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).

CT Image Acquisition 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:

- PR – Procedures (v3.3)
- DU – Device In-Use (SDTMIG for Medical Devices v1.1)

CT Image Acquisition 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
Imaging Technique Commence Indicator (o) 7072125 PRCTSTR	The indication of whether or not the imaging technique commenced. CDASH: No Match; SDTM: If Yes or No, PROCCUR (6407328) where PRTRT = "Imaging Procedure"	CHARACTER. Use choice list.
Imaging Technique Study Protocol Requirement Fulfill Indicator (o) 7072126 PRIMGPRT	The indication of whether or not the image captured met protocol requirements. CDASH: If Yes, PRSCAT (6413048) = "Imaging performed per protocol"; SDTM: If Yes, PRSCAT (No CDE) = "Imaging performed per protocol"	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Imaging Technique Without Contrast Agent Performed Indicator (o) 7072132 PRNENHIG	The indication of whether or not an emission scan was performed without the administration of a contrast agent. CDASH: PRTRT (6411539); SDTM: If Yes, PRTRT (No CDE) = "Non-enhanced imaging"	CHARACTER. Use choice list.
Scanner Device Kilovolt Peak Value (o) 7072133 KILVTPK	The kilovolt peak (kVp) setting used in obtaining the image represented as a numerical value. CDASH: No Match; SDTM: DUORRES (No CDE) where DUTEST = "Kilovolt peak setting used" and DUTESTCD = "KILVTPK"	NUMBER
Scanner Device Milliampere Value (o) 7072134 MILAMP	The milliampere (mA) setting used in obtaining the image represented as a numerical value. CDASH: No Match; SDTM: DUORRES (No CDE) where DUTEST = "Milliampere setting used" and DUTESTCD = "MILAMP"	NUMBER
Scanner Device Milliampere second Value (o) 7072135 IMGMAS	The milliampere-second (mAs) setting used in obtaining the image represented as a numerical value. CDASH: No Match; SDTM: DUORRES (No CDE) where DUTEST = "Image mAs Value" and DUTESTCD = "IMGMAS"	NUMBER
Device-In-Use Result Unit (o) 7245948 DUORRESU	The unit of measure for the device-in-use data that was collected. CDASH: No Match; SDTM: DUORRESU (No CDE)	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Computed Tomography Dose Length Product Value (o) 7072136 IMGDLP	The product of the number of computed tomography scans multiplied by the scan width represented as a numerical value. CDASH: No Match; SDTM: DUORRES (No CDE) where DUTEST = "Dose length product (DLP)" and DUTESTCD = "IMGDLP"	NUMBER
Computed Tomography Dose Index Volume Value (o) 7072137 IMGCTDI	The expression of radiation dose in computed tomography dosimetry represented as a numerical value. CDASH: No Match; SDTM: DUORRES (No CDE) where DUTEST = "Computed tomography dose index volume (CTDI vol)" and DUTESTCD = "IMGCTDI"	NUMBER
Slice Number Identifier (o) 7072138 SLICNUM	A unique identifier assigned to a specific image within a series of images. CDASH: No Match; SDTM: DUORRES (No CDE) where DUTEST = "Slice Number" and DUTESTCD = "SLICNUM"	CHARACTER
Image Slice Thickness Value (o) 7072139 SLCTHKMM	The image slice thickness represented as a numerical value. CDASH: No Match; SDTM: DUORRES (No CDE) where DUTEST = "Slice Thickness" and DUORRESU = Millimeter, DUTESTCD = "STHICK"	NUMBER
Device-In-Use Result Unit (o) 7245948 DUORRESU	The unit of measure for the device-in-use data that was collected. CDASH: No Match; SDTM: DUORRESU (No CDE)	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Image Series Number Identifier (o) 7072140 SERSNUM	A unique identifier assigned to an image series within the collection of images that comprise the exam. CDASH: No Match; SDTM: DUORRES (No CDE) where DUTEST = "Series Number" and DUTESTCD = "SERSNUM"	CHARACTER
Image Instance Number Identifier (o) 7072141 IMGNUM	A unique identifier assigned to an individual image. CDASH: No Match; SDTM: DUSPID (No CDE)	CHARACTER
DICOM Scanner Device Kilovolt Peak Value (o) 7072142 IMGKVP	The kilovolt peak (kVp) setting used in obtaining the image represented as a numerical value reported using DICOM standards. CDASH: No Match; SDTM: DUORRES (No CDE) where DUTEST = "Kilovolt peak setting used" and DUTESTCD = "KILVTPK"	NUMBER
DICOM Scanner Device Milliampere Value (o) 7072143 XRYTBMA	The milliampere (mA) setting used in obtaining the image represented as a numerical value reported using DICOM standards. CDASH: No Match; SDTM: DUORRES (No CDE) where DUTEST = "Milliampere setting used" and DUTESTCD = "MILAMP"	NUMBER
DICOM Scanner Device Milliampere second Value (o) 7072144 MASBTMM	The milliampere-second (mAs) setting used in obtaining the image represented as a numerical value reported using DICOM standards. CDASH: No Match; SDTM: DUORRES (No CDE) where DUTEST = "Image mAs Value" and DUTESTCD = "IMGMAS"	NUMBER

