

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).

Progression CDISC Aligned NCI Standard Template Module Definitions

Mapping to the CDASH:

N/A

Mapping to the SDTM:

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

- RS – Disease Response and Clin Classification (v3.3)
- TU – Tumor/Lesion Identification (v3.3)

Progression 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
Disease Response Most Recent Evaluation Date (o) 7038803 RSMTRDT	The date disease response was evaluated, represented in an unambiguous date format (e.g., DD-MON-YYYY). CDASH: No Match; SDTM: RSDTC (6651952) where RSTESTCD (6620609) = "RTNPRGEV" RSTEST (6620604) = "Most Recent Disease Status Evaluation"	DATE
Progressive Disease Or Recurrent Disease Present Indicator (o) 7038804 RLPGIND	The indication of whether or not progressive disease or recurrent disease was present. CDASH: No Match; SDTM: RSORRES (6642369) where RSTESTCD (6620609) = "RLPGIND" and RSTEST (6620604)= "Disease progress or relapse indicator"	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Disease Response Most Recent Negation Evaluation Text (o) 7038805 RSDZRPTX	The description of the reason disease status was not evaluated. CDASH: No Match; SDTM: RSREASND (6642040)	CHARACTER
Progressive Disease Or Recurrent Disease Post Last Personal Contact Present Type (o) 7038806 PRGRCNT	The indication of the type of progressive disease or recurrent disease. CDASH: No Match; SDTM: RSORRES (6642369) where RSTESTCD (6620609) = "PRGRCNT" and RSTEST (6620604) = "Progressive/recurrent disease"	CHARACTER. Use choice list.
Progressive Disease or Recurrent Disease Evaluation Date (o) 7038807 RSPRGDT	The date progressive disease or recurrent disease was identified, represented in an unambiguous date format (e.g., DD-MON-YYYY). CDASH: No Match; SDTM: RSDTC (6651952) where RSTESTCD (6620609) = "PRGREEV", RSTEST (6620604) = "Progressive/recurrent disease evaluation"	DATE
Progressive Disease Anatomic Site (o) 7038808 TUPGDZST	The anatomic site where progressive disease occurred. CDASH: No Match; SDTM: TULOC (6621372)	CHARACTER. Use choice list.
Progressive Disease Anatomic Site Text (o) 7038809 TULOCX	The anatomic site where progressive disease occurred not previously listed. CDASH: No Match; SDTM: TULOC (6621372)	CHARACTER
Disease Response Evaluation Method Type (o) 7038810 TUEVALTP	The method used to determine disease response. CDASH: No Match; SDTM: TUMETHOD (No CDE)	CHARACTER. Use choice list.

Annotated CRF: Progression 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: Progression CDISC Aligned NCI Standard Template

Optional Questions

CRF Question	Value Domain
<p>Date of most recent disease status evaluation (7038803) CDE Short Name: RSMTRDT</p> <div style="border: 1px solid blue; padding: 2px; margin: 10px 0;">CDASH: No Match</div> <div style="border: 1px solid red; padding: 2px; margin: 10px 0;"> SDTM: RSDTC (6651952) where RSTESTCD (6620609) = "RTNPRGEV" RSTEST (6620604) = "Most Recent Disease Status Evaluation" </div>	<p>DATE – Maximum Length = 11</p>
<p>Did the patient's disease progress or relapse during the indicated period? (7038804) CDE Short Name: RLPGIND</p> <div style="border: 1px solid blue; padding: 2px; margin: 10px 0;">CDASH: No Match</div> <div style="border: 1px solid red; padding: 2px; margin: 10px 0;"> SDTM: RSORRES (6642369) where RSTESTCD (6620609) = "RLPGIND" and RSTEST (6620604)= "Disease progress or relapse indicator" </div>	<p>CHARACTER – Maximum Length = 2</p> <p> <input type="checkbox"/> N – No <input type="checkbox"/> NA – Not Applicable <input type="checkbox"/> U – Unknown <input type="checkbox"/> Y – Yes </p>
<p>If evaluation was not done specify reason (7038805) CDE Short Name: RSDZRPTX</p> <div style="border: 1px solid blue; padding: 2px; margin: 10px 0;">CDASH: No Match</div> <div style="border: 1px solid red; padding: 2px; margin: 10px 0;"> SDTM: RSREASND (6642040) </div>	<p>CHARACTER – Maximum Length = 200</p>

