

# 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).

## PET Emissions Scan 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)

## PET Emissions Scan 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
Positron Emission Tomography Emission Scan Start Time (m) 7072187 PRSCANST	The time the emission scan started represented in an unambiguous time format (e.g., hh:mm:ss)  CDASH: PRSTDAT (6409578); SDTM: PRSTDTC (No CDE)	CHARACTER
Positron Emission Tomography Emission Scan End Time (m) 7072188 PRSCANEN	The time the emission scan ended represented in an unambiguous time format (e.g., hh:mm:ss).  CDASH: PRENDAT (6409579); SDTM: PRENDTC (No CDE)	CHARACTER
DICOM Image Pixel Measurement Sequence Text (m) 7072113 PXLMSSEQ	The description of the physical characteristics of the pixels in the frame.  CDASH: No Match; SDTM: DUORRES (No CDE) where DUTEST = "Pixel Measures Sequence" and DUTESTCD (No CDE) = "PXLMSSEQ"	CHARACTER

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Emission Scan Post Tracer Injection Route of Administration Start Time Minute Value (m) 7072114 MINPSIST	The number of minutes the emission scan started following injection of the tracer represented as a numerical value.  CDASH: No Match; SDTM: No Match	NUMBER
Positron Emission Tomography Emission Scan With Computed Tomography with Contrast Or Magnetic Resonance Imaging Performed Indicator (m) 7072115 PETCTMRI	The indication of whether or not a contrast-enhanced CT or MRI was performed as part of the PET emission scan.  CDASH: PRTRT (6411539); SDTM: If Yes, PRTRT (No CDE) = "PET/CT" or "PET/MRI", PRPRES = Y	CHARACTER. Use choice list.
Positron Emission Tomography Emission Scan Type (o) 7072116 PETEMTYP	The type of positron emission tomography emission scan series obtained.  CDASH: No Match; SDTM: DUORRES (No CDE) where DUTEST = "PET emission scan type" and DUTESTCD = "PETEMTYP"	CHARACTER. Use choice list.
Emission Scan Image Series Performed Indicator (o) 7072117 PRSCNSER	The indication of whether or not an emission scan series was performed.  CDASH: No Match; SDTM: No Match	CHARACTER. Use choice list.
Emission Scan Image Acquisition Mode Type (o) 7072118 IMAQDIM	The setting on a positron emission tomography scanner that determines how the device will sense photon during image capture.  CDASH: No Match; SDTM: DUORRES (No CDE) where DUTEST = "Image Acquisition Dimensionality" and DUTESTCD = "IMAQDIM"	CHARACTER. Use choice list.

<b>Field Name (Partition Status) CDE ID # Short Name</b>	<b>Definition CDISC Mapping and Instruction</b>	<b>Format</b>
Scanner Patient Bed Position Number (o) 7072119 SCNBEDNM	The number of bed positions scanned using an emission scanner.  CDASH: No Match; SDTM: No Match	NUMBER
Image Plane Slice Thickness Value (o) 7072120 STHICK	The nominal slice thickness relative to the patient based coordinate system represented as a numerical value.  CDASH: No Match; SDTM: DUORRES (No CDE) where DUTEST = "Slice Thickness" and 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.
Emission Scan Post Tracer Injection Route of Administration End Time Minute Value (o) 7072121 MINPSIEN	The number of minutes the emission scan ended following the injection of the tracer represented as a numerical value.  CDASH: No Match; SDTM: No Match	CHARACTER. Use choice list.
Emission Scan Post Tracer Injection Route of Administration Acquisition Duration Minute Value (o) 7072122 MINPSINJ	The duration of the emission scan following the injection of the tracer represented as a numerical value.  CDASH: No Match; SDTM: No Match	NUMBER

## Annotated CRF: PET Emissions Scan 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: PET Emissions Scan CDISC Aligned NCI Standard Template

Mandatory Questions

CRF Question	Value Domain
<b>Emission scan start time (7072187)</b> <b>CDE Short Name: PRSCANST</b>  <div style="border: 1px solid blue; padding: 2px; margin-bottom: 5px;">CDASH: PRSTDAT (6409578)</div> <div style="border: 1px solid red; padding: 2px;">SDTM: PRSTDTC (No CDE)</div>	CHARACTER – Maximum Length = 8
<b>Emission scan stop time (7072188)</b> <b>CDE Short Name: PRSCANEN</b>  <div style="border: 1px solid blue; padding: 2px; margin-bottom: 5px;">CDASH: PRENDAT (6409579)</div> <div style="border: 1px solid red; padding: 2px;">SDTM: PRENDTC (No CDE)</div>	CHARACTER – Maximum Length = 8
<b>Pixel Measures Sequence (7072113)</b> <b>CDE Short Name: PXLMSSEQ</b>  <div style="border: 1px solid blue; padding: 2px; margin-bottom: 5px;">CDASH: No Match</div> <div style="border: 1px solid red; padding: 2px;">SDTM: DUORRES (No CDE) where DUTEST = "Pixel Measures Sequence" and DUTESTCD (No CDE) = "PXLMSSEQ"</div>	CHARACTER – Maximum Length = 200
<b>Minutes post injection start time (7072114)</b> <b>CDE Short Name: MINPSIST</b>  <div style="border: 1px solid blue; padding: 2px; margin-bottom: 5px;">CDASH: No Match</div> <div style="border: 1px solid red; padding: 2px;">SDTM: No Match</div>	NUMBER – Maximum Length = 5

