Review “CDASH Mapping” for NCI Standard Forms

NCI CDISC Harmonization Working Group Meeting

12 August 2020

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Topics

CDASH Mapping on NCI Standard Forms

- *Screening*
- *Off Treatment*
- *Off Study*
- *RECIST 1.1*

NCI Standard Forms Review

Project Plan / Goals

CDASH Off Treatment and Off Study Reasons - Integration Consistency

- Theradex is using CDE 6355981 for the reasons a patient goes off treatment and off study. Looks like it is one of the standard CDEs used by a number of organizations. It is a critical element of an SDTM submission.

	Long Name	Preferred Question Text	Owned By	Used By Context	Registration Status	Workflow Status	Public ID	Version
☐	Disposition Event Dictionary-Derived/Standardized Term	What was the subject's status?	NCI Standards	AMC, COG, NRDS, Theradex	Qualified	RELEASED	6355981	1.0

- CDEs that appear to be used across all our networks

	Long Name	Preferred Question Text	Owned By	Used By Context	Registration Status	Workflow Status	Public ID	Version
☐	Disposition Event Dictionary-Derived/Standardized Term	What was the subject's status?	NCI Standards	AMC, COG, NRDS, Theradex	Qualified	RELEASED	6355981	1.0
☐	Off Treatment Reason Category	Off Treatment Reason	NCIP	ABTC, AECC, Alliance, CITN, CTEP, LCC, NCIP, SWOG	Qualified	RELEASED	2956831	1.0

CDASH Off Treatment and Off Study Reasons - Integration Consistency

- Theradex Web Reporting system (WRS) is used by both the ETCTN and NCTN
- Did mapping into WRS via DMU
  - The previous simpler list of reasons has greatly expanded due to CDISC CT
  - The values highlighted in violet below are new, and we are mapping many of them to "Other".
  - May need to update our list of values in WRS
  - AMC, COG and Theradex are using this CDE, other members of the NCTN are missing.
  - Need confirmation from NCI to expand the list of reasons.

Picklist Mappings for Off Treatment Reason

Your Value	Web Reporting Value
Complete	Treatment completed per protocol criteria
Adverse Event	Adverse Event/Side Effects/Complications
Death	Death on study during active treatment
Recurrent Disease	No mapped value
Failure To Meet Continuation Criteria	No mapped value
Failure to Meet Randomization Criteria	No mapped value
Lack of Efficacy	No mapped value
Non-Compliance With Non-Study Device	No mapped value
Non-Compliance With Study Device	No mapped value
Non-Compliance With Study Drug	No mapped value
Physician Decision	No mapped value
Pregnancy	No mapped value
Progressive Disease	Disease progression, relapse during active treatment
Protocol Deviation	No mapped value
Protocol Violation	No mapped value
Protocol-Specified Withdrawal Criterion Met	No treatment, per protocol criteria
Randomized By Mistake	No mapped value
Randomized By Mistake With Study Treatment	No mapped value
Recovery	No mapped value
Trial Site Terminated by Sponsor	No mapped value
Study Terminated By Sponsor	No mapped value
Technical Problem	No mapped value
Study Participant Withdrawal by Parent or Guardian	Patient withdrawal/refusal after beginning protocol therapy
Withdrawal by Participant	Patient withdrawal/refusal after beginning protocol therapy
Other	Other

patient has discontinued treatment is provided. In DMU, values will be mapped to one of the following:

- Treatment completed per protocol criteria
- Disease progression, relapse during active treatment

