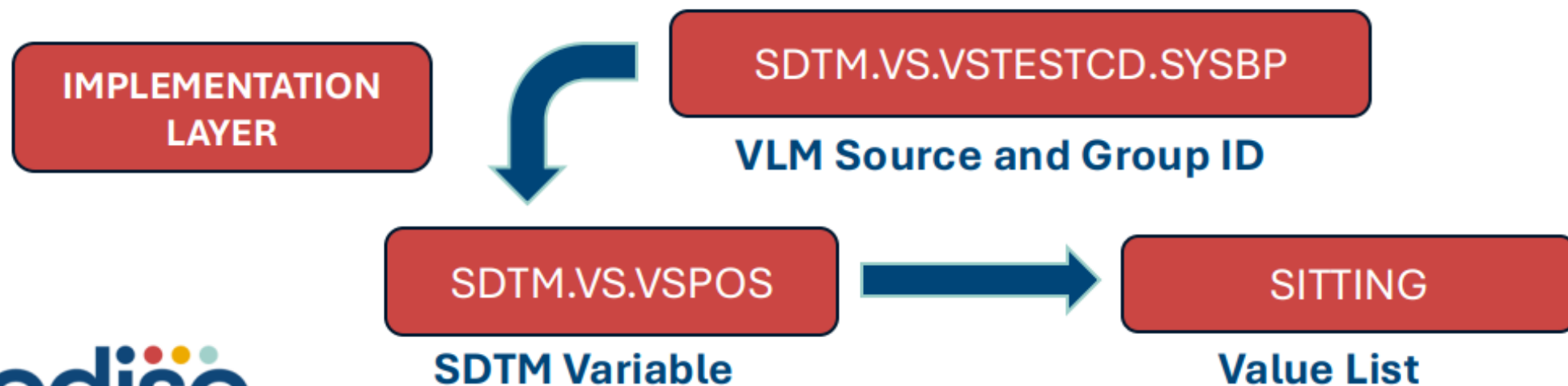
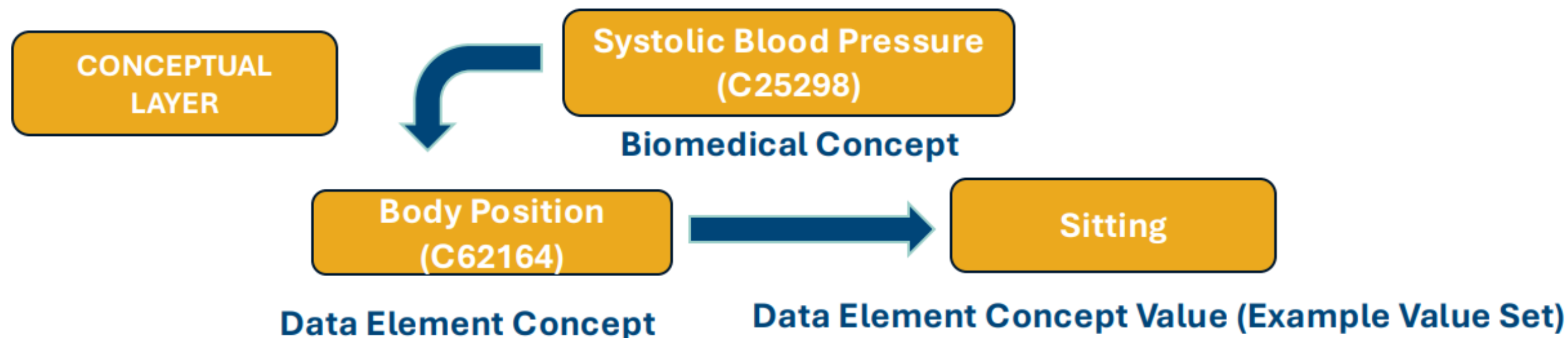
Anatomy of a Biomedical Concept



VSTEST	VSTESTCD	VSORRES	VSORRESU	VSLOC
Temperature	TEMP	101.3	F	ORAL

Implementation
Layer

Biomedical Concept Example Illustrated



Biomedical Concepts: An Illustrative Comparison

Biomedical Concept (BC)	Supermarket Barcode
Identifies a clinical concept	Identifies a product
Example: Systolic Blood Pressure	Example: Oreo packet
Defines what it means	Links to product information
Machine-readable	Machine-scannable
Reusable across systems	Reusable across stores
Enables consistency & traceability	Enables billing & inventory

