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 Intervention 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:

- MI – Microscopic Findings (v2.0)

Mapping to the SDTM:

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

- MI – Microscopic Findings (v3.3)
- BS – Biospecimen Findings (SDTMIG-PGx v1.0)

Diagnosis Intervention 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**
Biospecimen International Classification of Disease for Oncology, Third Edition Anatomic Site Code (m) 7038757 MISPCICD	The ICD-O-3 code that represents the anatomic site where biospecimens were collected. CDASH: No Match; SDTM: No Match, Can be a supplemental qualifier in SDTM	NUMBER
Microscopic Findings Specimen Type (m) 7273587 MISPECMN	The type of specimen used for a measurement or testing. CDASH: MISPEC (6409688); SDTM: MISPEC (No CDE)	CHARACTER. Use choice list.
Date of Specimen Collection (m) 6409597 MIDAT	The date of specimen collection represented in an unambiguous date format (e.g., DD-MON-YYYY). CDASH: MIDAT (6409597); SDTM: MIDTC (No CDE)	DATE

Field Name **(Partition Status)** **CDE ID #** **Short Name**	**Definition** **CDISC Mapping and Instruction**	**Format**
Biospecimen Collection Method Name (o) 7038758 MICOLLNM	The name of the biospecimen collection method. CDASH: No Match; SDTM: No Match	CHARACTER. Use choice list.
Biospecimen Fixative Type (o) 7038759 FIXNAM	The type of fixative used to preserve a biospecimen. CDASH: No Match; SDTM: BSORRES (No CDE) where BSTESTCD (No CDE) = "FIXNAM" and BSTEST (No CDE) = "Fixative Name"	CHARACTER. Use choice list.
Surgeon Name (o) 64344 SURGEON_NAME	the free text field for the name of operating surgeon. Not for FDA submission	CHARACTER

Annotated CRF: Diagnosis Intervention 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 Intervention CDISC Aligned NCI Standard Template

Mandatary Questions

CRF Question	Value Domain
Specimen Tissue Site (7038757) **CDE Short Name:** MISPCICD CDASH: No Match SDTM: No Match, Can be a supplemental qualifier in SDTM	NUMBER – Maximum Length = 15
Specimen Tissue Type (7273587) **CDE Short Name:** MISPECMN CDASH: MISPEC (6409688) SDTM: MISPEC (No CDE)	CHARACTER – Maximum Length = 3 List of 63 PVs
Sample Collection Date (6409597) **CDE Short Name:** MIDAT CDASH: MIDAT (6409597) SDTM: MIDTC (No CDE)	DATE – Maximum Length = 11

Optional Questions

CRF Question	Value Domain
Procedure (7038758) **CDE Short Name:** MICOLLNM CDASH: No Match SDTM: No Match	CHARACTER – Maximum Length = 50 List of 163 PVs
Fixative (7038759) **CDE Short Name:** FIXNAM CDASH: No Match SDTM: BSORRES (No CDE) where BSTESTCD (No CDE) = "FIXNAM" and BSTEST (No CDE) = "Fixative Name"	CHARACTER – Maximum Length = 50 ☐ Acetone – Acetone ☐ Alcohol – Alcohol ☐ Formalin – Formalin ☐ Glutaraldehyde – Glutaraldehyde ☐ None – A specimen has no preservative and is processed as fresh tissue ☐ OCT media – OCT media ☐ Other – Other ☐ RNAlater – RNAlater ☐ Saline – Saline ☐ Unknown – Unknown
Surgeon Name (64344) **CDE Short Name:** SURGEON_NAME CDASH: Not for FDA submission SDTM: Not for FDA submission	CHARACTER – Maximum Length = 100