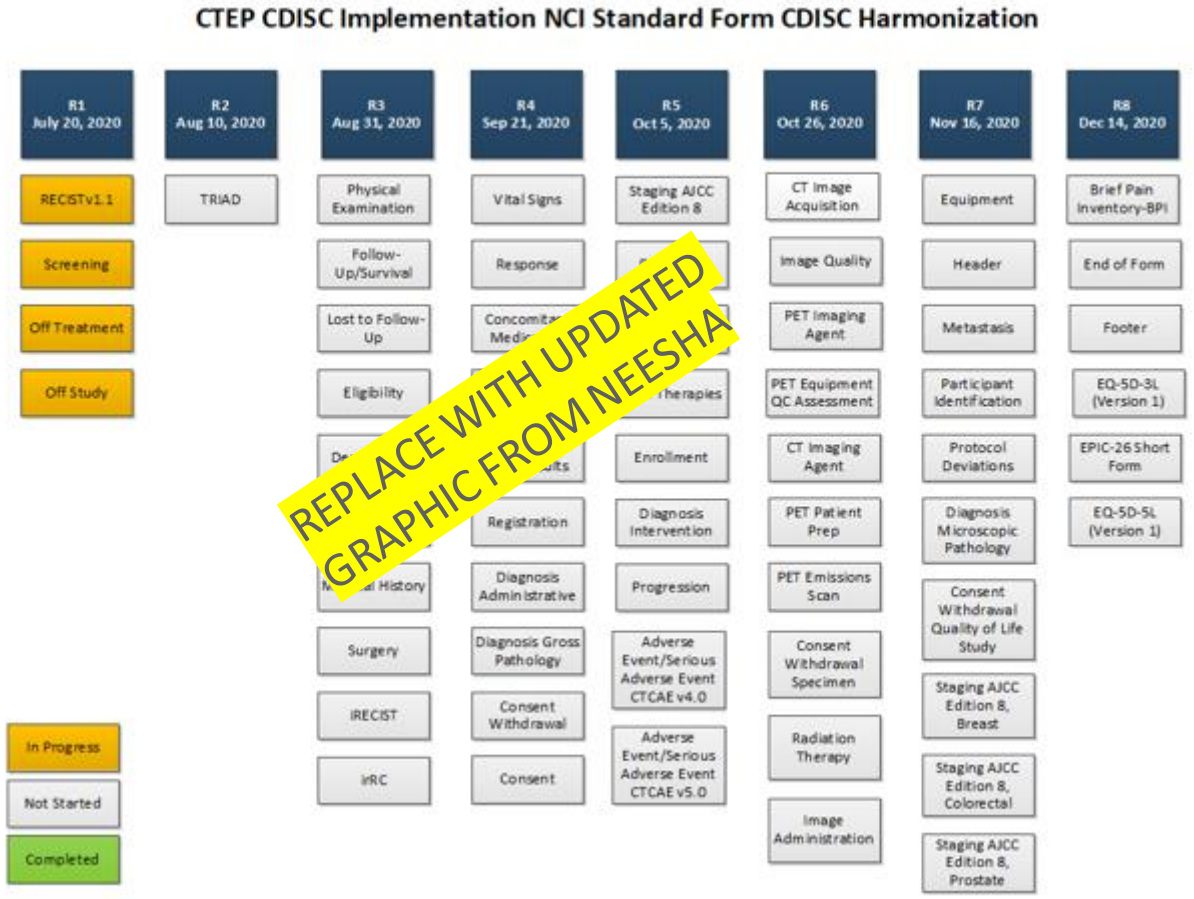
DMU Complete Data Submission Requirements (Draft)

24 September 2019

IT DATA ITEMS	Field Required?	Dictionary Mapping Required?	Definition
			• Adverse Event/Side Effects/Complications • Death on study during active treatment • Patient withdrawal/refusal after beginning protocol therapy • Patient withdrawal/refusal prior to beginning a protocol therapy • Alternative therapy • Patient off-treatment for other complicating disease • Lost to follow-up • Cytogenetic resistance • Disease progression before active treatment • No treatment, per protocol criteria • Other
Off Treatment Other Reason	No		A Verbatim reason for off-treatment if "Other" selected.