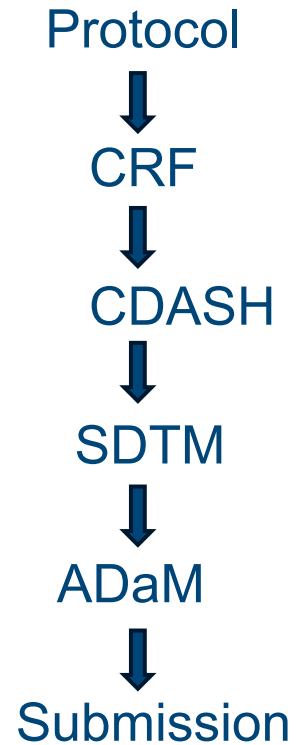
3. Biomedical Concepts in Practice

How Do We Adopt Them?

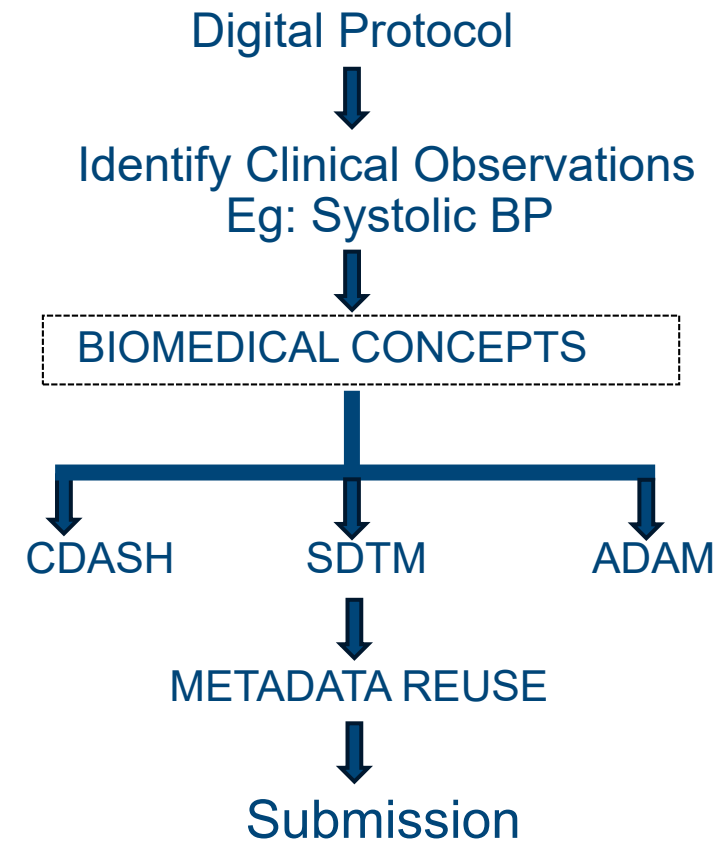


