Manual for the Completion of CDISC Aligned NCI Standard Case Report Form (CRF) Modules

Introduction

In 2006, members of the National Cancer Institute's Center for Biomedical Informatics and Information Technology (NCI CBIIT) in conjunction with the cancer Data Standards Registry and Repository (caDSR) user community initiated a Case Report Form (CRF) harmonization activity. CRFs submitted from the community were reviewed and inventoried. The Harmonization group then reviewed all questions on the CRF and partitioned them into four categories:

- Mandatory – A data collection variable that must be on the CRF (e.g., a regulatory requirement (if applicable)).
- Conditional – A data collection variable that must be collected on the CRF for specific cases that may be dictated by local or sponsor defined business rules.
- Optional – A data collection variable that is available for use if needed. There is no regulatory or business requirement for inclusion of this element on the CRF; if the design and scientific questions posed in the study dictate the need to collect this type of data; this is the element to include on the CRF.
- Non-harmonized – A data collection variable that is, by consensus, to primarily belong to a different CRF module or is not belonging to any defined module.

A template form with modules that contain questions or variables representing data to be collected and a companion electronic CRF instruction manual was developed. These CRF modules were vetted and adopted by the caDSR stakeholder community as metadata standards.

Since the original CRFs and manuals were adopted, the Food & Drug Administration (FDA) published guidelines for submission of clinical trial study data using the Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTM) for Investigational New Drug (IND) trials starting after December 2017. In response, NCI CBIIT has aligned the NCI Standard CRF modules with the CDISC data collection standard, Clinical Data Acquisition Standards Harmonization (CDASH) where data is expected to be submitted to FDA in SDTM format.

The instruction manual is a set of directions to guide data collection in each module template. Specific implementation instructions are not present; various groups may wish to implement the contents of a module in a variety of software applications.

The instructions include the field name, description or definition of each field, and any special formatting notes that apply to entries – such as the inclusion of full dates, use of values from a choice list only, etc. Finally, each question (or data item) is noted as Mandatory (m), Conditional (c), or Optional (o).

Image Administration CDISC Aligned NCI Standard Template Module Definitions

Mapping to the CDASH:

This NCI Standard Template Form maps to the following domains in the CDASHIG v2.0 metadata table:

- PR – Procedures (v2.0)

Mapping to the SDTM:

This NCI Standard Template Form maps to the following domains in the SDTMIG v3.3 metadata table:

- MO – Morphology (v3.3)
- PR – Procedures (v3.3)
- DI – Device Identifiers (SDTMIG for Medical Devices v1.1)

Image Administration CDISC Aligned NCI Standard Template Module Template Instructions

Field Descriptions and Instructions

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Procedure Start Date (m) 6409578 PRSTDAT	The date or start date of when the procedure started or was performed represented in an unambiguous date format (e.g., DD-MON-YYYY). CDASH: PRSTDAT (6409578); SDTM: PRSTDTC (No CDE)	DATE
Imaging Technique Prior Occurrence Date (o) 7072168 PRIMPRDT	The date the previous imaging occurred represented in an unambiguous date format (e.g., DD-MON-YYYY). CDASH: No Match; SDTM: No Match	DATE
Timepoint Event Category (o) 7072169 PRTPTCAT	The category of events based on their occurrence at a point in time. CDASH: No Match; SDTM: No Match	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Timepoint Event Assessment Period Type (o) 7072170 PRATPT	The specific point in the time continuum an event occurred. CDASH: No Match; SDTM: PRTPT (6640412)	CHARACTER. Use choice list.
Performed Imaging Instance Type (o) 7072171 PRFIMGTY	The description of the type of occurrence of the imaging procedure. CDASH: No Match; SDTM: No Match	CHARACTER. Use choice list.
Imaging Technique Modality Type (o) 7072172 IMGTYPE	The description of data acquisition by an imaging device. CDASH: No Match; SDTM: DIVAL (No Match) where DIPARM = "Image Modality Type" and DIPARMCD = "IMGTYPE"	CHARACTER. Use choice list.
Image Acquisition Start Time (o) 7072192 PRIMAGST	The time the scan started represented in an unambiguous time format (e.g., hh:mm:ss). CDASH: PRSTDAT (6409578); SDTM: PRSTDTC (No CDE)	CHARACTER
Imaging Acquisition Scan Start Time Hour Value (o) 7072173 PRSTTIMH	The hour the imaging acquisition started represented as a numerical value. CDASH: No Match; SDTM: PRSTDTC (No CDE)	NUMBER
Imaging Acquisition Scan Start Time Minute Value (o) 7072174 PRSTTIMM	The minute the imaging acquisition started represented as a numerical value. CDASH: No Match; SDTM: PRSTDTC (No CDE)	NUMBER
Imaging Acquisition Scan Start Time Second Value (o) 7072175 PRSTTIMS	The second the imaging acquisition started represented as a numerical value. CDASH: No Match; SDTM: PRSTDTC (No CDE)	NUMBER

