



2023

US

INTERCHANGE

FALLS CHURCH, VA | 18-19 OCTOBER



CDISC Biomedical Concepts and Dataset Specializations

COSA Biomedical Concept & OpenStudyBuilder Workshop

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CDISC Biomedical Concepts and SDTM Dataset Specializations

Background and Introduction



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**:

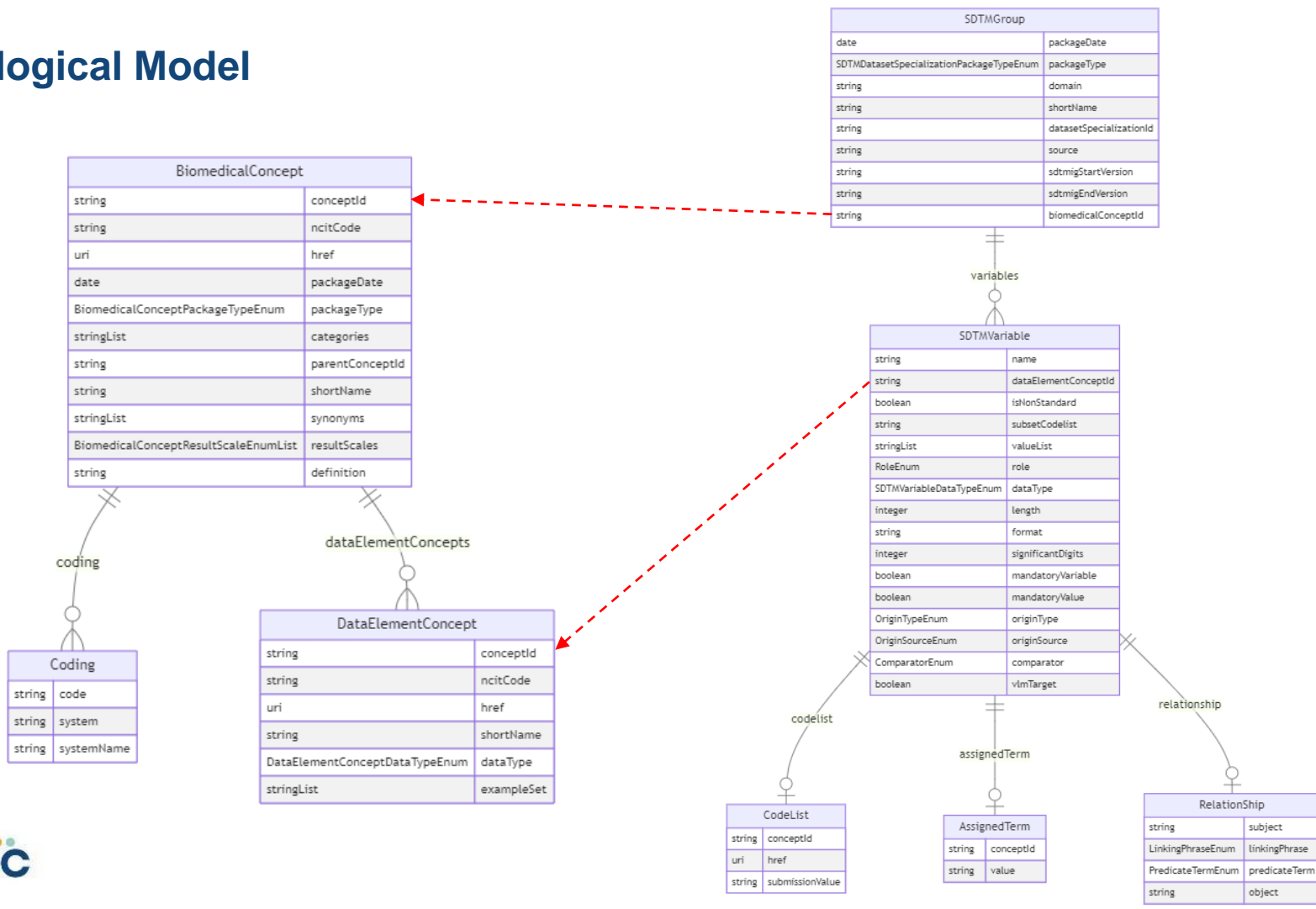
- Extend foundational standards
 - Add explicit relationships between variables
 - Additional operational metadata, e.g., data type, etc.
- Conceptual Layer – abstract BC's
 - Provides semantics - aligned with NCI terminology
 - Supports study design, Schedule of Activities (SOA)
- Implementation Layer - 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