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Device-In-Use Result Unit (o) 7245948 DUORRESU	The unit of measure for the device-in-use data that was collected. CDASH: No Match; SDTM: DUORRESU (No CDE)	CHARACTER. Use choice list.
DICOM Computed Tomography Dose Index Volume Value (o) 7072145 CTDIVOL	The expression of radiation dose in computed tomography dosimetry represented as a numerical value reported using DICOM standards. CDASH: No Match; SDTM: DUORRES (No CDE) where DUTEST = "Computed tomography dose index volume (CTDI vol)" and DUTESTCD = "IMGCTDI"	NUMBER
DICOM Image Slice Thickness Value (o) 7072146 SLCTKMM	The image slice thickness represented as a numerical value reported using DICOM standards. CDASH: No Match; SDTM: DUORRES (No CDE) where DUTEST = "Slice Thickness" and DUORRESU = Millimeter, DUTESTCD = "STHICK"	NUMBER
Device-In-Use Result Unit (o) 7245948 DUORRESU	The unit of measure for the device-in-use data that was collected. CDASH: No Match; SDTM: DUORRESU (No CDE)	CHARACTER. Use choice list.
DICOM Image Series Number Identifier (o) 7072147 SERIBYT	The image slice thickness represented as a numerical value reported using DICOM standards. CDASH: No Match; SDTM: DUORRES (No CDE) where DUTEST = "Series Number" and DUTESTCD = "SERSNUM"	CHARACTER

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
DICOM Image Instance Number Identifier (o) 7072148 IMGINSTN	A unique identifier assigned to an individual image reported using DICOM standards. CDASH: No Match; SDTM: DUSPID (No CDE)	CHARACTER

Annotated CRF: CT Image Acquisition 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: CT Image Acquisition CDISC Aligned NCI Standard Template

Optional Questions

CRF Question	Value Domain
Did CT imaging commence? (7072125) **CDE Short Name:** PRCTSTR CDASH: No Match SDTM: If Yes or No, PROCCUR (6407328) where PRTRT = "Imaging Procedure"	CHARACTER – Maximum Length = 2 ☐ N – No ☐ NA – Not Applicable ☐ U – Unknown ☐ Y – Yes
Was imaging performed per protocol? (7072126) **CDE Short Name:** PRIMGPRT CDASH: If Yes, PRSCAT (6413048) = "Imaging performed per protocol"; SDTM: If Yes, PRSCAT (No CDE) = "Imaging performed per protocol"	CHARACTER – Maximum Length = 2 ☐ N – No ☐ NA – Not Applicable ☐ U – Unknown ☐ Y – Yes
Was non-enhanced imaging performed? (7072132) **CDE Short Name:** PRNENHIG CDASH: PRTRT (6411539) SDTM: If Yes, PRTRT (No CDE) = "Non-enhanced imaging"	CHARACTER – Maximum Length = 2 ☐ N – No ☐ NA – Not Applicable ☐ U – Unknown ☐ Y – Yes

