Using Controlled Terminologies with CDISC Standards

LPO Webinar

2 April 2019

NIH NATIONAL CANCER INSTITUTE

Upon completion of this webinar, you should be able to:

- Explain the importance of using consistent, well-defined values to represent your collected data
- Find, understand and effectively use the published CDISC controlled terminology
- Request new terms, when needed
- Identify controlled terminology used for the study using Define.xml
- Identify non-CDISC terminologies that are required for use in SDTM

CDISC Controlled Terminology Basics

- Value lists: Defined concepts with a *single representation (required for FDA submissions)*

ACN (Action Taken with Study Treatment)

NCI Code: C66767, Codelist extensible: No

C66767	ACN			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C49503	DOSE INCREASED		An indication that a medication schedule was modified by addition; either by changing the frequency, strength or amount. (NCI)	Dose Increased
C49504	DOSE NOT CHANGED		An indication that a medication schedule was maintained. (NCI)	Dose Not Changed
C150826	DOSE RATE REDUCED		An indication that the administration of a medication was modified by reducing the rate at which the dose was	Dose Rate Reduced
C49505	DOSE REDUCED			
C49501	DRUG INTERRUPTED		An indication that a medication schedule was modified by temporarily terminating a prescribed regimen of medication. (NCI)	Drug Interrupted
C49502	DRUG WITHDRAWN		An indication that a medication schedule was modified through termination of a prescribed regimen of medication. (NCI)	Drug Withdrawn
C48660	NOT APPLICABLE	NA;Not Applicable	Determination of a value is not relevant in the current context. (NCI)	Not Applicable
C17998	UNKNOWN	U;UNK;Unknown	Not known, not observed, not recorded, or refused. (NCI)	Unknown

Use EXACT spelling and case of published CDISC Submission Value

CDISC Controlled Terminology Basics

- Some codelists have a very specific use case:

VSRESU (Units for Vital Signs Results)

NCI Code: C66770, Codelist extensible: Yes

C66770	VSRESU
NCI Code	CDISC Submissi Value
C25613	%
C49673	beats/min
C49674	breaths/min
C42559	C
C49668	cm
C147129	cmHg
C44277	F

CVTEST (Cardiovascular Test Name)

NCI Code: C101846, Codelist extensible: Yes

C101846	CVTEST			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Ter
C139038	Aneurysm Indicator	Aneurysm Indicator	An indication as to whether there is the presence of one or more aneurysms.	Aneurysm Indicator
C127535	Annular a' Velocity	Annular a' Velocity	The peak velocity of the annular motion during late ventricular diastole (the active filling of the ventricle).	Annular a' Velocity
C127536	Annular e' Velocity	Annular e' Velocity	The peak velocity of the annular motion during early ventricular diastole (the passive filling of the ventricle).	Annular e' Velocity
C139042	Annular Plane Systolic Excursion	Annular Plane Systolic Excursion	The longitudinal displacement of a cardiac valve annulus toward the apex of the heart.	Annular Plane Systol Excursion
C139045	Annular S' Velocity	Annular S' Velocity	The peak velocity of the annular motion during ventricular systole.	Annular S' Velocity
C122038	Aortic Augmentation Index	Aortic Augmentation Index	The augmentation pressure divided by the aortic pulse pressure (aortic systolic minus aortic diastolic pressure) multiplied by 100, expressed as a percentage.	Aortic Augmentation Index
C122083	Aortic Augmentation Index at 75bpm	Aortic Augmentation Index at 75bpm	The aortic augmentation index normalized to a heart rate of 75 beats per minute.	Aortic Augmentation Index at 75bpm
C122084	Aortic Augmentation Pressure	Aortic Augmentation Pressure	The difference between the second pressure peak in the aortic wave, secondary to the pressure wave reflection from the sites of peripheral arterial impedance mismatch (P2) and the first pressure peak in the aortic wave form, secondary to ventricular ejection (P1).	Aortic Augmentation Pressure
C122085	Aortic Augmentation Pressure Peak P1	Aortic Augmentation Pressure Peak P1	The first pressure peak in the aortic wave form secondary to ventricular ejection.	Augmentation Pressu Point P1

CDISC Controlled Terminology Basics

- Other codelists are more general and can be used for multiple purposes:

NRIND (Reference Range Indicator)

NCI Code: C78736, Codelist extensible: Yes

C78736	NRIND			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C78802	ABNORMAL		Reported values outside the typical or expected range. (NCI)	Abnormal Reference Range
C78800	HIGH		Reported values above the typical or expected range. (NCI)	Value Above Reference Range

NY (No Yes Response)

NCI Code: C66742, Codelist extensible: No

C66742	NY			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C49487	N	No	The non-affirmative response to a question. (NCI)	No
C48660	NA	NA;Not Applicable	Determination of a value is not relevant in the current context. (NCI)	Not Applicable
C17998	U	U;UNK;Unknown	Not known, not observed, not recorded, or refused. (NCI)	Unknown
C49488	Y	Yes	The affirmative response to a question. (NCI)	Yes

CDISC Controlled Terminology Basics

- Some values may appear in more than one codelist:

Same meaning, Same Code

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value
C17998	C66767	1	Action Taken with Study Treatment	UNKNOWN
C17998	C101859	2	Cardiac Procedure Indication	UNKNOWN
C17998	C101850	3	Coronary Vessel Disease Extent	UNKNOWN
C17998	C66790	4	Ethnic Group	UNKNOWN
C17998	C71113	5	Frequency	UNKNOWN
C17998	C85495	6	Microbiology Susceptibility Testing Result Category	UNKNOWN
C17998	C127265	7	Mode of Disease Transmission	UNKNOWN
C17998	C101834	8	Normal Abnormal Response	UNKNOWN
C17998	C66768	9	Outcome of Event	UNKNOWN
C17998	C128689	10	Race As Collected	UNKNOWN
C17998	C66728	11	Relation to Reference Period	UNKNOWN
C17998	C101848	12	Risk Assessment	UNKNOWN
C17998	C124304	13	Subject Status Response	UNKNOWN

UNKNOWN appears in 13 different codelists (2018-12-21 Pkg 36)

CDISC Controlled Terminology Basics

- CDISC terminology is developed by Volunteer SME teams (like all CDISC standards)
  - Weekly Meetings (unless noted below)
  - Collaboration and documentation on CDISC Wiki (open, transparent)

Current Active Teams

CDISC Glossary	Cardiovascular	Medical Devices (ad hoc)
ECG	Flow Cytometry / Immunophenotyping / IHC	General
Lab	**Oncology (ad hoc)**	PGx (ad hoc)
PK	Protocol Entities	QRS
SDTM Domain Abbreviations (ad hoc)	SEND	Microbiology

CDISC Controlled Terminology Basics

- CDISC Terminology is maintained by NCI Enterprise Vocabulary Services (EVS)
  - Expert staff
  - Established processes
  - Validated Technologies

  - CDISC Controlled Terminology is published quarterly
    - March, June, September and December
    - Terms may be added, removed or modified (mostly they are added)
    - Multiple file formats (Excel, CSV, ODM.XML, RDF/OWL, PDF, HTML)

CDISC Controlled Terminology Basics

- Other benefits of having CDISC Terminology managed by NCI EVS
  - Connected to all of the published vocabularies in the NCI Thesaurus (NCIt) and NCI Metathesaurus (NCIm)
    - >6.7 million terms, >2.8 million biomedical concepts, >85 sources, >31 million relationships
    - NCI Term browser available for public use

https://www.cancer.gov/research/resources/terminology

CDISC Controlled Terminology Basics

- In addition to published, standardized terminology files, there are also
  - Diff Files
    - Details of every change from previous version
  - Mapping Files
    - Mapping to healthcare terminologies (e.g., UCUM, LOINC)
    - Value level codelist relationships

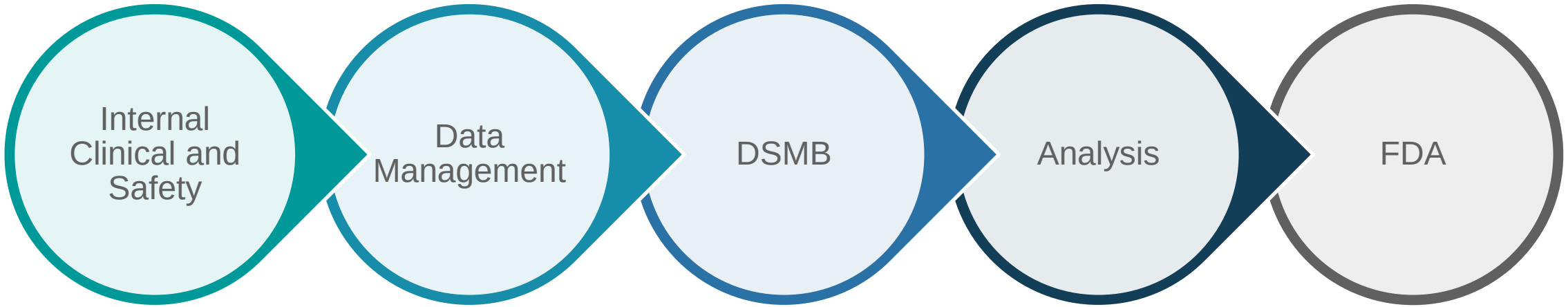
We will look at all of these types of files, but first…WHY use controlled terminology?

Why Use CDISC Controlled Terminology?

The value of consistency

CDISC Controlled Terminology Supports Data Review

Think about all the different people who view data throughout its lifecycle:



Consistent, well-defined values supports common understanding among all stakeholders

Consistent, well-defined values builds transparency and traceability into the data flow/lifecycle

Without Controlled Terminology: Unnecessary Variability and Ambiguity

Study #1

SUBJID	SEX
2001	M
2002	F
2003	F
2004	M
2005	F

Study #2

ID	GENDER
A1	Male
A2	Male
A3	Female
A4	Female
A5	Male

Study #3

PTID	GENDER
01	1
02	1
03	2
04	2
05	1

Study #4

USUBID	SEX
00011-A	0
00012-A	1
00013-A	1
00014-A	0
00015-A	1

Adapted from slide courtesy of Armando Oliva, M.D. and Amy Malla, FDA ~2010

Why FDA Reviewers Want Standardized Controlled Terminology

Values reported for AESER with Number of Unique Subjects using each value, from a combined dataset of >4000 clinical studies.

AESER	No. of unique sub	AESER	No. of unique sub
N	797851	U	149
Y	176275	NA	62
NULL	127301	0	56
1	37373	NOT COLLECTED	27
NO	29808	D	8
2	15298	Unknown	3
YES	9805	*	1

From Bridging Collaborative presentation 4 March 2019, Vashali Popat, FDA

FDA Requires CDISC Controlled Terminology

Reference: FDA Data Standards Catalog

CDISC Controlled Terminology is Required for Conformance to SDTM

- SDTM data should contain the **CDISC Submission Value**
  - SDTM variables should contain CT using exact spelling and case
  - **Controlled Terminology <u>represents</u>** the collected value
    - Data collection may have used a synonym
    - Numeric codes may have been used for data collection
- Reference Controlled Terms, Codelist column in SDTMIG specification tables for required terminology for SDTMIG variables

DM – Specification

dm.xpt, Demographics — Special Purpose, Version 3.3. One record per subject, Tabulation.

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format[1]	Role	CDISC Notes	Core

- Refer to SDTMIG 4.3 for Coding and Controlled Terminology Assumptions

SDTMIG Controlled Terms, Codelist or Format Specification

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format[1]	Role
STUDYID	Study Identifier	Char		Identifier
DOMAIN	Domain Abbreviation	Char	VS	Identifier
USUBJID	Unique Subject Identifier	Char		Identifier
VSSEQ	Sequence Number	Num		Identifier
VSGRPID	Group ID	Char		Identifier
VSSPID	Sponsor-Defined Identifier	Char		Identifier
VSTESTCD	Vital Signs Test Short Name	Char	(VSTESTCD)	Topic
VSTEST	Vital Signs Test Name	Char	(VSTEST)	Synonym Qualifier

How do we know which SDTM variables require controlled terminology?

The name of a CDISC codelist, represented as a hyperlink in parentheses, e.g., "(NY)".

SDTMIG Controlled Terms, Codelist or Format Specification

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format[1]	Role
STUDYID	Study Identifier	Char		Identifie
DOMAIN	Domain Abbreviation	Char	ML	Identifie
USUBJID	Unique Subject Identifier	Char		Identifier
MLSEQ	Sequence Number	Num		Identifier
MLGRPID	Group ID	Char		Identifier
MLSPID	Sponsor-Defined Identifier	Char		Identifier
MLTRT	Name of Meal	Char	*	
MLCAT	Category for Meal	Char	*	
MLSCAT	Subcategory for Meal	Char	*	Qualifier

How do we know which SDTM variables require controlled terminology?

A single asterisk, "*", when CDISC controlled terminology is not available at the current time…

SDTMIG Controlled Terms, Codelist or Format Specification

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format[1]	Role
STUDYID	Study Identifier	Char		Identifier
DOMAIN	Domain Abbreviation	Char	DM	
USUBJID	Unique	Char		Identifier

How do we know which SDTM variables require controlled terminology?

The single applicable value for the variable DOMAIN, e.g., "PR".

Variable Name	Variable Label	Type	Controlled Terms, Codelis or Format[1]	Role
STUDYID	Study Identifier	Char		
DOMAIN	Domain Abbreviation	Char	AE	
USUBJID	Unique Subject Identifier	Char		

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format[1]	Role
STUDYID	Study Identifier	Char		Identifier
DOMAIN	Domain Abbreviation	Char	DV	Identifier
USUBJID	Unique Subject Identifier	Char		Identifier

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format[1]	Role
STUDYID	Study Identifier	Char		Identifier
DOMAIN	Domain Abbreviation	Char	LB	Identifier
USUBJID	Unique Subject Identifier	Char		Identifier

SDTMIG Controlled Terms, Codelist or Format Specification

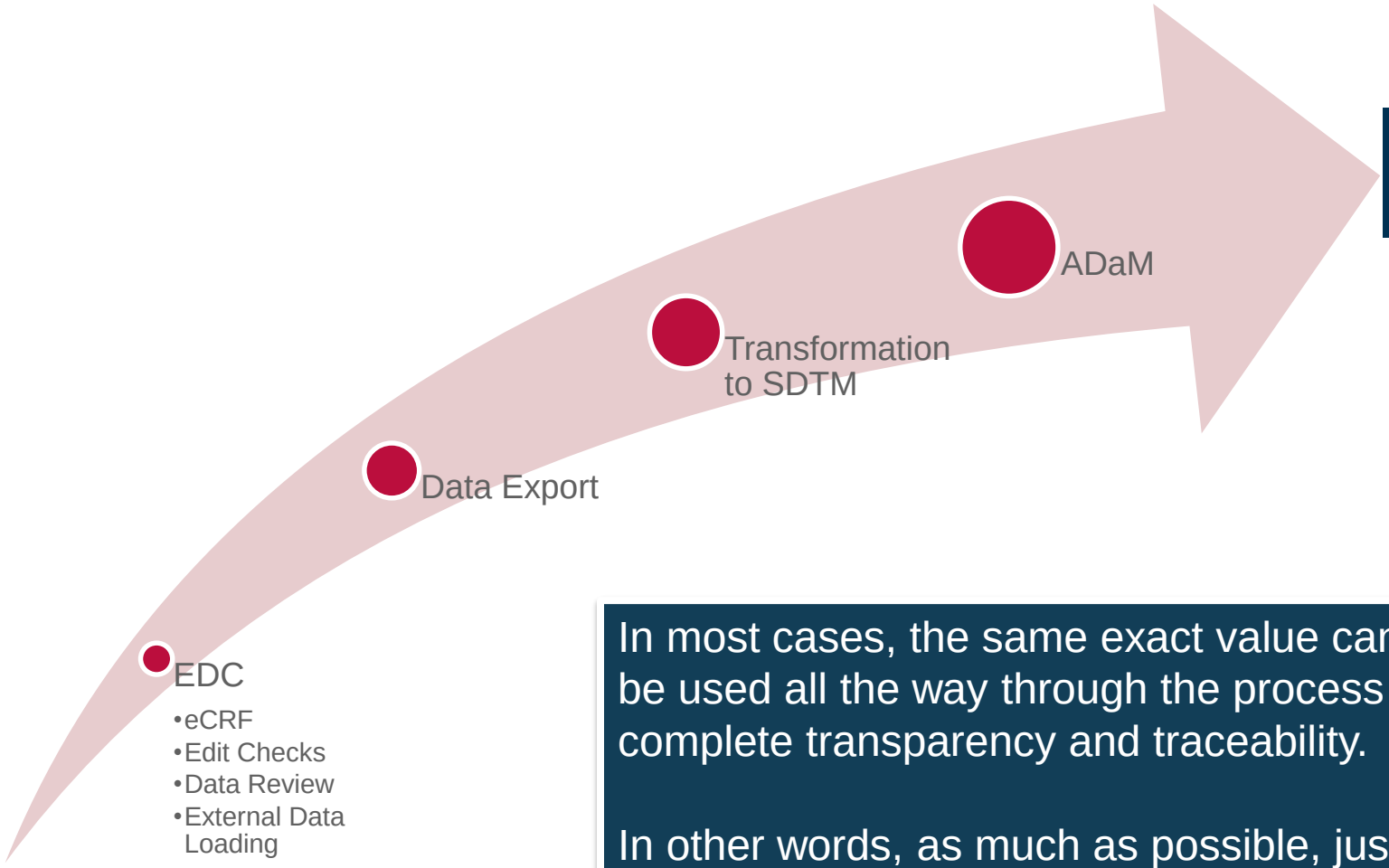
COUNTRY	Country	Char	ISO 3166-1 Alpha-3	Record Qualifi

A short reference to an external terminology, such as "MedDRA" or "ISO 3166 Alpha-3".