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Image Acquisition End Time (o) 7072196 PRIMAGEN	The time the scan ended represented in an unambiguous time format (e.g., hh:mm:ss). CDASH: PRENDAT (6409579); SDTM: PRENDTC (No CDE)	CHARACTER
Imaging Acquisition Scan End Time Hour Value (o) 7072176 PRENTIMH	The hour the imaging acquisition ended represented as a numerical value. CDASH: No Match; SDTM: PRENDTC (No CDE)	NUMBER
Imaging Acquisition Scan End Time Minute Value (o) 7072177 PRENTIMM	The minute the imaging acquisition ended represented as a numerical value. CDASH: No Match; SDTM: PRENDTC (No CDE)	NUMBER
Imaging Acquisition Scan End Time Second Value (o) 7072178 PRENTIMS	The second the imaging acquisition ended represented as a numerical value. CDASH: No Match; SDTM: PRENDTC (No CDE)	NUMBER
Image Interpretation Date (o) 7072179 MOIPRTDT	The date the image was interpreted by an individual represented in an unambiguous date format (e.g., DD-MON-YYYY). CDASH: No Match; SDTM: MODTC (6651848)	DATE
Image Technologist Identifier (o) 2583553 IMG_TECHT_ID	One or more characters used to identify a person skilled in the performance of medical imaging. Not for FDA submission	CHARACTER
Image Reader Identifier (o) 7072180 MOEVALR	A unique identifier assigned to an individual interpreting the image. CDASH: No Match; SDTM: MOEVAL (6620817)	CHARACTER

Annotated CRF: Image Administration CDISC Aligned NCI Standard Template

This annotated CRF is ONLY used to show CDISC mapping without consideration of the CRF layout. CDASH mapping is in **Blue**, and SDTM mapping is in **Red**.

Form Name: Image Administration CDISC Aligned NCI Standard Template

Mandatary Questions

CRF Question	Value Domain
Date of imaging (6409578) **CDE Short Name:** PRSTDAT CDASH: PRSTDAT (6409578) SDTM: PRSTDTC (No CDE)	DATE – Maximum Length = 11

Optional Questions

CRF Question	Value Domain
Date of previous imaging (7072168) **CDE Short Name:** PRIMPRDT CDASH: No Match SDTM: No Match	DATE – Maximum Length = 11
Timepoint (7072169) **CDE Short Name:** PRTPTCAT CDASH: No Match SDTM: No Match	CHARACTER – Maximum Length = 50 ☐ Baseline – Baseline ☐ Course – Course ☐ Cycle – Cycle ☐ Day – Day ☐ Follow up – Follow-up ☐ Hour – Hour ☐ Minute – Minute ☐ Month – Month ☐ Multiple Dose Phase – Multiple Dose Treatment Epoch ☐ Post randomization – Post Randomization ☐ Post registration – Post Registration ☐ Post Treatment Phase – Post Treatment Epoch ☐ Preregistration – Provisional Registration ☐ Pretreatment – Pretreatment ☐ Randomization – Randomization ☐ Registration – Registration ☐ Screening – Screening ☐ Single Ascending Dose Phase – Single Ascend Dose Treatment Epoch ☐ Visit – Visit ☐ Week – Week ☐ Year – Year
Timepoint (7072170) **CDE Short Name:** PRATPT CDASH: No Match SDTM: PRTPT (6640412)	CHARACTER – Maximum Length = 100 List of 700 PVs

CRF Question	Value Domain
Performed imaging instance type (7072171) **CDE Short Name:** PRFIMGTY CDASH: No Match SDTM: No Match	CHARACTER – Maximum Length = 15 ☐ Primary – Primary ☐ Repeat – Repeat ☐ Reproducibility – Reproducibility
Modality (7072172) **CDE Short Name:** IMGTYPE CDASH: No Match SDTM: DIVAL (No Match) where DIPARM = "Image Modality Type" and DIPARMCD = "IMGTYPE"	CHARACTER – Maximum Length = 30 ☐ CT – Computed Tomography ☐ DXA – Dual-energy X-ray Absorptometry ☐ FL – Fluoroscopy ☐ MRI – Magnetic Resonance Imaging ☐ PET – Positron Emission Tomography ☐ RI – Radiography ☐ SPECT – Single Photon Emission Computed Tomography ☐ US – Ultrasonography
Image start time (7072192) **CDE Short Name:** PRIMAGST CDASH: PRSTDAT (6409578) SDTM: PRSTDTC (No CDE)	CHARACTER – Maximum Length = 8
Time scan initiated: hour (7072173) **CDE Short Name:** PRSTTIMH CDASH: No Match SDTM: PRSTDTC (No CDE)	NUMBER – Maximum Length = 5
Time scan initiated: minutes (7072174) **CDE Short Name:** PRSTTIMM CDASH: No Match SDTM: PRSTDTC (No CDE)	NUMBER– Maximum Length = 5

CRF Question	Value Domain
Time scan initiated: seconds (7072175) **CDE Short Name:** PRSTTIMS CDASH: No Match SDTM: PRSTDTC (No CDE)	NUMBER – Maximum Length = 5
Image stop time (7072196) **CDE Short Name:** PRIMAGEN CDASH: PRENDAT (6409579) SDTM: PRENDTC (No CDE)	CHARACTER – Maximum Length = 8
Time scan completed: hour (7072176) **CDE Short Name:** PRENTIMH CDASH: No Match SDTM: PRENDTC (No CDE)	NUMBER – Maximum Length = 5
Time scan completed: minutes (7072177) **CDE Short Name:** PRENTIMM CDASH: No Match SDTM: PRENDTC (No CDE)	NUMBER – Maximum Length = 5
Time scan completed: seconds (7072178) **CDE Short Name:** PRENTIMS CDASH: No Match SDTM: PRENDTC (No CDE)	NUMBER – Maximum Length = 5
Date of interpretation (7072179) **CDE Short Name:** MOIPRTDT CDASH: No Match SDTM: MODTC (6651848)	DATE – Maximum Length = 11

CRF Question	Value Domain
Technologist ID (2583553) **CDE Short Name:** IMG_TECHT_ID CDASH: Not for FDA submission SDTM: Not for FDA submission	CHARACTER – Maximum Length = 80
Reader ID (7072180) **CDE Short Name:** MOEVALR CDASH: No Match SDTM: MOEVAL (6620817)	CHARACTER – Maximum Length = 40