CRF Question	Value Domain
Kilovolt peak setting used (7072133) **CDE Short Name:** KILVTPK CDASH: No Match SDTM: DUORRES (No CDE) where DUTEST = "Kilovolt peak setting used" and DUTESTCD = "KILVTPK"	NUMBER – Maximum Length = 5
Milliampere setting used (7072134) **CDE Short Name:** MILAMP CDASH: No Match SDTM: DUORRES (No CDE) where DUTEST = "Milliampere setting used" and DUTESTCD = "MILAMP"	NUMBER – Maximum Length = 5
mAs (7072135) **CDE Short Name:** IMGMAS CDASH: No Match SDTM: DUORRES (No CDE) where DUTEST = "Image mAs Value" and DUTESTCD = "IMGMAS"	NUMBER – Maximum Length = 5
Unit (7245948) **CDE Short Name:** DUORRESU CDASH: No Match SDTM: DUORRESU (No CDE)	CHARACTER – Maximum Length = 100 ☐　mAmp – Milliampere
Dose length product (DLP) (7072136) **CDE Short Name:** IMGDLP CDASH: No Match SDTM: DUORRES (No CDE) where DUTEST = "Dose length product (DLP)" and DUTESTCD = "IMGDLP"	NUMBER – Maximum Length = 5

CRF Question	Value Domain
Computed tomography dose index volume (CTDI vol) (7072137) **CDE Short Name:** IMGCTDI CDASH: No Match SDTM: DUORRES (No CDE) where DUTEST = "Computed tomography dose index volume (CTDI vol)" and DUTESTCD = "IMGCTDI"	NUMBER – Maximum Length = 5
Slice Number (7072138) **CDE Short Name:** SLICNUM CDASH: No Match SDTM: DUORRES (No CDE) where DUTEST = "Slice Number" and DUTESTCD = "SLICNUM"	CHARACTER – Maximum Length = 40
Slice Thickness (7072139) **CDE Short Name:** SLCTHKMM CDASH: No Match SDTM: DUORRES (No CDE) where DUTEST = "Slice Thickness" and DUORRESU = Millimeter, DUTESTCD = "STHICK"	NUMBER – Maximum Length = 5
Unit (7245948) **CDE Short Name:** DUORRESU CDASH: No Match SDTM: DUORRESU (No CDE)	CHARACTER – Maximum Length = 100 ☐ mm – Millimeter
Series Number (7072140) **CDE Short Name:** SERSNUM CDASH: No Match SDTM: DUORRES (No CDE) where DUTEST = "Series Number" and DUTESTCD = "SERSNUM"	CHARACTER – Maximum Length = 40

CRF Question	Value Domain
Image Number (7072141) **CDE Short Name:** IMGNUM CDASH: No Match SDTM: DUSPID (No CDE)	CHARACTER – Maximum Length = 40
kVp (7072142) **CDE Short Name:** IMGKVP CDASH: No Match SDTM: DUORRES (No CDE) where DUTEST = "Kilovolt peak setting used" and DUTESTCD = "KILVTPK"	NUMBER – Maximum Length = 5
X-Ray Tube Current in mA (7072143) **CDE Short Name:** XRYTBMA CDASH: No Match SDTM: DUORRES (No CDE) where DUTEST = "Milliampere setting used" and DUTESTCD = "MILAMP"	NUMBER – Maximum Length = 5
mAs (7072144) **CDE Short Name:** MASBTMM CDASH: No Match SDTM: DUORRES (No CDE) where DUTEST = "Image mAs Value" and DUTESTCD = "IMGMAS"	NUMBER – Maximum Length = 5
Unit (7245948) **CDE Short Name:** DUORRESU CDASH: No Match SDTM: DUORRESU (No CDE)	CHARACTER – Maximum Length = 100 ☐ mAmp – Milliampere

CRF Question	Value Domain
CTDIvol (7072145) **CDE Short Name:** CTDIVOL CDASH: No Match SDTM: DUORRES (No CDE) where DUTEST = "Computed tomography dose index volume (CTDI vol)" and DUTESTCD = "IMGCTDI"	NUMBER – Maximum Length = 5
Slice Thickness (7072146) **CDE Short Name:** SLCTKMM CDASH: No Match SDTM: DUORRES (No CDE) where DUTEST = "Slice Thickness" and DUORRESU = Millimeter, DUTESTCD = "STHICK"	NUMBER – Maximum Length = 5
Unit (7245948) **CDE Short Name:** DUORRESU CDASH: No Match SDTM: DUORRESU (No CDE)	CHARACTER – Maximum Length = 100 mm – Millimeter
Series Number (7072147) **CDE Short Name:** SERIBYT CDASH: No Match SDTM: DUORRES (No CDE) where DUTEST = "Series Number" and DUTESTCD = "SERSNUM"	CHARACTER – Maximum Length = 40
Instance Number (7072148) **CDE Short Name:** IMGINSTN CDASH: No Match SDTM: DUSPID (No CDE)	CHARACTER – Maximum Length = 40