AELLT	Lowest Level Term	Char	MedDRA	Var Qualifier
AELLTCD	Lowest Level Term Code	Num	MedDRA	Variable Qualifier
AEDECOD	Dictionary-Derived Term	Char	MedDRA	Synonym Qualifier
AEPTCD	Preferred Term Code	Num	MedDRA	Variable Qualifier
AEHLT	High Level Term	Char	MedDRA	Variable Qualifier
AEHLTCD	High Level Term Code	Num	MedDRA	Variable Qualifier
AEHLGT	High Level Group Term	Char	MedDRA	Variable Qualifier
AEHLGTCD	High Level Group Term Code	Num	MedDRA	Variable Qualifier

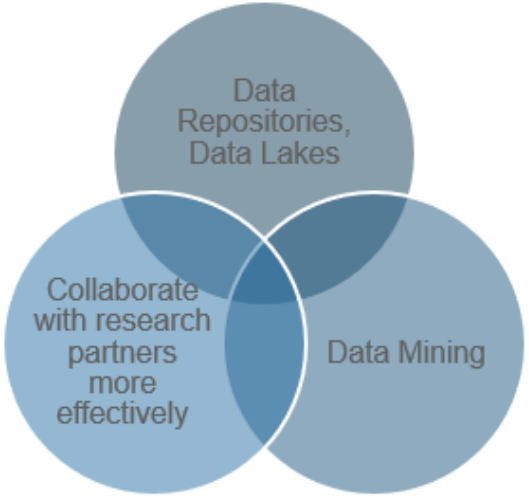
How do we know which SDTM variables require controlled terminology?

Controlled Terminology Supports Programming and Data Re-Use



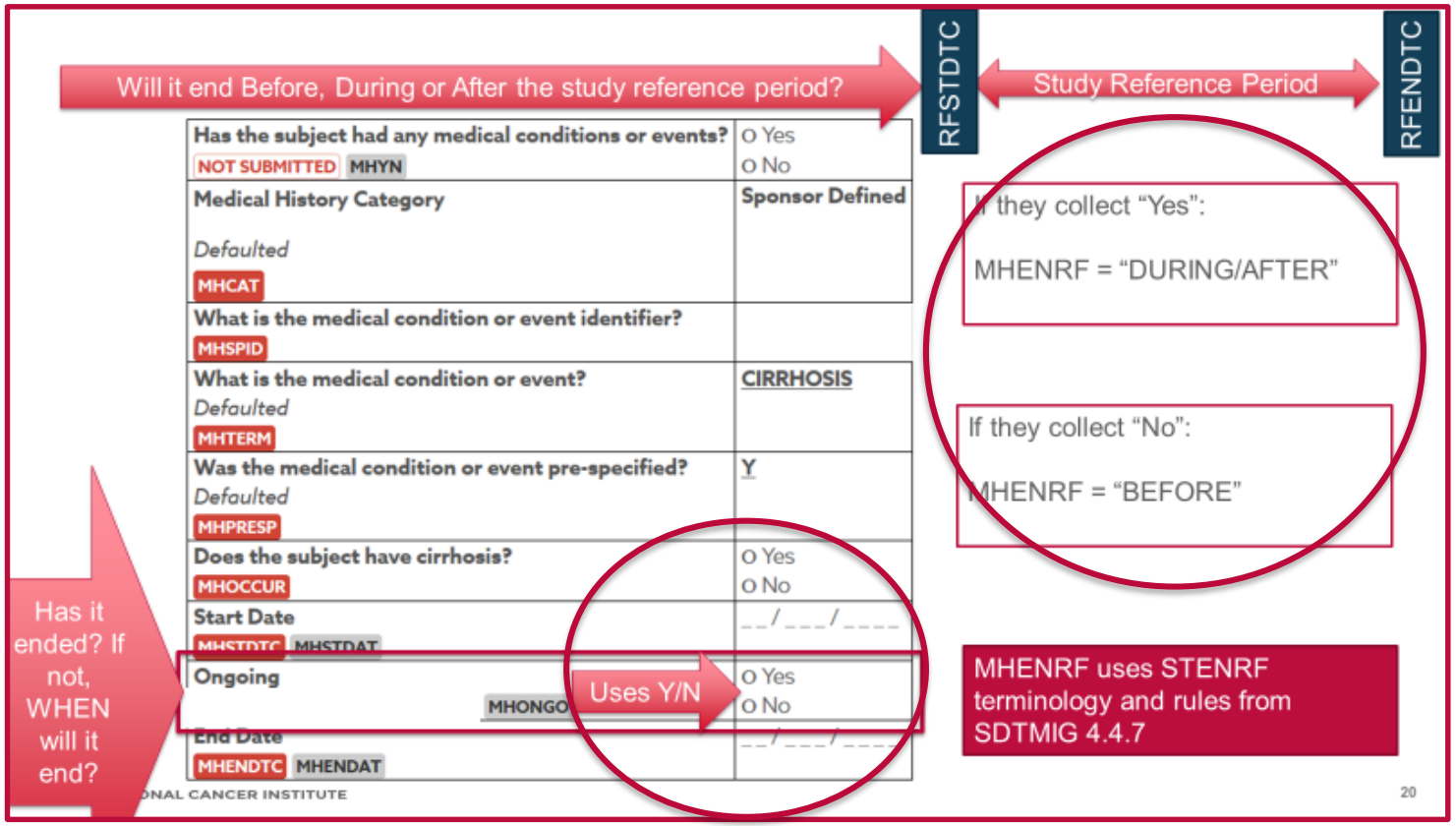
In most cases, the same exact value can be used all the way through the process for complete transparency and traceability.

In other words, as much as possible, just use the SDTM CDISC Controlled Terminology value to collect the data.



Controlled Terminology is Required for Conformance to CDASH

- In most cases, CDASH CT requirements are aligned with SDTM Terminology
- In a FEW cases, CDASH provides a codelist that is more user-friendly



Is it ongoing Yes/No

vs.

Will it end before or during/after the study reference period?

Known Issues: Overloaded Domains

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format[1]	Role
STUDYID	Study Identifier	Char		Identifier
DOMAIN	Domain Abbreviation	Char	DS	Identifier
USUBJID	Unique Subject Identifier	Char		Identifier
DSSEQ	Sequence Number	Num		Identifier
DSGRPID	Group ID	Char		Identifier
DSREFID	Reference ID	Char		Identifier
DSSPID	Sponsor-Defined Identifier	Char		Identifier
DSTERM	Reported Term for the Disposition Event	Char		Topic
DSDECOD	Standardized Disposition Term	Char	(NCOMPLT)(PROTMLST)	
DSCAT	Category for Disposition Event	Char	(DSCAT)	Grouping Qualifier
DSSCAT	Subcategory for Disposition Event	Char	*	Grouping Qualifier

Some domains are "overloaded" with meaning, so they may have multiple codelists for a single variable.

Disposition Domain - Two Concepts that Use Two Separate Codelists

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format[1]	Role
STUDYID	Study Identifier	Char		Identifier
DOMAIN	Domain Abbreviation	Char	DS	Identifier
USUBJID	Unique Subject Identifier	Char		Identifier
DSSEQ	Sequence Number	Num		Identifier
DSGRPID	Group ID	Char		Identifier
DSREFID	Reference ID	Char		Identifier
DSSPID	Sponsor-Defined Identifier	Char		Identifier
DSTERM	Reported Term for the Disposition Event	Char		Topic
DSDECOD	Standardized Disposition Term	Char	(NCOMPLT) (PROTMLST)	Synonym Qualifier
DSCAT	Category for Disposition Event	Char	(DSCAT)	Grouping Qualifier
DSSCAT	Subcategory for Disposition Event	Char	*	Grouping Qualifier

C114118	PROTMLST
NCI Code	**CDISC Submission Value**
C132447	ELIGIBILITY CRITERIA MET
C16735	INFORMED CONSENT OBTAINED
C114209	RANDOMIZED

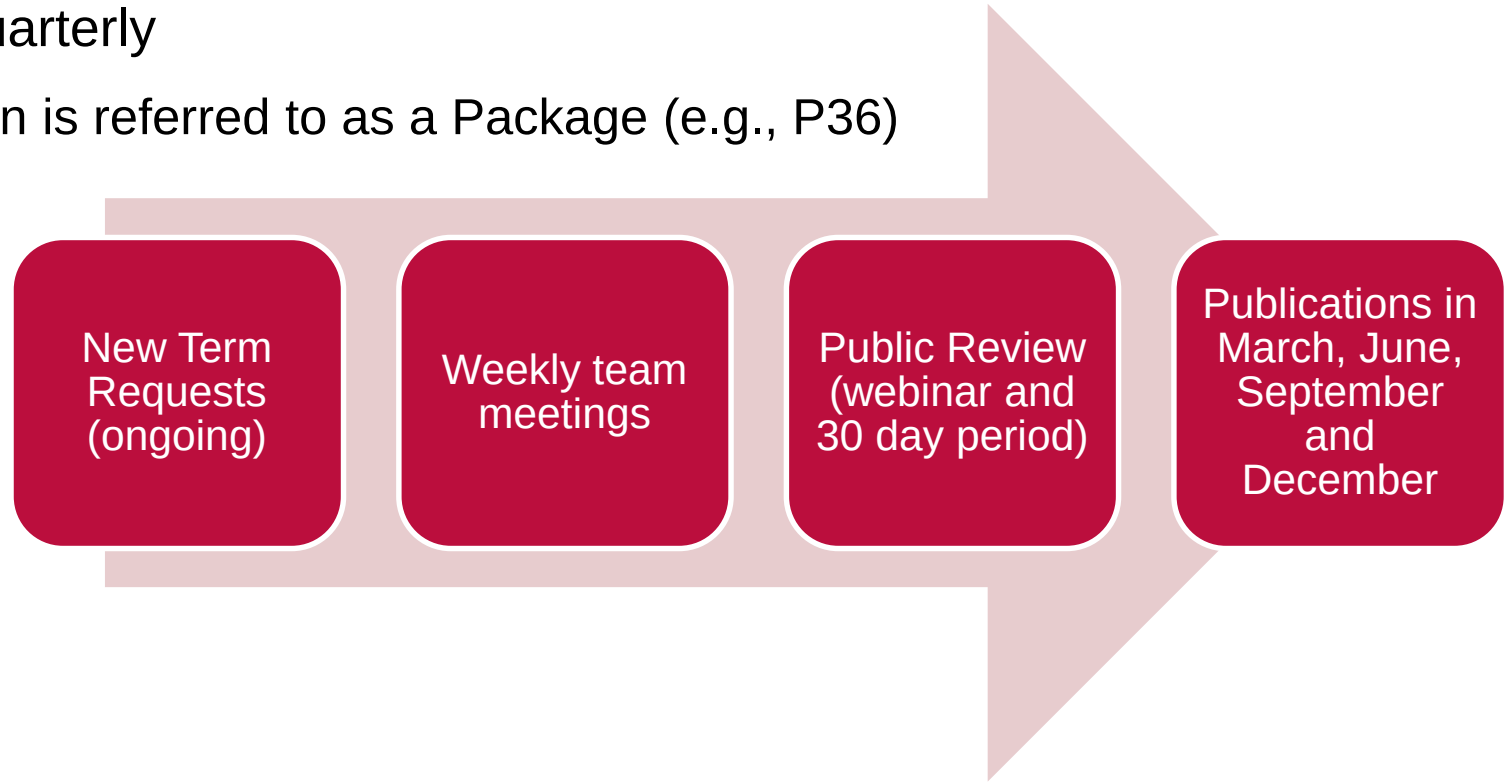
C66727	NCOMPLT
NCI Code	**CDISC Submission Value**
C41331	ADVERSE EVENT
C25250	COMPLETED
C28554	DEATH
C38155	DISEASE RELAPSE
C139236	FAILURE TO MEET CONTINUATION CRITERIA
C105448	FAILURE TO MEET RANDOMIZATION CRITERIA
C48226	LACK OF EFFICACY
C48227	LOST TO FOLLOW-UP

CDISC Controlled Terminology

Where to find it, How to use it

Controlled Terminology Documentation

- Published in two places:
  - NCI EVS https://www.cancer.gov/research/resources/terminology/cdisc
  - CDISC Library https://www.cdisc.org/members-only/cdisc-library-archives
- Published Quarterly
  - Each version is referred to as a Package (e.g., P36)



Controlled Terminology Public Review Webinar

CDISC Public Webinar: Quarterly Controlled Terminology Updates

REGISTER NOW

Date and Time:

TUE, 16 APR 2019, 10:00 AM - 11:00 AM Central Standard Time

Description:

This webinar will include a description of the P38 publication, including changes that occurred post-public review, and the P39 public review package. Controlled Terminology is the set of codelists and valid values used with data items within CDISC-defined datasets. Controlled Terminology provides the values required for submission to FDA and PMDA in CDISC-compliant datasets.

Panelists:

- Erin Muhlbradt, Clincal/Biomedical Information Specialist, MSC
- Chris Gemma, Project Manager, CDISC

Webinar La

Click **here** to

https://www.cdisc.org/events/education/webinars

Review Structure of CT Standards Documentation

- No matter which file format you use, the content for that package is the same in all of them
- Review the structure and content of Excel and PDF files:

	A	B	C	D	E	F	G	H
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51	C49503	C66767		Action Taken with Study Treatment	DOSE INCREASED			
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53	C150826	C66767		Action Taken with Study Treatment	DOSE RATE REDUCED			
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56	C49502	C66767		Action Taken with Study Treatment	DRUG WITHDRAWN			
57	C48660	C66767		Action Taken with Study Treatment	NOT APPLICABLE	NA; Not Applicable		
58	C17998	C66767		Action Taken with Study Treatment	UNKNOWN	U; UNK; Unknown		
59	C101865		No	Acute Coronary Syndrome Presentation Category	ACSPCAT	Acute Coronary Syndro Category		
60	C80383	C101865		Acute Coronary Syndrome Presentation Category	NON-ST ELEVATION MYOCARDIAL INFARCTION	NON-STEMI; NSTEMI		
61	C17649	C101865		Acute Coronary Syndrome Presentation Category	OTHER	Other		
62	C101888	C101865		Acute Coronary Syndrome Presentation Category	ST ELEVATION MYOCARDIAL INFARCTION	STEMI		
63	C66914	C101865		Acute Coronary Syndrome Presentation Category	STABLE ANGINA			

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C49505	DOSE REDUCED		An indication that a medication schedule was modified by subtraction, either by changing the frequency, strength or amount. (NCI)	Dose Reduced
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codelist Short Name and Long Name
CDISC Submission Value = Short Name
Codelist Name = Long Name

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56	C49502	C66767		Action Taken with Study Treatment	DRUG WITHDRAWN			
57	C48660	C66767		Action Taken with Study Treatment	NOT APPLICABLE	NA; Not Applicable		
58	C17998	C66767		Action Taken with Study Treatment	UNKNOWN	U; UNK; Unknown		
59	C101865		No	Acute Coronary Syndrome Presentation Category	ACSPCAT	Acute Coronary Syndro Category		
60	C80383	C101865		Acute Coronary Syndrome Presentation Category	NON-ST ELEVATION MYOCARDIAL INFARCTION	NON-STEMI; NSTEMI		
61	C17649	C101865		Acute Coronary Syndrome Presentation Category	OTHER	Other		
62	C101888	C101865		Acute Coronary Syndrome Presentation Category	ST ELEVATION MYOCARDIAL INFARCTION	STEMI		
63	C66914	C101865		Acute Coronary Syndrome Presentation Category	STABLE ANGINA			

ACN (Action Taken with Study Treatment)

NCI Code: C66767, Codelist extensible: No

C66767 ACN

NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C49503	DOSE INCREASED		An indication that a medication schedule was modified by addition; either by changing the frequency, strength or amount. (NCI)	Dose Increased
C49504	DOSE NOT CHANGED		An indication that a medication schedule was maintained. (NCI)	Dose Not Changed
C150826	DOSE RATE REDUCED		An indication that the administration of a medication was modified by reducing the rate at which the dose was given, without reducing the total dose administered.	Dose Rate Reduced
C49505	DOSE REDUCED		An indication that a medication schedule was modified by subtraction, either by changing the frequency, strength or amount. (NCI)	Dose Reduced
C49501	DRUG INTERRUPTED		An indication that a medication schedule was modified by temporarily terminating a prescribed regimen of medication. (NCI)	Drug Interrupted
C49502	DRUG WITHDRAWN		An indication that a medication schedule was modified through termination of a prescribed regimen of medication. (NCI)	Drug Withdrawn
C48660	NOT APPLICABLE	NA;Not Applicable	Determination of a value is not relevant in the current context. (NCI)	Not Applicable
C17998	UNKNOWN	U;UNK;Unknown	Not known, not observed, not recorded, or refused. (NCI)	Unknown

Code = a unique value within NCI EVS systems for each defined value.

