

CDISC Biomedical Concepts and Dataset Specializations Pragmatic Implementation and Tangible Value

Jon Neville, Senior Director Standards Development, CDISC Lex Jansen, Senior Director Data Science Development, CDISC Linda Lander, Director Data Science, CDISC









Meet the Speakers

Jon Neville

Title: Senior Director, Standards Development

Organization: CDISC

Jon Neville has been working in CDSIC standards development since 2009. He has been working at CDISC for 6 years, where he is currently Senior Director, Standards Development at CDISC

Lex Jansen

Title: Senior Director, Data Science Development

Organization: CDISC

Lex Jansen is an independent consultant, currently working as Senior Director, Data Science Development at CDISC. Before he was a Principal Solution Consultant and Principal Software Developer at SAS Institute.

Linda Lander Title: Director, Data Science

Organization: CDISC

Linda Lander is an independent contractor, currently working as Director Data Science and Biomedical Concepts Product Owner at CDISC. Before she was Director Data Standards at GlaxoSmithKline



Disclaimer and Disclosures

- The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.
- The authors have no conflicts to disclose

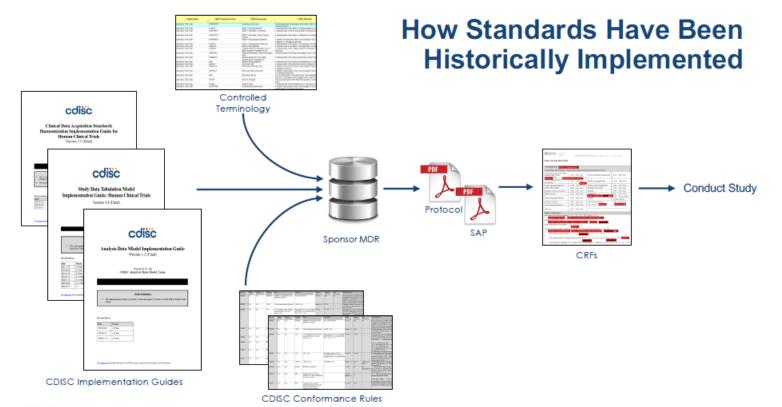
Agenda

- 1. CDISC Biomedical Concepts Introduction and Background
- 2. SDTM Dataset Specializations as Define-XML Building Blocks
- 3. Retrieval of BCs and SDTM Dataset Specializations using CDISC Library APIs
- 4. Key Accomplishments, Current Status and What's Coming

CDISC Biomedical Concepts and SDTM Dataset Specializations

Background and Introduction

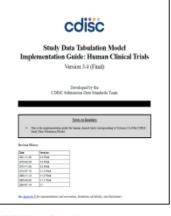
CDISC Biomedical Concepts and SDTM Dataset Specializations





#ClearDataClearImpact

Example: Vital Signs in SDTM



......

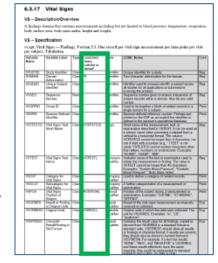
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SDTMIG: 461 pages

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Controlled Terminology

Controlled Terminology: >35,000 terms in almost 1000 code lists



Vital Signs Domain: Specification for how to construct vital signs data

n a agent																					
Row	STUDYID	DOMAIN	USUBJID	VSSEQ	VSTESTCD	VSTEST	VSPOS	VSORRES	VSORRESU	VSSTRESC	VSSTRESN	VSSTRESU	VSSTAT	VSREASND	VSLOC	VSLOBXFL	VISITNUM	VISIT	VISITDY	VSDTC	VSDY.
1	ABC	VS	ABC-001- 001	1	SVSBP	Systolic Blood Pressure	SITTING	154	mmHg	154	154	mmHg			BRACHIAL ARTERY	٧	1	Baseline	1	2022-06- 19T08:45	1
2	ABC	VS	ABC-001- 001	2	DUABP	Diastolic Blood Pressure	SITTING	44	mmHg	44	44	mmHg			BRACHIAL ARTERY	Y	1	Baseline	1	2022-06- 19T08:45	1
3	ABC	VS	ABC-001- 001	3	HEIGHT	Height		157	cm	157	157	om				Y	1	Baseline	1	2022-06- 19	1
4	ABC	VS	ABC-001- 001	4	WEIGHT	Weight		90.5	kg	90.5	90.5	kg				Y	1	Baseline	1	2022-06-	1
5	ABC	VS	ABC-001- 001	5	PULSE	Pulse Rate		72	beats/min	72	72	beats/min			CAROTID ARTERY	Y	1	Baseline	1	2022-06- 19	1
6	ABC	VS	ASC-001- 001	6	RESP	Raspiratory Rate		34	breaths/min	34	34	breaths/min				Y	1	Baseline	1	2022-06-	1
7	ABC	VS	ASC-001- 001	7	TEMP	Temperature		37.1	С	37.1	37.1	с			EAR.	v	1	Sateline	1	2022-06-	1

Vital Signs Dataset

Repeat 100s of times for all your study data concepts...