Progress on CDASH Mapping of NCI Standard Forms

- CDASH Mapping Completed (curation in caDSR in progress):
  - RECIST V1.1
  - Screening
  - Off Treatment
  - Off study
- CDASH Mapping In Progress
  - TRIAD
    - *mostly these forms are used for Image QC, but any data point(s) that might be used in clinical study analysis will be mapped to CDASH*



NCI Standard Forms Review

Approach

Approach to CDASH Mapping of NCI Standard Forms

- Working with an Excel file export of CDEs, **Reviewed**

Questions

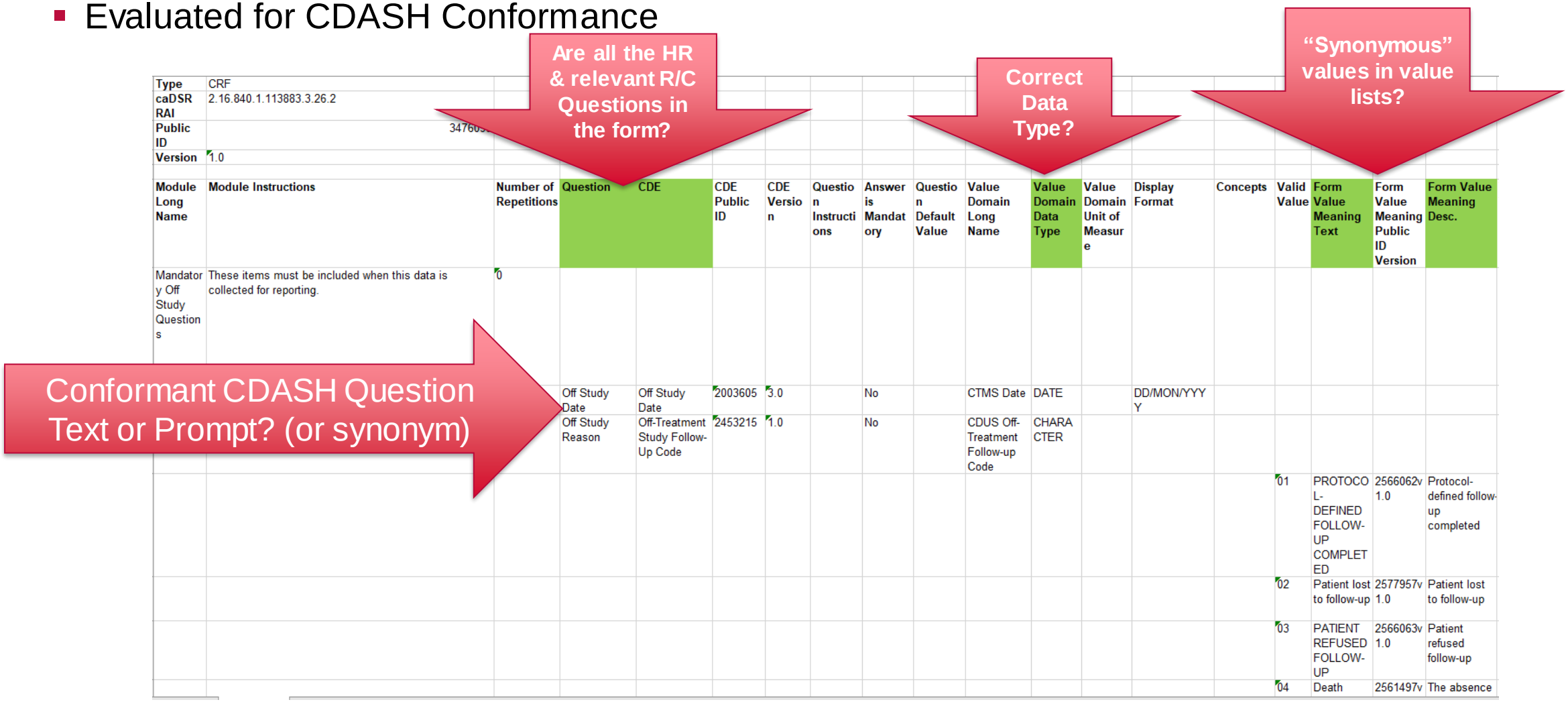
Data Types

Value Lists

Type	CRF																		
caDSR RAI	2.16.840.1.113883.3.26.2																		
Public ID	3476099																		
Version	1.0																		
Module Long Name	**Module Instructions**	**Number of Repetitions**	**Question**	**CDE**	**CDE Public ID**	**CDE Version**	**Question Instructions**	**Answer is Mandatory**	**Question Default Value**	**Value Domain Long Name**	**Value Domain Data Type**	**Value Domain Unit of Measure**	**Display Format**	**Concepts**	**Valid Value**	**Form Value Meaning Text**	**Form Value Meaning Public ID Version**	**Form Value Meaning Desc.**
Mandatory Off Study Questions	These items must be included when this data is collected for reporting.	0																
			Off Study Date	Off Study Date	2003605	3.0		No		CTMS Date	DATE		DD/MON/YYYY					
			Off Study Reason	Off-Treatment Study Follow-Up Code	2453215	1.0		No		CDUS Off-Treatment Follow-up Code	CHARACTER							
															01	PROTOCOL-DEFINED FOLLOW-UP COMPLETED	2566062v 1.0	Protocol-defined follow-up completed
															02	Patient lost to follow-up	2577957v 1.0	Patient lost to follow-up
															03	PATIENT REFUSED FOLLOW-UP	2566063v 1.0	Patient refused follow-up
															04	Death	2561497v	The absence

Approach to CDASH Mapping of NCI Standard Forms

- Evaluated for CDASH Conformance



Type	CRF
caDSR RAI	2.16.840.1.113883.3.26.2
Public ID	3476…
Version	1.0

Module Long Name	Module Instructions	Number of Repetitions	Question	CDE	CDE Public ID	CDE Version	Question Instructions	Answer is Mandatory	Question Default Value	Value Domain Long Name	Value Domain Data Type	Value Domain Unit of Measure	Display Format	Concepts	Valid Value	Form Value Meaning Text	Form Value Meaning Public ID Version	Form Value Meaning Desc.
Mandatory Off Study Questions	These items must be included when this data is collected for reporting.	0																
			Off Study Date	Off Study Date	2003605	3.0		No		CTMS Date	DATE		DD/MON/YYYY					
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															04	Death	2561497v	The absence