Review Structure of CT Standards Documentation

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51	C49503	C66767		Action Taken with Study Treatment	DOSE INCREASED			
52	C49504	C66767		Action Taken with Study Treatment	DOSE NOT CHANGED			
53	C150826	C66767		Action Taken with Study Treatment	DOSE RATE REDUCED			
54	C49505	C66767		Action Taken with Study Treatment	DOSE REDUCED			
55	C49501	C66767		Action Taken with Study Treatment	DRUG INTERRUPTED			
56	C49502	C66767		Action Taken with Study Treatment	DRUG WITHDRAWN			
57	C48660	C66767		Action Taken with Study Treatment	NOT APPLICABLE	NA; Not Applicable		
58	C17998	C66767		Action Taken with Study Treatment	UNKNOWN	U; UNK; Unknown		
59	C101865		No	Acute Coronary Syndrome Presentation Category	ACSPCAT	Acute Coronary Syndro Category		
60	C80383	C101865		Acute Coronary Syndrome Presentation Category	NON-ST ELEVATION MYOCARDIAL INFARCTION	NON-STEMI; NSTEMI		
61	C17649	C101865		Acute Coronary Syndrome Presentation Category	OTHER	Other		
62	C101888	C101865		Acute Coronary Syndrome Presentation Category	ST ELEVATION MYOCARDIAL INFARCTION	STEMI		
63	C66914	C101865		Acute Coronary Syndrome Presentation Category	STABLE ANGINA			

ACN (Action Taken with Study Treatment)

NCI Code: C66767, Codelist extensible: No

C66767	ACN			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C49503	DOSE INCREASED		An indication that a medication schedule was modified by addition; either by changing the frequency, strength or amount. (NCI)	Dose Increased
C49504	DOSE NOT CHANGED		An indication that a medication schedule was maintained. (NCI)	Dose Not Changed
C150826	DOSE RATE REDUCED		An indication that the administration of a medication was modified by reducing the rate at which the dose was given, without reducing the total dose administered.	Dose Rate Reduced
C49505	DOSE REDUCED		An indication that a medication schedule was modified by subtraction, either by changing the frequency, strength or amount. (NCI)	Dose Reduced
C49501	DRUG INTERRUPTED		An indication that a medication schedule was modified by temporarily terminating a prescribed regimen of medication. (NCI)	Drug Interrupted
C49502	DRUG WITHDRAWN		An indication that a medication schedule was modified through termination of a prescribed regimen of medication. (NCI)	Drug Withdrawn
C48660	NOT APPLICABLE	NA;Not Applicable	Determination of a value is not relevant in the current context. (NCI)	Not Applicable
C17998	UNKNOWN	U;UNK;Unknown	Not known, not observed, not recorded, or refused. (NCI)	Unknown

Codelist Code = a unique value for this codelist within NCI EVS systems.
In Excel, appears on each value within that codelist, too. In PDF, appears at top of codelist.

Review Structure of CT Standards Documentation

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50	C66767		No	Action Taken with Study Treatment	ACN	Action Taken with Study Treatment	Terminology specifying changes to the study treatment as a result of an adverse event.	CDISC SDTM Action Taken with Study Treatment Terminology
51	C49503	C66767		Action Taken with Study Treatment	DOSE INCREASED			
52	C49504	C66767		Action Taken with Study Treatment	DOSE NOT CHANGED			
53	C150826	C66767		Action Taken with Study Treatment	DOSE RATE REDUCED			
54	C49505	C66767		Action Taken with Study Treatment	DOSE REDUCED			
55	C49501	C66767		Action Taken with Study Treatment	DRUG INTERRUPTED			
56	C49502	C66767		Action Taken with Study Treatment	DRUG WITHDRAWN			
57	C48660	C66767		Action Taken with Study Treatment	NOT APPLICABLE	NA; Not Applicable		
58	C17998	C66767		Action Taken with Study Treatment	UNKNOWN	U; UNK; Unknown		
59	C101865		No	Acute Coronary Syndrome Presentation Category	ACSPCAT	Acute Coronary Syndro Category		
60	C80383	C101865		Acute Coronary Syndrome Presentation Category	NON-ST ELEVATION MYOCARDIAL INFARCTION	NON-STEMI; NSTEMI		
61	C17649	C101865		Acute Coronary Syndrome Presentation Category	OTHER	Other		
62	C101888	C101865		Acute Coronary Syndrome Presentation Category	ST ELEVATION MYOCARDIAL INFARCTION	STEMI		
63	C66914	C101865		Acute Coronary Syndrome Presentation Category	STABLE ANGINA			

Codelist Extensibility:
If Yes: we may add values that do not already exist in the codelist
If No: we may not add values

ACN (Action Taken with Study Treatment)

NCI Code: C66767, Codelist extensible: No

C66767 ACN

NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C49503	DOSE INCREASED		An indication that a medication schedule was modified by addition; either by changing the frequency, strength or amount. (NCI)	Dose Increased
C49504	DOSE NOT CHANGED		An indication that a medication schedule was maintained. (NCI)	Dose Not Changed
C150826	DOSE RATE REDUCED		An indication that the administration of a medication was modified by reducing the rate at which the dose was given, without reducing the total dose administered.	Dose Rate Reduced
C49505	DOSE REDUCED		An indication that a medication schedule was modified by subtraction, either by changing the frequency, strength or amount. (NCI)	Dose Reduced
C49501	DRUG INTERRUPTED		An indication that a medication schedule was modified by temporarily terminating a prescribed regimen of medication. (NCI)	Drug Interrupted
C49502	DRUG WITHDRAWN		An indication that a medication schedule was modified through termination of a prescribed regimen of medication. (NCI)	Drug Withdrawn
C48660	NOT APPLICABLE	NA;Not Applicable	Determination of a value is not relevant in the current context. (NCI)	Not Applicable
C17998	UNKNOWN	U;UNK;Unknown	Not known, not observed, not recorded, or refused. (NCI)	Unknown

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51	C49503	C66767		Action Taken with Study Treatment	DOSE INCREASED			
52	C49504	C66767		Action Taken with Study Treatment	DOSE NOT CHANGED			
53	C150826	C66767		Action Taken with Study Treatment	DOSE RATE REDUCED			
54	C49505	C66767		Action Taken with Study Treatment	DOSE REDUCED			
55	C49501	C66767		Action Taken with Study Treatment	DRUG INTERRUPTED			
56	C49502	C66767		Action Taken with Study Treatment	DRUG WITHDRAWN			
57	C48660	C66767		Action Taken with Study Treatment	NOT APPLICABLE	NA; Not Applicable		
58	C17998	C66767		Action Taken with Study Treatment	UNKNOWN	U; UNK; Unknown		
59	C101865		No	Acute Coronary Syndrome Presentation Category	ACSPCAT	Acute Coronary Syndro Category		
60	C80383	C101865		Acute Coronary Syndrome Presentation Category	NON-ST ELEVATION MYOCARDIAL INFARCTION	NON-STEMI; NSTEMI		
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62	C101888	C101865		Acute Coronary Syndrome Presentation Category	ST ELEVATION MYOCARDIAL INFARCTION	STEMI		
63	C66914	C101865		Acute Coronary Syndrome Presentation Category	STABLE ANGINA			

ACN (Action Taken with Study Treatment)

NCI Code: C66767, Codelist extensible: No

C66767 ACN

NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C49503	DOSE INCREASED		An indication that a medication schedule was modified by addition; either by changing the frequency, strength or amount. (NCI)	Dose Increased
C49504	DOSE NOT CHANGED		An indication that a medication schedule was maintained. (NCI)	Dose Not Changed
C150826	DOSE RATE REDUCED		An indication that the administration of a medication was modified by reducing the rate at which the dose was given, without reducing the total dose administered.	Dose Rate Reduced
C49505	DOSE REDUCED		An indication that a medication schedule was modified by subtraction, either by changing the frequency, strength or amount. (NCI)	Dose Reduced
C49501	DRUG INTERRUPTED		An indication that a medication schedule was modified by temporarily terminating a prescribed regimen of medication. (NCI)	Drug Interrupted
C49502	DRUG WITHDRAWN		An indication that a medication schedule was modified through termination of a prescribed regimen of medication. (NCI)	Drug Withdrawn
C48660	NOT APPLICABLE	NA;Not Applicable	Determination of a value is not relevant in the current context. (NCI)	Not Applicable
C17998	UNKNOWN	U;UNK;Unknown	Not known, not observed, not recorded, or refused. (NCI)	Unknown

CDISC Submission Value:
This is the value that must be used in the submission variable (SDTM, ADaM, SEND)
Use Exact SPELLING and CASE.

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52	C49504	C66767		Action Taken with Study Treatment	DOSE NOT CHANGED			
53	C150826	C66767		Action Taken with Study Treatment	DOSE RATE REDUCED			
54	C49505	C66767		Action Taken with Study Treatment	DOSE REDUCED			
55	C49501	C66767		Action Taken with Study Treatment	DRUG INTERRUPTED			
56	C49502	C66767		Action Taken with Study Treatment	DRUG WITHDRAWN			
57	C48660	C66767		Action Taken with Study Treatment	NOT APPLICABLE	NA; Not Applicable		
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62	C101888	C101865		Acute Coronary Syndrome Presentation Category	ST ELEVATION MYOCARDIAL INFARCTION	STEMI		
63	C66914	C101865		Acute Coronary Syndrome Presentation Category	STABLE ANGINA			

ACN (Action Taken with Study Treatment)

NCI Code: C66767, Codelist extensible: No

C66767	ACN			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C49503	DOSE INCREASED		An indication that a medication schedule was modified by addition; either by changing the frequency, strength or amount. (NCI)	Dose Increased
C49504	DOSE NOT CHANGED		An indication that a medication schedule was maintained. (NCI)	Dose Not Changed
C150826	DOSE RATE REDUCED		An indication that the administration of a medication was modified by reducing the rate at which the dose was given, without reducing the total dose administered.	Dose Rate Reduced
C49505	DOSE REDUCED		An indication that a medication schedule was modified by subtraction, either by changing the frequency, strength or amount. (NCI)	Dose Reduced
C49501	DRUG INTERRUPTED		An indication that a medication schedule was modified by temporarily terminating a prescribed regimen of medication. (NCI)	Drug Interrupted
C49502	DRUG WITHDRAWN		An indication that a medication schedule was modified through termination of a prescribed regimen of medication. (NCI)	Drug Withdrawn
C48660	NOT APPLICABLE	NA;Not Applicable	Determination of a value is not relevant in the current context. (NCI)	Not Applicable
C17998	UNKNOWN	U;UNK;Unknown	Not known, not observed, not recorded, or refused. (NCI)	Unknown

CDISC Synonym
An alternative value that may be used for data collection, or is provided to increase understanding of the meaning for this value. Not all possible synonyms are included.

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52	C49504	C66767		Action Taken with Study Treatment	DOSE NOT CHANGED			
53	C150826	C66767		Action Taken with Study Treatment	DOSE RATE REDUCED			
54	C49505	C66767		Action Taken with Study Treatment	DOSE REDUCED			
55	C49501	C66767		Action Taken with Study Treatment	DRUG INTERRUPTED			
56	C49502	C66767		Action Taken with Study Treatment	DRUG WITHDRAWN			
57	C48660	C66767		Action Taken with Study Treatment	NOT APPLICABLE	NA; Not Applicable		
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62	C101888	C101865		Acute Coronary Syndrome Presentation Category	ST ELEVATION MYOCARDIAL INFARCTION	STEMI		
63	C66914	C101865		Acute Coronary Syndrome Presentation Category	STABLE ANGINA			

ACN (Action Taken with Study Treatment)

NCI Code: C66767, Codelist extensible: No

C66767	ACN			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C49503	DOSE INCREASED		An indication that a medication schedule was modified by addition; either by changing the frequency, strength or amount. (NCI)	Dose Increased
C49504	DOSE NOT CHANGED		An indication that a medication schedule was maintained. (NCI)	Dose Not Changed
C150826	DOSE RATE REDUCED		An indication that the administration of a medication was modified by reducing the rate at which the dose was given, without reducing the total dose administered.	Dose Rate Reduced
C49505	DOSE REDUCED		An indication that a medication schedule was modified by subtraction, either by changing the frequency, strength or amount. (NCI)	Dose Reduced
C49501	DRUG INTERRUPTED		An indication that a medication schedule was modified by temporarily terminating a prescribed regimen of medication. (NCI)	Drug Interrupted
C49502	DRUG WITHDRAWN		An indication that a medication schedule was modified through termination of a prescribed regimen of medication. (NCI)	Drug Withdrawn
C48660	NOT APPLICABLE	NA;Not Applicable	Determination of a value is not relevant in the current context. (NCI)	Not Applicable
C17998	UNKNOWN	U;UNK;Unknown	Not known, not observed, not recorded, or refused. (NCI)	Unknown

CDISC Definition
The definition for the CDISC Submission Value. If the value you collected meets this definition, you must use the associated CDISC Submission Value in your submission data.

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52	C49504	C66767		Action Taken with Study Treatment	DOSE NOT CHANGED			
53	C150826	C66767		Action Taken with Study Treatment	DOSE RATE REDUCED			
54	C49505	C66767		Action Taken with Study Treatment	DOSE REDUCED			
55	C49501	C66767		Action Taken with Study Treatment	DRUG INTERRUPTED			
56	C49502	C66767		Action Taken with Study Treatment	DRUG WITHDRAWN			
57	C48660	C66767		Action Taken with Study Treatment	NOT APPLICABLE	NA; Not Applicable		
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63	C66914	C101865		Acute Coronary Syndrome Presentation Category	STABLE ANGINA			

ACN (Action Taken with Study Treatment)

NCI Code: C66767, Codelist extensible: No

C66767	ACN			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C49503	DOSE INCREASED		An indication that a medication schedule was modified by addition; either by changing the frequency, strength or amount. (NCI)	Dose Increased
C49504	DOSE NOT CHANGED		An indication that a medication schedule was maintained. (NCI)	Dose Not Changed
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C49505	DOSE REDUCED		An indication that a medication schedule was modified by subtraction, either by changing the frequency, strength or amount. (NCI)	Dose Reduced
C49501	DRUG INTERRUPTED		An indication that a medication schedule was modified by temporarily terminating a prescribed regimen of medication. (NCI)	Drug Interrupted
C49502	DRUG WITHDRAWN		An indication that a medication schedule was modified through termination of a prescribed regimen of medication. (NCI)	Drug Withdrawn
C48660	NOT APPLICABLE	NA;Not Applicable	Determination of a value is not relevant in the current context. (NCI)	Not Applicable
C17998	UNKNOWN	U;UNK;Unknown	Not known, not observed, not recorded, or refused. (NCI)	Unknown

NCI Preferred Term
The standard NCI term that is synonymous with this CDISC term.

CT for Different Standards

SDTM Controlled Terminology Documentation

- Referenced in specification tables of most CDISC Standards
  - Codelists that are used by CDASH to collect values
  - Codelists used in SDTM to represent collected, derived or assigned values
  - Codelists used in ADaM for values that are carried through to analysis
  - Codelists used in SEND that are aligned with the same concepts in SDTM Terminology

CDASHIG

CDASHIG Variable	CDASHIG Variable Label	Question Text	Prompt	Data Type	CDASHIG Core	SDTMIG Target	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
AELOC	Adverse Event Location	What is the anatomical location of the adverse event?	Anatomical Location	Char	O	AELOC	(LOC)	N/A	Collected or pre-p using a subset list location.
AESEV	Adverse Event Severity/Intensity	What is the severity of the adverse event?	Severity	Char	R/C	AESEV	(AESEV)	N/A	Either AESEV or AE guidelines for CSR
AESER	Adverse Event Serious Event	Was the adverse event serious?	Serious	Char	R/C	AESER	(NY)	N/A	This field is relate AESER or all the A to which the data
AEACN	Action Taken	What action was	Action Taken	Char	R/C	AEACN	(ACN)	N/A	CDISC Controlled

SDTMIG

Observation Class	Domain Prefix	Variable Name (minus domain prefix)	Variable Name	Variable Label	Ty	Controlled Terms or Form	Ro
Events	AE		AELOC	Location of Event	Char	(LOC)	Re
Events	AE	SEV	AESEV	Severity/Intensity	Char	(AESEV)	Re
Events	AE	SER	AESER	Serious Event	Char	(NY)	Re
Events	AE	ACN	AEACN	Action Taken with Study Treatment	Char	(ACN)	Record Qualifier

The same SDTM codelists are specified for the same variables across CDASH-SDTM (and ADaM).