Biomedical Concepts Across the Study Lifecycle

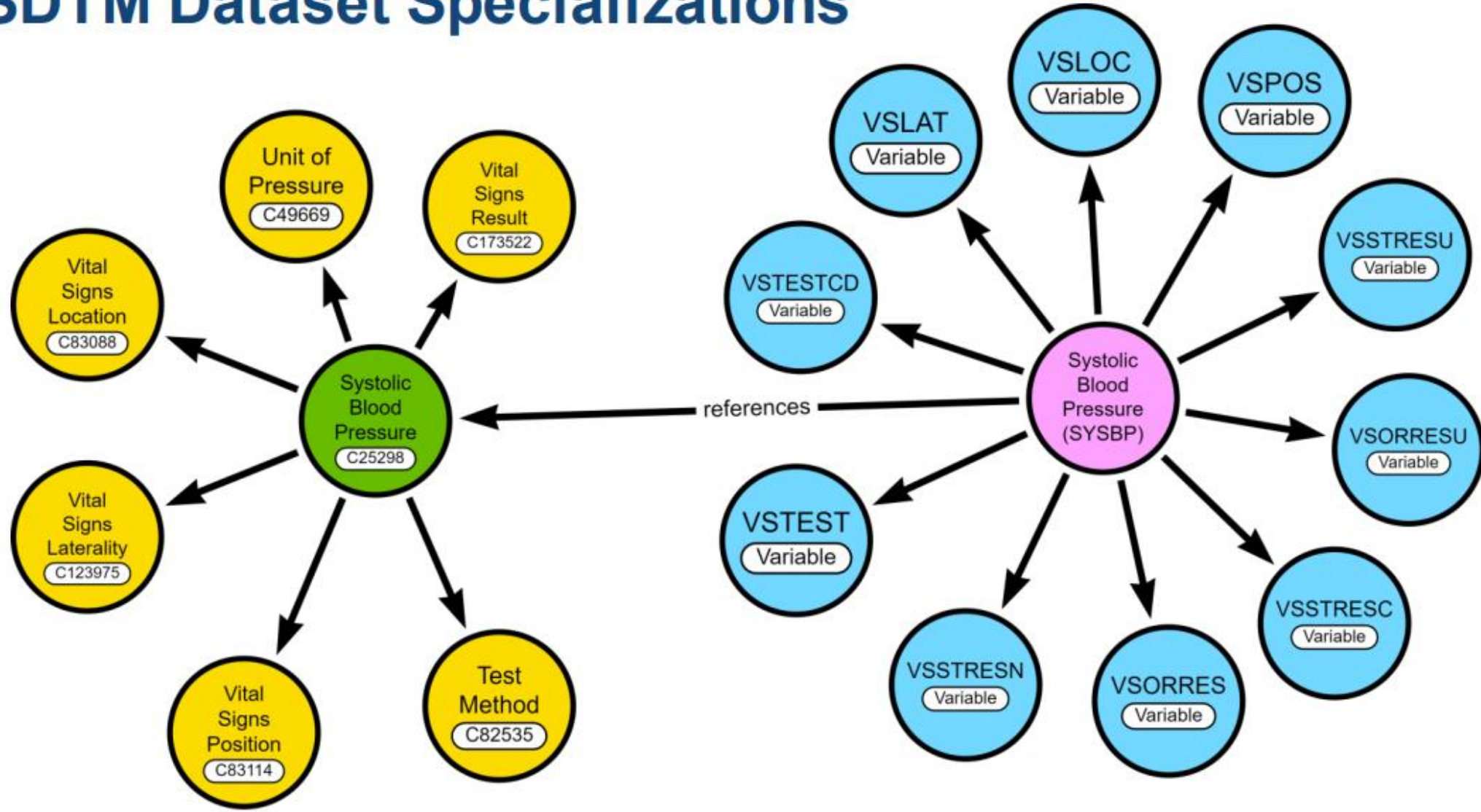
Traditional approach



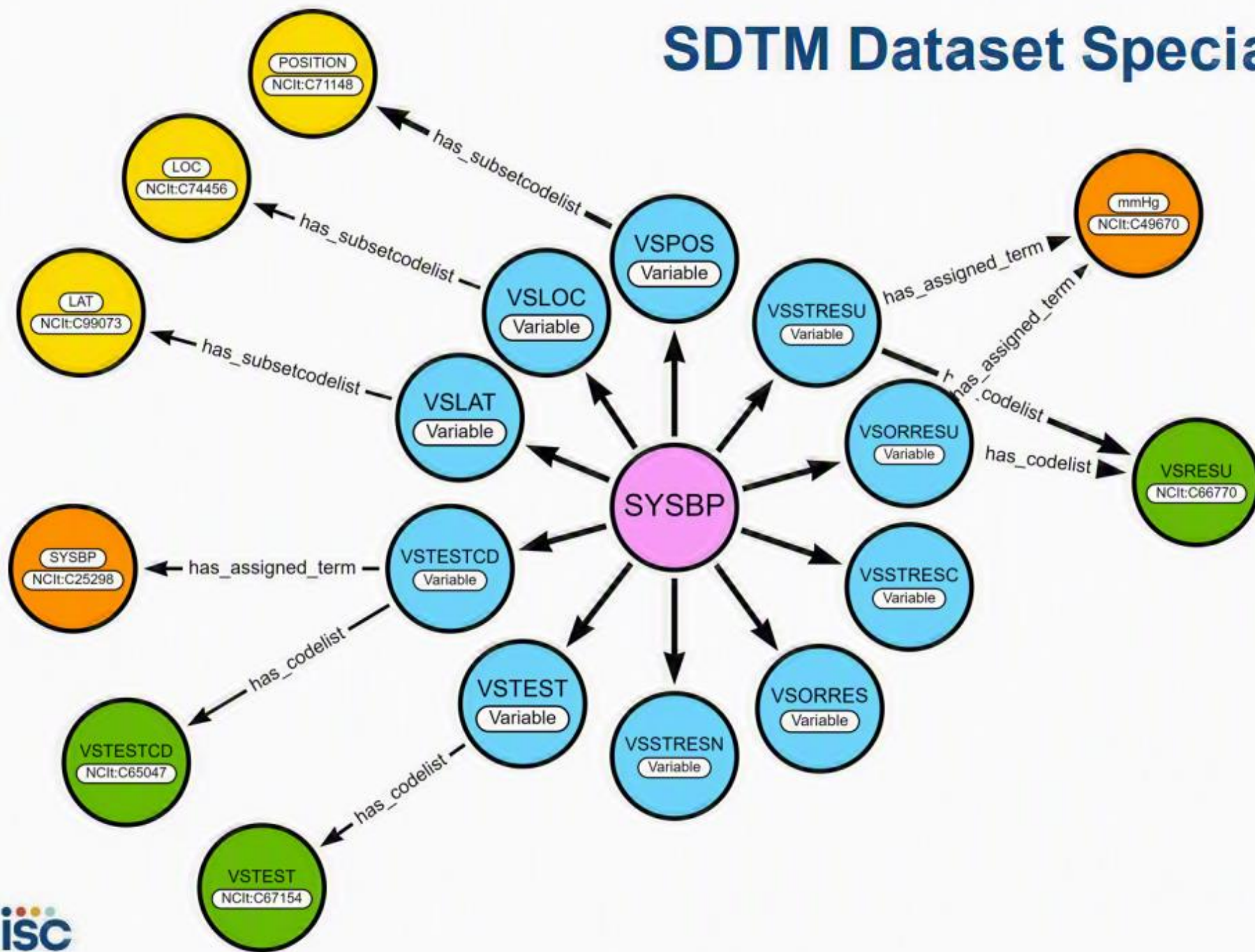
Practical Adoption