CDISC Biomedical Concepts and SDTM Dataset Specializations

Problem:

- 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

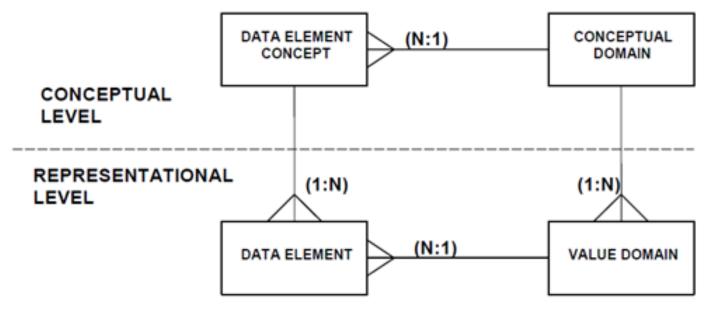
CDISC has evolved:

- CDISC Library has published data standards as groups of linked metadata
- Defined relationships between variables, associated terminology codelists, and linkages across standards
- CDISC 360 piloted the 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





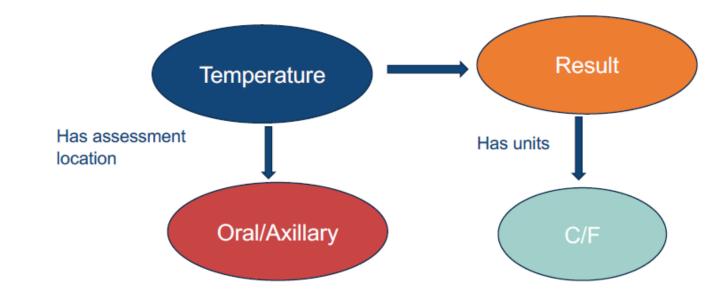
What Is a Biomedical Concept (BC)?

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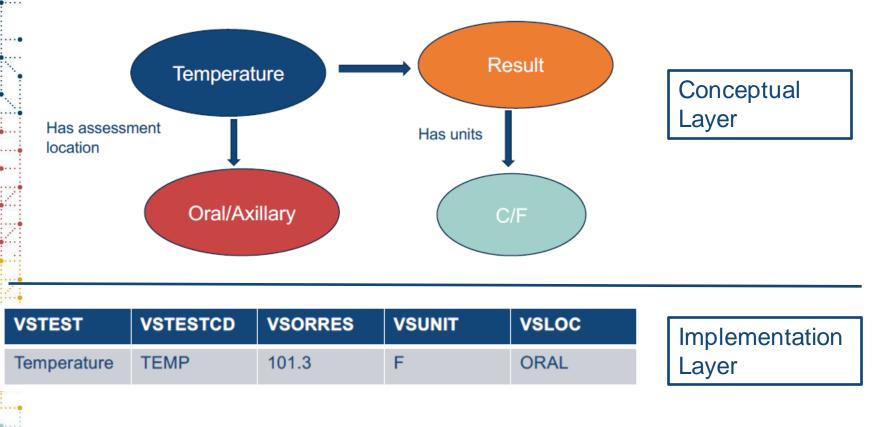
• Independent of study

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



What Is a Biomedical Concept (BC)?





CDISC Biomedical Concepts and SDTM Dataset Specializations

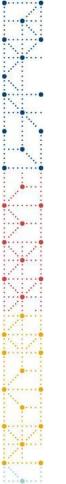
Developing Biomedical Concepts allows accurate and **more consistent implementation** of the *conceptual content* being implemented

3 Key pieces of the **Pragmatic Implementation:**

- Extend foundational standards
 - Add explicit relationships between variables
 - Additional operational metadata, e.g., data type, etc.
- Conceptual Layer abstract BC's
 - Provides semantics aligned with NCI terminology
 - Supports study design, Schedule of Activities (SOA)
- Implementation Layer Dataset Specializations with VLM definitions
 - Supports programmers
 - Pre-configured building blocks for Define-XML
 - Tailored to BCs to link with unambiguous semantics & definitions
 - Dataset specializations as an extended dataset structure