AESEV

CDISC Submission Value
MILD
MODERATE
SEVERE

NY

CDISC Submission Value
N
NA
U
Y

LOC

CDISC Submission Value
5TH LUMBAR SPINOUS PROCESS
ABDOMINAL AORTA
ABDOMINAL CAVITY
ABDOMINAL LYMPH NODE
ABDOMINAL REGION
ABDOMINAL SKIN
ABDOMINAL WALL
ABDUCENS NERVE
ACCESSORY RENAL ARTERY
ACETABULUM

ACN

CDISC Submission Value
DOSE INCREASED
DOSE NOT CHANGED
DOSE RATE REDUCED
DOSE REDUCED
DRUG INTERRUPTED
DRUG WITHDRAWN
NOT APPLICABLE
UNKNOWN

SDTM Controlled Terminology Documentation Used in both CDASHIG and SDTMIG

- --TESTCD can be used in **data collection** as part of the Variable Names
- --TEST can be used in **data collection** as all or part of the Prompts displayed
- --TESTCD, --TEST Codelists are also used to represent standardized short and long test names in SDTM data

VSTESTCD
CDISC Submission Value
ABSKNF
BMI
BMR
BODLNGTH
BODYFATM

VSTEST
CDISC Submission Value
Abdominal Skinfold Thickness
Basal Metabolic Rate
Body Fat Measurement
Body Frame Size
Body Length
Body Mass Index
Body Surface Area
Chest Circumference
Diastolic Blood Pressure
Energy Expenditure

STUDYID	DOMAIN	USUBJID	VSSEQ	VSTESTCD	VSTEST	VSPOS	VSORRES	VSORRESU
ABC	VS	ABC-001-001	1	SYSBP	Systolic Blood Pressure	Sitting	154	mmHg
ABC	VS	ABC-001-001	2	SYSBP	Systolic Blood Pressure	Sitting	152	mmHg
ABC	VS	ABC-001-001	3	DIABP	Diastolic Blood Pressure	Sitting	44	mmHg
ABC	VS	ABC-001-001	4	DIABP	Diastolic Blood Pressure	Sitting	48	mmHg
ABC	VS	ABC-001-001	5	PULSE	Pulse Rate	Sitting	72	beats/min
ABC	VS	ABC-001-001	6	TEMP	Temperature		34.7	C

CDASH Controlled Terminology Documentation

- CDASH Terminology is a handful of codelists that are (mostly) Subsets of SDTM codelists
  - EXCEPTION: CDASH has one unique codelist for SUNCF

SUNCF (Substance Use Never/Current/Former Classification)

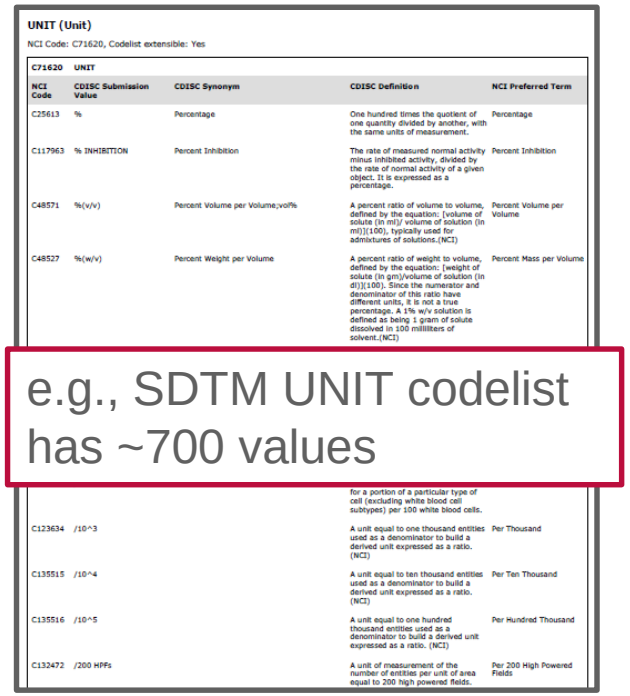
NCI Code: C83004, Codelist extensible: Yes

C83004	SUNCF			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C25471	CURRENT		Occurring in or belonging to the present time. (NCI)	Current
C25627	FORMER	Previous	Occurring prior to something else. (NCI)	Previous
C70543	NEVER		Not ever; at no time in the past.	Never

- If used for data collection, this gets *translated* into SDTM data
  - CURRENT = Relative timing variables will indicate ONGOING use (or use that will end DURING/AFTER study reference period) and OCCUR values will be “Y”
  - FORMER = Relative timing variables will indicate use that ended BEFORE the study and OCCUR values will be “Y”
  - NEVER = OCCUR values will be “N”

CDASH Controlled Terminology Documentation

- CDASH Terminology subsets are always a starting point only
- CDASH requires the use of the full SDTM codelists which are referenced in CDASHIG specification table



UNIT (Unit)

NCI Code: C71620, Codelist extensible: Yes

C71620	UNIT			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C25613	%	Percentage	One hundred times the quotient of one quantity divided by another, with the same units of measurement.	Percentage
C117963	% INHIBITION	Percent Inhibition	The rate of measured normal activity minus inhibited activity, divided by the rate of normal activity of a given object. It is expressed as a percentage.	Percent Inhibition
C48571	%(v/v)	Percent Volume per Volume;vol%	A percent ratio of volume to volume, defined by the equation: [volume of solute (in ml)/ volume of solution (in ml)](100), typically used for admixtures of solutions.(NCI)	Percent Volume per Volume
C48527	%(w/v)	Percent Weight per Volume	A percent ratio of weight to volume, defined by the equation: [weight of solute (in gm)/volume of solution (in dl)](100). Since the numerator and denominator of this ratio have different units, it is not a true percentage. A 1% w/v solution is defined as being 1 gram of solute dissolved in 100 milliliters of solvent.(NCI)	Percent Mass per Volume
			for a portion of a particular type of cell (excluding white blood cell subtypes) per 100 white blood cells.	
C123634	/10^3		A unit equal to one thousand entities used as a denominator to build a derived unit expressed as a ratio. (NCI)	Per Thousand
C135515	/10^4		A unit equal to ten thousand entities used as a denominator to build a derived unit expressed as a ratio. (NCI)	Per Ten Thousand
C135516	/10^5		A unit equal to one hundred thousand entities used as a denominator to build a derived unit expressed as a ratio. (NCI)	Per Hundred Thousand
C132472	/200 HPFs		A unit of measurement of the number of entities per unit of area equal to 200 high powered fields.	Per 200 High Powered Fields

e.g., SDTM UNIT codelist has ~700 values

DAORRESU (Unit of Drug Dispensed or Returned)

NCI Code: C78421, Codelist extensible: Yes

C78421	DAORRESU
NCI Code	CDISC Submission Value
C48474	BAG
C48477	BOTTLE
C48478	BOX
C48480	CAPSULE
C48484	CONTAINER
C48490	DISK
C48520	PACKAGE
C48521	PACKET
C48524	PATCH

EGORRESU (ECG Original Units)

NCI Code: C78422, Code

C78422	EGORRESU
NCI Code	CDISC Submi Value
C49673	beats/min
C41140	msec
C42535	sec

EXDOSU (Units for Exposure)

NCI Code: C78423, Codelist extensible: Yes

C78423	EXDOSU	
NCI Code	CDISC Submission Value	CDIS
C48480	CAPSULE	Capsu
C48155	g	Gram
C28253	mg	Milligr
C28254	mL	Millilit

CMDOSU (Concomitant Medication Dose Units)

NCI Code: C78417, Codelist extensible: Yes

C78417	CMDOSU			
NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C48480	CAPSULE	Capsule Dosing Unit;cap	A dosing measurement based on the capsule unit.(NCI)	Capsule Dosing Unit
C48155	g	Gram	A unit of mass equal to one thousandth (1E-3) of a kilogram, the kilogram being the base unit of mass in the International System of Units (SI).	Gram
C48579	IU	IE;International Unit	The unitage assigned by the WHO (World Health Organization) to International Biological Standards - substances, classed as biological according to the criteria provided by WHO Expert Committee on Biological Standardization, to enable the results of biological and immunological assay procedures to be expressed in the same way throughout the world. The definition of an international unit is generally arbitrary and technical, and has to be officially approved by the International Conference for Unification of Formulae.(NCI)	International Unit
253	mg	Milligram	A unit of mass equal to one thousandth (1E-3) of a gram.	Milligram
254	mL	Milliliter;cm3	A unit of volume equal to one thousandth (1E-3) of a liter.	Milliliter
060	PUFF	Puff Dosing Unit	A means of delivering a defined dose of a therapeutic aerolized solution into either the upper or lower respiratory tract. Metered-dose inhalers or spray pumps are devices that provide a puff dose for delivery into either the oral or the nasal cavity.(NCI)	Puff Dosing Unit
542	TABLET	Tablet Dosing Unit;tab	A dosing measurement based on the tablet unit.(NCI)	Tablet Dosing Unit
152	ug	Microgram;mcg	A unit of mass equal to one millionth (1E-6) of a gram.	Microgram

e.g., CDASH has created a few manageable, useful UNIT subsets to be used for specific topics.

CDASH terminology is NOT intended to be complete
It is provided for convenience

CDASH Controlled Terminology Documentation

- The CDASH Subset, if one is available, will be referenced in CDASHIG specification table alongside the SDTM codelist from which it has been sub-setted

SDTM Codelist	CDASH Codelist (Subset)
(UNIT)	(CMDOSU)
(FRM)	(CMDOSFRM)

CDASH subset is optional

SDTM codelist is required for use

ADaM Controlled Terminology Documentation

- ADaM also references some SDTM codelists
- ADaM data uses some of the same terminology as CDASH and SDTM, when the concepts mean the same thing (and the same variable is used)

Table 3.2.2 ADSL Subject Demographics Variables

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
AGE	Age	Num		Req	DM.AGE. If analysis needs require a derived age that does not match DM.AGE, then AAGE must be added
AGEU	Age Units	Char	(AGEU)	Req	DM.AGEU
AGEGRy	Pooled Age Group y	Char		Perm	Character description of a grouping or pooling of the subject's age for analysis purposes. For example, AGEGR1 might have values of "<18", "18-65", and ">65"; AGEGR2 might have values of "Less than 35 y old" and "At least 35 y old".
AGEGRyN	Pooled Age Group y (N)	Num		Perm	The numeric code for AGEGRy. Orders the grouping or pooling of subject age for analysis and reporting. One-to-one mapping to AGEGRy within a study.
AAGE	Analysis Age	Num		Cond	Age used for analysis that is derived differently from DM.AGE. AAGE is required if age is calculated differently than in SDTM.
SEX	Sex	Char	(SEX)	Req	The sex of the subject is a required variable in ADSL; must be identical to DM.SEX.
RACE	Race	Char	(RACE)	Req	The race of the subject is a required variable in ADSL; must be identical to DM.RACE.
RACEGRy	Pooled Race Group y	Char		Perm	Character description of a grouping or pooling of the subject's race for analysis purposes.
RACEGRyN	Pooled Race Group y (N)	Num		Perm	The numeric code for RACEGRy. Orders the grouping or pooling of subject race for analysis and reporting. One-to-one mapping to RACEGRy within a study.

ADaM Controlled Terminology Documentation

- ADaM codelists are for standardized analysis concepts that are only used in ADaM

Table 3.2.6 ADSL Treatment Timing Variables

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
TRTSDT	Date of First Exposure to Treatment	Num		Cond	Date of first exposure to treatment for a subject in a study. TRTSDT and/or TRTSDTM are required if there is an investigational product. Note that TRTSDT is not required to have the same value as the SDTM DM variable RFXSTDTC. While both of these dates reflect the concept of first
TRTSTM	Time of First Exposure to Treatment	Num			
TRTSDTM	Datetime of First Exposure to Treatment	Num			
TRTSDTF	Date of First Exposure Imput. Flag	Char	(DATEFL)		
TRTSTMF	Time of First Exposure Imput. Flag	Char	(TIMEFL)		
TRTEDT	Date of Last Exposure to Treatment	Num		Cond	Date of last exposure to treatment for a subject in a study. TRTEDT and/or TRTEDTM are required if there is an investigational product. Note that TRTEDT is not required to have the same value as the SDTM DM variable RFXENDTC. While both of these dates reflect the concept of last exposure, the ADaM date may be derived to support the analysis which may not necessarily be the very last date in the SDTM EX domain.
TRTETM	Time of Last Exposure to Treatment	Num		Perm	Time of last exposure to treatment for a subject in a study.

DATEFL (Date Imputation Flag)

NCI Code: C81223, Codelist extensible: No

C81223	DATEFL			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred**
C81212	D		Day Imputed: Day is imputed.	Day Imputed
C81211	M		Month Imputed: Month and day are imputed.	Month Day Impu
C81210	Y		Year Imputed: Entire date (year, month and day) is imputed.	Year Month Day

SEND Controlled Terminology Documentation

- SEND Terminology includes some codelists that are identical to SDTM Terminology, when the values have the same meaning for both clinical and non-clinical studies

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value
C66781		No	Age Unit	AGEU
C25301	C66781		Age Unit	DAYS
C25529	C66781		Age Unit	HOURS
C29846	C66781		Age Unit	MONTHS
C29844	C66781		Age Unit	WEEKS
C29848	C66781		Age Unit	YEARS

ReadMe | SEND Terminology 2019-03-29

	Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value
385	C66781		No	Age Unit	AGEU
386	C25301	C66781		Age Unit	DAYS
387	C25529	C66781		Age Unit	HOURS
388	C29846	C66781		Age Unit	MONTHS
389	C29844	C66781		Age Unit	WEEKS
390	C29848	C66781		Age Unit	YEARS

ReadMe | SDTM Terminology 2019-03-29

SEND Controlled Terminology Documentation

- But SEND codelists as a whole are unique to non-clinical data:

SPECIES	Species	Char	(SPECIES)

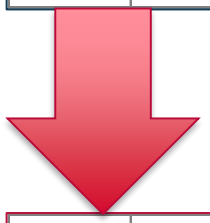
CL.C77808.SPECIES	Species (SPECIES)	text Extensible: Yes	C77808	Species	Terminology related to the common name for an animal used as the test system in a study (e.g., dog, monkey, mouse, rabbit, rat).	CDISC SEND Laboratory Animal Species Terminology
	BOVINE		C14192	Cattle	The domesticated ungulates, Bos primigenius taurus and Bos primigenius indicus.	Cow
	CAT		C14191		The domestic cat, Felis catus. (NCI)	Cat
	CHICKEN		C14193		The common domestic fowl, Gallus gallus. (NCI)	Chicken
	CHIMPANZEE		C14297		The anthropoid ape, Pan troglodytes.	Chimpanzee
	CHINCHILLA		C91815		A member of the Chinchillidae family of crepuscular rodents.	Chinchilla
	DOG		C14201		The domestic dog, Canis familiaris. (NCI)	Dog
	FERRET		C77097	Domestic Ferret	The common domestic mammal, Mustela putorious.	Ferret
	FISH		C14207		Any jawed or jawless organisms in the phylum Chordata including the jawless fish, armored fish, cartilaginous fish, ray-finned fish and lobe-finned fish.	Fish
	FROG		C14265		An amphibian in the order Anura, which includes the toads. (NCI)	Frog
	GERBIL		C77807		Any of the small mammals belonging to the Gerbillinae subfamily.	Gerbil
	GOAT		C14210		Any one of several species in the genus Capra, most commonly Capra hircus.	Goat
	GUINEA PIG		C14211		The domesticated guinea pig, Cavia porcellus. (NCI)	Guinea Pig
	HAMSTER		C14212		Any member of the subfamily cricetinae and the genuses	Hamster

Protocol Controlled Terminology Documentation

- PRM Protocol Concepts are similar to SDTM Trial Design concepts, and some terms may be exactly the same as some SDTM Trial Summary Parameters

Protocol Terminology: Clinical Study Attribute Terminology “Study Type”

C142175	C67152		Trial Summary Parameter Test Name	Study Type



SDTM Terminology: Trial Summary Parameter “Study Type”

C142175	C142191		Clinical Study Attribute Terminology	Study Type

Protocol Controlled Terminology Documentation

- Protocol Concepts go beyond subject level data, into trial operations

C132308		NA	Physical Address Attribute Terminology	Physical Address Attribute Terminology	Physical Address Attribute Terminology	A terminology value set relevant to the attributes of the physical address entity.	CDISC Protocol Entities Physical Address Attribute Terminology
C25160	C132308		Physical Address Attribute Terminology	City		A relatively large and/or densely populated area of human habitation with administrative or legal status that may be specified as a component of a postal address.	City
C25464	C132308		Physical Address Attribute Terminology	Country		A sovereign nation occupying a distinct territory and ruled by an autonomous government.	Country
C87189	C132308		Physical Address Attribute Terminology	Geographic Locality		A distinct geographic area in the immediate vicinity of a particular place, such as a city, neighborhood or district.	Locality
C16632	C132308		Physical Address Attribute Terminology	Geographic Region		Any demarcated area of the Earth; may be determined by both natural and human boundaries, such as a state or province.	Geographic Area
C25621	C132308		Physical Address Attribute Terminology	Postal Code		An alphanumeric code assigned to a mail delivery area.	Postal Code
C25632	C132308		Physical Address Attribute Terminology	Province		A sub-division of a country created by the central government for administrative purposes. Provinces are usually, but not always, less autonomous than states, and must obey the laws of the central government.	Province
C87194	C132308		Physical Address Attribute Terminology	State		A sub-division of a country that forms part of a federal union. States are usually, but not always, more autonomous than provinces and may have different laws from the central government.	State
C25690	C132308		Physical Address Attribute Terminology	Street Address		The street name and building number where an entity is located.	Street Address
C154681		NA	Protocol Contact Role Response	Protocol Contact Role Response	Protocol Contact Role Response	The terminology relevant to the role that the individual or entity plays with respect to being a contact within a study protocol.	CDISC Protocol Entities Protocol Contact Role Response Terminology
C154709	C154681		Protocol Contact Role Response	Biostatistician		A person who is responsible for the statistical aspects of the clinical or pre-clinical study. (NCI)	Biostatistician
C154708	C154681		Protocol Contact Role Response	Clinical Informaticist	Clinical Informatician	An individual that designs, implements, evaluates and/or analyzes information technology in a healthcare or research setting. (NCI)	Clinical Informaticist
C51811	C154681		Protocol Contact Role Response	Clinical Research Coordinator	CRC	A person to whom a clinical investigator delegates routine administrative requirements of a protocol. The duties and responsibilities of a clinical research coordinator may vary across different infrastructures. Generally, the coordinator manages the subject's clinical trial participation and provides a vital linkage between the subject, the investigator, and the sponsor. (NCI)	Clinical Coordinator
C127526	C154681		Protocol Contact Role Response	Contact for Public Queries		The study contact person who is responsible for questions from the public.	Public Queries Study Contact
C51818	C154681		Protocol Contact Role Response	Coordinating Investigator		An investigator assigned the responsibility for the coordination of investigators	Coordinating Investigator

CDISC **Glossary**

Industry terms defined

CDISC Glossary (CDISC Glossary)