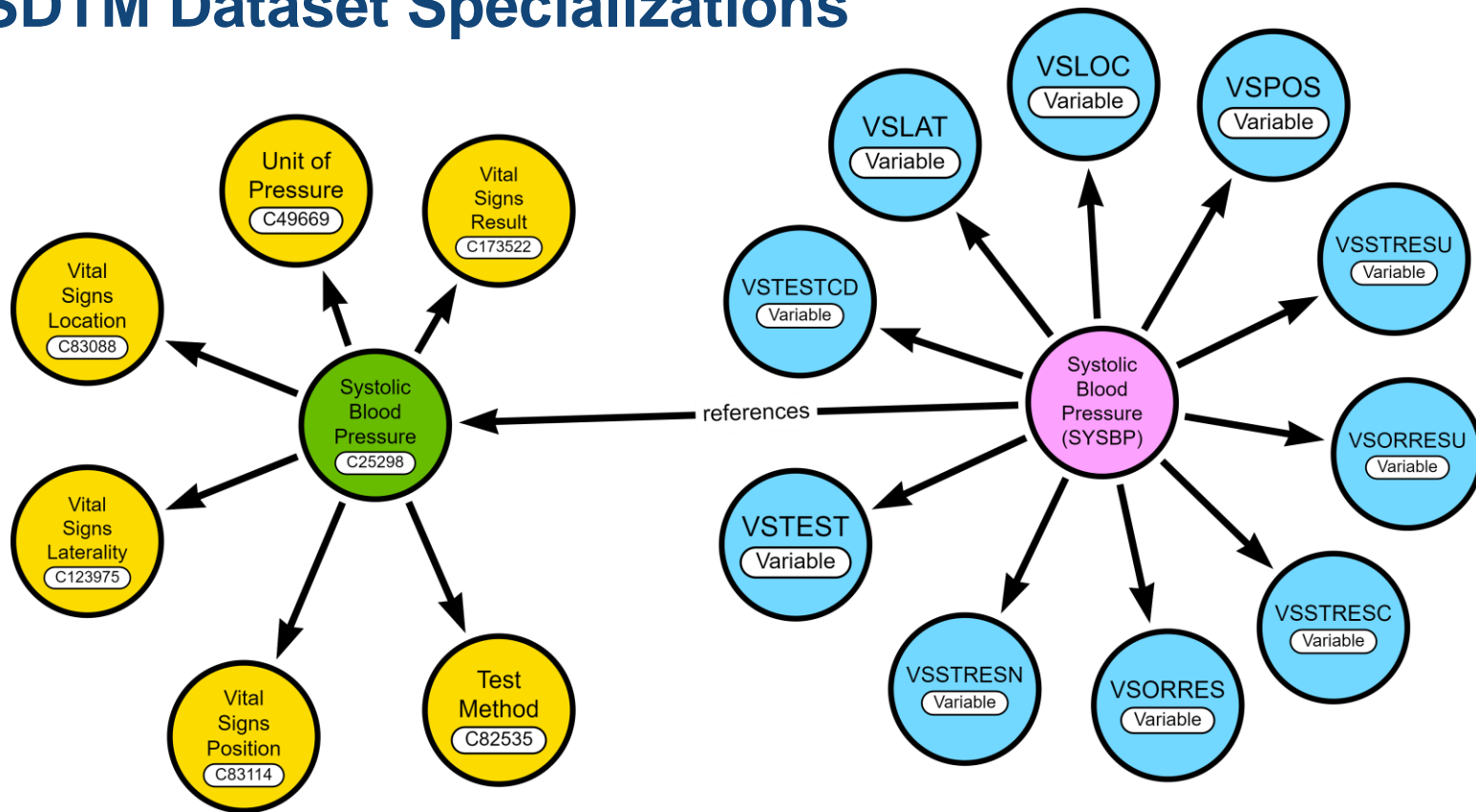
SDTM Dataset Specializations

Building Blocks for Define-XML

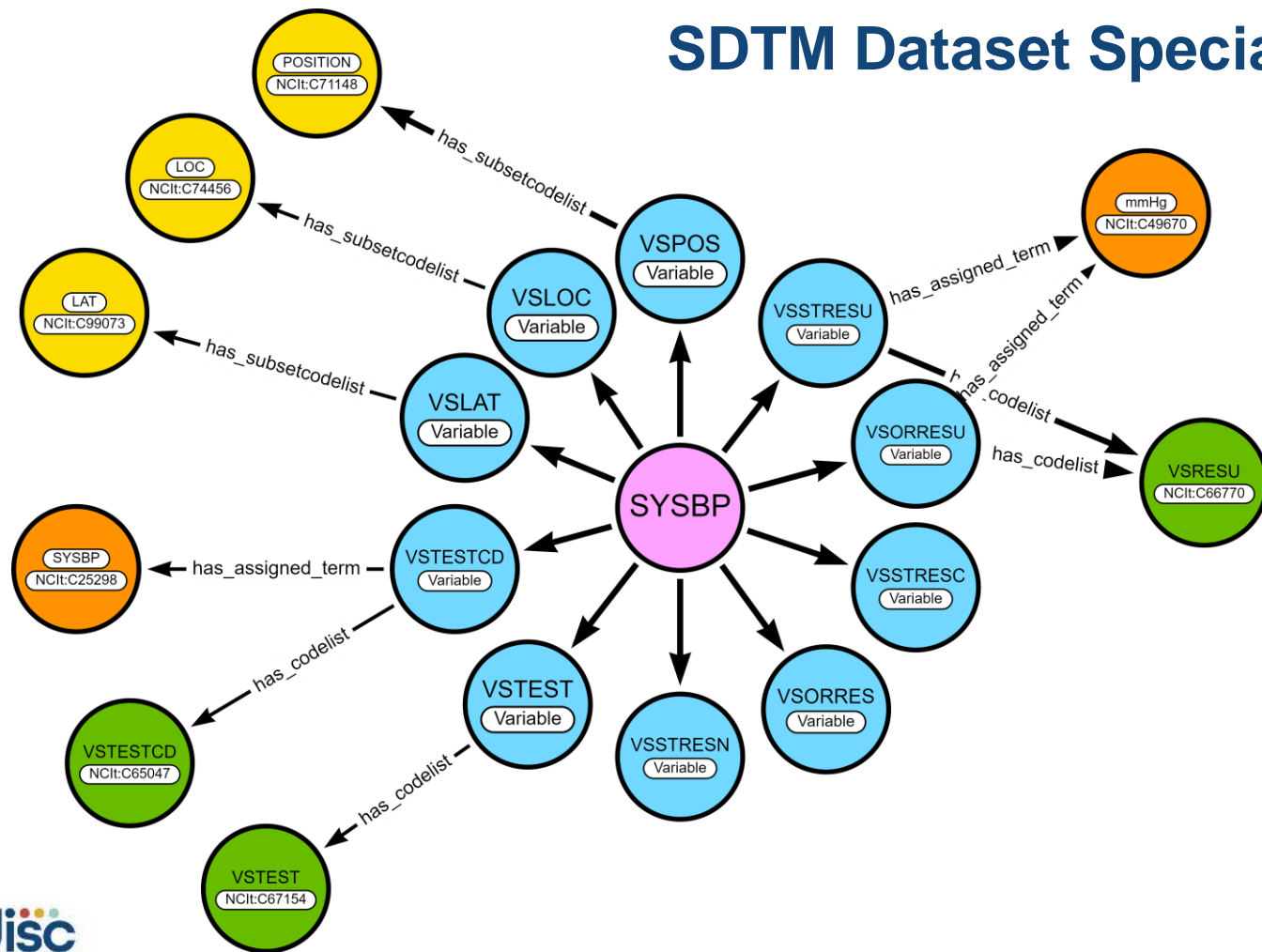
The logical Model



CDISC Biomedical Concepts and SDTM Dataset Specializations



