

CDASH Conformance Rules for CRF Question Text and Prompt

LPO Webinar Series: CDASH Conformance

Session 4

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

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

- However, 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

The wording of the questions on the CRF helps maintain alignment with SDTM

- **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 <ul style="list-style-type: none"> • 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	Collect values that mean the same thing as the value “as represented” in SDTM	DataDictionary and DataDictionaryEntries match required SDTM Controlled Terminology <ul style="list-style-type: none"> • 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. Use Controlled Terminology for Findings Class test-specific questions / prompts.	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

CDASH Conformance Rule: Use Published **Question Text** or **Prompt**

CDASHIG V2.0 provides 2 wording options:

CDASH specifies **HOW TO WORD THE CRF QUESTIONS**

Using either the full sentence **Question Text** or the short **Prompt** (can use both on same CRF)

PURPOSE: To maintain a consistent meaning between the question and the associated SDTM variable.

Study	Site
Birth Date <small>BRTHDTC</small> <small>BRTHDD BRTHMO BRTHYR BRTHDAT</small>	
Sex <small>SEX</small>	
Do you consider yourself Hispanic/Latino or not Hispanic/Latino? <small>ETHNIC</small>	
Which of the following five racial designations best describes you? More than one choice is acceptable. <small>RACE</small>	

Question Text	Prompt
What is the subject's date of birth?	Birth Date
What is the sex of the subject?	Sex
Do you consider yourself Hispanic/Latino or not Hispanic/Latino?	Ethnicity
Which of the following five racial designations best describes you? (More than one choice is acceptable.)	Race

Text in parentheses is optional
- more about this in a minute

How this has been implemented in the NCI GLIB ALS

The full CDASHIG Question Text has been loaded into the NCI GLIB ALS as **PreText**.

Start with the CDASH Question Text that has been published in the NCI GLIB ALS (PreText)

Use it "as is" if you can, and if you want to use a full sentence.

FormOID	FieldOID	PreText
DM	FORM_OID	FORM_OID
DM	DM_BRTHDAT	What is the subject's date of birth?
DM	DM_BIRTHYY	What is the subject's year of birth?
DM	DM_BIRTHMO	What is the subject's month of birth?
DM	DM_BIRTHDAY	What is the subject's day of birth?
DM	DM_BIRTHTIME	What is the subject's time of birth?
DM	DM_BIRTHAGE	What is the subject's age?
DM	DM_BIRTHAGEUNIT	What is the age unit used?
DM	DM_DMDAT	What is the date of collection?
DM	DM_SEX	What is the sex of the subject?
DM	DM_ETHNIC	Do you consider yourself Hispanic/Latino or not Hispanic/Latino?
DM	DM_CETHNIC	What is the ethnicity of the subject?
DM	DM_RACE	Which of the following five racial designations best describes you? (More than one choice is acceptable.)

How this has been implemented in the NCI GLIB ALS

FormOID	FieldOID	DraftFieldName	VariableOID	DataDictionaryName	PreText
MH	FORM_OID	PID6446129_V1_0	FORM_OID		FORM_OID
MH	MH_MHYN	Any Medical History Event PID6401576_V1_0	MH_MHYN	CDISC_SDTCM_YES_PID6343 337_V1_0F	Were any medical conditions or events reported?; Has the subject had any medical conditions or events?
MH	MH_MHCAT	Category for Medical History PID6413031_V1_0	MH_MHCAT	Q_TBD	[Medical History Category]; NULL
MH	MH_MHSCAT	Subcategory for Medical History Event			[Medical History Subcategory]; NULL
	MH_DAT				What was the date the medical history was collected?
	MH_SPID				[Line Number/MH Number]
	MH_EVDTYP				What was the medical history event date type?
	MH_TERM				What is the medical condition or event term?
	MH_OCCUR	Occurrence PID6401581_V1_0	MH_MHOCUR	CDISC_SDTCM_YES_PID6343 337_V1_0F	Did the subject have [pre-specified medical condition/event/group of medical conditions]?
	MH_PRESP	Medical History Event Pre-Specified PID6401586_V1_0	MH_MHPRESP	CDISC_SDTCM_YES_PID6343 337_V1_0F	Medical History Event Pre-Specified
	MH_PRIOR	Prior Medical History Event PID6408638_V1_0	MH_MHPRIOR	CDISC_SDTCM_YES_PID6343 337_V1_0F	Did the medical condition or event start prior to study start?
MH	MH_MHONGO	Ongoing Medical History Event PID6408640_V1_0	MH_MHONGO	CDISC_SDTCM_YES_PID6343 337_V1_0F	Is the medical condition or event ongoing?
MH	MH_MHCTRL	Medical History Disease or Symptom Under Control PID6408641_V1_0	MH_MHCTRL	CDISC_SDTCM_YES_PID6343 337_V1_0F	Is the medical condition or event under control?
MH	MH_MHSTDAT	Medical History Event Start Date PID6409589_V1_0	MH_MHSTDAT		What was the medical condition or event start date?
MH	MH_MHENDAT	Medical History Event End Date PID6409590_V1_0	MH_MHENDAT		What was the medical condition or event end date?

