CDASH Conformance Rules for Using Controlled Terminologies

LPO Webinar Series: CDASH Conformance
Session 3

NIH NATIONAL CANCER INSTITUTE

CDASH Conformance Rules Webinar Series

- CDASH Conformance Rules describe how to "conform" to the CDASH standard in such a way that the "harmonization" with SDTM is maintained
- This Webinar Series will cover each conformance rule, with examples of which rules are "built in" to the NCI GLIB ALS and how they have been addressed

Session	Topic Covered
1	Introduction to how CDASH is harmonized with SDTM at the Model and IG level
2	Conformance Rule: Use Variable Naming Conventions that make it easy to create SDTM datasets
3	Conformance Rule: Use the required SDTM controlled terminology to collect data
4	Conformance Rule: Use the published Question Text or Prompt to ask the questions on the CRF
5	Conformance Rule: Follow the Core Designations Conformance Rule: Follow CDASH Best Practices

CDASH Alignment to SDTM

Same overall structure

- Same general observation classes
- Same special purpose domains

Covered in Session 1

Same domain topics and naming conventions (DM = DM, AE=AE)

- ver, CDASH does not put restrictions on how to organize questions
- Multiple domain questions can be on the same data collection form (DM, VS)
- Multiple data collection forms can all be about the same topic (VS at each visit)

Mostly the same variables

Covered in Session 2

- Same meaning (definitions are important) ensured through QText/Prompt
- A few differences to meet data collection needs DAT/TIM vs DTC, Findings class with multiple TESTs)
- Additional variables (e.g., common non-standard concepts, edit checks)

Same terminology

- Same meaning (definitions)
- Can display synonyms (user friendly) but should store the CDISC Submission Value to avoid transformations
- Use --TESTCD terminology to construct EDC variable names / --TEST for prompts

CDASH Conformance

CDASH Conformance Rule	Rationale	How This is Reflected in NCI GLIB ALS
Use Variable Naming Conventions that make it easy to create SDTM datasets	Foundational purpose of CDASH is to implement SDTM before we collect the data. CDASH also has to accommodate data entry needs (like splitting date and time into two fields) using standard collection variables	FieldOIDs are linked to SDTM • Directly link the collected value to the associated SDTM dataset and variable • Standard syntax (pattern) allows us to write standard SDTM programs
Use the required SDTM controlled terminology to • **Collect data (DataDictionary values)** • **Create prompts (PreText, User values)** • **Create denormalized variables**	**Collect values that mean the same thing as the value "as represented" in SDTM**	**DataDictionary and DataDictionaryEntries match required SDTM Controlled Terminology** • **CodedData uses value required for submission data** • **UserDataString uses same or synonymous value**
Follow the Core Designations	Reflects the minimum set of questions needed to get a meaningful record	Requirements not indicated in ALS. Must reference CDASHIG for this information
Use the published Question Text or Prompt to ask the questions on the CRF	Ensure the question means the same thing as the target SDTM variable	PreText uses the flexible Question Text published in CDASHIG. Apply flexibility rules as needed
Follow CDASH Best Practices	Widely vetted clinical data management practices	Not indicated in ALS. Must reference CDASHIG for this information

SDTM Controlled Terminology

10,000s of defined concepts

- each with a ***single representation*** that *must be used* for FDA review: *CDISC Submission Value*

Published Quarterly (with DIFF files)

- Terms may be added, removed or modified
- *Tip: Published on NCI EVS website first (multiple formats)*

Maintained by NCI Enterprise Vocabulary Services (EVS)

- Expert staff
- Existing processes
- Technologies

Controlled Terminology Conformance

Use as published

- For **data collection**, synonyms (including NCI Preferred terms) *may be* used to display values on the CRF
- *For SDTM, use only the CDISC Submission Value and use the exact spelling and case* - ***Store in EDC Variable***

Extensibility

- 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

CT Documentation Content

- SDTM Controlled Terminology (CT) Published in multiple file formats (e.g., .xls, .pdf, .odm, .csv)
- **No matter which file format you use, the <u>content</u> for each version is the <u>same</u> in all of them**
- Review the structure and content of Excel and PDF files:

	A	B	C	D	E	F
1	Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Syn
50	C66767		No	Action Taken with Study Treatment	ACN	Action Taken with Study
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

Review Content of CT Standards Documentation

Hint: If you don't know the Codelist (long) Name, you can search for the codelist short name (the one that is specified for the variable in SDTMIG or CDASHIG) in the **PDF** file.