SDTM Dataset Specializations

Building Blocks for Define-XML



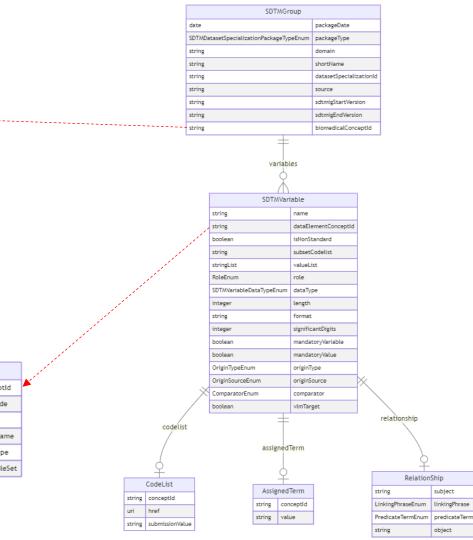
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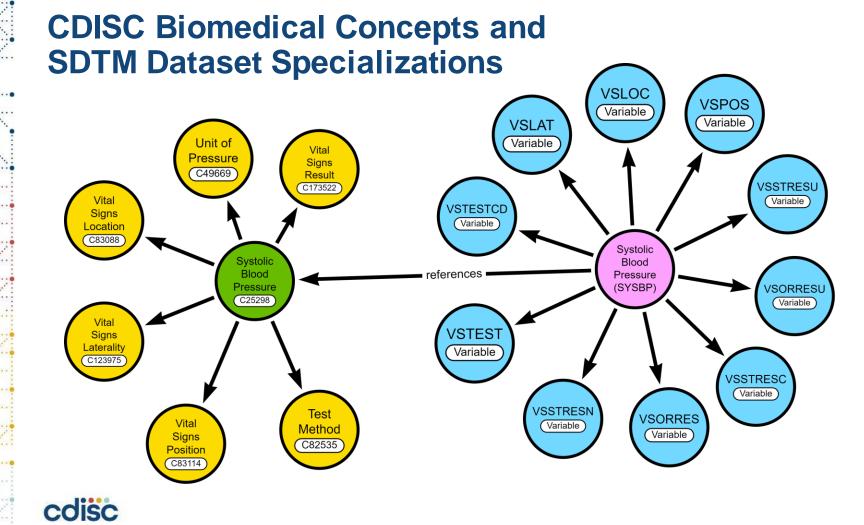
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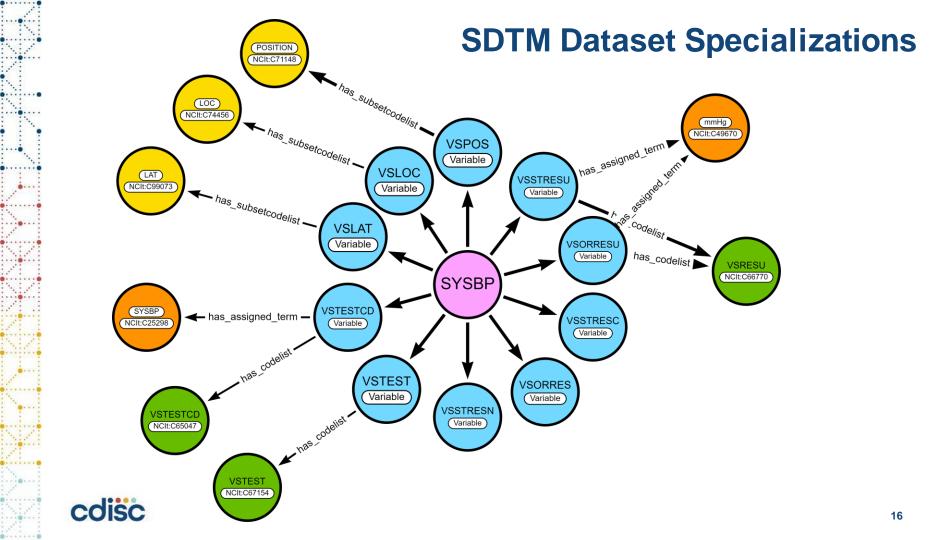
The logical Model

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		BiomedicalC	oncept					
	string			conceptId	4			
	string			ncitCode				
	uri			href				
	date			packageDate				
	Biomedical	ConceptPackageTypeE	inum	packageType				
	stringList			categories				
	string			parentConceptId				
	string			shortName				
	stringList			synonyms				
	Biomedical	ConceptResultScaleEn	umList	resultScales				
	string			definition				
	coding			dataElement	Concepts			
	Ŷ			DataEleme	ntConcept	t		
	() Coding		string			conceptId		
string	code		string			ncitCode		
string	system		uri			href		
string	systemName		string			shortName		
string	systemmarile	J	DataEl	ementConceptData	TypeEnum	dataType		
			stringL	ist		exampleSet		