CRF Question	Value Domain
<p>Progressive/recurrent disease (7038806) CDE Short Name: PRGRCNT</p> <div data-bbox="289 321 769 373" style="border: 1px solid blue; padding: 2px; margin-bottom: 10px;"> <p>CDASH: No Match</p> </div> <div data-bbox="289 405 769 552" style="border: 1px solid red; padding: 2px;"> <p>SDTM: RSORRES (6642369) where RSTESTCD (6620609) = "PRGRCNT" and RSTEST (6620604) = "Progressive/recurrent disease"</p> </div>	<p>CHARACTER – Maximum Length = 30</p> <ul style="list-style-type: none"> <input type="checkbox"/> Biochemical recurrence – Biochemical Recurrent Malignant Neoplasm <input type="checkbox"/> Distant progression – Distant Disease Progression <input type="checkbox"/> First distant progression – First Distant Disease Progression <input type="checkbox"/> First distant recurrence – First Local Recurrent Malignant Neoplasm <input type="checkbox"/> First local progression – First Local Disease Progression <input type="checkbox"/> First local recurrence – First Local Recurrent Malignant Neoplasm <input type="checkbox"/> First regional progression – First Regional Disease Progression <input type="checkbox"/> First regional recurrence – First Regional Recurrent Malignant Neoplasm <input type="checkbox"/> Progression – Disease Progression <input type="checkbox"/> Progression/Recurrence (NOS) – Disease Progression Recurrent Malignant Neoplasm Not Otherwise Specified <input type="checkbox"/> Recurrence – Recurrent Malignant Neoplasm <input type="checkbox"/> Symptomatic deterioration – Symptomatic Deterioration
<p>Date of progression (or relapse) (7038807) CDE Short Name: RSPRGDT</p> <div data-bbox="289 1287 769 1339" style="border: 1px solid blue; padding: 2px; margin-bottom: 10px;"> <p>CDASH: No Match</p> </div> <div data-bbox="289 1371 769 1539" style="border: 1px solid red; padding: 2px;"> <p>SDTM: RSDTC (6651952) where RSTESTCD (6620609) = "PRGREEV", RSTEST (6620604) = "Progressive/recurrent disease evaluation"</p> </div>	<p>DATE – Maximum Length = 11</p>
<p>Sites of progression (7038808) CDE Short Name: TUPGDZST</p> <div data-bbox="289 1675 769 1728" style="border: 1px solid blue; padding: 2px; margin-bottom: 10px;"> <p>CDASH: No Match</p> </div> <div data-bbox="289 1759 769 1812" style="border: 1px solid red; padding: 2px;"> <p>SDTM: TULOC (6621372)</p> </div>	<p>CHARACTER – Maximum Length = 40</p> <p>List of 91 PVs</p>

CRF Question	Value Domain
<p>Other specify (7038809) CDE Short Name: TULOCX</p> <p>CDASH: No Match</p> <p>SDTM: TULOC (6621372)</p>	<p>CHARACTER – Maximum Length = 200</p>
<p>What was the method used to determine progression or recurrence? (7038810) CDE Short Name: TUEVALTP</p> <p>CDASH: No Match</p> <p>SDTM: TUMETHOD (No CDE)</p>	<p>CHARACTER – Maximum Length = 25</p> <ul style="list-style-type: none"> <input type="checkbox"/> Biomarkers – Biomarker <input type="checkbox"/> Clinical Assessment – Clinical Assessment Tool <input type="checkbox"/> Cytogenetics – Cytogenetic Analysis <input type="checkbox"/> Imaging – Imaging Technique <input type="checkbox"/> Immunological – Immunologic Technique <input type="checkbox"/> Laboratory Test(s) – Laboratory Procedure <input type="checkbox"/> Molecular – Molecular Analysis <input type="checkbox"/> Morphologic – Morphologic Finding <input type="checkbox"/> Pathologic – Pathologic Finding