Approach to CDASH Mapping of NCI Standard Forms

- Created a second tab in the Workbook to show the CDASH mapping

For Each NCI Quesion

Provided conformant CDASH options

For each response value

Mapped to values in required SDTM terminology

Additional comments

	A	B	C	D	E	F	G
1	NCI CRF Question	CDASH Question Text	CDASH Prompt	NCI Response Values	CDISC CT	CDASH FieldOID	Comments / Questions
2	Off Study Date	What was the Off Study Date	Off Study Date			DS_DSSTDAT	
	Off Study Reason	What was the Subject's Status (when they came off study)	Status (when they came off study)	PROTOCOL-DEFINED FOLLOW-UP COMPLETED	COMPLETED	DS_DSDECOD	If DSDECOD is different from response value, populate DSTERM with the response value.
3				Adverse event/side effects/compliations	ADVERSE EVENT		If DSDECOD is different from response value, populate DSTERM with the response

CDASH Question Text (full sentence)

CDASH Prompt

Added FieldOID using our variable pattern

NCI Standard Forms Review

Content: Off Treatment

Standard Form Mapped to CDASH: Off Treatment

	A	B	C	D	E	F	G
1	**NCI CRF Question**	**CDASH Question Text**	**CDASH Prompt**	**NCI Response Values**	**CDISC CT**	**CDASH FieldOID**	**Comments / Questions**
2	Off Intervention Date	What was the Off Treatment Date	Off Treatment Date			DS_DSSTDAT	
3	Off Treatment Reason	What was the Subject's Status (when they came off treatment)	Status (when they came off treatment)	Treatment completed per protocol criteria	COMPLETED	DS_DSDECOD	
4				Disease progression, relapse during active treatment	PROGRESSIVE DISEASE		CDISC terminology splits out relapse and progressive disease into two terms.
5				Disease progression, relapse during active treatment	DISEASE RELAPSE		CDISC terminology splits out relapse and progressive disease into two terms.
6				Adverse event/side effects/compliations	ADVERSE EVENT		
7				DEATH ON STUDY	DEATH		
8				Patient withdrawal/refusal after beginning protocol therapy	WITHDRAWAL BY SUBJECT		
9				Patient withdrawal/refusal prior to beginning a protocol therapy	WITHDRAWAL BY SUBJECT		
10				Alternative Therapy	OTHER		Option: Extend the CT
11				PATIENT OFF-TREATMENT FOR OTHER COMPLICATING DISEASE	OTHER		Option: Extend the CT
12				Lost to Follow-up	LOST TO FOLLOW-UP		
13				Cytogenetic resistance	OTHER		Option: Extend the CT
14				Disease progression before active treatment	PROGRESSIVE DISEASE		
15				No treatment, per protocol criteria	OTHER		Option: Extend the CT
16				Other	OTHER		
17	Off Treatment, Other Specify	If Other, Specify	Other, Specify			DS_DSTERM	If DSDECOD is different from response value, populate DSTERM with response value.