SDTM Dataset Specializations

Attribute	Description
datasetSpecializationId	Identifier for SDTM Value Level Metadata group
domain	Domain for the SDTM specialization group
shortName	SDTM group short name which provides a user friendly and intuitive name for the datasetSpecializationId
source	SDTM VLM Source which categorizes VLM groups by topic variable
sdtmigStartVersion	The earliest SDTMIG version applicable to the SDTM dataset specialization
sdtmigEndVersion	The last SDTMIG version that is applicable to the SDTM dataset specialization
biomedicalConceptId	Biomedical Concept identifier



SDTM Dataset Specializations

Attribute		Description				
Name		Name of the variable included in the SDTM dataset specialization				
dataElementCor	nceptld	Biomedical Concept Data Element Concept identifier				
isNonStandard		Flag that indicates if the variable is a non-standard variable				
	conceptld	C-code for a codelist in NCIt				
codelist	href	Link to NCIt for the codelist				
	submissionValue	CDISC submission value for the codelist				
subsetCodelist		Subset codelist short name				
valueList	1	List of SDTM submission values used if subset codelist is not applicable				
	conceptId	C-code for assigned term in NCIt				
assignedTerm		Submission value for assigned term in NCIt if it exists, or an assigned value				
	value	which will be the default value				
role		SDTM variable role				



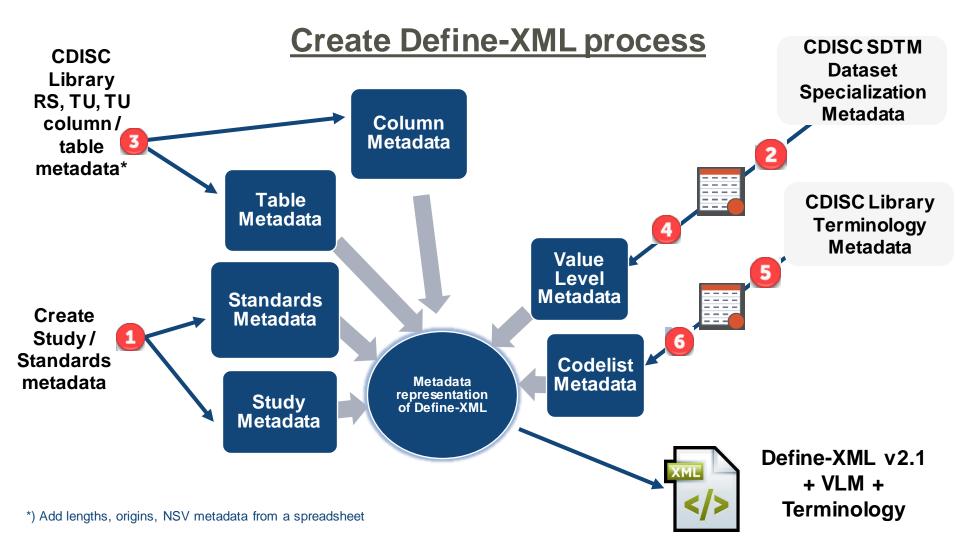
Attribute		Description					
relationship	Subject	Subject in a variable relationship					
	linkingPhrase	Variable relationship descriptive linking phrase					
	predicateTerm	Short variable relationship linking phrase for programming					
	object	Object in a variable relationship					
datatype		Variable data type					
length		Variable length					
format		Variable display format					
significantDigits	S	Variable significant digits					
mandatoryVaria	able	Indicator that variable must be present within the SDTM group					
mandatoryValu	е	Indicator that variable must be populated within the SDTM group					
originType		Variable origin type (Assigned, Collected, Derived, Protocol, Predecessor)					
originSource		Variable origin source (Investigator, Sponsor, Subject, Vendor)					
comparator		Comparison operator for SDTM group variables included in VLM (EQ, IN)					
vlmTarget		Target variable for VLM (true/false)					



- Value Level Metadata and
- Controlled Terminology metadata for the RS, TR, and TU domains
- SDTM Dataset Specializations are considered pre-configured building blocks, from which end-users can select and configure to build Define-XML Value Level Metadata
- Exercise: present Oncology RECIST 1.1 SDTM Dataset Specializations as Value Level Metadata in Define-XML v2.1
- Oncology RECIST 1.1
 - 13 Biomedical Concepts
 - 13 SDTM Specializations (RS, TR, TU))
- REST API:
 - GET Biomedical Concepts: /mdr/bc/biomedicalconcepts?category=RECIST 1.1
 - GET SDTM Specializations: /mdr/specializations/sdtm/datasetspecializations?domain=RS



