

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 Quality 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)

Image Quality 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 Completed Indicator (m) 7069008 PRIMGCP	The indication of whether or not imaging was completed. CDASH: PRTRTCMP (6408623) where PRTRT (6411539) = "Imaging"; SDTM: PROCCUR (No CDE) where PRTRT (No CDE) = "Imaging"	CHARACTER. Use choice list.
Image Quality Category (m) 7069009 PRIMGQL	The qualitative description of medical imaging. CDASH: No Match; SDTM: No Match	CHARACTER. Use choice list.
Suboptimal Image Reason (m) 7069010 PRIMGQAF	The description of the cause of inferior image quality. CDASH: No Match; SDTM: No Match	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Suboptimal Image Reason Text (m) 7069011 PRIMGQFX	The description of the cause of inferior image quality not previously listed. CDASH: No Match; SDTM: No Match	CHARACTER
Imaging Technique Incomplete Medical Variance Reason (c) 7069012 PRMRESND	The description of the medical reason imaging was not completed. CDASH: PRREASND (6421528); SDTM: No Match; Conditionality Rule: Based on the protocol and imaging modality used requires the capture of medical reason.	CHARACTER. Use choice list.
Imaging Technique Incomplete Variance Reason (o) 7069013 PRIRESND	The description of the non-medical reason imaging was not completed. CDASH: PRREASND (6421528); SDTM: No Match	CHARACTER. Use choice list.
Imaging Technique Incomplete Variance Reason Text (o) 7069014 PRRESNDX	The description of the non-medical reason imaging was not completed not previously listed. CDASH: PRREASND (6421528); SDTM: No Match	CHARACTER

Annotated CRF: Image Quality 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 Quality CDISC Aligned NCI Standard Template

Mandatory Questions

CRF Question	Value Domain
<p>Was imaging completed? (7069008) CDE Short Name: PRIMGCP</p> <div style="border: 1px solid blue; padding: 5px; margin: 10px 0;"> <p>CDASH: PRTRTCMP (6408623) where PRTRT (6411539) = "Imaging"</p> </div> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: PROCCUR (No CDE) where PRTRT (No CDE) = "Imaging"</p> </div>	<p>CHARACTER – Maximum Length = 2</p> <ul style="list-style-type: none"> <input type="checkbox"/> N – No <input type="checkbox"/> NA – Not Applicable <input type="checkbox"/> U – Unknown <input type="checkbox"/> Y – Yes
<p>Indicate the image quality (7069009) CDE Short Name: PRIMGQL</p> <div style="border: 1px solid blue; padding: 5px; margin: 10px 0;"> <p>CDASH: No Match</p> </div> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: No Match</p> </div>	<p>CHARACTER – Maximum Length = 20</p> <ul style="list-style-type: none"> <input type="checkbox"/> Adequate Quality – Sufficient Quality <input type="checkbox"/> Exemplary Quality – Exemplary Quality <input type="checkbox"/> Limited Quality – Limited Quality <input type="checkbox"/> Not Adequate Quality – Negation Sufficient Quality
<p>Which of the following affected the Quality of the image? (check all apply) (7069010) CDE Short Name: PRIMGQAF</p> <div style="border: 1px solid blue; padding: 5px; margin: 10px 0;"> <p>CDASH: No Match</p> </div> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: No Match</p> </div>	<p>CHARACTER – Maximum Length = 45</p> <ul style="list-style-type: none"> <input type="checkbox"/> image acquisition or processing error – image acquisition or processing error <input type="checkbox"/> image noise artifact – Image Noise Artifact <input type="checkbox"/> incomplete or incorrect imaging protocol – incomplete or incorrect imaging protocol <input type="checkbox"/> motion-related artifact – Motion Related Artifact <input type="checkbox"/> Other – Other <input type="checkbox"/> patient artifact – Patient Motion Artifact <input type="checkbox"/> procedural artifact – Protocol Error Artifact

CRF Question	Value Domain
<p data-bbox="240 205 784 268">Which of the following affected the Quality of the image? (Other specify) (7069011)</p> <p data-bbox="240 275 618 306">CDE Short Name: PRIMGQFX</p> <div data-bbox="287 352 769 405" style="border: 1px solid blue; padding: 2px; margin: 10px 0;">CDASH: No Match</div> <div data-bbox="287 438 769 491" style="border: 1px solid red; padding: 2px; margin: 10px 0;">SDTM: No Match</div>	<p data-bbox="816 205 1300 237">CHARACTER – Maximum Length = 200</p>

Conditional Questions

CRF Question	Value Domain
<p>Medical reason imaging was not completed (7069012)</p> <p>CDE Short Name: PRMRESND</p> <p>CDASH: PRREASND (6421528)</p> <p>SDTM: No Match</p>	<p>CHARACTER – Maximum Length = 50</p> <ul style="list-style-type: none"> <input type="checkbox"/> Abnormal laboratory level – Abnormal Laboratory Test Result <input type="checkbox"/> Adverse Event – Adverse Event <input type="checkbox"/> Claustrophobia – Claustrophobia <input type="checkbox"/> Injection complication – Injection Complication <input type="checkbox"/> Other – Other <input type="checkbox"/> Progressive disease – PD

Optional Questions

CRF Question	Value Domain
<p>(Provide) Reason imaging was not completed (7069013) CDE Short Name: PRIRESND</p> <p>CDASH: PRREASND (6421528)</p> <p>SDTM: No Match</p>	<p>CHARACTER – Maximum Length = 50</p> <ul style="list-style-type: none"> <input type="checkbox"/> Equipment failure/error – Diagnostic, Therapeutic, and Research Equipment Failure <input type="checkbox"/> Medical reason – Medical Contraindication <input type="checkbox"/> Other – Other <input type="checkbox"/> Participant death – Participant Death <input type="checkbox"/> Participant refusal – Participant Refuse <input type="checkbox"/> Participant withdrew – Participant Withdraw <input type="checkbox"/> Scheduling problem – Schedule Problem <input type="checkbox"/> Unknown – Unknown
<p>Other reason imaging was not completed (7069014) CDE Short Name: PRRESNDX</p> <p>CDASH: PRREASND (6421528)</p> <p>SDTM: No Match</p>	<p>CHARACTER – Maximum Length = 200</p>