CRF Question	Value Domain
<p data-bbox="240 205 803 237"><b>CT or MR Scan obtained with PET (7072115)</b></p> <p data-bbox="240 243 609 275"><b>CDE Short Name: PETCTMRI</b></p> <div data-bbox="287 321 769 373" style="border: 1px solid blue; padding: 2px; margin: 10px 0;">CDASH: PRTRT (6411539)</div> <div data-bbox="287 407 769 520" style="border: 1px solid red; padding: 2px; margin: 10px 0;">SDTM: If Yes, PRTRT (No CDE) = "PET/CT" or "PET/MRI", PRPRES = Y</div>	<p data-bbox="816 205 1274 237">CHARACTER – Maximum Length = 2</p> <ul data-bbox="816 296 1112 457" style="list-style-type: none"><li data-bbox="816 296 950 327"><input type="checkbox"/> N – No</li><li data-bbox="816 338 1112 369"><input type="checkbox"/> NA – Not Applicable</li><li data-bbox="816 380 1031 411"><input type="checkbox"/> U – Unknown</li><li data-bbox="816 422 966 453"><input type="checkbox"/> Y – Yes</li></ul>

## Optional Questions

CRF Question	Value Domain
<p><b>PET emission scan type (7072116)</b>  <b>CDE Short Name: PETEMTYP</b></p> <p>CDASH: No Match</p> <p>SDTM: DUORRES (No CDE) where DUTEST = "PET emission scan type" and DUTESTCD = "PETEMTYP"</p>	<p>CHARACTER – Maximum Length = 35</p> <p><input type="checkbox"/> Dynamic – Dynamic</p> <p><input type="checkbox"/> Static – Static</p> <p><input type="checkbox"/> Whole Body – Whole Body</p>
<p><b>Was this scan series performed? (7072117)</b>  <b>CDE Short Name: PRSCNSER</b></p> <p>CDASH: No Match</p> <p>SDTM: No Match</p>	<p>CHARACTER – Maximum Length = 2</p> <p><input type="checkbox"/> N – No</p> <p><input type="checkbox"/> NA – Not Applicable</p> <p><input type="checkbox"/> U – Unknown</p> <p><input type="checkbox"/> Y – Yes</p>
<p><b>Emission acquisition mode (7072118)</b>  <b>CDE Short Name: IMAQDIM</b></p> <p>CDASH: No Match</p> <p>SDTM: DUORRES (No CDE) where DUTEST = "Image Acquisition Dimensionality" and DUTESTCD = "IMAQDIM"</p>	<p>CHARACTER – Maximum Length = 25</p> <p><input type="checkbox"/> 1 – 2D</p> <p><input type="checkbox"/> 2 – 3D</p> <p><input type="checkbox"/> Time of Flight – Time of Flight</p>
<p><b>Number of bed positions scanned (7072119)</b>  <b>CDE Short Name: SCNBEDNM</b></p> <p>CDASH: No Match</p> <p>SDTM: No Match</p>	<p>NUMBER – Maximum Length = 10</p>
<p><b>Slice Thickness (7072120)</b>  <b>CDE Short Name: STHICK</b></p> <p>CDASH: No Match</p> <p>SDTM: DUORRES (No CDE) where DUTEST = "Slice Thickness" and DUTESTCD = STHICK"</p>	<p>NUMBER – Maximum Length = 5</p>

CRF Question	Value Domain
<p><b>Original Units (7245948)</b>  <b>CDE Short Name: DUORRESU</b></p> <p>CDASH: No Match</p> <p>SDTM: DUORRESU (No CDE)</p>	<p>CHARACTER – Maximum Length = 100</p> <p><input type="checkbox"/> mm – Millimeter</p>
<p><b>Minutes post injection stop time (7072121)</b>  <b>CDE Short Name: MINPSIEN</b></p> <p>CDASH: No Match</p> <p>SDTM: No Match</p>	<p>NUMBER – Maximum Length = 5</p>
<p><b>Minutes post-injection (7072122)</b>  <b>CDE Short Name: MINPSINJ</b></p> <p>CDASH: No Match</p> <p>SDTM: No Match</p>	<p>NUMBER – Maximum Length = 5</p>