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- Value Level Metadata and
- Controlled Terminology metadata for the RS, TR, and TU domains

CDISC01		Date/Time of Define-XML document generation: 2023-10-11T14:27:04-04:00 Define-XML version: 2.1.6	
Standards		Define Anti-Version 21.10 Define Anti-Version 21.10	
▼ Datasets		Stylesheet version: 2019-02-11	
RS (Disease Response and Clin Classi TR (Tumor/Lesion Results)	Study Name	CDISC01	
TU (Tumor/Lesion Identification)	Study Description	CDISC Test Study	
Controlled Terminology	Protocol Name	CDISC01	
Expand all VLM	Metadata Name	Study CDISC01_1, Data Definitions V-1	
	Metadata Description	Data Definitions for CDISC01-01 SDTM datasets	

This Define-XML document is based on RS, TR and TU dataset and column metadata extracted from the CDISC Library. Value level metadata (VLM) and codelists were programmatically created by extracting metadata from CDISC SDTM Dataset Specializations and the CDISC Library.

Standards for Study CDISC01

Standard	Туре	Status	Documentation
SDTMIG 3.3	IG	Final	
CDISC/NCI SDTM 2023-09-29	ст	Final	
CDISC/NCI DEFINE-XML 2023-06-30	ст	Final	

Datasets

Dataset	Description	Class	Structure	Purpose	Keys	Documentation	Location
<u>RS</u> [SDTMIG 3.3]	Disease Response and Clin Classification	FINDINGS	One record per response assessment or clinical classification assessment per time point per visit per subject per assessor per medical evaluator	Tabulation	STUDYID, RSDTC, USUBJID, RSTESTCD, RSNAM, RSEVAL, RSEVALID, RSGRPID, VISITNUM		<u>rs.xpt</u> සි
TR [SDTMIG 3.3]	Tumor/Lesion Results	FINDINGS	One record per tumor measurement/assessment per visit per subject per assessor	Tabulation	STUDYID, VISITNUM, TRDTC, USUBJID, TRTESTCD, TRMETHOD, TRNAM, TREVAL, TREVALID, TRLNKID		tr.xpt @
<u>TU</u> [SDTMIG 3.3]	Tumor/Lesion Identification	FINDINGS	One record per identified tumor per subject per assessor	Tabulation	STUDYID, TUEVALID, TULNKID, VISITNUM, TUDTC, USUBJID, TUTESTCD, TULOC, TULAT, TUMETHOD, TUNAM, TUEVAL		<u>tu.xpt</u> ही



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Subcategory

- Value Level Metadata and

RSSCAT

- Controlled Terminology metadata for the RS, TR, and TU domains

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Standards					Quaimer			Investigator)
 Datasets RS (Disease Response and Clin Cla 	RSORRES VLM		Result or Finding in	text	Result	200		Collected (Source:
TR (Tumor/Lesion Results)			Original Units		Qualifier			Investigator)
TU (Tumor/Lesion Identification)		EPOCH = "TREATMENT" and	New Lesion Progression	text	Qualifier		Oncology Response Assessment Result, subset for	Collected (Source:
 Controlled Terminology 		RSCAT = "RECIST 1.1" and					New Lesion Progression - Original (Res)	Investigator)
▼ CodeLists		RSEVAL = "INVESTIGATOR" and					 "EQUIVOCAL" = "Equivocal" 	
Directionality		<u>RSTESTCD</u> = "NEWLPROG" (New Lesion Progression)					 "UNEQUIVOCAL" = "Unequivocal" 	
Epoch, subset								
Evaluator, subset		EPOCH = "TREATMENT" and	Non-Target Response	text	Qualifier		Oncology Response Assessment Result, subset for	Collected (Source:
Laterality		RSCAT = "RECIST 1.1" and RSEVAL = "INVESTIGATOR" and					Non-Target Response - Original (Res)	Investigator)
Anatomical Location		<u>RSTESTCD</u> = "NTRGRESP"					"CR" = "Complete Remission"	
Medical Evaluator Identifier		(Non-target Response)					 "NE" = "Unevaluable" 	
Method, subset							"NON-CR/NON-PD" = "Non Complete Response/Non	
Not Done							Progressive Disease"	
No Yes Response, subset							 "PD" = "Progressive Disease" 	
No Yes Response, subset for Non							-	
No Yes Response, subset for Targ		EPOCH = "TREATMENT" and	Overall Response	text	Qualifier		Oncology Response Assessment Result, subset for	Collected (Source:
No Yes Response, subset for Non		RSCAT = "RECIST 1.1" and RSEVAL = "INVESTIGATOR" and					<u>Overall Response - Original (Res)</u>	Investigator)
No Yes Response, subset for Targ		<u>RSTESTCD</u> = "OVRLRESP"					[7 Terms]	
Category of Oncology Response /		(Overall Response)						
Oncology Response Assessment			T	have the	0			
Oncology Response Assessment		EPOCH = "TREATMENT" and RSCAT = "RECIST 1.1" and	Target Response	text	Qualifier		Oncology Response Assessment Result, subset for Target Response - Original (Res)	Collected (Source:
Oncology Response Assessment		KOCAT - RECIST 1.1 and					Target Response - Originar (Res)	Investigator)

