

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).

Diagnosis 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:

- MH – Medical History (v2.0)
- MI – Microscopic Findings (v2.0)
- 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:

- MH – Medical History (v3.3)
- MI – Microscopic Findings (v3.3)
- PR – Procedures (v3.3)
- TU – Tumor/Lesion Identification (v3.3)

Diagnosis 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
Medical History Event Start Date (m) 6409589 MHSTDAT	The start date of medical history event or condition represented in an unambiguous date format (e.g., DD-MON-YYYY). CDASH: MHSTDAT (6409589); SDTM: MHSTDTC (No CDE)	DATE
Medical History Event Dictionary- Derived/Standardized Term (c) 6421492 MHDECOD	The dictionary text description of MHTERM or the modified topic variable (MH MODIFY), if applicable. CDASH: MHDECOD (6421492); SDTM: MHDECOD (No CDE); Conditionality Rule: This is to be used for those trials in which there is a MedDRA reporting requirement.	CHARACTER

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Tumor Location SNOMED-CT Code (c) 6922527 TULOCSMD	The SNOMED-CT code for the site in or on the body at which the tumor identification test or result is performed or collected. CDASH: No Match; SDTM: No Match, Can be a supplemental qualifier; Conditionality Rule: This CDE is to be used for those trials that require collection of the primary tumor location using a SNOMED-CT code.	CHARACTER
Location of the Tumor/Lesion (c) 6621372 TULOC	The site in or on the body at which the tumor identification test or result is performed or collected. CDASH: No Match; SDTM: TULOC (6621372); Conditionality Rule: This CDE is to be used for those trials that are not using either the SNOMED-CT codes or ICD-O-3 codes to report location of the primary tumor.	CHARACTER. Use choice list.
Tumor Location ICD-O-3 Code (c) 6922526 TULOCICD	The ICD-O-3 code for the site in or on the body at which the tumor identification test or result is performed or collected. CDASH: No Match; SDTM: No Match, Can be a supplemental qualifier; Conditionality Rule: This CDE is to be used for those trials that require collection of the primary tumor location using a ICD-O-3 code.	CHARACTER. Use choice list.
Reviewing Pathologist Identifier Name (o) 64320 RVWG_PATHOLOGIS_NAME	Name of the reviewing pathologist. Not for FDA submission	CHARACTER

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Diagnosis Timepoint Name (o) 7008670 MHDATPT	The name of the timepoint when diagnosis was established. CDASH: MHEVD TYP (6421487); SDTM: MHEVD TYP (6421487)	CHARACTER. Use choice list.
Diagnosis Sequence Type (o) 7008671 MHDIA GTP	The order of diagnosis made in relation to the sequence of all diagnoses. CDASH: MHCAT (6413031); SDTM: MHCAT (No CDE)	CHARACTER. Use choice list.
Diagnosis Procedure Category Method Type (o) 7008672 PRASMETP	The category of the method used to establish a diagnosis. CDASH: PRSCAT (6413048); SDTM: PRSCAT (No CDE)	CHARACTER. Use choice list.
Neoplasm Histologic Grade (o) 7008673 MIHSTGRD	The degree of abnormality of cancer cells. CDASH: MIORRES (6421502); SDTM: MIORRES (No CDE) where MITESTCD (6620591) = "HISTGRD"	CHARACTER. Use choice list.
International Classification of Disease, Tenth Revision Diagnosis Code (o) 7008674 TUICD	The code that represents diagnosis using the International Classification of Disease, Tenth Revision. CDASH: No Match; SDTM: No Match, Can be a supplemental qualifier	NUMBER
World Health Organization Morphology Category (o) 7008675 TUWHOCT	The code that represents the histologic category of a tumor using the World Health Organization Classification of Tumors. CDASH: No Match; SDTM: No Match, Can be a supplemental qualifier	CHARACTER

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Neoplasm Histologic Type Name (o) 7008676 MHHISTNM	The name representing the histologic diagnosis of a tumor. CDASH: MHTERM (6421489); SDTM: MHTERM (No CDE)	CHARACTER. Use choice list.
Neoplasm Histologic Type Text (o) 7008677 MHHSTNMX	The name representing the histologic diagnosis of a tumor not previously listed. CDASH: MHTERM (6421489); SDTM: MHTERM (No CDE)	CHARACTER

Annotated CRF: Diagnosis 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: Diagnosis CDISC Aligned NCI Standard Template

Mandatory Questions

CRF Question	Value Domain
Date of current pathologic diagnosis (6409589) CDE Short Name: MHSTDAT <div style="border: 1px solid blue; padding: 2px; width: fit-content; margin: 5px 0;">CDASH: MHSTDAT (6409589)</div> <div style="border: 1px solid red; padding: 2px; width: fit-content; margin: 5px 0;">SDTM: MHSTDTC (No CDE)</div>	DATE – Maximum Length = 11