SDTM Dataset Specializations



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

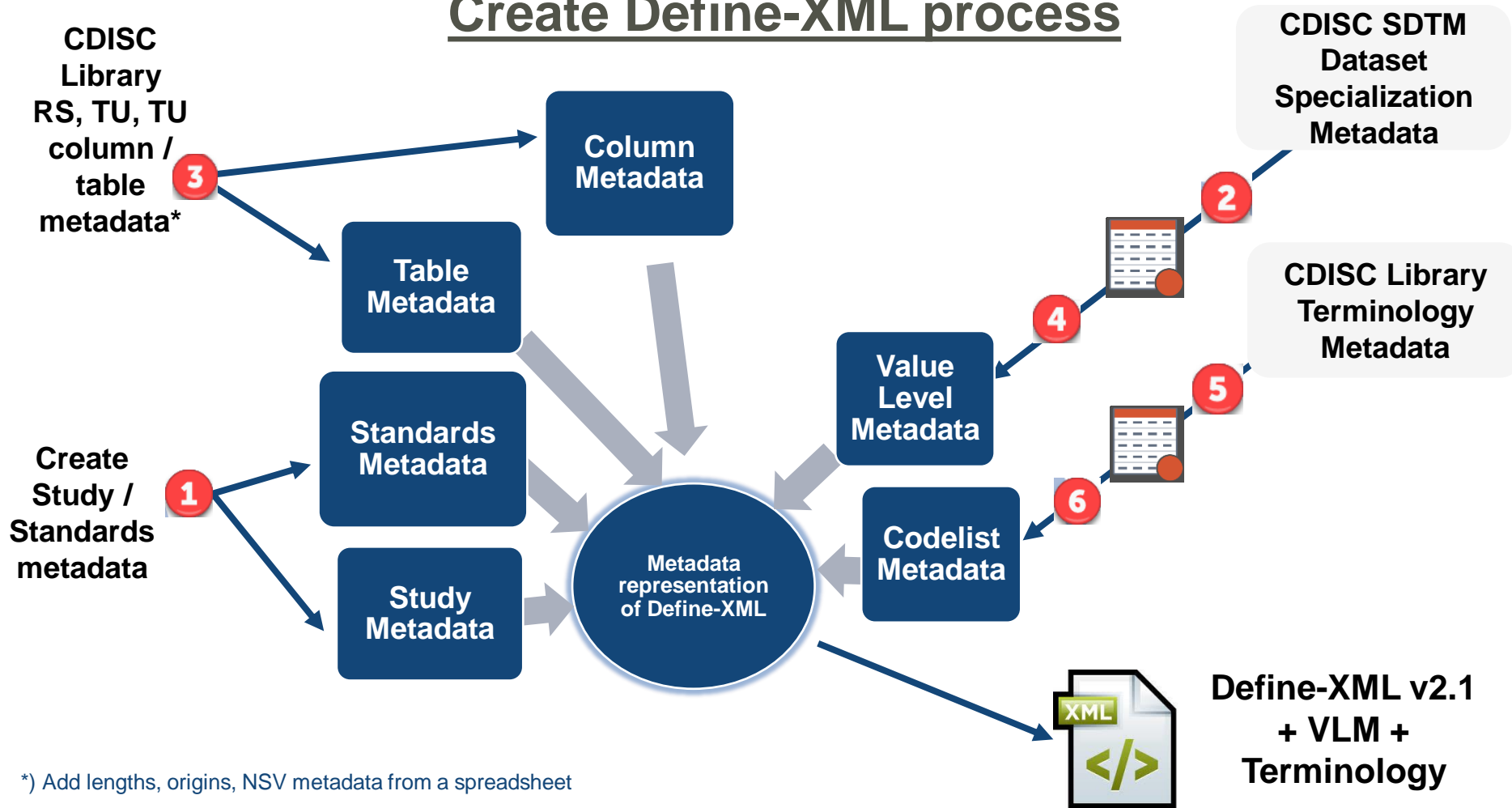
SDTM Dataset Specializations

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		Variable significant digits
mandatoryVariable		Indicator that variable must be present within the SDTM group
mandatoryValue		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)