text

Grouping

Qualifier

200

Collected (Source:

Investigator)



- Value Level Metadata and
- Controlled Terminology metadata for the RS, TR, and TU domains

CDISC01	TRSTRESC VLM		Character Result/Finding in Std Format	text	Result Qualifier	200	Tumor or Lesion Properties Test Result [22 Terms]	Derived (Source: Sponsor)
CDISCOI			in Sta Format		Quanter		[22 Terms]	Sponsor)
Standards		EPOCH IN (Lymph Node State	text	Qualifier		Tumor or Lesion Properties Test Result,	Derived (Source:
▼ Datasets		"SCREENING",			-		subset for Lymph Node State -	Sponsor)
RS (Disease Response and Clin		"TREATMENT"					Standardized (Char Res)	
TR (Tumor/Lesion Results)) and					"NON-PATHOLOGICAL"	
TU (Tumor/Lesion Identificatior		TREVAL IN ("PATHOLOGICAL"	
 Controlled Terminology 		"ADJUDICATOR", "INDEPENDENT ASSESSOR",						
▼ CodeLists		"INVESTIGATOR"						
Directionality) and						
Epoch, subset		TRMETHOD IN (
Evaluator, subset		"CALIPER MEASUREMENT						
Laterality		METHOD",						
Anatomical Location		"CT SCAN",						
Medical Evaluator Identifier		"ENDOSCOPY",						
Method, subset		"LYMPHANGIOGRAPHY", "MAMMOGRAPHY",						
Not Done		"MRI",						
		"NUCLEAR RADIOLOGY",						
No Yes Response, subset		"PET SCAN",						
No Yes Response, subset for		"PET/CT SCAN",						
No Yes Response, subset for		"PET/MRI SCAN",						
No Yes Response, subset for		"PHOTOGRAPHY",						
No Yes Response, subset for		"SCINTIGRAPHY",						
Category of Oncology Respor		"TOTAL BODY RADIOGRAPHY",						
Oncology Response Assessme		"ULTRASOUND",						
Oncology Response Assessme		"X-RAY") and						
Oncology Response Assessme		TRTESTCD = "LNSTATE"						
Oncology Response Assessm		(Lymph Node State)						
Oncology Response Assessm								

- Value Level Metadata and
- Controlled Terminology metadata for the RS, TR, and TU domains

CDISC01	TUSTRESC VLM		Tumor/Lesion ID Result Std. Format	text	Result Qualifier	200	Tumor or Lesion Identification Test Results [28 Terms]	Derived (Source: Sponsor)
RS (Disease Response and Clin TR (Tumor/Lesion Results) TU (Tumor/Lesion Identification Controlled Terminology CodeLists Directionality Epoch, subset Evaluator, subset Laterality Anatomical Location Medical Evaluator Identifier Method, subset Not Done No Yes Response, subset for No Yes Response, subset for Category of Oncology Respor Oncology Response Assessm Oncology Response Assessm Oncology Response Assessm		EPOCH = "SCREENING" and TUEVAL = "INVESTIGATOR" and TUTESTCD = "NTIND" (Non- Target Indicator)	Non-Target Indicator	text	Qualifier	24	No Yes Response, subset for Non- Target Indicator - Standardized (Char Res) • "N" = "No" • "U" = "Unknown" • "Y" = "Yes"	Derived (Source: Sponsor)
		EPOCH = "SCREENING" and TUEVAL = "INVESTIGATOR" and TUTESTCD = "TIND" (Target Indicator)	Target Indicator	text	Qualifier	24	No Yes Response, subset for Taroet Indicator - Standardized (Char Res) • "N" = "No" • "U" = "Unknown" • "Y" = "Yes"	Derived (Source: Sponsor)
		EPOCH = "TREATMENT" and TUEVAL IN ("ADJUDICATOR", "INVESTIGATOR") and TUHETHOD IN ("CALIPER MEASUREMENT METHOD", "CT SCAN", "ENDOSCOPY", "LYMPHANGIOGRAPHY", "MOMMONAPH"	Tumor Merged	text	Qualifier	24	Tumor or Lesion Identification Test Results, subset for Tumor Merged - Standardized (Char Res) • "TARGET"	Derived (Source: Sponsor)