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C66767 ACN

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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
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C49502	DRUG WITHDRAWN		An indication that a medication schedule was modified through termination of a prescribed regimen of medication. (NCI)	Drug Withdrawn
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codelist Short Name and Long Name
CDISC Submission Value = Short Name
Codelist Name = Long Name

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

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In Excel, appears on each value within that codelist, too. In PDF, appears at top of codelist.

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

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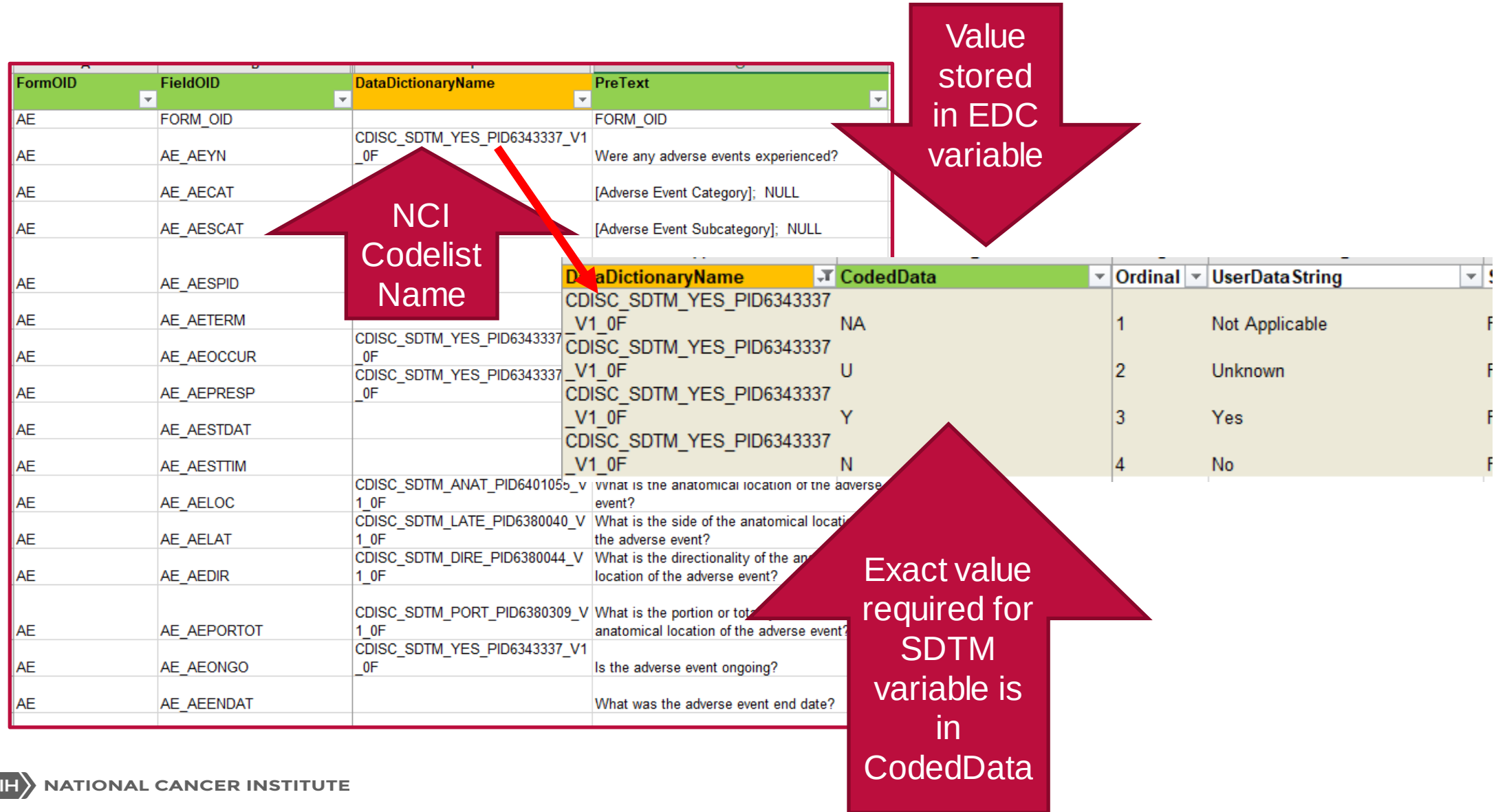
Use EXACT spelling and case of published CDISC Submission Value in SDTM variables