Fairly straightforward mapping

NCI Standard Forms Review

Content: Off Study

Standard Form Mapped to CDASH: Off Study

	A	B	C	D	E	F	G
1	**NCI CRF Question**	**CDASH Question Text**	**CDASH Prompt**	**NCI Response Values**	**CDISC CT**	**CDASH FieldOID**	**Comments / Questions**
2	Off Study Date	What was the Off Study Date	Off Study Date			DS_DSSTDAT	
3	Off Study Reason	What was the Subject's Status (when they came off study)	Status (when they came off study)	PROTOCOL-DEFINED FOLLOW-UP COMPLETED	COMPLETED	DS_DSDECOD	If DSDECOD is different from response value, populate DSTERM with the response value.
4				Adverse event/side effects/compliations	ADVERSE EVENT		If DSDECOD is different from response value, populate DSTERM with the response value.
5				Death	DEATH		
6				PATIENT REFUSED FOLLOW-UP	NON-COMPLIANCE WITH STUDY SCHEDULE		If DSDECOD is different from response value, populate DSTERM with the response value.
7				Patient lost to follow-up	LOST TO FOLLOW-UP		If DSDECOD is different from response value, populate DSTERM with the response value.
8				Other	OTHER		
9	Off Study Other, Specify	If Other, Specify	Other, Specify			DS_DSTERM	If DSDECOD is different from response value, populate DSTERM with the response value.

Fairly straightforward mapping

NCI Standard Forms Review

Content: Screening

Standard Form Mapped to CDASH: Screening

Mapping depends on how used in study

	A	B	C	D	E	F	G
1	**NCI CRF Question**	**CDASH Question Text**	**CDASH Prompt**	**NCI Response Values**	**CDISC CT**	**CDASH FieldOID**	**Comments / Questions**
2	Does the participant meet all screening criteria?	Were all entry criteria met?	Met Criteria	Yes, No	Y, N	DV_DVYN	Use to determine if the participant was enrolled in error. If yes, this will be a Protocol Deviation record.
	If not, which screening criteria not met?			None			If the person was enrolled in error, the specific Criterion (or multiple criteria) would be the protocol deviations. DVDECOD could standardize these with a value of "ENROLLED, NOT ELIGIBLE", DVCAT could be used to indicate these Protocol Deviations are related to IE criteria.
3		What was the description of the inclusion criterion the subject did not meet or the exclusion criterion the subject met?	Exception Criterion Description		Would use study-specific list of IE criteria	DV_DVTERM SUPPDV_QVAL_IEVRSDAT	
4	Checklist Version Date						
5	Screen Completion Date	What was the [protocol milestone/disposition event/other event name] date? What was the Screening Completion Date?	[Protocol Milestone/Disposition Event/Other Event Name] Date Screening Completion Date			DS_DSSTDAT	

First three questions would be Protocol Deviation (DV) records if these questions are asked after the person has started on the study.