Uncougy Response Assessme	La INiza April, J	
Portion/Totality	"TOTAL BODY	
Relation to Reference Period	RADIOGRAPHY", "ULTRASOUND".	
Tumor or Lesion Properties Te	"X-RAY"	
Tumor or Lesion Properties Te) and	
Tumor or Lesion Properties Te	TUTESTCD = "TUMERGE"	
Tumor or Locion Proportion Tr	(Tumor Meraed)	



Conclusion

- SDTM Dataset Specializations can be represented as Value Level Metadata definitions in Define-XML v2.1.
- These definitions contain detailed metadata, including Controlled Terminology subsets.
- The SDTM Dataset Specializations can be considered pre-configured building blocks, from which end-users can select and configure to build Define-XML Value Level Metadata
- SDTM dataset specializations are ready to be used as building blocks for Define-XML.
- This provides immediate benefits to SDTM programmers and opens the door to efficient programming and automation



Retrieval of Biomedical Concepts and SDTM Dataset Specializations

Using CDISC Library APIs

API Endpoints in CDISC Library

- Biomedical Concepts and SDTM Specialization are published in packages
- Packages have new content and updates to existing content
- Not cumulative!

2022-10-26 2023-02-13 2023-03-31 2023-07-06 2023-10-03

API request template for Biomedical Concepts
/mdr/bc/packages
/mdr/bc/packages/{package}/biomedicalconcepts
<pre>/mdr/bc/packages/{package}/biomedicalconcepts/{biomedicalconcept}</pre>

/mdr/specializations/sdtm/packages

API request template for SDTM Specializations

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

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

API Endpoints in CDISC Library

• Biomedical Concepts and SDTM Specialization can now also be requested through the API (v2 only) with all the latest versions

API request template for Biomedical Concepts	API v2 Only?	Return Latest Version Only?
/mdr/bc/biomedicalconcepts	v	<
/mdr/bc/biomedicalconcepts/{biomedicalconcept}	Ø	<
/mdr/bc/categories	Ø	
/mdr/bc/biomedicalconcepts?category={category}	Ø	<



API Endpoints in CDISC Library

 Biomedical Concepts and SDTM Specialization can now also be requested through the API (v2 only) with all the latest versions

API request template for SDTM Specialization	API v2 Only?	Return Latest Version Only?
/mdr/specializations/sdtm/datasetspecializations	Ø	•
<pre>/mdr/specializations/sdtm/datasetspecializations/{datasetspecialization}</pre>	Ø	Ø
/mdr/specializations/sdtm/domains	Ø	
<pre>/mdr/specializations/sdtm/datasetspecializations?domain={domain}</pre>	Ø	•
API request template for Specializations	API v2 Only?	Return Latest Version Only?
<pre>/mdr/specializations/datasetspecializations?biomedicalconcept= {biomedicalconcept}</pre>	0	0



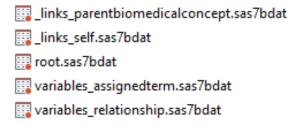
API Requests in SAS

```
%let ApiKey=<your_personal_api_key>;
%let baseURL=https://library.cdisc.org/api/cosmos/v2;
```

```
filename json_out temp;
proc http
  method = 'GET'
  url="&baseURL/mdr/specializations/sdtm/datasetspecializations/SYSBP"
  out=json_out;
  headers
    "api-key" = "&ApiKey"
    "Accept" = "application/json";
run;
```

```
filename json_map temp;
libname json_out json map=json_map automap=create fileref=json_out;
```

```
proc copy in = json_out out = work;
run;
```



- 📴 _links_parentpackage.sas7bdat
- 🧱 alldata.sas7bdat
- 🧱 variables.sas7bdat
- 🔛 variables_codelist.sas7bdat
- 🧱 variables_valuelist.sas7bdat