CDISC Biomedical Concepts and SDTM Dataset Specializations



SDTM Dataset Specializations



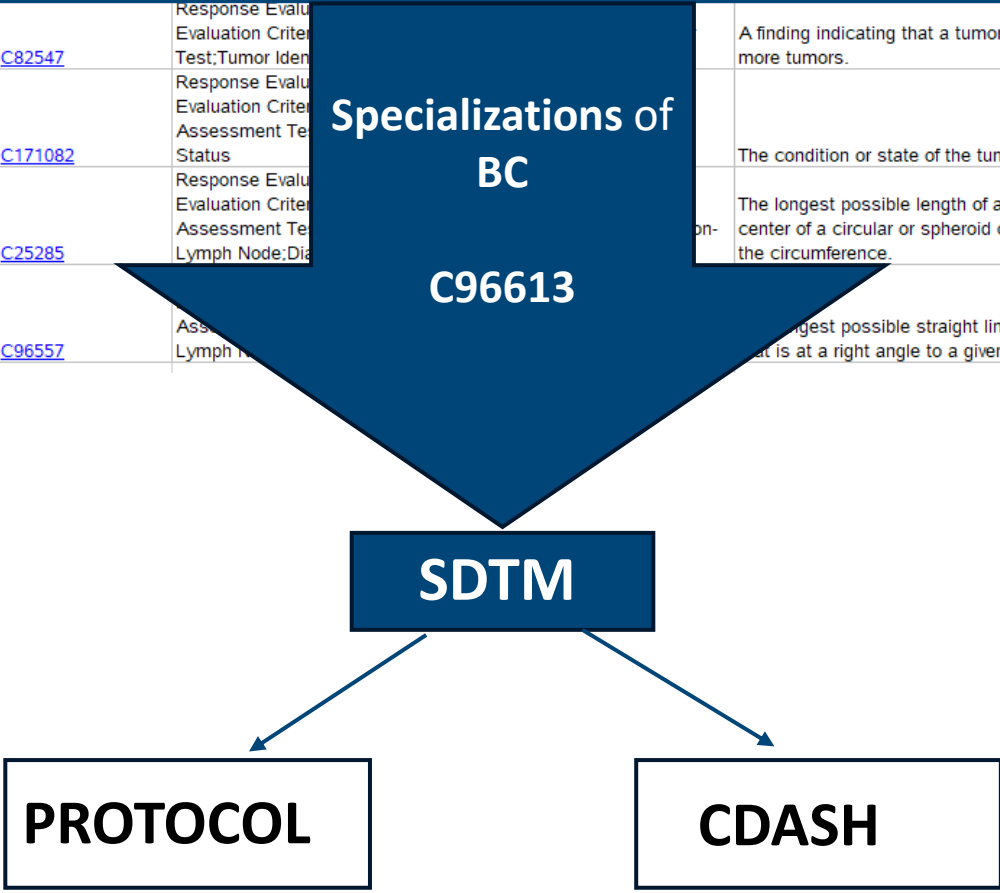
4. Oncology Biomedical Concepts: Use Case