NCI Code: C67497, Codelist extensible: NA

C67497 CDISC Glossary

NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C80442	510(k)		510(k). Premarket Notification (PMN) required for certain medical devices. See http://www.fda.gov/cdrh/510khome.html.	Premarket Device Notification

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition	NCI Preferred Term
C67497		NA	CDISC Glossary	CDISC Glossary	CDISC Glossary	The terminology of the Clinical Data Interchange Standards Consortium (CDISC) glossary.	CDISC Glossary Terminology
C80442	C67497		CDISC Glossary	510(k)		510(k). Premarket Notification (PMN) required for certain medical devices. See http://www.fda.gov/cdrh/510khome.html.	Premarket Device Notification
C42610	C67497		CDISC Glossary	abbreviation		A set of letters that are drawn from a word or from a sequence of words and that are used for brevity in place of the full word or phrase. NOTE: An abbreviation is NOT pronounced as a word, but each letter is read in sequence (e.g., NIH). Compare to acronym.	Abbreviation
C71733	C67497		CDISC Glossary	absorption		The process by which medications reach the blood stream when administered other than intravenously, for example, through nasal membranes. See also ADME (pharmacokinetics).	Biological Absorption
C156638	C67497		CDISC Glossary	accelerated approval	fast track designation	Regulatory mechanism by which new drugs meant to treat serious life-threatening diseases and that provide meaningful therapeutic benefit to patients over existing treatments can be approved rapidly. [after FDA, Guidance for Industry Expedited Programs for Serious Conditions - Drugs and Biologics; after NIH-FDA BEST (Biomarkers, Endpoints, and other Tools) Resource https://www.ncbi.nlm.nih.gov/books/NBK338448/]	Accelerated Approval
C93495	C67497		CDISC Glossary			letters (e.g., ANSI) or a combination of A) of a name or phrase. NOTE: An a word, not by speaking each letter on	Acronym
C142550	C67497		CDISC Glossary			A to an NDA sponsor announcing an al letter, approvable letter, not-approvable	FDA Action Letter
C142528	C67497		CDISC Glossary			to capture data; usually used for EDC	Electronic Data Capture Activation
C82533	C67497		CDISC Glossary			intended to furnish pharmacological activity sis, cure, mitigation, treatment, or he structure or any function of the body of s Medical Dictionary]	Active Ingredient
C98704	C67497		CDISC Glossary			ely planned opportunity for modification of he study design and hypotheses based on ata) from subjects in the study. [FDA, sign Clinical Trials for Drugs and Biologics]	Adaptive Design
C142382	C67497		CDISC Glossary	adequate and well-controlled studies		Studies used to support drug marketing authorization and intended to provide substantial evidence of effectiveness required by law to support a conclusion that a drug is effective. NOTE: For additional information see COA glossary of terms. [After 1. FDA Clinical Outcome Assessment (COA) Glossary; 2. 21 CFR 314.126]	Adequate and Well-controlled Study

CDISC Glossary used to be published each year in Applied Clinical Trials.

Since 2017 Glossary team operates same as other CDISC Controlled Terminology teams - same process, same publication schedule

C14238 2	adequate and well-controlled studies	Studies used to support drug marketing authorization and intended to provide substantial evidence of effectiveness required by law to support a conclusion that a drug is effective. NOTE: For additional information	Adequate and Well-controlled Study

Controlled Terminology **Conformance**

- In SDTM, SEND and ADaM data use values exactly <u>as published</u>
  - Use only the **CDISC Submission Value** for **submission** data, with the exact **spelling** and **case**

	A	B	C	D	E	F
1	Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synony
50	C66767		No	Action Taken with Study Treatment	ACN	Action Taken with Study T
51	C49503	C66767		Action Taken with Study Treatment	DOSE INCREASED	
52	C49504	C66767		Action Taken with Study Treatment	DOSE NOT CHANGED	
53	C150826	C66767		Action Taken with Study Treatment	DOSE RATE REDUCED	
54	C49505	C66767		Action Taken with Study Treatment	DOSE REDUCED	
55	C49501	C66767		Action Taken with Study Treatment	DRUG INTERRUPTED	
56	C49502	C66767		Action Taken with Study Treatment	DRUG WITHDRAWN	
57	C48660	C66767		Action Taken with Study Treatment	NOT APPLICABLE	NA; Not Applicable
58	C17998	C66767		Action Taken with Study Treatment	UNKNOWN	U; UNK; Unknown
59	C101865		No	Acute Coronary Syndrome Presentation Category	ACSPCAT	Acute Coronary Syndrome Category
60	C80383	C101865		Acute Coronary Syndrome Presentation Category	NON-ST ELEVATION MYOCARDIAL INFARCTION	NON-STEMI; NSTEMI
61	C17649	C101865		Acute Coronary Syndrome Presentation Category	OTHER	Other
62	C101888	C101865		Acute Coronary Syndrome Presentation Category	ST ELEVATION MYOCARDIAL INFARCTION	STEMI
63	C66914	C101865		Acute Coronary Syndrome Presentation Category	STABLE ANGINA	

ACN (Action Taken with Study Treatment)

NCI Code: C66767, Codelist extensible: No

C66767	ACN			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C49503	DOSE INCREASED		An indication that a medication schedule was modified by addition; either by changing the frequency, strength or amount. (NCI)	Dose Increased
C49504	DOSE NOT CHANGED		An indication that a medication schedule was maintained. (NCI)	Dose Not Changed
C150826	DOSE RATE REDUCED		An indication that the administration of a medication was modified by reducing the rate at which the dose was given, without reducing the total dose administered.	Dose Rate Reduced
C49505	DOSE REDUCED		An indication that a medication schedule was modified by subtraction, either by changing the frequency, strength or amount. (NCI)	Dose Reduced
C49501	DRUG INTERRUPTED		An indication that a medication schedule was modified by temporarily terminating a prescribed regimen of medication. (NCI)	Drug Interrupted
C49502	DRUG WITHDRAWN		An indication that a medication schedule was modified through termination of a prescribed regimen of medication. (NCI)	Drug Withdrawn
C48660	NOT APPLICABLE	NA;Not Applicable	Determination of a value is not relevant in the current context. (NCI)	Not Applicable
C17998	UNKNOWN	U;UNK;Unknown	Not known, not observed, not recorded, or refused. (NCI)	Unknown

Controlled Terminology **Conformance**

- In SDTM, SEND and ADaM, follow Extensibility rules
  - If No, no other values may be added to this codelist
  - If Yes, other values may be added
    - First, confirm that the value you need is not already there - look at synonyms and definitions

	A	B	C	D	E	F
1	Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)
50	C66767		No	Action Taken with Study Treatment	ACN	Action Taken with Study Treatment
51	C49503	C66767		Action Taken with Study Treatment	DOSE INCREASED	
52	C49504	C66767		Action Taken with Study Treatment	DOSE NOT CHANGED	
53	C150826	C66767		Action Taken with Study Treatment	DOSE RATE REDUCED	
54	C49505	C66767		Action Taken with Study Treatment	DOSE REDUCED	
55	C49501	C66767		Action Taken with Study Treatment	DRUG INTERRUPTED	
56	C49502	C66767		Action Taken with Study Treatment	DRUG WITHDRAWN	
57	C48660	C66767		Action Taken with Study Treatment	NOT APPLICABLE	NA; Not Applicable
58	C17998	C66767		Action Taken with Study Treatment	UNKNOWN	U; UNK; Unknown
59	C101865		No	Acute Coronary Syndrome Presentation Category	ACSPCAT	Acute Coronary Syndrome Presentation Category
60	C80383	C101865		Acute Coronary Syndrome Presentation Category	NON-ST ELEVATION MYOCARDIAL INFARCTION	NON-STEMI; NSTEMI
61	C17649	C101865		Acute Coronary Syndrome Presentation Category	OTHER	Other
62	C101888	C101865		Acute Coronary Syndrome Presentation Category	ST ELEVATION MYOCARDIAL INFARCTION	STEMI
63	C66914	C101865		Acute Coronary Syndrome Presentation Category	STABLE ANGINA	

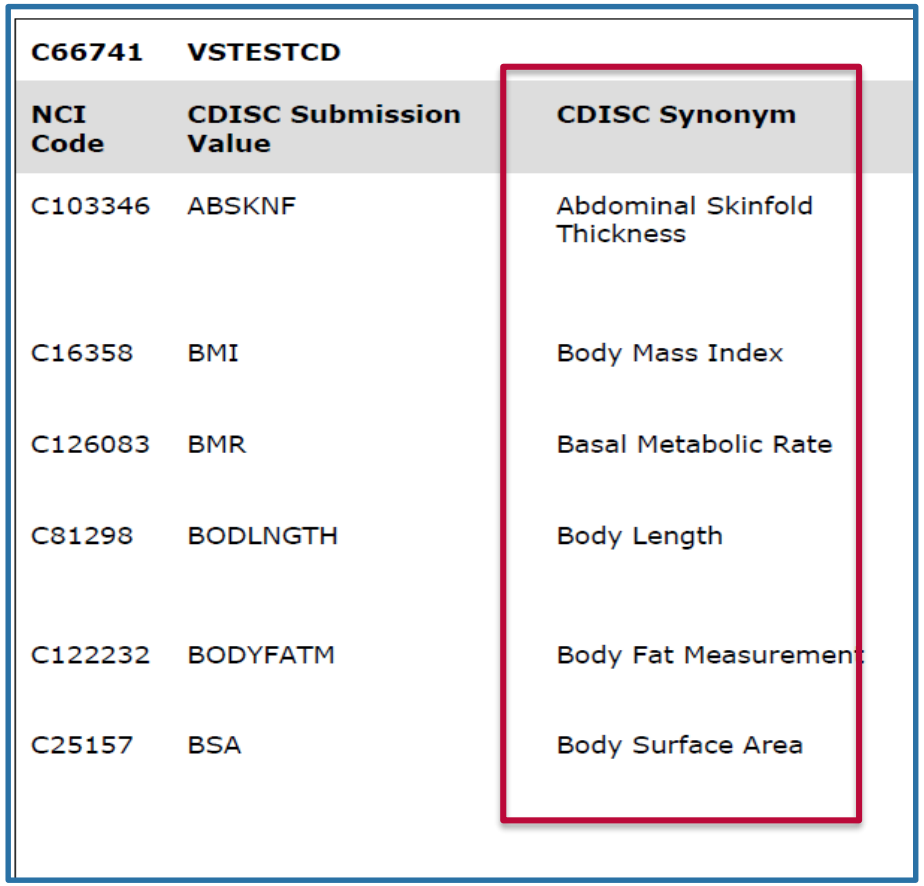
CONROL (Contact Role for Clinical Study)

NCI Code: C127257, Codelist extensible: Yes

C127257	CONROL			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C127522	CA APPLICANT		The person responsible for the competent authority application.	Competent Authority Applicant
C127523	CENTRAL CONTACT FOR RECRUITMENT		The contact person providing centralized, coordinated recruitment information for the entire study. (clinicaltrials.gov)	Central Contact for Recruitment
C127524	CENTRAL CONTACT FOR RECRUITMENT BACKUP		The secondary contact person providing centralized, coordinated recruitment information for the entire study. (clinicaltrials.gov)	Central Contact for Recruitment Backup
C127525	CLINICAL NETWORK CONTACT		The main or principal contact person for the clinical investigator network.	Clinical Investigator Network Contact
C127526	CONTACT FOR PUBLIC QUERIES		The study contact person who is responsible for questions from the public.	Public Queries Study Contact
C127527	CONTACT FOR SCIENTIFIC QUERIES		The study contact person who is responsible for questions from the scientific community.	Scientific Queries Study Contact
C127528	FACILITY CONTACT		The main or principal contact person at the facility.	Facility Contact
C127529	FACILITY CONTACT BACKUP		The secondary contact person at the facility.	Facility Contact Backup

Controlled Terminology **Conformance**

- For data collection, synonyms (including NCI Preferred terms) may be used to promote usability
- *CDASH allows the use of Synonyms to display the question to the site (but you still need to store the CDISC Submission Value in the database variable because that is the value that gets passed to the SDTM variable.*



C66741	VSTESTCD	
NCI Code	**CDISC Submission Value**	**CDISC Synonym**
C103346	ABSKNF	Abdominal Skinfold Thickness
C16358	BMI	Body Mass Index
C126083	BMR	Basal Metabolic Rate
C81298	BODLNGTH	Body Length
C122232	BODYFATM	Body Fat Measurement
C25157	BSA	Body Surface Area

CT Diff Files

Review Structure of CT Diff File

- Each new version of CT has a Diff file that details the changes from previous version.

Release date of version for which the Diff file was created.

Release Date	Request Code	Change Type	NCI Code	CDISC Term Type	CDISC Codelist (Short Name)	CDISC Codelist (Long Name)	Change Summary	Original	New	Change Implementation Instructions
2018-12-21	CDISC-3393	Add	C156536	Term	LBTEST	Laboratory Test Name	Add new term to existing codelist	- - -	Decanoylcarnitine	
2018-12-21	CDISC-3407	Add	C156537	Term	LBTEST	Laboratory Test Name	Add new term to existing codelist	- - -	Delta Aminolevulinate	
2018-12-21	CDISC-3407	Add	C156538	Term	LBTEST	Laboratory Test Name	Add new term to existing codelist	- - -	Delta Aminolevulinate/Creatinine	
2018-12-21	CDISC-3407	Add	C156539	Term	LBTEST	Laboratory Test Name	Add new term to existing codelist	- - -	Porphobilinogen	
2018-12-21	CDISC-3407	Add	C156540	Term	LBTEST	Laboratory Test Name	Add new term to existing codelist	- - -	Porphobilinogen/Creatinine	
2018-12-21	CDISC-3250	Add	C17768	Term	LBTEST	Laboratory Test Name	Add new term to existing codelist	- - -	Cell Morphology	
2018-12-21	CDISC-2944	Add	C38082	Term	LBTEST	Laboratory Test Name	Add new term to existing codelist	- - -	Fraction of Inspired Oxygen	
2018-12-21	CDISC-3612	Update	C74684	CDISC Definition	LBTEST	Laboratory Test Name	Update CDISC Definition	A measurement of the uric acid crystals present in a biological specimen.	A measurement of the uric acid crystals (including acid urate and urate crystals) present in a biological specimen.	
2018-12-21	CDISC-3612	Update	C74684	CDISC Synonym	LBTEST	Laboratory Test Name	Add new CDISC Synonym	- - -	Acid Urate Crystals	
2018-12-21	CDISC-3612	Remove	C74912	Term	LBTEST	Laboratory Test Name	Remove term entirely from codelist	Acid Urate Crystals	- - -	C74912 is removed from codelist and being replaced with C74684, which is currently in the codelist. We could not find evidence that Acid Urate Crystals are appreciably different enough from Uric Acid Crystals such that they could be assayed separately. Acid Urate Crystals is being added as a synonym to C74864 to help with mapping.
2018-12-21	CDISC-3375	Add	C81183	Term	LBTEST	Laboratory Test Name	Add new term to existing codelist	- - -	Amino Acids	
2018-12-21	CDISC-3339	Update	C81958	CDISC Submission	LBTEST	Laboratory Test Name	Update CDISC Submission Value	Antithrombin	Antithrombin Activity	The submission value is being updated to better

Review Structure of CT Diff File

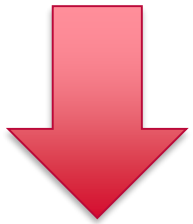
Release Date	Request Code	Change Type	NCI Code	CDISC Term Type	CDISC Codelist (Short Name)	CDISC Codelist (Long Name)	Change Summa
2018-12-21	CDISC-3393	Add	C156536				
2018-12-21	CDISC-3407	Add	C156537				
2018-12-21	CDISC-3407	Add	C156538				
2018-12-21	CDISC-3407	Add	C156539				
2018-12-21	CDISC-3407	Add	C156540	Term	LBTEST	Laboratory Test Name	Add new term to exis codelist
2018-12-21	CDISC-3250	Add	C17768	Term	LBTEST	Laboratory Test Name	Add new term to exis codelist
2018-12-21	CDISC-2944	Add	C38082	Term	LBTEST	Laboratory Test Name	Add new term to exis codelist
2018-12-21	CDISC-3612	Update	C74684	CDISC Definition	LBTEST	Laboratory Test Name	Update CDISC Defini
2018-12-21	CDISC-3612	Update	C74684	CDISC Synonym	LBTEST	Laboratory Test Name	Add new CDISC Syn
2018-12-21	CDISC-3612	Remove	C74912	Term	LBTEST	Laboratory Test Name	Remove term entirely codelist
2018-12-21	CDISC-3375	Add	C81183	Term	LBTEST	Laboratory Test Name	Add new term to exis codelist
2018-12-21	CDISC-3339	Update	C81958	CDISC Submission	LBTEST	Laboratory Test Name	Update CDISC Subm Value

Request Code - for traceability to the New Term Request Tracker.