Key Achievements and Next Steps

Current Status and Future Plans

CDISC Biomedical Concepts

2023 Key Achievements

- Curation of new Biomedical Concepts (BCs) and SDTM Dataset Specializations
 - 208 BCs and 171 SDTM Dataset Specializations currently available via CDISC Library APIs
 - Additional BCs and SDTM will be loaded end of Q42023
 - Streamlined curation process and documentation
- New API Endpoints to find and retrieve BCs/SDTM Dataset Specializations
- Established versioning and change management for BCs and APIs
 - Loaded multiple packages of BCs/SDTM Dataset Specializations
 - Retrieval of the latest version of BCs/SDTM across packages
 - Established lineage across versions
- Supported CDISC Oncology SDS Team to create, validate and release BCs and SDTM Dataset Specializations for RECIST 1.1 Disease Response Criteria
 - Retrievable via CDISC Library APIs
- Supported Digital Data Flow Phase 2-3 (DDF)
 - Created BCs/SDTM Dataset Specializations for example COVID and Alzheimer's protocols
 - Integration of CDISC BC model into USDM to support eDC automation



Supporting Digital Data Flow Phase 3 (DDF3)

- DDF 3 Pilot Study
 - Development of additional biomedical concepts to cover the CDISC Pilot Study (LZZT)
 - Allows for a full exemplar USDM protocol Design

The information contained in this clinical multiprotect is Depring to 2006 ELLU yes of Company.		Protocol Attachment LZZT.1 Schedule of Events for Protocol H2Q-MC-LZZT(c)								
copyright to 2009 bit City and Company.		VISIT	1	2	3	4	5		7	8
	ACTIVITY	WEEK	-2	و.		2	4		6	
	Informed consent		х							
	Patient number assigned		x							
	Hachinski ≤4		х							
	MMSE 10-23		X							
Xanomeline (LY246708)	Physical examination		X							
Kanonionio (Erzeoroo)	Medical History		x							
	Habits		х							
	Chest x-ray		х							
Protocol H2Q-MC-LZZT(c)	Apo E genotyping					x				
	Patient randomized				X					
Safety and Efficacy of the Xanomeline	Vital signs/Temperature		х	х	x	x	x		x	3
	Ambulatory ECG placed			X						
Transdermal Therapeutic System (TTS) in Patients	Ambulatory ECG removed				x					
with Mild to Moderate Alzheimer's Disease	ECG		х			x	x		x	2
	Placebo TTS test		X							
	CT Scan (if not within		X							
	last year and patient passes									
	all other screens)									
	Concomitant Medications		Х		X	X	х		X	2
	Laboratory (Chem/Hemat):		х			x	х		х	2
	Laboratory (Urinalysis)		Х			х				
	Plasma Specimen				X	x	х		x	
	(Xanomeline)									
	Hemoglobin A _{1C}		X ^a							
	Study drug record				x	х	х		х	3
	Medications dispensed Medications returned				1					
	Medications returned TTS Acceptability Survey	-		-	-	-	-	-	-	-
	ADAS-Cog	-	р		x	-	-	-	-	3
	CIBIC+	-	P		X	-	-		-	2
	DAD	-	P		X	-	-	-	-	2
	NPLX	-	P		X	x	x	-	x	X ³
	Adverse events	-	X	x	X	X		-	X	X
	Abbreviations: CT = c X = Performed at this via	it.	mograp	nhy; EC	G = ele	ctrocard	iogram		-	
	X^a = Performed at this vi X^b = Performed at this vi P = Practice only - It is n	isit and via	teleph	one inte	rview 2	weeks	followin			
Xanomeline (LY246708) H2G-MC-L22T(c) Copyright © 2006 Eli Lilly and Company Clinical Study Protocol Cocument Page 1	P = Practice only = II is n and NPI-X be administer considered as study data	ed at Visit	1. Data	a from t	his sam				, DAD,	

Supporting Digital Data Flow Phase 3 (DDF3)

Supporting Study Design and eDC automation

- Integration of the CDISC BC model into USDM to support EDC automation
- Building a complete set of BCs and SDTM Dataset Specializations for the Pilot Study (Alzheimer's Disease)
- Attaching CDISC BCs/SDTM Dataset Specializations to Activities which are in turn attached to timepoints in the SoA which provides:
 - Decision occurs at either protocol design or eDC stage
- Ends with a detailed study specification (next level after SoA)
- What's the big deal?
 - Precise definition of all data points
 - Increased standardization and cross-study consistency
 - Higher quality specifications



Looking to Future

Upcoming Activities and Future Plans

- CDASH dataset specializations
- FHIR dataset specializations
- Include metadata for transformational algorithms in CDISC Dataset Specializations
 - Participation and alignment with OAK project to begin building end to end data flow CDASH SDTM, etc.
- Support new TAUGs
- Support CDISC Oncology SDS Team to create more BCs/SDTM Specializations
- Migration of BC content from CDISC community
 - Currently working with Novo-Nordisk to migrate/load a sampling of their BCs to CDISC Library
- Establish User friendly search, visualizations and exports
- Continue to improve and streamline the BC curation process
- Hoping to get more 'BCs' from the community