Oncology Biomedical Concepts (BCs) for RECIST 1.1

- CDISC Oncology SDS Subteam are early adopters of the CDISC Biomedical Concepts
 - Constructed following the CDISC BC Model
 - Used the SDTMIG for TU, TR and RS, Disease Response Supplement for RECIST 1.1 and Codetable Mapping Files as source reference files
 - Developed both Conceptual BCs and (SDTM) specializations
- RECIST 1.1 is a biomedical concept **category** which encompasses individual biomedical concepts used within the criteria for clinical data

package_date	short_name	bc_id	ncit_code	parent_bc_id	bc_categories	definition	example_set
2023-07-06	Matted Tumor Mass Present	C94525	C94525	C82547	Evaluation Criteria in Solid Tumors Version 1.1;Tumor Identifier Test;Tumor Identification;RECIST 1.1;Merged	A finding indicating that two or more tumors have merged to create a single cancerous mass.	TARGET
2023-07-06	Response in Target Lesion	C94534	C94534	C50995	Response Evaluation Criteria in Solid Tumors;Response Evaluation Criteria in Solid Tumors Version 1.1;Disease Response Assessment Test;Disease Response;RECIST 1.1;Target	A qualitative or quantitative measurement of the response of a target lesion(s) to the therapy.	SD;PR;CR;PD
2023-07-06	Response in Non-Target Lesion	C94535	C94535	C50995	Response Evaluation Criteria in Solid Tumors;Response Evaluation Criteria in Solid Tumors Version 1.1;Disease Response Assessment Test;Disease Response;RECIST 1.1;Non-Target	A qualitative or quantitative measurement of the response of a non-target lesion(s) to the therapy.	CR; PR; SD; PD; NA; NE; NED
2023-07-06	Overall Response	C96613	C96613	C50995	Response Evaluation Criteria in Solid Tumors;Response Evaluation Criteria in Solid Tumors Version 1.1;Disease Response Assessment Test;Disease Response;RECIST 1.1;Overall	An assessment of the overall response of the disease to the therapy.	CR; PR; SD; PD; NA; NE; NED
2023-07-06	Tumor Fragmentation	C96642	C96642	C82547	Response Evaluation Criteria in Solid Tumors;Tumor Identifier Test;Tumor Identification;RECIST 1.1;Merged	A finding indicating that a tumor mass has been divided into two or more tumors.	TARGET
2023-07-06	Tumor Status	C96643	C96643	C171082	Response Evaluation Criteria in Solid Tumors;Response Evaluation Criteria in Solid Tumors Version 1.1;Disease Response Assessment Test;Disease Response;RECIST 1.1;Target	The condition or state of the tumor at a particular time.	PRESENT;ABSENT;UNEQUIVOCAL;EQUIVOCAL
2023-07-06	Longest Diameter	C96684	C96684	C25285	Response Evaluation Criteria in Solid Tumors;Response Evaluation Criteria in Solid Tumors Version 1.1;Disease Response Assessment Test;Disease Response;RECIST 1.1;Non-Target	The longest possible length of a straight line passing through the center of a circular or spheroid object that connects two points on the circumference.	12;15;17;TOO SMALL TO MEASURE
2023-07-06	Longest Perpendicular	C96685	C96685	C96557	Response Evaluation Criteria in Solid Tumors;Response Evaluation Criteria in Solid Tumors Version 1.1;Disease Response Assessment Test;Disease Response;RECIST 1.1;Non-Target	The longest possible straight line or plane through a body or figure that is at a right angle to a given line or plane.	12;15;17