Status	Date of Submissic	Request Cod	Submitter Name	Submitter Affiliation	Submitter E-mail	Request Type	CDISC Codelis	New Term or Codelist/Existing Term or Code Number	Detailed Desc
Closed	Fr , 5 Jan 20 0 AM	CDISC-3189	Barbara Lentz	Bayer	barbara.lentz1@bayer.com	Create New Term	SDTM-MEDEVAL	ADJUDICATOR 1	An individual that presides c between individuals or orgar given a designation of one.
		CDISC-3190	Barbara Lentz	Bayer	barbara.lentz1@bayer.com	Create New Term	SDTM-MEDEVAL	ADJUDICATOR 2	An individual that presides c between individuals or orgar given a designation of two.
Closed	Fr Jan 20 1:25 AM	CDISC-3191	Barbara Lentz	Bayer	barbara.lentz1@bayer.com	Create New Term	SDTM-MEDEVAL	ADJUDICATOR 3	An individual that presides c between individuals or orgar given a designation of three
Closed	Friday, 5 Jan 2018 11:26 AM	CDISC-3192	Craig Zwickl	Independent/ SEND CT Lead	czwickl@cdisc.org	Create New Term	SEND-BGTEST	CUMULATIVE BODY WEIGHT GAIN	At the SEND F2F in Oct 201 discussion involving FDA re for a need to include the cur gain across all intervals in th These data are currently bei multiple sponsors as an ext codelist.
Closed	Friday, 5 Jan 2018 11:27 AM	CDISC-3193	Craig Zwickl	Independent/ SEND CT Lead	czwickl@cdisc.org	Create New Term	SEND-FWTEST	CUMULATIVE FOOD CONSUMPTION	At the SEND F2F in Oct 201 discussion involving FDA re for a need to include the cur consumption across all inte datasets. These data are cu submitted by multiple spons to the codelist.
Closed	Friday, 12 Jan 2018 10:58 AM	CDISC-3194	Craig Zwickl	Independent/ SEND CT Lead	czwickl@cdisc.org	Create New Codelist	NEW	NULLFLAVOR	Codelist is identified for use does not exist. SEND leade develop this codelist and to controlled terminology from section 7.6.4, which are take Each term will be requested
Closed	Friday, 12 Jan 2018 11:02 AM	CDISC-3195	Craig Zwickl	Independent/ SEND CT Lead	czwickl@cdisc.org	Create New Term	NEW	NI or No information (CT team to decide, as only one preferred term is to be used) Include term in the new NULLFLAVOR codelist.	SENDIG v3.1 section 7.6.4, c terminology taken from ISO NULLFLAVOR codelist. ISO 21090 description: "The exceptional (missing, omitte improper). No information a being an exceptional value is the most general exceptiona default exceptional value."
Closed	Friday, 12 Jan 2018 11:02 AM	CDISC-3196	Craig Zwickl	Independent/ SEND CT Lead	czwickl@cdisc.org	Create New Term	NEW	INV or Invalid (CT team to decide, as only one preferred term is to be used) Include term in the new NULLFLAVOR codelist.	SENDIG v3.1 section 7.6.4, c terminology taken from ISO NULLFLAVOR codelist. ISO "The value as represented ir a member of the set of perm the constrained value doma

... | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018

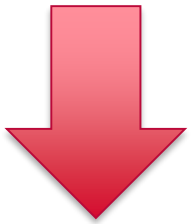
Review Structure of CT Diff File



Change Type:
Add
Update
Remove

Release Date	Request Code	Change Type	NCI Code	CDISC Term Type	CDISC Codelist (Short Name)	CDISC Codelist (Long Name)	Change Summary	Original	New	Change Implementation Instructions
2018-12-21	CDISC-3393	Add	C156536	Term	LBTEST	Laboratory Test Name	Add new term to existing codelist	- - -	Decanoylcarnitine	
2018-12-21	CDISC-3407	Add	C15	Term	LBTEST	Laboratory Test Name	Add new term to existing codelist	- - -	Delta Aminolevulinate	
2018-12-21	CDISC-3407	Add	C15			y Test Name	Add new term to existing codelist	- - -	Delta Aminolevulinate/Creatinine	
2018-12-21	CDISC-3407	Add	C15			y Test Name	Add new term to existing codelist	- - -	Porphobilinogen	
2018-12-21	CDISC-3407	Add	C15			y Test Name	Add new term to existing codelist	- - -	Porphobilinogen/Creatinine	
2018-12-21	CDISC-3250	Add	C17			y Test Name	Add new term to existing codelist	- - -	Cell Morphology	
2018-12-21	CDISC-2944	Add	C38			y Test Name	Add new term to existing codelist	- - -	Fraction of Inspired Oxygen	
2018-12-21	CDISC-3612	Update	C74684	CDISC Definition	LBTEST	Laboratory Test Name	Update CDISC Definition	A measurement of the uric acid crystals present in a biological specimen.	A measurement of the uric acid crystals (including acid urate and urate crystals) present in a biological specimen.	
2018-12-21	CDISC-3612	Update	C74684	CDISC Synonym	LBTEST	Laboratory Test Name	Add new CDISC Synonym	- - -	Acid Urate Crystals	
2018-12-21	CDISC-3612	Remove	C74912	Term	LBTEST	Laboratory Test Name	Remove term entirely from codelist	Acid Urate Crystals	- - -	C74912 is removed from codelist and being replaced with C74684, which is currently in the codelist. We could not find evidence that Acid Urate Crystals are appreciably different enough from Uric Acid Crystals such that they could be assayed separately. Acid Urate Crystals is being added as a synonym to C74864 to help with mapping.
2018-12-21	CDISC-3375	Add	C81183	Term	LBTEST	Laboratory Test Name	Add new term to existing codelist	- - -	Amino Acids	
2018-12-21	CDISC-3339	Update	C81958	CDISC Submission	LBTEST	Laboratory Test Name	Update CDISC Submission Value	Antithrombin	Antithrombin Activity	The submission value is being updated to better

Review Structure of CT Diff File



NCI Code for the affected term or codelist

Release Date	Request Code	Change Type	NCI Code	CDISC Term Type	CDISC Codelist (Short Name)	CDISC Codelist (Long Name)	Change Summary	Original	New	Change Implementation Instructions
2018-12-21	CDISC-3393	Add	C156536	Term	LBTEST	Laboratory Test Name	Add new term to existing codelist	- - -	Decanoylcarnitine	
2018-12-21	CDISC-3407	Add	C156537	Term	LBTEST	Laboratory Test Name	Add new term to existing	- - -	Delta Aminolevulinate	
2018-12-21	CDISC-3407	Add	C156538	Term	LB		sting	- - -	Delta Aminolevulinate/Creatinine	
2018-12-21	CDISC-3407	Add	C156539	Term	LB		sting	- - -	Porphobilinogen	
2018-12-21	CDISC-3407	Add	C156540	Term	LB		sting	- - -	Porphobilinogen/Creatinine	
2018-12-21	CDISC-3250	Add	C17768	Term	LB		sting	- - -	Cell Morphology	
2018-12-21	CDISC-2944	Add	C38082	Term	LBTEST	Laboratory Test Name	Add new term to existing codelist	- - -	Fraction of Inspired Oxygen	
2018-12-21	CDISC-3612	Update	C74684	CDISC Definition	LBTEST	Laboratory Test Name	Update CDISC Definition	A measurement of the uric acid crystals present in a biological specimen.	A measurement of the uric acid crystals (including acid urate and urate crystals) present in a biological specimen.	
2018-12-21	CDISC-3612	Update	C74684	CDISC Synonym	LBTEST	Laboratory Test Name	Add new CDISC Synonym	- - -	Acid Urate Crystals	
2018-12-21	CDISC-3612	Remove	C74912	Term	LBTEST	Laboratory Test Name	Remove term entirely from codelist	Acid Urate Crystals	- - -	C74912 is removed from codelist and being replaced with C74684, which is currently in the codelist. We could not find evidence that Acid Urate Crystals are appreciably different enough from Uric Acid Crystals such that they could be assayed separately. Acid Urate Crystals is being added as a synonym to C74864 to help with mapping.
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2018-12-21	CDISC-3339	Update	C81958	CDISC Submission	LBTEST	Laboratory Test Name	Update CDISC Submission Value	Antithrombin	Antithrombin Activity	The submission value is being updated to better

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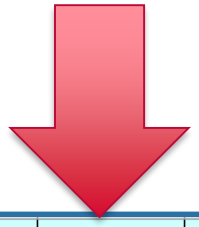

Release Date	Request Code	Change Type	NCI Code	CDISC Term Type	CDISC Codelist (Short Name)	CDISC Codelist (Long Name)	Change Summary	Original	New	Change Implementation Instructions
2018-12-21	CDISC-3393	Add	C156536	Term	LBTEST	Laboratory Test Name	Add new term to existing codelist	- - -	Decanoylcarnitine	
2018-12-21	CDISC-3407	Add	C156537	Term	LBTEST	Laboratory Test Name	Add new term to existing	- - -	Delta Aminolevulinate	
2018-12-21	CDISC-3407	Add	C156538	Term	LBTE				Delta Aminolevulinate/Creatinine	
2018-12-21	CDISC-3407	Add	C156539	Term	LBTE				Porphobilinogen	
2018-12-21	CDISC-3407	Add	C156540	Term	LBTE				Porphobilinogen/Creatinine	
2018-12-21	CDISC-3250	Add	C17768	Term	LBTE				Cell Morphology	
2018-12-21	CDISC-2944	Add	C38082	Term	LBTE				Fraction of Inspired Oxygen	
2018-12-21	CDISC-3612	Update	C74684	CDISC Definition	LBTE			ent of the uric acid crystals present in a biological specimen.	A measurement of the uric acid crystals (including acid urate and urate crystals) present in a biological specimen.	
2018-12-21	CDISC-3612	Update	C74684	CDISC Synonym	LBTEST	Laboratory Test Name	Add new CDISC Synonym	- - -	Acid Urate Crystals	
2018-12-21	CDISC-3612	Remove	C74912	Term	LBTEST	Laboratory Test Name	Remove term entirely from codelist	Acid Urate Crystals	- - -	C74912 is removed from codelist and being replaced with C74684, which is currently in the codelist. We could not find evidence that Acid Urate Crystals are appreciably different enough from Uric Acid Crystals such that they could be assayed separately. Acid Urate Crystals is being added as a synonym to C74864 to help with mapping.
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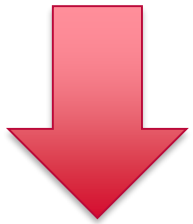
2018-12-21	CDISC-3339	Update	C81958	CDISC Submission	LBTEST	Laboratory Test Name	Update CDISC Submission Value	Antithrombin	Antithrombin Activity	The submission value is being updated to better

The type of metadata that changed
- CDISC Submission Value
- CDISC Synonym
- CDISC Definition

Review Structure of CT Diff File



The Short Name, or CDISC Submission Value, of the affected codelist

Release Date	Request Code	Change Type	NCI Code	CDISC Term Type	CDISC Codelist (Short Name)	CDISC Codelist (Long Name)	Change Summary	Original	New	Change Implementation Instructions
2018-12-21	CDISC-3393	Add	C156536	Term	LBTEST	Laboratory Test Name	Add new term to existing	- - -	Decanoylcarnitine	
2018-12-21	CDISC-3407	Add	C156537	Term	LBTEST	Laborat			Delta Aminolevulinate	
2018-12-21	CDISC-3407	Add	C156538	Term	LBTEST	Laborat			Delta Aminolevulinate/Creatinine	
2018-12-21	CDISC-3407	Add	C156539	Term	LBTEST	Laborat			Porphobilinogen	
2018-12-21	CDISC-3407	Add	C156540	Term	LBTEST	Laborat	codelist		Porphobilinogen/Creatinine	
2018-12-21	CDISC-3250	Add	C17768	Term	LBTEST	Laboratory Test Name	Add new term to existing codelist	- - -	Cell Morphology	
2018-12-21	CDISC-2944	Add	C38082	Term	LBTEST	Laboratory Test Name	Add new term to existing codelist	- - -	Fraction of Inspired Oxygen	
2018-12-21	CDISC-3612	Update	C74684	CDISC Definition	LBTEST	Laboratory Test Name	Update CDISC Definition	A measurement of the uric acid crystals present in a biological specimen.	A measurement of the uric acid crystals (including acid urate and urate crystals) present in a biological specimen.	
2018-12-21	CDISC-3612	Update	C74684	CDISC Synonym	LBTEST	Laboratory Test Name	Add new CDISC Synonym	- - -	Acid Urate Crystals	
2018-12-21	CDISC-3612	Remove	C74912	Term	LBTEST	Laboratory Test Name	Remove term entirely from codelist	Acid Urate Crystals	- - -	C74912 is removed from codelist and being replaced with C74684, which is currently in the codelist. We could not find evidence that Acid Urate Crystals are appreciably different enough from Uric Acid Crystals such that they could be assayed separately. Acid Urate Crystals is being added as a synonym to C74864 to help with mapping.
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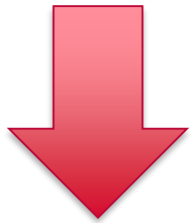

Release Date	Request Code	Change Type	NCI Code	CDISC Term Type	CDISC Codelist (Short Name)	CDISC Codelist (Long Name)	Change Summary	Original	New	Change Implementation Instructions
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2018-12-21	CDISC-3407	Add	C156537	Term	LBTEST	Laboratory Test Name	Add new term to existing codelist		minolevulinate	
2018-12-21	CDISC-3407	Add	C156538	Term	LBTEST	Laboratory Test Name	Add new term to existing codelist		minolevulinate/Creatinine	
2018-12-21	CDISC-3407	Add	C156539	Term	LBTEST	Laboratory Test Name	Add new term to existing codelist	- - -	Porphobilinogen	
2018-12-21	CDISC-3407	Add	C156540	Term	LBTEST	Laboratory Test Name	Add new term to existing codelist	- - -	Porphobilinogen/Creatinine	
2018-12-21	CDISC-3250	Add	C17768	Term	LBTEST	Laboratory Test Name	Add new term to existing codelist	- - -	Cell Morphology	
2018-12-21	CDISC-2944	Add	C38082	Term	LBTEST	Laboratory Test Name	Add new term to existing codelist	- - -	Fraction of Inspired Oxygen	
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2018-12-21	CDISC-3612	Update	C74684	CDISC Synonym	LBTEST	Laboratory Test Name	Add new CDISC Synonym	- - -	Acid Urate Crystals	
2018-12-21	CDISC-3612	Remove	C74912	Term	LBTEST	Laboratory Test Name	Remove term entirely from codelist	Acid Urate Crystals	- - -	C74912 is removed from codelist and being replaced with C74684, which is currently in the codelist. We could not find evidence that Acid Urate Crystals are appreciably different enough from Uric Acid Crystals such that they could be assayed separately. Acid Urate Crystals is being added as a synonym to C74864 to help with mapping.
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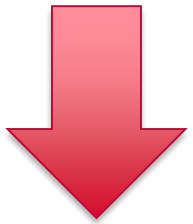
2018-12-21	CDISC-3339	Update	C81958	CDISC Submission	LBTEST	Laboratory Test Name	Update CDISC Submission Value	Antithrombin	Antithrombin Activity	The submission value is being updated to better

The Long Name, or Codelist Name, of the affected codelist

Review Structure of CT Diff File



A brief description of the type of change that was made

Release Date	Request Code	Change Type	NCI Code	CDISC Term Type	CDISC Codelist (Short Name)	CDISC Codelist (Long Name)	Change Summary	Original	New	Change Implementation Instructions
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2018-12-21	CDISC-3407	Add	C156538	Term	LBTEST	Laboratory Test Name	Add new term to existing codelist	- - -		
2018-12-21	CDISC-3407	Add	C156539	Term	LBTEST	Laboratory Test Name	Add new term to existing codelist	- - -		
2018-12-21	CDISC-3407	Add	C156540	Term	LBTEST	Laboratory Test Name	Add new term to existing codelist	- - -	Porphobilinogen/Creatinine	
2018-12-21	CDISC-3250	Add	C17768	Term	LBTEST	Laboratory Test Name	Add new term to existing codelist	- - -	Cell Morphology	
2018-12-21	CDISC-2944	Add	C38082	Term	LBTEST	Laboratory Test Name	Add new term to existing codelist	- - -	Fraction of Inspired Oxygen	
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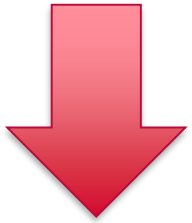

The value as it appeared in the previous version

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2018-12-21	CDISC-3393	Add	C156536	Term	LBTEST	Laboratory Test Name	Add new term to existing codelist	- - -	De	
2018-12-21	CDISC-3407	Add	C156537	Term	LBTEST	Laboratory Test Name	Add new term to existing codelist	- - -	Del	
2018-12-21	CDISC-3407	Add	C156538	Term	LBTEST	Laboratory Test Name	Add new term to existing codelist	- - -	Del	
2018-12-21	CDISC-3407	Add	C156539	Term	LBTEST	Laboratory Test Name	Add new term to existing codelist	- - -	Porphobilinogen	
2018-12-21	CDISC-3407	Add	C156540	Term	LBTEST	Laboratory Test Name	Add new term to existing codelist	- - -	Porphobilinogen/Creatinine	
2018-12-21	CDISC-3250	Add	C17768	Term	LBTEST	Laboratory Test Name	Add new term to existing codelist	- - -	Cell Morphology	
2018-12-21	CDISC-2944	Add	C38082	Term	LBTEST	Laboratory Test Name	Add new term to existing codelist	- - -	Fraction of Inspired Oxygen	
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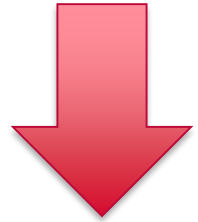
2018-12-21	CDISC-3339	Update	C81958	CDISC Submission	LBTEST	Laboratory Test Name	Update CDISC Submission Value	Antithrombin	Antithrombin Activity	The submission value is being updated to better

