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 Administrative 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 Administrative 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**
Data Source Type (o) 7008664 MILBSRC	The response describing the data source of microscopic findings. CDASH: No Match; SDTM: No Match	CHARACTER. Use choice list.
Laboratory/Vendor Name (o) 6411557 MINAM	The name or identifier of the vendor (e.g., laboratory) that provided the test results. CDASH: MINAM (6411557); SDTM: MINAM (No CDE)	CHARACTER
Microscopic Findings Reference ID (o) 6421498 MIREFID	An internal or external identifier such as specimen identifier. CDASH: MIREFID (6421498); SDTM: MIREFID (No CDE)	CHARACTER

Field Name **(Partition Status)** **CDE ID #** **Short Name**	**Definition** **CDISC Mapping and Instruction**	**Format**
Pathologic Finding Report Date (o) 7008665 MILBDT	The date a pathology report is issued represented in an unambiguous date format (e.g., DD-MON-YYYY). CDASH: No Match; SDTM: No Match	DATE
Reviewing Pathologist Identifier Name (o) 64320 RVWG_PATHOLOGIS_NAME	Name of the reviewing pathologist. Not for FDA submission	CHARACTER
Pathology Finding Report Identifier (o) 7008667 MIPSRPID	The unique identifier for a pathology report. CDASH: No Match; SDTM: No Match	CHARACTER
Specimen Submission Number (o) 7008668 BSSPCCNT	The numeric value indicating the number of specimen samples submitted. CDASH: No Match; SDTM: BSORRES (No CDE) where BSTESTCD = "SPCOUNT" and BSTEST = "Number of specimens submitted"	NUMBER

Annotated CRF: Diagnosis Administrative 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 Administrative CDISC Aligned NCI Standard Template

Optional Questions

CRF Question	Value Domain
Laboratory Data Source (7008664) **CDE Short Name:** MILBSRC CDASH: No Match SDTM: No Match	CHARACTER – Maximum Length = 50 ☐ Central Lab – Central Laboratory ☐ Other – Other, specify ☐ Referral Lab – Referral Laboratory ☐ Sponsor Lab – Sponsor Laboratory
Performing Laboratory Name (6411557) **CDE Short Name:** MINAM CDASH: MINAM (6411557) SDTM: MINAM (No CDE)	CHARACTER – Maximum Length = 200
Block # (6421498) **CDE Short Name:** MIREFID CDASH: MIREFID (6421498) SDTM: MIREFID (No CDE)	CHARACTER – Maximum Length = 40
Report Date (7008665) **CDE Short Name:** MILBDT CDASH: No Match SDTM: No Match	DATE – Maximum Length = 11

CRF Question	Value Domain
Reviewing pathologist (64320) **CDE Short Name:** RVWG_PATHOLOGIS_NAME CDASH: Not for FDA submission SDTM: Not for FDA submission	CHARACTER – Maximum Length = 100
Path Report ID# (7008667) **CDE Short Name:** MIPSRPID CDASH: No Match SDTM: No Match	CHARACTER – Maximum Length = 40
Number of specimens submitted (7008668) **CDE Short Name:** BSSPCCNT CDASH: No Match SDTM: BSORRES (No CDE) where BSTESTCD = "SPCOUNT" and BSTEST = "Number of specimens submitted"	NUMBER – Maximum Length = 10