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

CDASH - we can use synonyms (published or not) to **display** the values on our CRFs.

How this is implemented in the NCI GLIB ALS



FormOID	FieldOID	DataDictionaryName	PreText
AE	FORM_OID		FORM_OID
AE	AE_AEYN	CDISC_SDTM_YES_PID6343337_V1_0F	Were any adverse events experienced?
AE	AE_AECAT		[Adverse Event Category]; NULL
AE	AE_AESCAT		[Adverse Event Subcategory]; NULL
AE	AE_AESPID		
AE	AE_AETERM		
AE	AE_AEOCCUR	CDISC_SDTM_YES_PID6343337_0F	
AE	AE_AEPRESP	CDISC_SDTM_YES_PID6343337_0F	
AE	AE_AESTDAT		
AE	AE_AESTTIM		
AE	AE_AELOC	CDISC_SDTM_ANAT_PID6401055_V1_0F	What is the anatomical location of the adverse event?
AE	AE_AELAT	CDISC_SDTM_LATE_PID6380040_V1_0F	What is the side of the anatomical location of the adverse event?
AE	AE_AEDIR	CDISC_SDTM_DIRE_PID6380044_V1_0F	What is the directionality of the anatomical location of the adverse event?
AE	AE_AEPORTOT	CDISC_SDTM_PORT_PID6380309_V1_0F	What is the portion or total anatomical location of the adverse event?
AE	AE_AEONGO	CDISC_SDTM_YES_PID6343337_V1_0F	Is the adverse event ongoing?
AE	AE_AEENDAT		What was the adverse event end date?

DataDictionaryName	CodedData	Ordinal	UserDataString
CDISC_SDTM_YES_PID6343337_V1_0F	NA	1	Not Applicable
CDISC_SDTM_YES_PID6343337_V1_0F	U	2	Unknown
CDISC_SDTM_YES_PID6343337_V1_0F	Y	3	Yes
CDISC_SDTM_YES_PID6343337_V1_0F	N	4	No

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C150826	DOSE RATE REDU		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 INTERRUPT		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

There will NOT be synonyms published for all Terms

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.

Review Content of CT Standards Documentation

	A	B	C	D	E	F	G	H
1	Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition	NCI Preferred Term
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			

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 tha ned. (NCI)	Dose Not Changed
C150826	DOSE RATE REDUCED		An indication tha was modified by red given, without r	Dose Rate Reduced
C49505	DOSE REDUCED		An indication tha d by subtraction, eith th or amount. (NCI)	Dose Reduced
C49501	DRUG INTERRUPTED		An indication tha d by temporarily tern medication. (NC	Drug Interrupted
C49502	DRUG WITHDRAWN		An indication tha d through termina medication. (NC	Drug Withdrawn
C48660	NOT APPLICABLE	NA;Not Applicable	Determination o t context. (NCI)	Not Applicable
C17998	UNKNOWN	U;UNK;Unknown	Not known, not observed, not recorded, or refused. (NCI)	Unknown

Sometimes you have to review the Definitions to determine additional synonyms

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.

Example: Allowed Synonym Based on Definition

e.g., what if you used "Treatment Permanently Stopped" as a response to the Action Taken With Study Treatment question on your CRF?