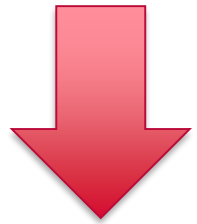
Review Structure of CT Diff File



The value as it appears in the current version

Release Date	Request Code	Change Type	NCI Code	CDISC Term Type	CDISC Codelist (Short Name)	CDISC Codelist (Long Name)	Change Summary	Original	New	Change Implementation Instructions
2018-12-21	CDISC-3393	Add	C156536	Term	LBTEST	Laboratory Test Name	Add new term to existing codelist	- - -	Decanoylcarnitine	
2018-12-21	CDISC-3407	Add	C156537	Term	LBTEST	Laboratory Test Name	Add new term to existing codelist	- - -	Delta Aminolevulinate	
2018-12-21	CDISC-3407	Add	C156538	Term	LBTEST	Laboratory Test Name			Delta Aminolevulinate/Creatinine	
2018-12-21	CDISC-3407	Add	C156539	Term	LBTEST	Laboratory Test Nam			Porphobilinogen	
2018-12-21	CDISC-3407	Add	C156540	Term	LBTEST	Laboratory Test Nam			Porphobilinogen/Creatinine	
2018-12-21	CDISC-3250	Add	C17768	Term	LBTEST	Laboratory Test Name	Add new term to existing codelist	- - -	Cell Morphology	
2018-12-21	CDISC-2944	Add	C38082	Term	LBTEST	Laboratory Test Name	Add new term to existing codelist	- - -	Fraction of Inspired Oxygen	
2018-12-21	CDISC-3612	Update	C74684	CDISC Definition	LBTEST	Laboratory Test Name	Update CDISC Definition	A measurement of the uric acid crystals present in a biological specimen.	A measurement of the uric acid crystals (including acid urate and urate crystals) present in a biological specimen.	
2018-12-21	CDISC-3612	Update	C74684	CDISC Synonym	LBTEST	Laboratory Test Name	Add new CDISC Synonym	- - -	Acid Urate Crystals	
2018-12-21	CDISC-3612	Remove	C74912	Term	LBTEST	Laboratory Test Name	Remove term entirely from codelist	Acid Urate Crystals	- - -	C74912 is removed from codelist and being replaced with C74684, which is currently in the codelist. We could not find evidence that Acid Urate Crystals are appreciably different enough from Uric Acid Crystals such that they could be assayed separately. Acid Urate Crystals is being added as a synonym to C74864 to help with mapping.
2018-12-21	CDISC-3375	Add	C81183	Term	LBTEST	Laboratory Test Name	Add new term to existing codelist	- - -	Amino Acids	
2018-12-21	CDISC-3339	Update	C81958	CDISC Submission	LBTEST	Laboratory Test Name	Update CDISC Submission Value	Antithrombin	Antithrombin Activity	The submission value is being updated to better

Review Structure of CT Diff File



Release Date	Request Code	Change Type	NCI Code	CDISC Term Type	CDISC Codelist (Short Name)	CDISC Codelist (Long Name)	Change Summary	Original	New	Change Implementation Instructions
2018-12-21	CDISC-3393	Add	C156536	Term	LBTEST	Laboratory Test Name	Add new term to existing codelist	- - -	Decanoylcarnitine	
2018-12-21	CDISC-3407	Add	C156537	Term	LBTEST	Laboratory Test Name	Add new term to existing codelist	- - -	Delta Aminolevulinate	
2018-12-21	CDISC-3407	Add	C156538	Term	LBTEST	Laboratory Test Name	Add new term to existing codelist	- - -	Delta Aminolevulinate/Creatinine	
2018-12-21	CDISC-3407	Add	C156539	Term	LBTEST	Laboratory Test Name	Add new term to existing codelist	- - -		
2018-12-21	CDISC-3407	Add	C156540	Term	LBTEST	Laboratory Test Name	Add new term to existing codelist	- - -		
2018-12-21	CDISC-3250	Add	C17768	Term	LBTEST	Laboratory Test Name	Add new term to existing codelist	- - -		
2018-12-21	CDISC-2944	Add	C38082	Term	LBTEST	Laboratory Test Name	Add new term to existing codelist	- - -		
2018-12-21	CDISC-3612	Update	C74684	CDISC Definition	LBTEST	Laboratory Test Name	Update CDISC Definition	A measurement of biological specime		
2018-12-21	CDISC-3612	Update	C74684	CDISC Synonym	LBTEST	Laboratory Test Name	Add new CDISC Synonym	- - -		
2018-12-21	CDISC-3612	Remove	C74912	Term	LBTEST	Laboratory Test Name	Remove term entirely from codelist	Acid Urate Crystals	- - -	C74912 is removed from codelist and being replaced with C74684, which is currently in the codelist. We could not find evidence that Acid Urate Crystals are appreciably different enough from Uric Acid Crystals such that they could be assayed separately. Acid Urate Crystals is being added as a synonym to C74864 to help with mapping.
2018-12-21	CDISC-3375	Add	C81183	Term	LBTEST	Laboratory Test Name	Add new term to existing codelist	- - -	Amino Acids	
2018-12-21	CDISC-3339	Update	C81958	CDISC Submission	LBTEST	Laboratory Test Name	Update CDISC Submission Value	Antithrombin	Antithrombin Activity	The submission value is being updated to better

Instructions for Implementers on how to handle this change. E.g., if you were using a value that was removed, this will tell you what value to use instead.

CT Mapping Files

Controlled Terminology Mapping Files

- Published on CDISC CT web page: https://www.cdisc.org/standards/terminology
- Some tests/measurements have standard response codelist
  - CV Codetable
  - ECG Codetable
  - Oncology Codetable
  - SC Codetable

C-code (Concept Code)	Subject Characteristics Test Code (SCTESTCD) (codelist code = C74559)	Subject Characteristics Test Name (SCTEST) (codelist code = C103330)	C-code (Concept Code)	No Yes Response (NY) (codelist code = C66742)
C112233	BRFEDIND	Breast Fed Indicator	C49487	N
C112233	BRFEDIND	Breast Fed Indicator	C17998	U
C112233	BRFEDIND	Breast Fed Indicator	C49488	Y
C102625	CNTCINV	Contact Investigation	C49487	N

C-code (Concept Code)	Subject Characteristics Test Code (SCTESTCD) (codelist code = C74559)	Subject Characteristics Test Name (SCTEST) (codelist code = C103330)	C-code (Concept Code)	No Yes Response (NY) (codelist code = C66742)	C-code (Concept Code)	Marital Status Response (MARISTAT) (codelist code = C76348)
C25188	MARISTAT	Marital Status			C76240	ANNULLED
C25188	MARISTAT	Marital Status			C51776	DIVORCED
C25188	MARISTAT	Marital Status			C53262	DOMESTIC PARTNER
C25188	MARISTAT	Marital Status			C76241	INTERLOCUTORY
C25188	MARISTAT	Marital Status			C51777	LEGALLY SEPARATED
C25188	MARISTAT	Marital Status			C51773	MARRIED
C25188	MARISTAT	Marital Status			C51774	NEVER MARRIED
C25188	MARISTAT	Marital Status			C76242	POLYGAMOUS
C25188	MARISTAT	Marital Status			C156541	SEPARATED
C25188	MARISTAT	Marital Status			C51775	WIDOWED

Oncology Mapping File

Published on CDISC CT web page: https://www.cdisc.org/standards/terminology

C-code (Concept Code)	Tumor or Lesion Identification Test Code (TUTESTCD) (codelist code = C96784	Tumor or Lesion Identification Test Name (TUTEST) (codelist code = C96783)		C-code (Concept Code)	Tumor or Lesion Identification Test Results (TUIDRS) (codelist code = C123650)
C123633	DRCRLTLC	Disease Recurrence Relative Location		C25321	DISTANT
C123633	DRCRLTLC	Disease Recurrence Relative Location		C67263	LOCAL
C123633	DRCRLTLC	Disease Recurrence Relative Location		C25388	LOCOREGIONAL
C123633	DRCRLTLC	Disease Recurrence Relative Location		C25643	REGIONAL
C119567	GRLIDENT	Graft Lesion Identification		C94521	NON-TARGET
C119567	GRLIDENT	Graft Lesion Identification		C94520	TARGET
C94189	LESIDENT	Lesion Identification		C94521	NON-TARGET
C94189	LESIDENT	Lesion Identification		C94520	TARGET
C119568	LMLIDENT	Limb Lesion Identification		C94521	NON-TARGET
C119568	LMLIDENT	Limb Lesion Identification		C94520	TARGET
C94525	TUMERGE	Tumor Merged		C94520	TARGET
C94523	TUMIDENT	Tumor Identification		C14172	BENIGN
C94523	TUMIDENT	Tumor Identification		C132466	BONE LESION
C94523	TUMIDENT	Tumor Identification		C103416	MEASURED
C94523	TUMIDENT	Tumor Identification		C94522	NEW
C94523	TUMIDENT	Tumor Identification		C132467	NEW BONE LESION
C94523	TUMIDENT	Tumor Identification		C103423	NON-MEASURABLE
C94523	TUMIDENT	Tumor Identification		C94521	NON-TARGET
C94523	TUMIDENT	Tumor Identification		C132468	NON-TARGET ENHANCING
C94523	TUMIDENT	Tumor Identification		C132469	NON-TARGET EXTRA NODAL
C94523	TUMIDENT	Tumor Identification		C132470	NON-TARGET NODAL
C94523	TUMIDENT	Tumor Identification		C132471	NON-TARGET NON-ENHANCING
C94523	TUMIDENT	Tumor Identification		C103425	NOT MEASURED
C94523	TUMIDENT	Tumor Identification		C94520	TARGET
C94523	TUMIDENT	Tumor Identification		C103442	TARGET EXTRA NODAL
C94523	TUMIDENT	Tumor Identification		C103443	TARGET NODAL
C94523	TUMIDENT	Tumor Identification		C103444	TARGET NODULE
C96642	TUSPLIT	Tumor Split		C94520	TARGET
C119569	VSLIDENT	Vessel Lesion Identification		C94521	NON-TARGET
C119569	VSLIDENT	Vessel Lesion Identification		C94520	TARGET

Controlled Terminology Mapping Files

- Collected Race and Ethnicity maps to FDA codelist
  - Racec-Ethnicc Codetable
- Published on CDISC CT web page: https://www.cdisc.org/standards/terminology

C-code (Concept Code)	Race As Collected (RACEC) (codelist code = C128689)		C-code (Concept Code)	Race (RACE) (codelist code = C74457)
C18237	ALASKA NATIVE		C41259	AMERICAN INDIAN OR ALASKA NATIVE
C43877	AMERICAN INDIAN		C41259	AMERICAN INDIAN OR ALASKA NATIVE
C41259	AMERICAN INDIAN OR ALASKA NATIVE		C41259	AMERICAN INDIAN OR ALASKA NATIVE
C77810	CARIBBEAN INDIAN		C41259	AMERICAN INDIAN OR ALASKA NATIVE
C44950	CENTRAL AMERICAN INDIAN		C41259	AMERICAN INDIAN OR ALASKA NATIVE
C44265	GREENLAND INUIT		C41259	AMERICAN INDIAN OR ALASKA NATIVE
C44268	INUPIAT INUIT		C41259	AMERICAN INDIAN OR ALASKA NATIVE
C44269	SIBERIAN ESKIMO		C41259	AMERICAN INDIAN OR ALASKA NATIVE
C44953	SOUTH AMERICAN INDIAN		C41259	AMERICAN INDIAN OR ALASKA NATIVE
C44270	YUPIK ESKIMO		C41259	AMERICAN INDIAN OR ALASKA NATIVE
C41260	ASIAN		C41260	ASIAN
C16310	ASIAN AMERICAN		C41260	ASIAN
C41262	ASIAN INDIAN		C41260	ASIAN
C43671	BANGLADESHI		C41260	ASIAN
C43673	BHUTANESE		C41260	ASIAN
C43674	BURMESE		C41260	ASIAN
C43399	CAMBODIAN		C41260	ASIAN
C43391	CHINESE		C41260	ASIAN
C43393	FILIPINO		C41260	ASIAN
C43398	HMONG		C41260	ASIAN
C43715	INDONESIAN		C41260	ASIAN
C43718	IWO JIMAN		C41260	ASIAN
C43392	JAPANESE		C41260	ASIAN
C43395	KOREAN		C41260	ASIAN
C43397	LAOTIAN		C41260	ASIAN
C43722	MALAGASY		C41260	ASIAN
C43716	MALAYSIAN		C41260	ASIAN
C43719	MALDIVIAN		C41260	ASIAN
C43864	MONGOLIAN		C41260	ASIAN
C43720	NEPALESE		C41260	ASIAN
C43717	OKINAWAN		C41260	ASIAN

Controlled Terminology Mapping Files

- Published on CDISC CT web page: https://www.cdisc.org/standards/terminology
- SDTM Unit variables must use CDISC Submission Values from UNIT codelist
  - E.g., UCUM - may have up to 12 unique representations

Code	Codelist Code	Codelist Extensible (Yes/No	Codelist Name	CDISC Submission Value	UCUM Expression	UCUM Expression	UCUM Expression	UCUM Expression	UCUM Expression	UCUM Expression	UCUM Expression	UCUM Expression	UCUM Expression	UCUM Expression	UCUM Expression	UCUM Expression
C119377	C85494		PK Units of Measure	IU/mL/g	[IU]/mL/g	[iU]/ml/g	u[iU]/mL/ug	m[iU]/mL/mg	u[IU]/ml/ug	m[IU]/ml/mg	[iU]/mL/g	[IU]/ml/g	u[iU]/ml/ug	m[IU]/mL/mg	u[IU]/mL/ug	m[iU]/ml/mg
C119378	C85494		PK Units of Measure	IU/mL/kg	[iU]/ml/kg	[IU]/mL/kg	u[iU]/ml/mg	u[IU]/mL/mg	m[iU]/mL/g	m[IU]/ml/g	[iU]/mL/kg	[IU]/ml/kg	u[iU]/mL/mg	u[IU]/ml/mg	m[IU]/mL/g	m[iU]/ml/g
C119377	C128685		PK Units of Measure - Dose mg	r												
C119378	C128685		PK Units of Measure - Dose mg	u												
C119377	C128686		PK Units of Measure - Dose ug	u												
C119377	C128684		PK Units of Measure - Weight g	l												
C119378	C128684		PK Units of Measure - Weight g	r												
C119378	C128683		PK Units of Measure - Weight kg	l												

Code	Codelist Code	Codelist Extensible (Yes/No	Codelist Name	CDISC Submission Value	UCUM Expression	UCUM Expression	UCUM Expression	UCUM Expression	UCUM Expression	UCUM Expression	UCUM Expression	UCUM Expression	UCUM Expression	UCUM Expression	UCUM Expression	UCUM Expression
C119485	C85494		PK Units of Measure	pmol/L/(kg/m2)	pmol/L/(kg/m2)	pmol/l/(kg/m2)										
C119486	C85494		PK Units of Measure	pmol/L/(mg/day)	pmol/l/(mg/d)	pmol/L/(mg/d)										
C119487	C85494		PK Units of Measure	pmol/L/(mg/kg)	pmol/l/(mg/kg)	pmol/L/(mg/kg)										
C119488	C85494		PK Units of Measure	pmol/L/(mg/kg/day)	pmol/l/(mg/kg/d)	pmol/L/(mg/kg/d)										
C119489	C85494		PK Units of Measure	pmol/L/(mg/m2)	pmol/l/(mg/m2)	pmol/L/(mg/m2)										
C119490	C85494		PK Units of Measure	pmol/L/(mg/m2/day)	pmol/L/(mg/m2/d)	pmol/l/(mg/m2/d)										
C119497	C85494		PK Units of Measure	pmol/L/kg	pmol/l/kg	pmol/L/kg										
C119498	C85494		PK Units of Measure	pmol/L/m2	pmol/l/m2	pmol/L/m2										
C44256	C85494		PK Units of Measure	RATIO	{RATIO}	{Ratio}										
C48152	C85494		PK Units of Measure	ug	ug											
C71205	C85494		PK Units of Measure	ug/day	ug/24.h	ug/d										
C67394	C85494		PK Units of Measure	ug/h	ug/h											
C71211	C85494		PK Units of Measure	ug/min	ug/min											
C119500	C85494		PK Units of Measure	ug/mL/(kg/m2)	ug/ml/(kg/m2)	ug/mL/(kg/m2)										
C119511	C85494		PK Units of Measure	ug/mL/m2	ug/ml/m2	ug/mL/m2										
C48509	C85494		PK Units of Measure	umol	umol											
C67406	C85494		PK Units of Measure	umol/day	umol/d	umol/24.h										
C85707	C85494		PK Units of Measure	umol/h	umol/h											
C48508	C85494		PK Units of Measure	umol/L	umol/l	umol/L	nmol/mL									
C119529	C85494		PK Units of Measure	umol/L/(kg/m2)	umol/l/(kg/m2)	umol/L/(kg/m2)										
C119542	C85494		PK Units of Measure	umol/L/m2	umol/L/m2	umol/l/m2										
C85708	C85494		PK Units of Measure	umol/min	umol/min											

New Term Requests

New Term Request process

- When is it appropriate to request new terms?
  - When terminology codelist you need does not exist
  - When you have a new term that can be added to an existing codelist
- Must first confirm that the values you need do not already exist (yours may be synonyms of existing values)
- How to request new terms / codelists
  - Online form https://ncitermform.nci.nih.gov/ncitermform/?version=cdisc

https://ncitermform.nci.nih.gov/ncitermform/?version=cdisc

Term Suggestion

Quick Links

Contact Information:

Business Email: *

Name:

Business Phone Number:

Organization:

Privacy Notice: For term submission purposes we request business contact information only, not personal information. Your business email, and any other business contact information that you enter, will be stored in a publicly-accessible web site in support of CDISC term submission tracking. CDISC personnel may contact you.