Protocol Specialization

bc_id	doma	vlm_source	vlm_group_id	short_name	sdtm_variable	cdelid	ion_value	value_list	assigned_term	assigned_value
C96613	RS	RS.RSTESTCD	OVLRESP	Overall Response (RECIST 1.1)	RSTESTCD	C96782	ONCRTSCD		C96613	OVLRESP
C96613	RS	RS.RSTESTCD	OVLRESP	Overall Response (RECIST 1.1)	RSTEST	C96781	ONCRTS		C96613	Overall Response
C96613	RS	RS.RSTESTCD	OVLRESP	Overall Response (RECIST 1.1)	RSCAT	C124298	ONCRSCAT		C124415	RECIST 1.1
C96613	RS	RS.RSTESTCD	OVLRESP	Overall Response (RECIST 1.1)	RSORRES	C96785	ONCRSR	CR;NE;PD;PR;SD;NED;NON-CR/NON-PD		
C96613	RS	RS.RSTESTCD	OVLRESP	Overall Response (RECIST 1.1)	RSDTC					

Table 36 presents the overall response at an individual time point for all possible combinations of tumor responses per RECIST 1.1

Table 36 Evaluation of overall response

Use only the first 8 rows for studies requiring measurable/target lesions at baseline. Use only the last 3 rows for studies without a requirement of evidence of disease at baseline.

TLs	NTLs	New Lesions	Overall Response
CR	CR or NA	No	CR
CR	Non-CR/Non-PD or NE	No	PR
PR	Non-PD or NA or NE	No	PR
SD	Non-PD or NA or NE	No	SD
NE	Non-PD or NA or NE	No	NE
PD	Any	Yes or No	PD
Any	PD	Yes or No	PD
Any	Any	Yes	PD
NA	CR	No	CR
NA	Non-CR/non-PD	No	Non-CR/non-PD ^a
NA	NE	No	NE
NA	Unequivocal PD	Yes or No	PD
NA	Any	Yes	PD
NA	NA	No	NED
NA	NA	NE	NE
NA	NA	Yes	PD

CR = complete response; PR = partial response; SD = stable disease; PD = progressive disease; NA = not applicable; NE = not evaluable; NED = no evidence of disease; NTL = non-target lesion; TL = target lesion.

CDASH Specialization

bc_id	doma	vlm_source	vlm_group_id	short_name	sdtm_variable	codelis	ion_value	value_list	assigned_tern	assigned_value
C96613	RS	RS.RSTESTCD	OVRLRESP	Overall Response (RECIST 1.1)	RSTESTCD	C96782	ONCRTSCD		C96613	OVRLRESP
C96613	RS	RS.RSTESTCD	OVRLRESP	Overall Response (RECIST 1.1)	RSTEST	C96781	ONCRTS		C96613	Overall Response
C96613	RS	RS.RSTESTCD	OVRLRESP	Overall Response (RECIST 1.1)	RSCAT	C124298	ONCRSCAT		C124415	RECIST 1.1
C96613	RS	RS.RSTESTCD	OVRLRESP	Overall Response (RECIST 1.1)	RSORRES	C96785	ONCRSR	CR;NE;PD;PR;SD;NED;NON-CR/NON-PD		
C96613	RS	RS.RSTESTCD	OVRLRESP	Overall Response (RECIST 1.1)	RSDTC					