	A	B	C	D		H
1	Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC	NCI Preferred Term
50	C66767		No	Action Taken with Study Treatment	ACN	CDISC SDTM Action Taken with Study Treatment Terminology
51	C49503	C66767		Action Taken with Study Treatment	DOSE INCREA	
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

This means you can use "Treatment Permanently Stopped" on your CRF (displayed as UserDataString), but you would "represent" it as "DRUG WITHDRAWN" (CodedValue in the DataDictionaryEntries) in SDTM.

It's best to just collect responses using values from the published codelists so the site has clear transparency into how their response is "represented" in the data.

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	Dose Increased
504	DOSE NOT CHANGED			
0826	DOSE RATE REDUCED			
505	DOSE REDUCED		An indication that a medication schedule was modified by subtraction, either by changing the frequency, strength or amount. (NCI)	Dose Reduced
501	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

Review the CDISC Submission Values and Synonyms. Not there? Next, review the Definitions

Review Content of CT Standards Documentation

	A	B	C	D	E	F	G	H
1	Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition	NCI Preferred Term
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			

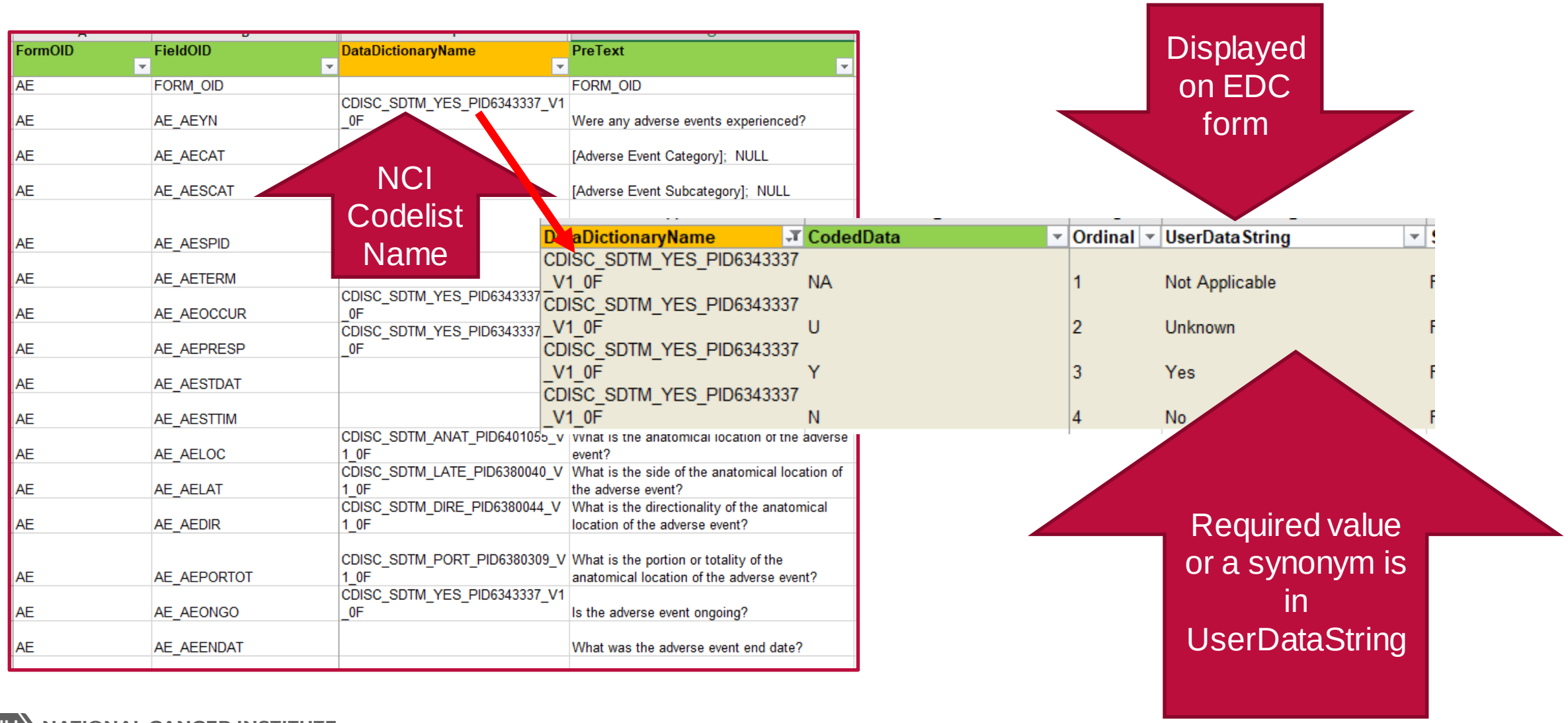
ACN (Action Taken with Study Treatment)