NCI Standard Forms Review

Content: RECIST v1.1

Standard Form Mapped to CDASH: RECIST V1.1 (1 of 3)

	A	B	C	D	E	F	G
1	**NCI CRF Question**	**CDASH Question Text**	**CDASH Prompt**	**NCI Response Values**	**CDISC CT**	**CDASH FieldOID**	**Comments / Questions**
2	Are there any target lesions?	Are there any target lesions	Any Target Lesions	Yes, No	Y, N	TU_TUORRES_TIND	This is an extension to the Tumor or Lesion Identification Test Code codelist (C96784) **because normally the Test Code used would be TUMIDENT with a collected value of TARGET**
3	Are there any non-target lesions?	Are there any non-target lesions	Any Non-Target Lesions	Yes, No	Y, N	TU_TUORRES_NTIND	"Non-target indicator" - NTIND is a standard value from C96784.
4	Lesion #	What is the Lesion Identifier	Lesion Identifier			TU_TULNKID	
5	Method of assessment	What was the assessment method	Assessment Method	Caliper, Chest x-ray, Color photography including ruler, CT, Cytology, Endoscopy, Histology, Laparoscopy, MRI, PET, PET/CT, Physical exam, Tumor marker, Ultrasound	METHOD	TU_TUMETHOD	Reference extensible METHOD codelist (C85492) to ensure the use of mappable values
6	Assessment date	What was the assessment date	Assessment Date			TU_TUDAT	
7	Measurable/Non-measurable	Is the tumor measureable?	Measurable	Measureable, Non-measurable	Y, N	TU_TUORRES_MEASIND	**"Measurable Indicator" - MEASIND is a standard value from C96784 for an Indicator question that uses Y/N terminology**
8	New lesions	Are there new lesions	New Lesions	Yes, No	Y, N	RS_RSORRES_NEWLIND	"New" indicates that this is part of disease response assessment
9	Location of tumor	What is the tumor location	Tumor Location	Uses coded values		TU_TULOC	CDISC requires de-code. Reference extensible LOC codelist (C74456)
10	Location of tumor	What is the tumor location	Tumor Location	Uses SNOMED	LOC	TU_TULOC	CDISC requires de-code. Reference extensible LOC codelist (C74456)
11	Location of tumor	What is the tumor location	Tumor Location	Uses decoded value list	LOC	TU_TULOC	CDISC requires de-code. Reference extensible LOC codelist (C74456)
12	Long axis	What is the longest diameter measurement	Longest Diameter			TR_TRORRES_LDIAM	Uses "Longest Diameter" LDIAM Test - standard value from C96779
13	Short axis	What is the short axis measurement	Short Axis			TR_TRORRES_LPERP	Uses "Longest Perpendicular; Short Axis Diameter" LPERP Test - standard value from C96779
14	Sum of diameters	What is the sum of diameters	Sum of Diameters			TR_TRORRES_SUMDIAM	Uses Sum of Diameters (SUMDIAM) - standard value from C96779

RECIST V1.1 was a little more challenging for a handful of questions.

Standard Form Mapped to CDASH: RECIST V1.1 (2 of 3)