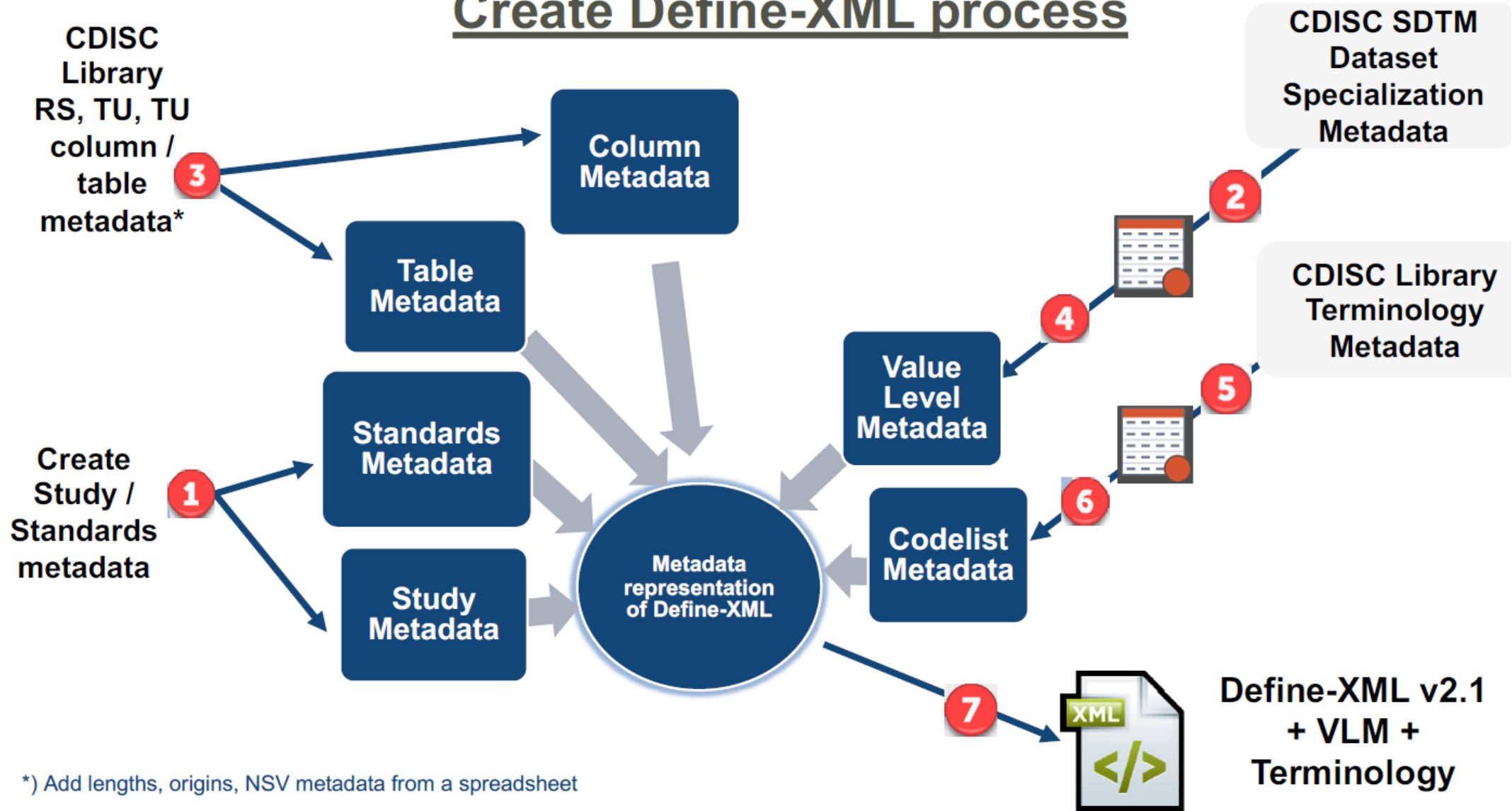
Forms												
CD	Name	Description	Repeating	Aliases	Therapeutic Area	Clinical Stage						
RS	Form RS - Disease Response	RS - Disease Response [en]	No									
Section												
CD	Name	Repeating	Description	Order No.	Mandatory	Aliases	Condition	IsReferenceData	Repeating Information	SASDatasetName	Domain	
CDASH_2-1_IG_33	RS - Disease Response	No	RS - Disease Response [en]	1	Yes						RS	
Questions												
CD	Name	bc_id	Text	DataType	Order No.	Mandatory	Terminology	Length	Significant Digits	Units	Description	
IT TRGRESP_RSORRES	TRGRESP_RSORRES	C94534	Target Response [en]	text	6	No	Target Response	15				
IT NTRGRESP_RSORRES	NTRGRESP_RSORRES	C94535	Non-Target Response [en]	text	7	No	Non-Target Response	15				
IT OVRLRESP_RSORRES	OVRLRESP_RSORRES	C96613	Overall Response [en]	text	8	No	Overall Response	15				

Terminologies								
OID	Name	DataType	SASFormatName	Terminology Aliases	Coded Value	Text	Order No.	
Overall Response	Overall Response	text			CR	Complete Response (CR)	1	
Overall Response	Overall Response	text			PR	Partial Response (PR)	2	
Overall Response	Overall Response	text			SD	Stable Disease (SD)	3	
Overall Response	Overall Response	text			NON-CR/NON-PD	Non Complete Response/Non Progressive Disease (NON-CR/NON-PD)	4	
Overall Response	Overall Response	text			PD	Progressive Disease (PD)	5	
Overall Response	Overall Response	text			NE	Not Evaluable (NE)	6	
Overall Response	Overall Response	text			NED	No Evidence of Disease (NED)	7	