Conditional Questions

CRF Question	Value Domain
<p>MedDRA disease code (6421492) CDE Short Name: MHDECOD</p> <p>CDASH: MHDECOD (6421492)</p> <p>SDTM: MHDECOD (No CDE)</p>	<p>CHARACTER – Maximum Length = 200</p>
<p>Location of tumor (6922527) CDE Short Name: TULOCSMD</p> <p>CDASH: No Match</p> <p>SDTM: No Match, can be a supplemental qualifier</p>	<p>CHARACTER – Maximum Length = 100</p>
<p>Location of tumor (6621372) CDE Short Name: TULOC</p> <p>CDASH: No Match</p> <p>SDTM: TULOC (6621372);</p>	<p>CHARACTER – Maximum Length = 200</p> <p>List of 1113 PVs</p>
<p>Location of tumor (6922526) CDE Short Name: TULOCICD</p> <p>CDASH: No Match</p> <p>SDTM: No Match, can be a supplemental qualifier</p>	<p>CHARACTER – Maximum Length = 9</p> <p>List of 409 PVs</p>

Optional Questions

CRF Question	Value Domain
<p>Reviewing pathologist (64320) CDE Short Name: RVWG_PATHOLOGIS_NAME</p> <p style="border: 1px solid blue; padding: 2px; display: inline-block;">CDASH: Not for FDA submission</p> <p style="border: 1px solid red; padding: 2px; display: inline-block; margin-top: 10px;">SDTM: Not for FDA submission</p>	<p>CHARACTER – Maximum Length = 100</p>
<p>Diagnosis timepoint (7008670) CDE Short Name: MHDATPT</p> <p style="border: 1px solid blue; padding: 2px; display: inline-block;">CDASH: MHEVDTYP (6421487)</p> <p style="border: 1px solid red; padding: 2px; display: inline-block; margin-top: 10px;">SDTM: MHEVDTYP (6421487)</p>	<p>CHARACTER – Maximum Length = 25</p> <ul style="list-style-type: none"> <input type="checkbox"/> At Progression – Disease Progression <input type="checkbox"/> At Restaging – Restaging <input type="checkbox"/> Current Diagnosis – Current Diagnosis <input type="checkbox"/> Initial Diagnosis – First Diagnosis <input type="checkbox"/> Initial same as Current – Initial diagnosis same as current
<p>Diagnosis type (7008671) CDE Short Name: MHDIAGTP</p> <p style="border: 1px solid blue; padding: 2px; display: inline-block;">CDASH: MHCAT (6413031);</p> <p style="border: 1px solid red; padding: 2px; display: inline-block; margin-top: 10px;">SDTM: MHCAT (No CDE)</p>	<p>CHARACTER – Maximum Length = 40</p> <ul style="list-style-type: none"> <input type="checkbox"/> Primary – Primary Diagnosis <input type="checkbox"/> Secondary – Secondary Diagnosis <input type="checkbox"/> Treatment-related – Treatment related secondary malignancy Diagnosis <input type="checkbox"/> Unknown – Unknown
<p>Assessment method (7008672) CDE Short Name: PRASMETP</p> <p style="border: 1px solid blue; padding: 2px; display: inline-block;">CDASH: PRSCAT (6413048)</p> <p style="border: 1px solid red; padding: 2px; display: inline-block; margin-top: 10px;">SDTM: PRSCAT (No CDE)</p>	<p>CHARACTER – Maximum Length = 40</p> <ul style="list-style-type: none"> <input type="checkbox"/> Cytologic – Cytological Procedure <input type="checkbox"/> Histologic – Histological Procedure <input type="checkbox"/> Histologic and Cytologic – Histologic and Cytologic Procedures <input type="checkbox"/> Imaging – Imaging Technique

CRF Question	Value Domain
<p>Tumor grade (7008673) CDE Short Name: MIHSTGRD</p> <p>CDASH: MIORRES (6421502)</p> <p>SDTM: MIORRES (No CDE) where MITESTCD (6620591) = "HISTGRD"</p>	<p>CHARACTER – Maximum Length = 14</p> <ul style="list-style-type: none"> <input type="checkbox"/> G1 – Well Differentiated <input type="checkbox"/> G2 – Moderately Differentiated <input type="checkbox"/> G3 – Poorly Differentiated <input type="checkbox"/> G4 – Undifferentiated Histology <input type="checkbox"/> GB – Borderline Histologic Grade <input type="checkbox"/> GX – Grade Cannot be Assessed <input type="checkbox"/> High Grade – High Grade <input type="checkbox"/> Intermediate Grade – Intermediate Grade <input type="checkbox"/> Low Grade – Low Grade <input type="checkbox"/> Not Applicable – Not Applicable
<p>ICD-10 Code (7008674) CDE Short Name: TUICD</p> <p>CDASH: No Match</p> <p>SDTM: No Match, can be a supplemental qualifier</p>	<p>NUMBER – Maximum Length = 15</p>
<p>Morphology (Histology) (7008675) CDE Short Name: TUWHOCT</p> <p>CDASH: No Match</p> <p>SDTM: No Match, can be a supplemental qualifier</p>	<p>CHARACTER – Maximum Length = 200</p>
<p>Histology (7008676) CDE Short Name: MHHISTNM</p> <p>CDASH: MHTERM (6421489)</p> <p>SDTM: MHTERM (No CDE)</p>	<p>CHARACTER – Maximum Length = 100</p> <p>List of 479 PVs</p>
<p>Histology, other (7008677) CDE Short Name: MHHSTNMX</p> <p>CDASH: MHTERM (6421489)</p> <p>SDTM: MHTERM (No CDE)</p>	<p>CHARACTER – Maximum Length = 200</p>