Term Information:

Fill in the following fields as appropriate. For multiple term submissions, please click on and download the Excel file CDISC Controlled Terminology Multiple Term Request Spreadsheet and add on your name and request date to the end of the file name. Email this completed file to NciEvsCdiscHelp@mail.nih.gov. In addition, please submit a CDISC New Term Request form indicating "File emailed separately" in Additional Information.

Vocabulary: CDISC Terminology

Request Type: None

CDISC Code List: Multiple

Note to user: CDASH and SDTM Terminology are the same and are contained within the SDTM codelists in the drop down list.

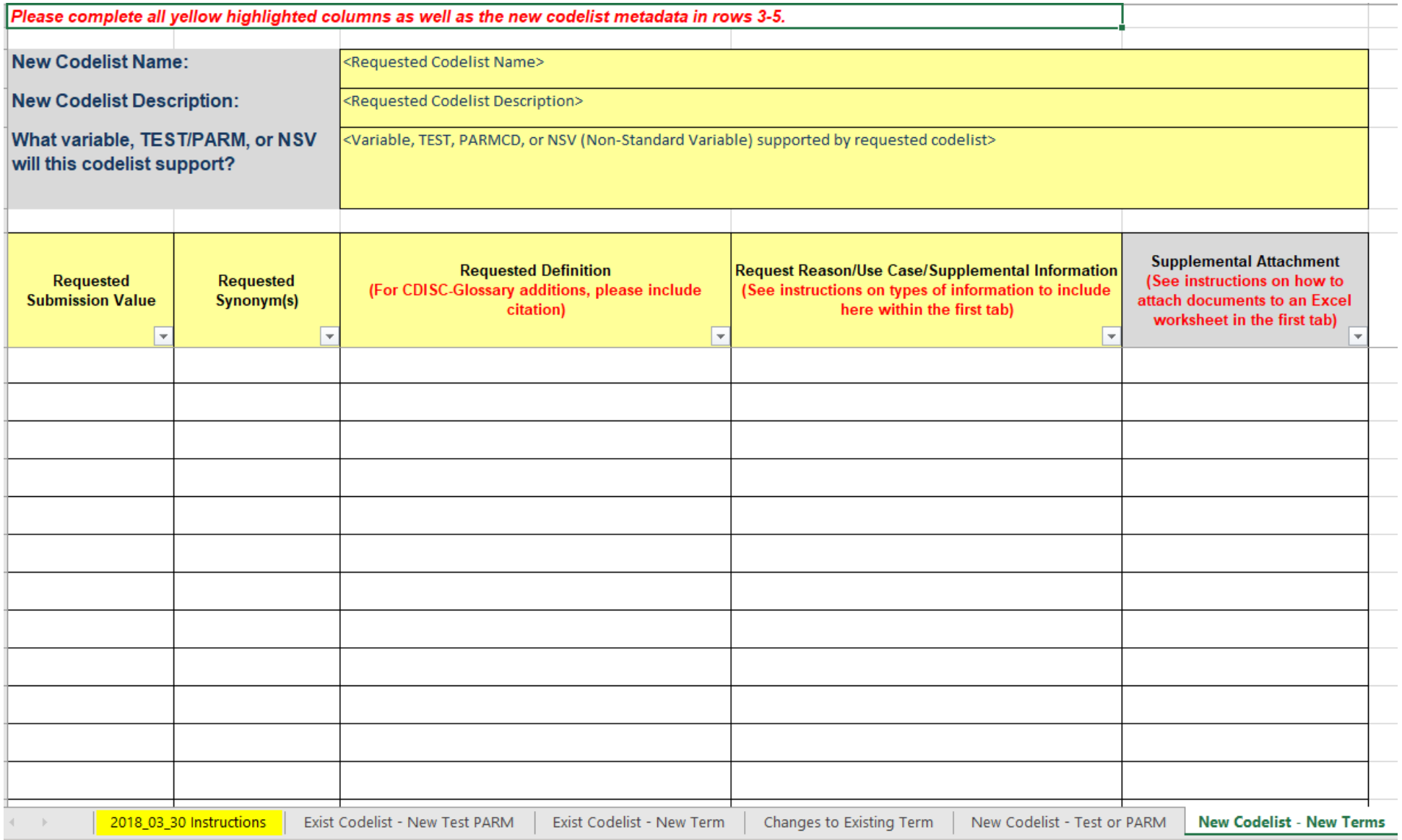
Enter Term or Codelist Request Information: *

Additional Information:

Reason for suggestion plus draft definition and examples of how this new term will be used (if emailing the spreadsheet above please enter "File emailed separately"): *

New Term Request process

- Uploadable form for larger volume requests



Please complete all yellow highlighted columns as well as the new codelist metadata in rows 3-5.

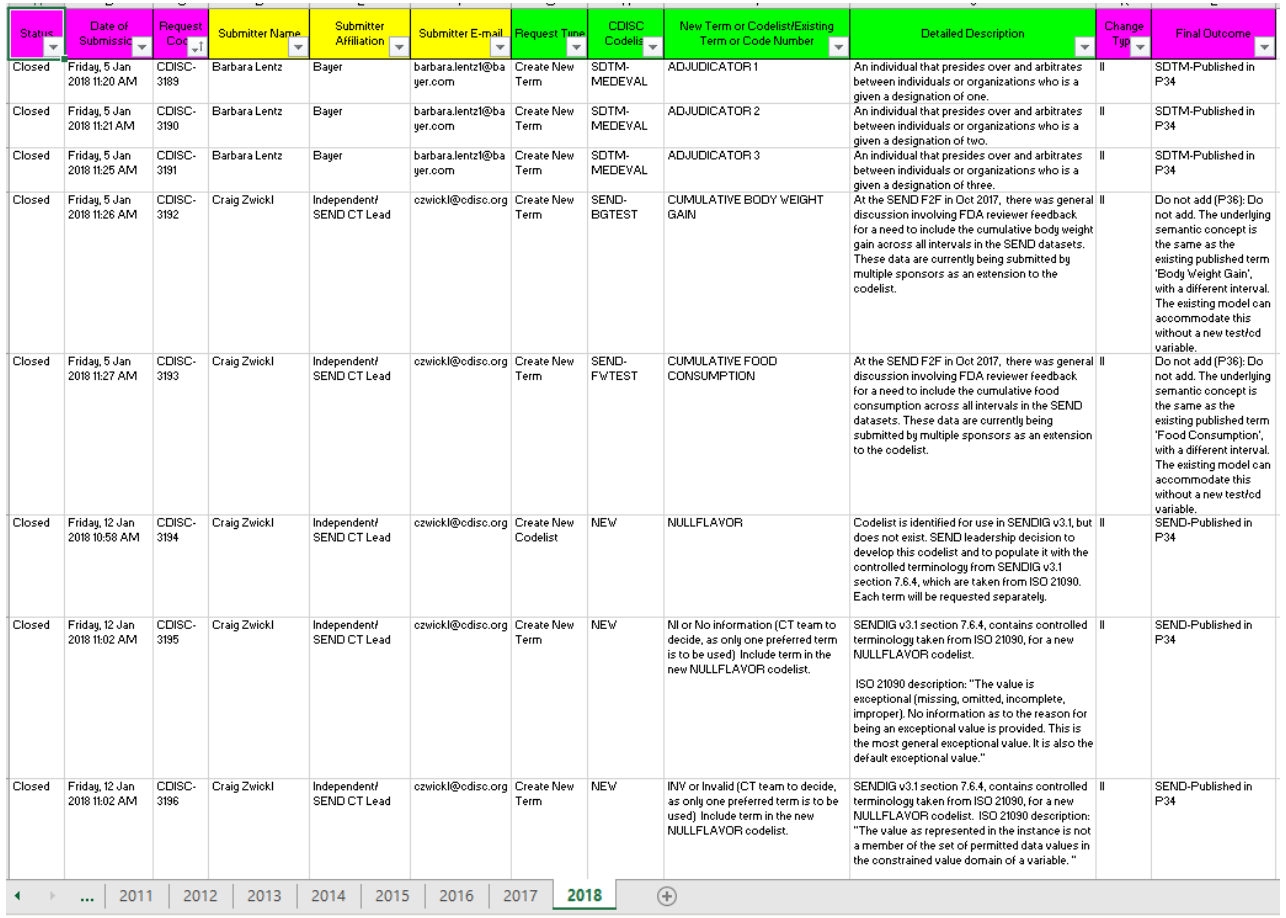
New Codelist Name:	<Requested Codelist Name>
New Codelist Description:	<Requested Codelist Description>
What variable, TEST/PARM, or NSV will this codelist support?	<Variable, TEST, PARMCD, or NSV (Non-Standard Variable) supported by requested codelist>

Requested Submission Value	Requested Synonym(s)	Requested Definition (For CDISC-Glossary additions, please include citation)	Request Reason/Use Case/Supplemental Information (See instructions on types of information to include here within the first tab)	Supplemental Attachment (See instructions on how to attach documents to an Excel worksheet in the first tab)

2018_03_30 Instructions | Exist Codelist - New Test PARM | Exist Codelist - New Term | Changes to Existing Term | New Codelist - Test or PARM | **New Codelist - New Terms**

New Term Request process

- Tracking progress of new term requests https://www.cancer.gov/research/resources/terminology/cdisc
  - Provide your contact information so the team can ask questions, if needed



Status	Date of Submissio	Request Cod	Submitter Name	Submitter Affiliation	Submitter E-mail	Request Type	CDISC Codelis	New Term or Codelist/Existing Term or Code Number	Detailed Description	Change Typ	Final Outcome
Closed	Friday, 5 Jan 2018 11:20 AM	CDISC-3189	Barbara Lentz	Bayer	barbara.lentz1@bayer.com	Create New Term	SDTM-MEDEVAL	ADJUDICATOR 1	An individual that presides over and arbitrates between individuals or organizations who is a given a designation of one.	II	SDTM-Published in P34
Closed	Friday, 5 Jan 2018 11:21 AM	CDISC-3190	Barbara Lentz	Bayer	barbara.lentz1@bayer.com	Create New Term	SDTM-MEDEVAL	ADJUDICATOR 2	An individual that presides over and arbitrates between individuals or organizations who is a given a designation of two.	II	SDTM-Published in P34
Closed	Friday, 5 Jan 2018 11:25 AM	CDISC-3191	Barbara Lentz	Bayer	barbara.lentz1@bayer.com	Create New Term	SDTM-MEDEVAL	ADJUDICATOR 3	An individual that presides over and arbitrates between individuals or organizations who is a given a designation of three.	II	SDTM-Published in P34
Closed	Friday, 5 Jan 2018 11:26 AM	CDISC-3192	Craig Zwickl	Independent/ SEND CT Lead	czwickl@cdisc.org	Create New Term	SEND-BGTEST	CUMULATIVE BODY WEIGHT GAIN	At the SEND F2F in Oct 2017, there was general discussion involving FDA reviewer feedback for a need to include the cumulative body weight gain across all intervals in the SEND datasets. These data are currently being submitted by multiple sponsors as an extension to the codelist.	II	Do not add (P36): Do not add. The underlying semantic concept is the same as the existing published term 'Body Weight Gain', with a different interval. The existing model can accommodate this without a new testcd variable.
Closed	Friday, 5 Jan 2018 11:27 AM	CDISC-3193	Craig Zwickl	Independent/ SEND CT Lead	czwickl@cdisc.org	Create New Term	SEND-FWTEST	CUMULATIVE FOOD CONSUMPTION	At the SEND F2F in Oct 2017, there was general discussion involving FDA reviewer feedback for a need to include the cumulative food consumption across all intervals in the SEND datasets. These data are currently being submitted by multiple sponsors as an extension to the codelist.	II	Do not add (P36): Do not add. The underlying semantic concept is the same as the existing published term 'Food Consumption', with a different interval. The existing model can accommodate this without a new testcd variable.
Closed	Friday, 12 Jan 2018 10:58 AM	CDISC-3194	Craig Zwickl	Independent/ SEND CT Lead	czwickl@cdisc.org	Create New Codelist	NEW	NULLFLAVOR	Codelist is identified for use in SENDIG v3.1, but does not exist. SEND leadership decision to develop this codelist and to populate it with the controlled terminology from SENDIG v3.1 section 7.6.4, which are taken from ISO 21090. Each term will be requested separately.	II	SEND-Published in P34
Closed	Friday, 12 Jan 2018 11:02 AM	CDISC-3195	Craig Zwickl	Independent/ SEND CT Lead	czwickl@cdisc.org	Create New Term	NEW	NI or No information (CT team to decide, as only one preferred term is to be used) Include term in the new NULLFLAVOR codelist.	SENDIG v3.1 section 7.6.4, contains controlled terminology taken from ISO 21090, for a new NULLFLAVOR codelist. ISO 21090 description: "The value is exceptional (missing, omitted, incomplete, improper). No information as to the reason for being an exceptional value is provided. This is the most general exceptional value. It is also the default exceptional value."	II	SEND-Published in P34
Closed	Friday, 12 Jan 2018 11:02 AM	CDISC-3196	Craig Zwickl	Independent/ SEND CT Lead	czwickl@cdisc.org	Create New Term	NEW	INV or Invalid (CT team to decide, as only one preferred term is to be used) Include term in the new NULLFLAVOR codelist.	SENDIG v3.1 section 7.6.4, contains controlled terminology taken from ISO 21090, for a new NULLFLAVOR codelist. ISO 21090 description: "The value as represented in the instance is not a member of the set of permitted data values in the constrained value domain of a variable."	II	SEND-Published in P34

... | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018

CT in Define.xml

Communicating Controlled Terminology to Agency

- In a submission to FDA or PMDA, Controlled Terminology that was used for a study is specified in the Define.xml file
- Tell them what you used *in this study* using Define.xml:
  - Include ALL of the available values (not just those that were selected in the records)
    - E.g., if all five Race values were available on your CRF, include all five (even if only 3 of them were actually used to record demographic records)
  - Include ONLY the values that were available for use in the study
    - E.g., You probably won't make the entire UNIT codelist available, so limit that codelist in your Define.xml file to those values that *could be recorded* in your study

Define.xml - Data Definition file provided with submission to FDA

SDTM-IG 3.1.2

Date of document generation: 2013-03-03T17:04:44

Stylesheet version: 2013-03-04

- Annotated Case Report Form
- Reviewers Guide
- Complex Algorithms
- ▸ Tabulation Datasets
- ▸ Value Level Metadata
- ▸ Controlled Terminology
- ▸ Computational Algorithms
- ▸ Comments

Tabulation Datasets for Study CDISC01 (SDTM-IG 3.1.2)

Dataset	Description	Class	Structure	Purpose	Keys	Location	Documentation
TA	Trial Arms	TRIAL DESIGN	One record per planned Element per Arm	Tabulation	STUDYID, ARMCD, TAETORD	ta.xpt	
TE	Trial Elements	TRIAL DESIGN	One record per planned Element	Tabulation	STUDYID, ETCD	te.xpt	
TI	Trial Inclusion/Exclusion Criteria	TRIAL DESIGN	One record per I/E criterion	Tabulation	STUDYID, IETESTCD	ti.xpt	
TS	Trial Summary	TRIAL DESIGN	One record per trial summary parameter value	Tabulation	STUDYID, TSPARMCD, TSSEQ	ts.xpt	
TV	Trial Visits	TRIAL DESIGN	One record per planned Visit per Arm	Tabulation	STUDYID, VISITNUM, ARMCD	tv.xpt	
DM	Demographics	SPECIAL PURPOSE	One record per subject	Tabulation	STUDYID, USUBJID	dm.xpt	See Reviewer's Guide, Section 2.1 Demographics Reviewers Guide

Define.xml - Controlled Terms (all value lists used in study)

SDTM-IG 3.1.2

- Annotated Case Report Form
- Reviewers Guide
- Complex Algorithms
- ▶ Tabulation Datasets
- ▶ Value Level Metadata
- ▼ Controlled Terminology
  - ▶ Controlled Terms
  - ▶ External Dictionaries
- ▶ Computational Algorithms
- ▶ Comments

Controlled Terms

Action Taken with Study Treatment [CL.ACN, *C66767*]

Permitted Value (Code)
DOSE NOT CHANGED [*C49504*]
DOSE REDUCED [*C49505*]
DRUG INTERRUPTED [*C49501*]
DRUG WITHDRAWN [*C49502*]

Domain Abbreviation (AE) [CL.AE.DOMAIN, *C66734*]

Permitted Value (Code)	Display Value (Decode)
AE [*C49562*]	Adverse Events

Relation to Reference Period (AEENRF) [CL.AEENRF, *C66728*]

Permitted Value (Code)
AFTER [*C38008*]

Causality [CL.AEREL]

Permitted Value (Code)
NOT RELATED
POSSIBLY RELATED
RELATED

Define.xml - External Dictionaries

External Dictionaries

Reference Name	External Dictionary	Dictionary Version
Adverse Event Dictionary (CL.AEDICT_F)	MEDDRA	8.0
Drug Dictionary (CL.DRUGDICT_F)	WHODRUG	200204
ISO3166 (CL.ISO3166)	ISO3166	

Other Terminologies

What else do you need for SDTM?

What Other Terminologies are Used in SDTM

- MedDRA https://www.meddra.org/
- WHODrug https://www.who-umc.org/whodrug/whodrug-portfolio/whodrug-global/
- LOINC https://loinc.org/
- ISO 3166 https://www.iso.org/obp/ui/#search
- SNOMED http://www.snomed.org/
- UNII https://www.fda.gov/forindustry/datastandards/substanceregistrationsystem-uniqueingredientidentifierunii/
- MED-RT https://www.cancer.gov/research/resources/terminology/fda

Q&A

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