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).

Metastasis 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)

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)
- TU – Tumor/Lesion Identification (v3.3)

Metastasis 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**
Metastatic Tumor Identifier Location Name (c) 7008678 METLOC	The anatomic site name of the identified metastatic tumor. CDASH: No Match; SDTM: TULOC (6621372) where TUTESTCD (6659640) = "METLOC"; Conditionality Rule: This CDE is to be used based on the reporting requirements of the clinical study to list the metastatic sites of involvement using NCI list of anatomic sites.	CHARACTER. Use choice list.
Metastatic Disease Involvement Anatomic Site ICD-O-3 Code (c) 7008679 METICDO3	The code that represents the metastatic tumor location using the ICD-O-3 coding system. CDASH: No Match; SDTM: No Match, Can be a supplemental qualifier; Conditionality Rule: This CDE is to be used based on the reporting requirements of the clinical study to list the metastatic sites of involvement using ICD-O-3 codes.	CHARACTER. Use choice list.

Field Name **(Partition Status)** **CDE ID #** **Short Name**	**Definition** **CDISC Mapping and Instruction**	**Format**
Metastatic Neoplasm Involvement Indicator (o) 7008680 MHMTDZNY	The indication of whether metastatic disease was present. CDASH: MHOCCUR (6401581) where MHTERM (6421489) = "Metastatic disease" and MHPRESP (6401586) = Y; SDTM: MHOCCUR (No CDE) where MHTERM = "Metastatic disease" and MHPRESP = Y	CHARACTER. Use choice list.
Metastatic Tumor Identifier Laterality Name (o) 7008681 TULATRNM	The name that describes the laterality of the metastatic tumor location. CDASH: No Match; SDTM: TULAT (6648992)	CHARACTER. Use choice list.

Annotated CRF: Metastasis 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: Metastasis CDISC Aligned NCI Standard Template

Conditional Questions

CRF Question	Value Domain
Metastatic sites of involvement (7008678) **CDE Short Name:** METLOC CDASH: No Match SDTM: TULOC (6621372) where TUTESTCD (6659640) = "METLOC"	CHARACTER – Maximum Length = 120 List of 378 PVs
Metastatic sites of involvement (7008679) **CDE Short Name:** METICDO3 CDASH: No Match SDTM: No Match, Can be a supplemental qualifier	CHARACTER – Maximum Length = 7 List of 409 PVs

Optional Questions

CRF Question	Value Domain
Metastatic disease involvement (7008680) **CDE Short Name:** MHMTDZNY CDASH: MHOCCUR (6401581) where MHTERM (6421489) = "Metastatic disease" and MHPRESP (6401586) = Y SDTM: MHOCCUR (No CDE) where MHTERM = "Metastatic disease" and MHPRESP = Y	CHARACTER – Maximum Length = 2 ☐ N – No ☐ NA – Not Applicable ☐ U – Unknown ☐ Y – Yes
Laterality (7008681) **CDE Short Name:** TULATRNM CDASH: No Match SDTM: TULAT (6648992)	CHARACTER – Maximum Length = 9 ☐ Anterior – Anterior ☐ Bilateral – Bilateral ☐ Caudal – Caudal ☐ Contralateral – Contralateral ☐ Cranial – cranial ☐ Ipsilateral – Ipsilateral ☐ Lateral – Lateral ☐ Left – Left ☐ Midline – Midline ☐ Posterior – Posterior ☐ Right – Right ☐ Unilateral – Unilateral