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

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

How this is implemented in the NCI GLIB ALS



FormOID	FieldOID	DataDictionaryName	PreText
AE	FORM_OID		FORM_OID
AE	AE_AEYN	CDISC_SDTM_YES_PID6343337_V1_0F	Were any adverse events experienced?
AE	AE_AECAT		[Adverse Event Category]; NULL
AE	AE_AESCAT		[Adverse Event Subcategory]; NULL
AE	AE_AESPID		
AE	AE_AETERM		
AE	AE_AEOCCUR	CDISC_SDTM_YES_PID6343337_0F	
AE	AE_AEPRESP	CDISC_SDTM_YES_PID6343337_0F	
AE	AE_AESTDAT		
AE	AE_AESTTIM		
AE	AE_AELOC	CDISC_SDTM_ANAT_PID6401055_V1_0F	What is the anatomical location of the adverse event?
AE	AE_AELAT	CDISC_SDTM_LATE_PID6380040_V1_0F	What is the side of the anatomical location of the adverse event?
AE	AE_AEDIR	CDISC_SDTM_DIRE_PID6380044_V1_0F	What is the directionality of the anatomical location of the adverse event?
AE	AE_AEPORTOT	CDISC_SDTM_PORT_PID6380309_V1_0F	What is the portion or totality of the anatomical location of the adverse event?
AE	AE_AEONGO	CDISC_SDTM_YES_PID6343337_V1_0F	Is the adverse event ongoing?
AE	AE_AEENDAT		What was the adverse event end date?

DataDictionaryName	CodedData	Ordinal	UserDataString
CDISC_SDTM_YES_PID6343337_V1_0F	NA	1	Not Applicable
CDISC_SDTM_YES_PID6343337_V1_0F	U	2	Unknown
CDISC_SDTM_YES_PID6343337_V1_0F	Y	3	Yes
CDISC_SDTM_YES_PID6343337_V1_0F	N	4	No

Other CDASH Conformance Rules that reference CT:

Use Published CT to Create Denormalized Metadata

- Denormalized Questions/Prompts (CDASHIG V2.0 Section 5.1 #4.a)
  - *In cases where the data collection is done in a denormalized presentation on the CRF, the relevant CDISC controlled terminology should be used in the Question Text or Prompt*
- Denormalized Variables (CDASHIG V2.0 Section 5.1 #5.b)
  - *In cases where the data collection is done in a denormalized way, appropriate CDISC controlled terminology must be used when it is available. For example, when collecting Vital Signs results in a denormalized eCRF, the variable names can be created by using terms from the Vital Signs Test Code codelist.*

Use Controlled Terminology to create Questions/Prompts (e.g., **Vital Signs** Data Collection Fields using CDASHIG and Controlled Terminology)

Identify the required VSTEST and VSORRESU Controlled Terminology from the CDASHIG Domain

Domain	CDASHIG Variable	Question Text	Prompt	Data Type	CDASHIG Core	SDTMIG Target	Controlled Terminology Codelist Name
VS	VSTEST	What is the vital sign test name?	Vital Sign Test Name	Char	HR	VSTEST; VSTESTCI	(VSTEST)
VS	VSORRESU	What was the unit of the measurement?	Unit	Char	R/C	VSORRESU	(VSRESU)