CDASH Specialization

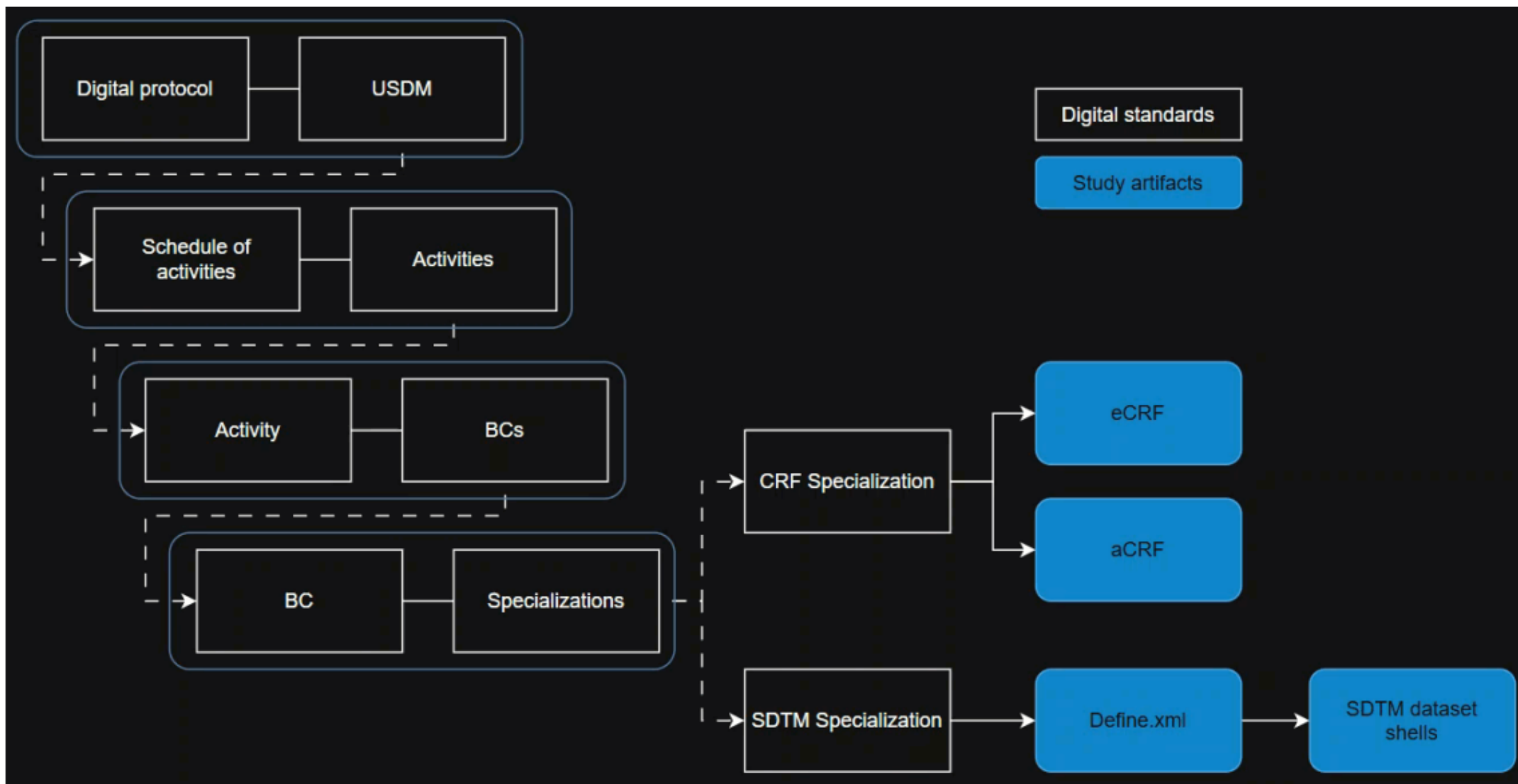
Form RS - Disease Response		
1 RS - Disease Response		
1.8	Overall Response	☐ [CR] Complete Response (CR) ☐ [PR] Partial Response (PR) ☐ [SD] Stable Disease (SD) ☐ [NON-CR/NON-PD] Non Complete Response/Non Progressive Disease (NON-CR/NON-PD) ☐ [PD] Progressive Disease (PD) ☐ [NE] Not Evaluable (NE) ☐ [NED] No Evidence of Disease (NED) OVRLRESP_RSORRES bc_id = C96613

Create Define-XML process



*) Add lengths, origins, NSV metadata from a spreadsheet

CDISC 360i Focus:





Early adopters shape the future. Late adopters follow it.





Thank You!





Questions?





References:

