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).

Consent 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:

- DS – Disposition (v2.0)

Mapping to the SDTM:

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

- DS – Disposition (v3.3)

Consent 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**
Informed Consent Complete Date (m) 6943360 DSICFSDT	The date of the informed consent form was signed represented in an unambiguous date format (e.g., DD-MON-YYYY). CDASH: DSTERM (6355980), DSSTDAT (6384212); SDTM: DSSTDTC where DSTERM='INFORMED CONSENT OBTAINED' and DSDECOD = 'INFORMED CONSENT OBTAINED' and DSCAT = 'PROTOCOL MILESTONE'	DATE

Field Name **(Partition Status)** **CDE ID #** **Short Name**	**Definition** **CDISC Mapping and Instruction**	**Format**
Informed Consent Complete Indicator (o) 6943361 DSICFCNY	An indication whether or not the informed form was completed. CDASH: DSTERM (6355980) where DSCAT (6355998) = "PROTOCOL MILESTONE"; SDTM: If Yes, DSTERM='INFORMED CONSENT OBTAINED' and DSDECOD = 'INFORMED CONSENT OBTAINED' and DSCAT = 'PROTOCOL MILESTONE'	CHARACTER. Use choice list.
Informed Consent Complete Type (o) 6943362 DSICFTYP	The type of informed consent completed. CDASH: DSSCAT (6384142) where DSCAT (6355998) = "PROTOCOL MILESTONE"; SDTM: DSSCAT where DSDECOD = 'INFORMED CONSENT OBTAINED' and DSCAT = 'PROTOCOL MILESTONE'	CHARACTER. Use choice list.
Informed Consent Complete Text (o) 6943363 DSICFTPX	The type of informed consent completed not previously listed. CDASH: DSSCAT (6384142) where DSCAT (6355998) = "PROTOCOL MILESTONE"; SDTM: DSSCAT where DSDECOD = 'INFORMED CONSENT OBTAINED' and DSCAT = 'PROTOCOL MILESTONE'	CHARACTER
Informed Consent Language Code (o) 6943364 DSICLGCD	The code that represents the language of the informed consent. CDASH: No match; SDTM: No match, Can be a supplemental qualifier in SDTM	CHARACTER

Field Name **(Partition Status)** **CDE ID #** **Short Name**	**Definition** **CDISC Mapping and Instruction**	**Format**
Informed Consent Legally Acceptable Representative Type (o) 6943365 DSICRLTP	The description of the individual authorized to consent for participation in the clinical trial. CDASH: No match; SDTM: No match, Can be a supplemental qualifier in SDTM	CHARACTER. Use choice list

Annotated CRF: Consent 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: Consent CDISC Aligned NCI Standard Template

Mandatory Questions

CRF Question	Value Domain
Date consent signed (6943360) **CDE Short Name:** DSICFSDT CDASH: DSTERM (6355980), DSSTDAT (6384212) SDTM: DSSTDTC where DSTERM='INFORMED CONSENT OBTAINED' and DSDECOD = 'INFORMED CONSENT OBTAINED' and DSCAT = 'PROTOCOL MILESTONE'	DATE – Maximum Length = 11

Optional Questions

CRF Question	Value Domain
Consented? (6943361) **CDE Short Name:** DSICFCNY CDASH: DSTERM (6355980) where DSCAT (6355998) = "PROTOCOL MILESTONE" SDTM: If Yes, DSTERM='INFORMED CONSENT OBTAINED' and DSDECOD = 'INFORMED CONSENT OBTAINED' and DSCAT = 'PROTOCOL MILESTONE'	CHARACTER – Maximum Length = 2 ☐ N – No ☐ NA – Not Applicable ☐ U – Unknown ☐ Y – Yes
Consent type (6943362) **CDE Short Name:** DSICFTYP CDASH: DSSCAT (6384142) where DSCAT (6355998) = "PROTOCOL MILESTONE" SDTM: DSSCAT where DSDECOD = 'INFORMED CONSENT OBTAINED' and DSCAT = 'PROTOCOL MILESTONE'	CHARACTER – Maximum Length = 50 ☐ Biomarker – Biomarker ☐ Correlative – Correlative Study ☐ Donor – Donor ☐ Genetic marker – Genetic Marker ☐ Medical Imaging – Imaging Technique ☐ Other – Other ☐ PK – Pharmacokinetics ☐ Quality of Life – Quality of Life ☐ Record Release – Record Release ☐ Screening – Screening ☐ Standard of Care – Standard Care ☐ Study Participation – Clinical Study Participation ☐ Tissue Bank – Tissue Collection
Consent type specify (6943363) **CDE Short Name: DSICFTPX** CDASH: DSSCAT (6384142) where DSCAT (6355998) = "PROTOCOL MILESTONE" SDTM: DSSCAT where DSDECOD = 'INFORMED CONSENT OBTAINED' and DSCAT = 'PROTOCOL MILESTONE'	CHARACTER – Maximum Length = 200

CRF Question	Value Domain
Consent language (6943364) **CDE Short Name:** DSICLGCD CDASH: No match SDTM: No match, Can be a supplemental qualifier in SDTM	CHARACTER – Maximum Length = 3
Who consented? (6943365) **CDE Short Name: DSICRLTP** CDASH: No match SDTM: No match	CHARACTER – Maximum Length = 20 ☐ Legal Representative – Legal Representation ☐ Patient – Patient