Codelist Code	Codelist Name	CDISC Submission Value
	Vital Signs Test Name	VSTEST
C67153	Vital Signs Test Name	Body Mass Index
C67153	Vital Signs Test Name	Diastolic Blood Pressure
C67153	Vital Signs Test Name	Heart Rate
C67153	Vital Signs Test Name	Respiratory Rate
C67153	Vital Signs Test Name	Systolic Blood Pressure
C67153	Vital Signs Test Name	Temperature

Codelist Code	Codelist Name	CDISC Submission Value
	Units for Vital Signs Results	VSRESU
C66770	Units for Vital Signs Results	beats/min
C66770	Units for Vital Signs Results	breaths/min
C66770	Units for Vital Signs Results	C
C66770	Units for Vital Signs Results	F
C66770	Units for Vital Signs Results	mmHg

Use Controlled Terminology to create Questions/Prompts (e.g., **Vital Signs** Data Collection Fields using CDASHIG and Controlled Terminology)

Identify the required VSTEST VSORRESU Controlled Terminology from the CDASHIG Domain

=

Use that terminology to create a conformant Prompt (and Unit) for the test in each log line

Prompts: FIND the VS measurements you need from the VSTEST Terminology

PreText uses CT = VSTEST (C67153)

Codelist Code	Codelist Name	CDISC Submission
	Vital Signs Test Name	VSTEST
C67153	Vital Signs Test Name	Body Mass Index
C67153	Vital Signs Test Name	Diastolic Blood Pressure
C67153	Vital Signs Test Name	Heart Rate
C67153	Vital Signs Test Name	Respiratory Rate
C67153	Vital Signs Test Name	Systolic Blood Pressure
C67153	Vital Signs Test Name	Temperature

Collection Date _ _ - _ _ - _ _ _ _ VS_VSDAT

Vital Signs

Collection Time _ _ : _ _ VS_VSTIM

VS_VSTEST	VS_VSORRES	VS_VSORRESU
Test Name	**Result**	**Unit**
Respiratory Rate		breaths/min
Heart Rate		beats/min
Systolic Blood Pressure		mmHg
Diastolic Blood Pressure		mmHg
Temperature		____C ____F
BMI		

synonym ok

Codelist Code	Codelist Name	CDISC Submission Value
	Units for Vital Signs Results	VSRESU
C66770	Units for Vital Signs Results	beats/min
C66770	Units for Vital Signs Results	breaths/min
C66770	Units for Vital Signs Results	C
C66770	Units for Vital Signs Results	F
C66770	Units for Vital Signs Results	mmHg

Unit Values are From CT = VSRESU (C66770)

Use Controlled Terminology to create Variable Names (i.e., FieldOIDs) (e.g., **Vital Signs** Data Collection Fields using CDASHIG and Controlled Terminology)

- Variable Pattern:
  - targetDataset_targetVariable_[--TESTCD]
- Example
  - Denormalized PreText using VSTEST Controlled Terminology
  - Denormalized FieldOIDs add VSTESTCD Controlled Terminology to normalized FieldOID

PreText	FieldOID
Temperature	VS_VSORRES_TEMP
Temperature Unit	VS_VSORRESU_TEMP
Systolic Blood Pressure	VS_VSORRES_SYSBP
Systolic Blood Pressure Unit	VS_VSORRESU_SYSBP
Diastolic Blood Pressure	VS_VSORRES_DIABP
Diastolic Blood Pressure Unit	VS_VSORRESU_DIABP
Heart Rate	VS_VSORRES_HR
Heart Rate Unit	VS_VSORRES_HR