Define-XML v2.1 document with SDTM Dataset Specialization:

- 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`

Create Define-XML process



Define-XML v2.1 document with SDTM Dataset Specialization:

- Value Level Metadata and
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CDISC01

Standards

▼ Datasets

RS (Disease Response and Clin Class)

TR (Tumor/Lesion Results)

TU (Tumor/Lesion Identification)

► Controlled Terminology

Expand all VLM

Collapse all VLM

Date/Time of Define-XML document generation: 2023-10-11T14:27:04-04:00

Define-XML version: 2.1.6

Define-XML Context: Submission

Stylesheet version: 2019-02-11

Study Name	CDISC01
Study Description	CDISC Test Study
Protocol Name	CDISC01
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	Type	Status	Documentation
SDTMIG 3.3	IG	Final	
CDISC/NCI SDTM 2023-09-29	CT	Final	
CDISC/NCI DEFINE-XML 2023-06-30	CT	Final	

Datasets

Dataset	Description	Class	Structure	Purpose	Keys	Documentation	Location
RS [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		rs.xpt 🔗
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 🔗
TU [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		tu.xpt 🔗

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CDISC01

Standards

▼ Datasets

RS (Disease Response and Clin Cla

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

No Yes Response, subset for Non

No Yes Response, subset for Targ

No Yes Response, subset for Non

No Yes Response, subset for Targ

Category of Oncology Response /

Oncology Response Assessment /

Oncology Response Assessment /

Oncology Response Assessment /

RSSCAT		Subcategory	text	Grouping Qualifier	200		Collected (Source: Investigator)
RSORRES VLM		Result or Finding in Original Units	text	Result Qualifier	200		Collected (Source: Investigator)
	EPOCH = "TREATMENT" and RSCAT = "RECIST 1.1" and RSEVAL = "INVESTIGATOR" and RSTESTCD = "NEWLPROG" (New Lesion Progression)	New Lesion Progression	text	Qualifier		Oncology Response Assessment Result, subset for New Lesion Progression - Original (Res) • "EQUIVOCAL" = "Equivocal" • "UNEQUIVOCAL" = "Unequivocal"	Collected (Source: Investigator)
	EPOCH = "TREATMENT" and RSCAT = "RECIST 1.1" and RSEVAL = "INVESTIGATOR" and RSTESTCD = "NTRGRESP" (Non-target Response)	Non-Target Response	text	Qualifier		Oncology Response Assessment Result, subset for Non-Target Response - Original (Res) • "CR" = "Complete Remission" • "NE" = "Unevaluable" • "NON-CR/NON-PD" = "Non Complete Response/Non Progressive Disease" • "PD" = "Progressive Disease"	Collected (Source: Investigator)
	EPOCH = "TREATMENT" and RSCAT = "RECIST 1.1" and RSEVAL = "INVESTIGATOR" and RSTESTCD = "OVRRESP" (Overall Response)	Overall Response	text	Qualifier		Oncology Response Assessment Result, subset for Overall Response - Original (Res) [7 Terms]	Collected (Source: Investigator)
	EPOCH = "TREATMENT" and RSCAT = "RECIST 1.1" and	Target Response	text	Qualifier		Oncology Response Assessment Result, subset for Target Response - Original (Res)	Collected (Source: Investigator)

