# 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**<br>**(Partition Status)**<br>**CDE ID #**<br>**Short Name** | **Definition**<br>**CDISC Mapping and Instruction** | **Format** |
|---|---|---|
| Disease Response Most Recent Evaluation Date<br>(o)<br>7038803<br>RSMTRDT | The date disease response was evaluated, represented in an unambiguous date format (e.g., DD-MON-YYYY).<br><br>CDASH: No Match; SDTM: RSDTC (6651952) where RSTESTCD (6620609) = "OVRLRESP" and RSTEST (6620604) = "Overall Response" | DATE |
| Progressive Disease Or Recurrent Disease Present Indicator<br>(o)<br>7038804<br>RLPGIND | The indication of whether or not progressive disease or recurrent disease was present.<br><br>CDASH: No Match; SDTM: RSORRES (6642369) where RSTESTCD (6620609) = "RLPGIND" and RSTEST (6620604)= "Disease progress or relapse indicator" | CHARACTER. Use choice list. |

| **Field Name**<br>**(Partition Status)**<br>**CDE ID #**<br>**Short Name** | **Definition**<br>**CDISC Mapping and Instruction** | **Format** |
|---|---|---|
| Disease Response Most Recent Negation Evaluation Text<br>(o)<br>7038805<br>RSDZRPTX | The description of the reason disease status was not evaluated.<br><br>CDASH: No Match; SDTM: RSREASND (6642040) | CHARACTER |
| Progressive Disease Or Recurrent Disease Post Last Personal Contact Present Type<br>(o)<br>7038806<br>PRGRCNT | The indication of the type of progressive disease or recurrent disease.<br><br>CDASH: No Match; SDTM: RSORRES (6642369) where RSTESTCD (6620609) = "OVRLRESP" and RSTEST (6620604) = "Overall Response" | CHARACTER. Use choice list. |
| Progressive Disease or Recurrent Disease Evaluation Date<br>(o)<br>7038807<br>RSPRGDT | The date progressive disease or recurrent disease was identified, represented in an unambiguous date format (e.g., DD-MON-YYYY).<br><br>CDASH: No Match; SDTM: RSDTC (6651952) where RSTESTCD (6620609) = "OVRLRESP" and RSTEST (6620604) = "Overall Response" | DATE |
| Progressive Disease Anatomic Site<br>(o)<br>7038808<br>TUPGDZST | The anatomic site where progressive disease occurred.<br><br>CDASH: No Match; SDTM: TULOC (6621372) | CHARACTER. Use choice list. |
| Progressive Disease Anatomic Site Text<br>(o)<br>7038809<br>TULOCX | The anatomic site where progressive disease occurred not previously listed.<br><br>CDASH: No Match; SDTM: TULOC (6621372) | CHARACTER |
| Disease Response Evaluation Method Type<br>(o)<br>7038810<br>TUEVALTP | The method used to determine disease response.<br><br>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 |
|---|---|
| **Date of most recent disease status evaluation (7038803)**<br>**CDE Short Name:** RSMTRDT<br><br>CDASH: No Match<br><br>SDTM: RSDTC (6651952) where RSTESTCD (6620609) = "OVRLRESP" and RSTEST (6620604) = "Overall Response" | DATE – Maximum Length = 11 |
| **Did the patient's disease progress or relapse during the indicated period? (7038804)**<br>**CDE Short Name:** RLPGIND<br><br>CDASH: No Match<br><br>SDTM: RSORRES (6642369) where RSTESTCD (6620609) = "RLPGIND" and RSTEST (6620604) = "Disease progress or relapse indicator" | CHARACTER – Maximum Length = 2<br><br>☐ N – No<br>☐ NA – Not Applicable<br>☐ U – Unknown<br>☐ Y – Yes |
| **If evaluation was not done specify reason (7038805)**<br>**CDE Short Name:** RSDZRPTX<br><br>CDASH: No Match<br><br>SDTM: RSREASND (6642040) | CHARACTER – Maximum Length = 200 |

| CRF Question | Value Domain |
|---|---|
| **Progressive/recurrent disease (7038806)**<br>**CDE Short Name:** PRGRCNT<br><br>CDASH: No Match<br><br>SDTM: RSORRES (6642369) where RSTESTCD (6620609) = "OVRLRESP" and RSTEST (6620604) = "Overall Response" | CHARACTER – Maximum Length = 30<br><br>☐ Biochemical recurrence – Biochemical Recurrent Malignant Neoplasm<br>☐ Distant progression – Distant Disease Progression<br>☐ First distant progression – First Distant Disease Progression<br>☐ First distant recurrence – First Local Recurrent Malignant Neoplasm<br>☐ First local progression – First Local Disease Progression<br>☐ First local recurrence – First Local Recurrent Malignant Neoplasm<br>☐ First regional progression – First Regional Disease Progression<br>☐ First regional recurrence – First Regional Recurrent Malignant Neoplasm<br>☐ Progression – Disease Progression<br>☐ Progression/Recurrence (NOS) – Disease Progression Recurrent Malignant Neoplasm Not Otherwise Specified<br>☐ Recurrence – Recurrent Malignant Neoplasm<br>☐ Symptomatic deterioration – Symptomatic Deterioration |
| **Date of progression (or relapse) (7038807)**<br>**CDE Short Name:** RSPRGDT<br><br>CDASH: No Match<br><br>SDTM: RSDTC (6651952) where RSTESTCD (6620609) = "OVRLRESP" and RSTEST (6620604) = "Overall Response" | DATE – Maximum Length = 11 |
| **Sites of progression (7038808)**<br>**CDE Short Name:** TUPGDZST<br><br>CDASH: No Match<br><br>SDTM: TULOC (6621372) | CHARACTER – Maximum Length = 40<br><br>List of 91 PVs |

| CRF Question | Value Domain |
| --- | --- |
| **Other specify (7038809)**<br>**CDE Short Name:** TULOCX<br><br>CDASH: No Match<br><br>SDTM: TULOC (6621372) | CHARACTER – Maximum Length = 200 |
| **What was the method used to determine progression or recurrence? (7038810)**<br>**CDE Short Name:** TUEVALTP<br><br>CDASH: No Match<br><br>SDTM: TUMETHOD (No CDE) | CHARACTER – Maximum Length = 25<br><br>☐ Biomarkers – Biomarker<br>☐ Clinical Assessment – Clinical Assessment Tool<br>☐ Cytogenetics – Cytogenetic Analysis<br>☐ Imaging – Imaging Technique<br>☐ Immunological – Immunologic Technique<br>☐ Laboratory Test(s) – Laboratory Procedure<br>☐ Molecular – Molecular Analysis<br>☐ Morphologic – Morphologic Finding<br>☐ Pathologic – Pathologic Finding |