Some questions structured differently from SDTM/CDASH assumptions

	A	B	C	D	E	F	G
1	**NCI CRF Question**	**CDASH Question Text**	**CDASH Prompt**	**NCI Response Values**	**CDISC CT**	**CDASH FieldOID**	**Comments / Questions**
15	Target lesion response	What is the Target Response	Target Response	CR, NE, Not Done, PD, PR, SD	ONCRSR (C96785)	RS_RSORRES_TRGRESP	Described as Target Lesion Response RECIST Type. **CDASH / SDTM would split out the "NOT DONE" value into a separate variable=RSSTAT**
16	Target lesions	What is the Target Response	Target Response	CR, NE, Not all evaluated, Not done, PD, PR, SD	ONCRSR (C96785)	RS_RSORRES_TRGRESP	Described as Target Lesions Response RECIS Overall Status. **CDASH / SDTM would split out the "NOT DONE" value into a separate variable=RSSTAT**
17	Non-target lesion response	What is the non-target response	Non-Target Response	CR, NE, Non-CR/non-PD, Not done, PD	ONCRSR (C96785)	RS_RSORRES_NTRGRESP	Described as Non-Target Lesion Response RECIST Type. **CDASH / SDTM would split o the "NOT DONE" value into a separate variable=RSSTAT**
18	Non-target lesions	What is the non-target response	Non-Target Response	CR, NE, Non-CR/non-PD, Not all evaluated, Not done, PD, Unequivocal PD	ONCRSR (C96785)	RS_RSORRES_NTRGRESP	Described as Non-Target Lesion Response RECIST Overall Status. **CDASH / SDTM woul split out the "NOT DONE" value into a separate variable=RSSTAT**
19	Time point	What is the planned timepoint?	*[displayed planned timeponit]*	Long list of values including hourly, weekly, monthly, Cycle-based, relation to treatment, etc.		RS_RSTPT	Recommend using --TPT for all of these as the do not cleanly correlate to other CDISC timing concepts like VISIT or EPOCH.
20	Tumor identification method	What was the tumor identification method	Tumor Identification Method	Yes, No	METHOD	TU_TUMETHOD	NCI form uses Free Text field
21	Lymph node	N/A (operational question)	N/A (operational question)		N/A (operational question)	N/A (operational question)	Lymph Node Present Indicator - This one need clarification on what they are asking about the Lymph Node - Is this asking about the presenc of *pathological* lymph nodes? If so, recommen using TRTESTCD=LNSTATE, TRTEST=Lymph Node State, TRORRES=Pathological, Non-pathological **23 June: Based on Mary's response (to the right) I would consider this to be an "operational" question (not clinical data).**

Standard Form Mapped to CDASH: RECIST V1.1 (3 of 3)

	A	B	C	D	E	F	G
1	**NCI CRF Question**	**CDASH Question Text**	**CDASH Prompt**	**NCI Response Values**	**CDISC CT**	**CDASH FieldOID**	**Comments / Questions**
22	Baseline measurable lesion	What is the measureable lesion type	Measurable Lesion Type	Bone lesions, Brain lesions, Cystic lesions, Lesions with prior local treatment, Malignant lymph node, Tumor lesion	Sponsor defined	TR_TRCAT (where TRTESTCD=MEASIND and TRORRES=Y)	Described as Baseline Neoplasm Measurable RECIST Type. CBIIT Confirmed this is related to the question above about "Measurable / Non-Measurable". Seems like a Category of the measureable neoplasm.
23	Baseline non-measurable lesion	What is the non-measureable lesion type	Non-Measurable Lesion Type	Abdominal masses, Abdominal organomegaly, Ascites, Bone lesions, Cystic lesions, Inflammatory breast tissue, Leptomeningeal disease, Lesions with prior local treatment, Lymphangitic involvement of skin or lung, Malignant lymph node, Pleural or pericardial effusion, Tumor lesions	Sponsor defined	TR_TRCAT (where TRTESTCD=MEASIND and TRORRES=N)	Described as Baseline Neoplasm Non-Measurable RECIST Type. CBIIT Confirmed this is related to the question above about "Measurable / Non-Measurable". Seems like a Category of the non-measureable neoplasm.
24	Overall response	What was the overall response	Overall Response	CR, NE, Non-CR/non-PD, PD, PR, SD	ONCRSR (C96785)	RS_RSORRES_OVRLRESP	Described as Overall Lesion Response RECIST Type
25	Duration of overall response	What was the duration of the overall response	Overal Response Duration			RS_RSDUR_OVRLRESP	CCG: Enter a numeric response which captures the maximum length of time over which response is maintained, measured from a date when criteria for complete or partial response are met until a date when recurrent or progressive disease is reported. **QUESTION:** Is the unit=DAYS?
26	Best overall response	What was the best overall response	Best Overall Response	CR, NE, PD, PR, SD, SD duration met otherwise NE, SD duration met otherwise PD	ONCRSR (C96785)	RS_RSORRRES_BESTRESP	
27	Date of imaging	What was the imaging date	Imaging Date			RS_RSDAT	CBIIT Confirmed this is a Disease Response date
28	Comments					CO_COVAL_[FormOID]	

Summary

- We will continue to work through the standard forms, providing CDASH Mapping
- It would be GREAT to have your feedback on these and how they support your study builds

Questions?

Send additional questions to the support email:

NCICDISCSupport.nih.gov