Codelist Code	Codelist Name	CDISC Submission Value
	Units for Vital Signs Results	VSRESU
C66770	Units for Vital Signs Results	beats/min
C66770	Units for Vital Signs Results	breaths/mi
C66770	Units for Vital Signs Results	C
C66770	Units for Vital Signs Results	cm
C66770	Units for Vital Signs Results	F
C66770	Units for Vital Signs Results	mmHg
	Vital Signs Test Code	VSTESTCD
C66741	Vital Signs Test Code	BMI
C66741	Vital Signs Test Code	DIABP
C66741	Vital Signs Test Code	HR
C66741	Vital Signs Test Code	SYSBP
C66741	Vital Signs Test Code	TEMP
	Vital Signs Test Name	VSTEST
C67153	Vital Signs Test Name	Body Mass
C67153	Vital Signs Test Name	Diastolic Blood Pressure
C67153	Vital Signs Test Name	Heart Rate
C67153	Vital Signs Test Name	Systolic Blood Pressure
C67153	Vital Signs Test Name	Temperature

You will find SOME examples of denormalized Fields in the GLIB ALS, but it was not practical to include all possible VSTESTs.

You can *create the additional ones* you need using the normalized FieldOIDs PLUS the relevant --TESTCD terminology

Controlled Terminology in NCI GLIB ALS

- Review NCI GLIB ALS DataDictionaries and DataDictionaryEntries
- Allowed to rename DataDictionary provided PID is still in the name
  - E.g., okay to shorten CDISC_SDTM_YES_PID6343337_V1_0F to NY_PID6343337 _V1_0F
  - Recommended to either keep the short codelist name (e.g., "YES") or use CDISC Submission Value for the relevant codelist (e.g., "NY")

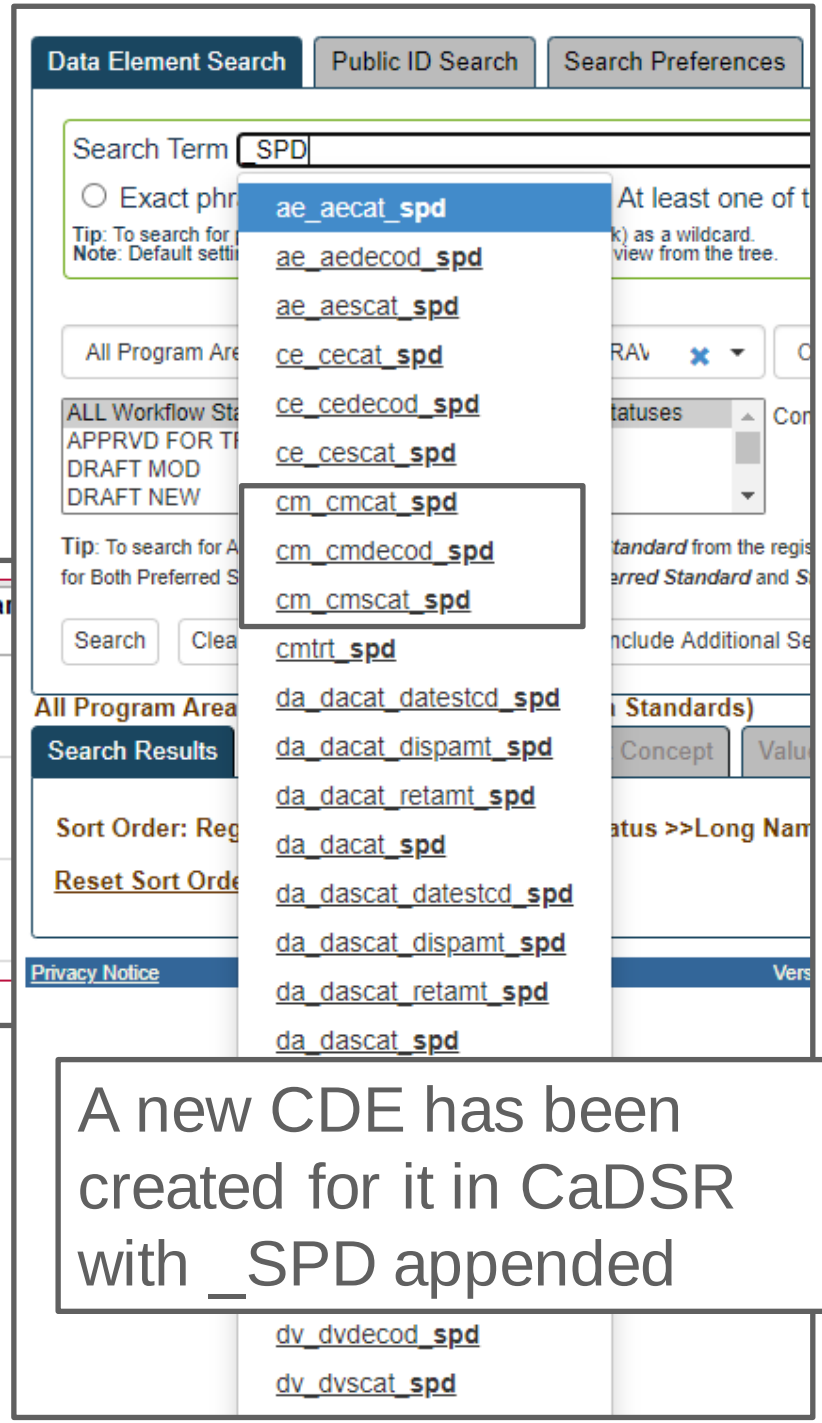
- NOTE: CDASH / SDTM allow you to add codelists to variables that do not already have a codelist specified
  - For NCI implementation, must follow CBIIT curation process and use non-enumerated CDEs without an enumerated value domain
  - In July 2019 version of NCI GLIB ALS: "LPO_TBD" is *no longer valid* - new CDEs have been drafted using "domainCode_variable_SPD" - will be published this way in CaDSR
  - If you need to add a DataDictionary to a non-enumerated CDE, you cannot use the existing variable name because enumerated / non-enumerated is an attribute of the CDE that cannot be changed. *Instead, add _SPD to the FieldOID. Check the draft CDEs in CaDSR.*