Both Question Text and Prompt are “parameterized”, flexible questions that are synonymous with the SDTM target variable

There is some flexibility built in already. Look for the special characters: [] () /

CDASH Question Text or Prompt: Controlled Flexibility Using Parameters/Options

- Text inside brackets [] should be replaced with protocol-specified text
 - Did the subject have [pre-specified clinical event/group of clinical events]?
 - Did the subject have **headache**?
- Text inside parentheses () is optional - you choose whether to use it or not
 - What was the procedure (start) date?
 - What was the procedure date?
- Text separated with a forward slash indicates optional wording from which to choose
 - What was the total daily dose of the (concomitant) [medication/treatment/therapy]?
 - What was the total daily dose of the medication?

CDASHIG V2.0 Sections 5.1.4, 3.5.2, 2.3.5

CDASH Question Text or Prompt: Controlled Flexibility Using the Prompt

- ✓ If you have tried to use the Question Text, including options, but you still need more flexibility in the question, or you want a shorter version, next look at the Prompt
 - ✓ CDASHIG includes both a full sentence Question Text and a short Prompt
 - ✓ You may use EITHER on your CRF
 - ✓ Sometimes a shorter version of the question just works better
 - ✓ Prompts include flexibility, too (look for the special characters)

Question Text (full sentence) Reference the CDASH Model for additional flexibility	(short) Prompt Reference the CDASH Model for additional flexibility
What is the visit name?	[Visit]
What was the (start) time of the lab specimen collection (.).	[Start] Collection Time
What was the name	[Lab Panel Name];

CDASH Question Text or Prompt: Controlled Flexibility Using the CDASH Model

CDASHIG V2.0 Sections 5.1.4, 3.5.2, 2.3.5

- **If you have tried the Question Text and Prompt and you still need more flexibility, go back to the **CDASH Model****
- You can use the additional flexibility from the CDASH Model to create *alternative* Question Text or Prompts that may be used (e.g., to change the tense, to change singular to plural, or to find alternative phrasing that still means the same thing)
 - CDASHIG Question Text: What was the individual dose (of the concomitant [medication/treatment/therapy] per administration)?
 - CDASH Model Question Text: What [is/ ~~was~~] the (~~individual~~) [~~dose/amount~~] (of --TRT) [~~taken/performed/administered/consumed~~/per administration])?
 - Conformant Question Text: What is the amount of Tramadol taken per administration?

CMDOSE

--DOSE

CDASH Question Text or Prompt: Controlled Flexibility Using the CDASH Model

CDASH Model contains “root” questions that add more flexibility without changing the meaning of the question:

- Past tense vs present tense
- Plural vs singular
- Optional phrases
- Alternative wording

	Question Text	Prompt
CDASH Variable		
--DAT	What [is/ was] the date the [event or intervention] [is/was] collected?; What [is/ was] the (start) date (of the [Finding])?	[Event/Intervention] Collection Date; [Finding] (Start) Date

If you get to this level and the question STILL does not work, make sure you are using the right Field, and **then let us know (NCICDISCSupport@nih.gov)**.

1. You may need to use a different Field, or
2. The CDASH question may be deficient

The CDISC Harmonization Working Group will report deficiencies to CDASH team



Using Controlled Terminology as Questions on the CRF

*Using the Findings Class --TEST
Terminology in Question Text and Prompts*

Findings Class Domains: Use Published --TEST Values to Create Prompts

FormOID	FieldOID	DraftFieldName	VariableOID	DataDictionaryName	PreText
DD	DD_DDTEST	Death Detail Assessment Name PID6422494_V1_0	DD_DDTEST	CDISC_SDTM_DEAT_PID6422479_V1_0F	Death Detail Assessment Test Name
EG	EG_EGTEST	ECG Test or Examination Name PID6408052_V1_0	EG_EGTEST	CDISC_SDTM_ECG_PID6406989_0F	ECG Test Name
FA	FA_FATEST	Findings About Test Name PID6423016_V1_0	FA_FATEST	LPO_TBD	[Measurement/Test/Examination/] (Name)
MI	MI_MITEST			6422501_V	Microscopic Test Name
SR	SR_SRTEST			409696_V	Skin Response Test Name
DA	DA_DATEST			6404690_V	Drug Accountability [Test Name]
LB	LB_LBTEST			6401058_V	Lab Test Name
PC	PC_PCTEST				Test Name
PE	PE_PETEST				[Body System]
RP	RP_RPTEST			6421124_V	Reproductive Finding Name
VS	VS_VSTEST			347747_V1	Vital Sign Test Name
RS	RS_RSTEST			6618781_V	[Measurement/Test/Examination/] (Name)
IS	IS_ISTEST			6643389_V	[Measurement/Test/Examination/] (Name)
MB	MB_MBTEST			6651971_V	[Measurement/Test/Examination/] (Name)
MS	MS_MSTEST	Name of Assessment PID6659367_V1_0	MS_MSTEST	CDISC_SDTM_MICR_PID6658295_V1_0F	[Measurement/Test/Examination/] (Name)
PP	PP_PPTEST	Parameter Name PID6649021_V1_0	PP_PPTEST	CDISC_SDTM_PHAR_PID6619168_V1_0F	[Measurement/Test/Examination/] (Name)
QS	QS_QSTEST	Question Name PID6659629_V1_0	QS_QSTEST	LPO_TBD	[Measurement/Test/Examination/] (Name)
SS	SS_SSTEST	Status Name PID6659310_V1_0	SS_SSTEST	CDISC_SDTM_SUBJ_PID6658099_V1_0F	[Measurement/Test/Examination/] (Name)

NCI GLIB ALS filtered on FieldOIDs that end with "TEST".

Remember: the "--ORRES" field is used to collect the value / result.

The "--TEST" field is used (e.g., for log forms) when the test needs to be pre-populated or entered where "[domain] Test (Name)" is the column header in the log form. E.g., (Vital Signs) Test Name.

Example Log Form: Using VSTEST Values as Prompt on CRF

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



VSTEST
values

Collection Date Collection Time

Test Name	Result	Unit
Respiratory Rate		breaths/min
Heart Rate		beats/min
Systolic Blood Pressure		mmHg
Diastolic Blood Pressure		mmHg
Temperature		____C ____F
BMI	<input type="text" value="synonym ok"/>	

Findings Class Domains: Use Published --TEST Values to Create Prompts

FormOID	FieldOID	DraftFieldName	VariableOID	DataDictionaryName	PreText
DD	DD_DDORRES	Death Details Result PID6421598_V1_0	DD_DDORRES		What was the result of the death detail assessment?
EG	EG_EGORRES	ECG Result PID6414259_V1_0	EG_EGORRES		What was the result of the ECG? What [is/was] the [result/amount/(subject's characteristic)] (of the [measurement/test/examination/question/assessment])?
FA	FA_FAORRES				
MI	MI_MIORRES				
SR	SR_SSORRES				What was the result of the examination? What was the result of the skin response measurement?
DA	DA_DAORRES				What is the result of the drug accountability assessment?
LB	LB_LBORRES				
NV	NV_NVORRES				What was the result of the test? What [is/was] the [result/amount/(subject's characteristic)] (of the [measurement/test/examination/question/assessment])?
OE	OE_OEORRES				What [is/was] the [result/amount/(subject's characteristic)] (of the [measurement/test/examination/question/assessment])?
PC	PC_PCORRES				
PE	PE_PEORRES				What was the result of the test? What [is/was] the [result/amount/(subject's characteristic)] (of the [measurement/test/examination/question/assessment])?
RP	RP_RPORRES				What was the result for the reproductive system question? What [is/was] the [result/amount/(subject's characteristic)] (of the [measurement/test/examination/question/assessment])?
RE	RE_REORRES	Result or Finding in Original Units PID6790458_V1_0	RE_REORRES		
VS	VS_VSORRES	Vital Signs Result PID6355977_V1_0	VS_VSORRES		What was the result of the measurement? What [is/was] the [result/amount/(subject's

NCI GLIB ALS filtered on FieldOIDs that end with "ORRES".
 original result

The --ORRES Field is used to collect a result for the test or measurement in a Findings class domain.

--TEST values are also used for **non-log** forms where the test names becomes (part of) the PreText for the Results (--ORRES) fields.

The word "Test" can be replaced with a specific test (e.g., "Heart Rate") in either the PreText (Question Text) or the Prompt (in CDASH-CT-Metadata) using controlled terminology for --TEST.

Example **Non-log** Form: Using VSTEST Values as Prompt on CRF

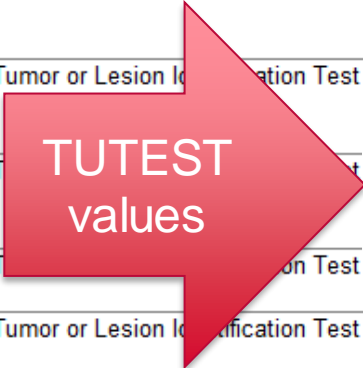
Codelist Code	Codelist Name	CDISC Submission Value
	Vital Signs Test Name	VSTEST
C67153	Vital Signs Test Name	Body Mass Index
C67153	Vital Signs Test Name	Diastolic Blood Pressure
C67153	Vital Signs Test Name	Heart Rate
C67153	Vital Signs Test Name	Respiratory Rate
C67153	Vital Signs Test Name	Systolic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



PreText	Vital Signs Data	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_VSORRESU_HR]

Example Non-log form: Using TUTEST Values as Prompt on CRF

Codelist Name	CDISC Submission Value
Tumor or Lesion Identification Test Name	TUTEST
Tumor or Lesion Identification Test Name	Cardiovascular Lesion Indicator
Tumor or Lesion Identification Test Name	Disease Recurrence Relative Location
Tumor or Lesion Identification Test Name	Fibrotic Lesion Indicator
Tumor or Lesion Identification Test Name	Graft Lesion Identification
Tumor or Lesion Identification Test Name	Lesion Identification
Tumor or Lesion Identification Test Name	Limb Lesion Identification
Tumor or Lesion Identification Test Name	Measurable Tumor Indicator
Tumor or Lesion Identification Test Name	Metastatic Tumor Site Indicator
Tumor or Lesion Identification Test Name	Metastatic Tumor Site Indicator
Tumor or Lesion Identification Test Name	Tumor Split
Tumor or Lesion Identification Test Name	Vessel Lesion Identification



TUTEST values

PreText	Tumor Identification (TU) Data	FieldOID
Measurable Tumor?	<input type="checkbox"/> Y <input type="checkbox"/> N	[TU_TUORRES_MEASIND]

Example Non-log Form: Using TRTEST Values as Prompt on CRF

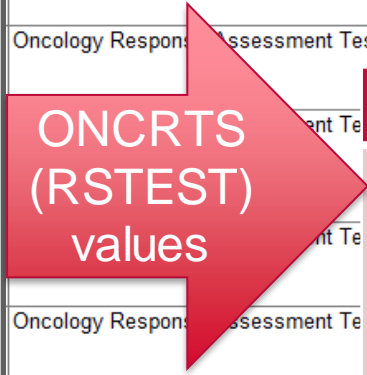
Codelist Name	CDISC Submission Value
Tumor or Lesion Properties Test Name	TRTEST
Tumor or Lesion Properties Test Name	Area
Tumor or Lesion Properties Test Name	Diameter
Tumor or Lesion Properties Test Name	Longest Diameter
Tumor or Lesion Properties Test Name	Longest Perpendicular
Tumor or Lesion Properties Test Name	Number of New Bone Lesions
Tumor or Lesion Properties Test Name	Organ State
Tumor or Lesion Properties Test Name	Palpable State
Tumor or Lesion Properties Test Name	Percent Change Baseline in Organ Enlarge



PreText	Tumor Result (TR) Data		FieldOID
Longest Diameter			[TR_TRORES_LDIAM]
Longest Diameter Unit	mm		[TR_TRORESU_LDIAM]

Example Non-log Form: Using ONCRTS (RSTEST) Values as Prompt on CRF

Codelist Name	CDISC Submission Value
Oncology Response Assessment Test Name	ONCRTS
Oncology Response Assessment Test Name	Anatomic Response
Oncology Response Assessment Test Name	Best Overall Response
Oncology Response Assessment Test Name	Bone Marrow Involvement Indicator
Oncology Response Assessment Test Name	Bone Response
Oncology Response Assessment Test Name	Disease Recurrence Indicator
Oncology Response Assessment Test Name	Hematologic Response
Oncology Response Assessment Test Name	Liver Response
Oncology Response Assessment Test Name	Metabolic Response
Oncology Response Assessment Test Name	Metastatic Indicator
Oncology Response Assessment Test Name	Minimal Residual Disease Respons



PreText	Response (RS) Data	FieldOID
Best Overall Response	<input type="radio"/> CR <input type="radio"/> PR <input type="radio"/> SD <input type="radio"/> PD	[RS_RSORRES_BESTRESP]

Session 4 Summary

- CDASH Conformance Rules covered in this session are related to ensuring that each question on the CRF *means the same thing* as the definition of its target variable in SDTM
- CDASH Question Text and Prompt are designed to maintain a consistent meaning between the collected data and the SDTM data
 - CDASH Question Text and Prompt have built-in flexibility including optional and protocol-specific word choices in the CDASHIG and additional options in the CDASH Model
- Findings Class domains use --TEST controlled terminology to make test-specific Prompts or Questions

Questions?

*NCI**CDISC**Support@nih.gov*