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CDISC01

Standards

▼ Datasets

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

No Yes Response, subset for

No Yes Response, subset for

No Yes Response, subset for

No Yes Response, subset for

Category of Oncology Respon

Oncology Response Assessm

Oncology Response Assessm

Oncology Response Assessm

Oncology Response Assessm

Oncology Response Assessm

TRSTRESC VLM		Character Result/Finding in Std Format	text	Result Qualifier	200	Tumor or Lesion Properties Test Result [22 Terms]	Derived (Source: Sponsor)
	EPOCH IN ("SCREENING", "TREATMENT") and TREVAL IN ("ADJUDICATOR", "INDEPENDENT ASSESSOR", "INVESTIGATOR") and TRMETHOD IN ("CALIPER MEASUREMENT METHOD", "CT SCAN", "ENDOSCOPY", "LYMPHANGIOGRAPHY", "MAMMOGRAPHY", "MRI", "NUCLEAR RADIOLOGY", "PET SCAN", "PET/CT SCAN", "PET/MRI SCAN", "PHOTOGRAPHY", "SCINTIGRAPHY", "TOTAL BODY RADIOGRAPHY", "ULTRASOUND", "X-RAY") and TRTESTCD = "LNSTATE" (Lymph Node State)	Lymph Node State	text	Qualifier		Tumor or Lesion Properties Test Result, subset for Lymph Node State - Standardized (Char Res) <ul style="list-style-type: none"> "NON-PATHOLOGICAL" "PATHOLOGICAL" 	Derived (Source: Sponsor)

Define-XML v2.1 document with SDTM Dataset Specialization:

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CDISC01

Standards

▼ Datasets

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

No Yes Response, subset for

No Yes Response, subset for

No Yes Response, subset for

No Yes Response, subset for

Category of Oncology Response

Oncology Response Assessment

Oncology Response Assessm

Oncology Response Assessm

Oncology Response Assessment

...con...R...on...A...m

Incubity Response Assessment

Portion/Totality

Relation to Reference Period

Tumor or Lesion Properties T

Tumor or Lesion Properties T

Tumor or Lesion Properties T

TUSTRESC	VLM		Tumor/Lesion ID Result Std. Format	text	Result Qualifier	200	Tumor or Lesion Identification Test Results [28 Terms]	Derived (Source: Sponsor)
		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) <ul style="list-style-type: none">"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 Target Indicator - Standardized (Char Res) <ul style="list-style-type: none">"N" = "No""U" = "Unknown""Y" = "Yes"	Derived (Source: Sponsor)
		EPOCH = "TREATMENT" and TUEVAL IN ("ADJUDICATOR", "INDEPENDENT ASSESSOR", "INVESTIGATOR") and TUMETHOD IN ("CALIPER MEASUREMENT METHOD", "CT SCAN", "ENDOSCOPY", "LYMPHANGIOGRAPHY", "IMMUNOHISTOCHEMISTRY") and TUTESTCD = "TUMERGE" (Tumor Merged)	Tumor Merged	text	Qualifier	24	Tumor or Lesion Identification Test Results, subset for Tumor Merged - Standardized (Char Res) <ul style="list-style-type: none">"TARGET"	Derived (Source: Sponsor)
		TOTAL BODY RADIOGRAPHY, "ULTRASOUND", "X-RAY") and TUTESTCD = "TUMERGE" (Tumor Merged)						



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

API request template for Biomedical Concepts

2023-02-13

`/mdr/bc/packages`

2023-03-31

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

2023-07-06

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

2023-10-03

API request template for SDTM Specializations

`/mdr/specializations/sdtm/packages`

`/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?
<code>/mdr/bc/biomedicalconcepts</code>	✓	✓
<code>/mdr/bc/biomedicalconcepts/{biomedicalconcept}</code>	✓	✓
<code>/mdr/bc/categories</code>	✓	
<code>/mdr/bc/biomedicalconcepts?category={category}</code>	✓	✓

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?
<code>/mdr/specializations/sdtm/datasetspecializations</code>	✓	✓
<code>/mdr/specializations/sdtm/datasetspecializations/{datasetspecialization}</code>	✓	✓
<code>/mdr/specializations/sdtm/domains</code>	✓	
<code>/mdr/specializations/sdtm/datasetspecializations?domain={domain}</code>	✓	✓

API request template for Specializations	API v2 Only?	Return Latest Version Only?
<code>/mdr/specializations/datasetspecializations?biomedicalconcept={biomedicalconcept}</code>	✓	✓


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/datasetsspecializations/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_parentbiomedicalconcept.sas7bdat

 _links_self.sas7bdat


 root.sas7bdat


 variables_assignedterm.sas7bdat


 variables_relationship.sas7bdat

 _links_parentpackage.sas7bdat

 alldata.sas7bdat

 variables.sas7bdat

 variables_codelist.sas7bdat

 variables_valuelist.sas7bdat