Updates to GLIB ALS for LPO_TBD Dictionaries

Note: New *enumerated* CDEs have been drafted in CaDSR with _SPD Short names

FormOID	FieldOID	DraftFieldName	VariableOID	DataDictionar
CM	CM_CMCAT	Category for Concomitant Medication PID6400575_V1_0	CM_CMCAT	LPO_TBD
CM	CM_CMSCAT	Subcategory for Concomitant Medication PID6400576_V1_0	CM_CMSCAT	LPO_TBD
CM	CM_CMDECOD	Concomitant Meds Dictionary or Standardized Term PID6400966_V1_0	CM_CMDECOD	LPO_TBD

If the DataDictionary for any Field looks like this in the NCI GLIB ALS



A new CDE has been created for it in CaDSR with _SPD appended

Example: MHCAT

New
CDE
New PID

CDE:	1	2
Public ID:	6413031	7199998
Version	1.0	1.0
Long Name:	Category for Medical History	Category for Medical History
Short Name:	MHCAT	MH_MHCAT_SPD
Preferred Question Text:	What was the category of the medical history?	What was the category of the medical history?
Definition:	A grouping of topic-variable values based on user defined characteristics.	A grouping of topic-variable values based on sponsor defined characteristics.
Value Domain:	CDISC Variable Terminology Category	Medical History Category Clinical Study Sponsor Defined Category
Data Element Concept:	Medical History Domain Medical History Category	Medical History Domain Medical History Category
Context:	NCI Standards	NRDS
Workflow Status:	RELEASED	DRAFT NEW
Origin:	CDISC:Clinical Data Interchange Standards Consortium	CDISC:Clinical Data Interchange Standards Consortium
Registration Status:	Qualified	Incomplete

Session 3 Summary

- CDASH Conformance Rule covered in this session is to use published SDTM Controlled Terminology in data collection
  - As the values in response lists (DataDictionaries)
  - To display standardized names of tests for Findings Class data (--TEST) on the CRF
  - To create denormalized variables (FieldOID)
- NCI GLIB ALS DataDictionaryEntries conform to this CDASH rule
  - CodedData (value stored in the variable) uses the SDTM CDISC Submission Values (except for case)
  - UserDataString (value displayed on the CRF) uses the same value, or a synonym

Questions?

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