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).

Registration 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:

- DM – Demographics (v2.0)
- 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:

- DM – Demographics (v3.3)
- DS – Disposition (v3.3)
- TS – Trial Summary (v3.3)

Registration 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**
Study Identifier (m) 6380045 STUDYID	A unique identifier for a study. CDASH: STUDYID (6380045); SDTM: STUDYID (No CDE)	CHARACTER
Study Registration Date (m) 7068980 DSREGDT	The date the patient was registered for consideration to participate in a clinical study represented in an unambiguous date format (e.g., DD-MON-YYYY). CDASH: DSSTDAT (6384212) where DSTERM (6355980) = "REGISTRATION"; SDTM: DSSTDTC where DSTERM = "REGISTRATION", DSDECOD = 'OTHER' and DSCAT = 'OTHER EVENT'	DATE

Field Name **(Partition Status)** **CDE ID #** **Short Name**	**Definition** **CDISC Mapping and Instruction**	**Format**
Participant Prior Clinical Study Participation Ind-3 (c) 2746466 PART_PR_CL_ST_PT_IND	The yes/no/unknown indicator that asks whether the participant was on a prior protocol with this group. Conditionality Rule: In an intergroup study organization, in which a person may have been enrolled in another study within the group.; Not for FDA submission	CHARACTER. Use choice list.
Participant Prior Clinical Study Identifier (c) 2822790 PART_PRIOR_CLSTDY_ID	The unique numeric or alphanumeric identification that was assigned to a participant from a previous study. Conditionality Rule: In an intergroup study organization, in which a person may have been enrolled in another study within the group.; Not for FDA submission	CHARACTER
Stratification Factors Text (c) 7068992 STRATFCT	The description of pre-treatment factors by which patients are segregated to assure equal balance prior to randomization to the intervention arms of a clinical trial. CDASH: No Match; SDTM: TSVAL (No CDE) where TSPARM (No CDE) = "Stratification Factors" and TSPARMCD (No CDE) = "STRATFCT"; Conditionality Rule: Using in protocols that include stratification factors.	CHARACTER

Field Name **(Partition Status)** **CDE ID #** **Short Name**	**Definition** **CDISC Mapping and Instruction**	**Format**
Patient Subgroup Code (c) 1925 PT_SUBGRP_CD	the subgroup (stratum) is a unique patient characteristic that will be utilized to uniformly group patients for separate analysis or treatment. Each subgroup should have a unique code for identification. The investigator will provide a code (up tp 10 characters) for each subgroup with the Protocol Submission Checklist. Conditionality Rule: The element is mandated by the sponsor, specifically the Cancer Treatment Evaluation Program (CTEP) in this case.; Not for FDA submission	CHARACTER
Registration Name Institution Institution Name (c) 2551737 2551668v1.0:2178533v1.0	Name of the registering institution. Conditionality Rule: Use of element is mandated by the sponsor for regulatory reporting.; Not for FDA submission	CHARACTER
Patient Randomization Date (c) 7068993 DSRANDT	The date the patient was assigned to treatment and/or control groups to participate in a clinical trial represented in an unambiguous date format (e.g., DD-MON-YYYY). CDASH: DSSTDAT (6384212) where DSTERM (6355980) = "RANDOMIZATION"; SDTM: DSSTDTC where DSTERM = "RANDOMIZATION", DSDECOD = 'RANDOMIZED', and DSCAT = 'PROTOCOL MILESTONE' Conditionality Rule: Use in randomized trials only.	DATE

Field Name **(Partition Status)** **CDE ID #** **Short Name**	**Definition** **CDISC Mapping and Instruction**	**Format**
Registering Institution Identification Code (o) 2003307 REG_INST_ID_CD	Code that uniquely identifies the institution where the research participant was registered in a clinical trial. Not for FDA Submission	CHARACTER
Treating Physician Name (o) 62749 TREATING_DR_NAME	the name of the physician treating a person for specific medical conditions/problems. Not for FDA Submission	CHARACTER
Responsible Person Name (o) 2006163 RSPBLPERSON_NAME	The legal name of the person who documented information on the case report form or other document. Not for FDA Submission	CHARACTER
Responsible Person Phone Number (o) 2175 RSPBL_PERSON_PH_NUM	the telephone number to use to contact the person who documented the information on the case report form. Not for FDA Submission	CHARACTER
Responsible Person Fax Number (o) 2176 RSPBL_PERSON_FAX_NUM	the telephone number to reach a fax machine for the person who documented the information on the case report form. Not for FDA Submission	CHARACTER
Clinical Research Associate Responsible Person Name (o) 2452692 CRA_RSPBLPERSON_NAME	The legal name of the clinical research associate who documented information on the case report form or other document. Not for FDA Submission	CHARACTER

Field Name **(Partition Status)** **CDE ID #** **Short Name**	**Definition** **CDISC Mapping and Instruction**	**Format**
Clinical Research Associate Person Telephone Number (o) 2661003 CRA_PER_TEL_NUM	the telephone number of the person who is employed by a study sponsor or by a contract research organization (CRO), operates independently from the clinical study site and functions as a monitor, and/or auditor, and/or a project director within a particular trial or institution. Not for FDA Submission	CHARACTER
Clinical Research Associate Person Fax Number (o) 2661012 CRA_PERS_FAX_NUM	the facsimile number, a telecommunications technology used to transfer copies of documents using devices operating over the telephone network, of the contact the person who is employed by a study sponsor or by a contract research organization (CRO), operates independently from the clinical study site and functions as a monitor, and/or auditor, and/or a project director within a particular trial or institution. Not for FDA Submission	CHARACTER
Treatment Projected Begin Date (o) 657 TX_PROJECTED_BEGDT	the month, day, and year on which protocol treatment is scheduled to begin. Not for FDA Submission	DATE
Specialist Physician Name (o) 2746480 SPEC_MD_NM	The physician involved in the protocol treatment working with the treating physician specializing in a treatment. Not for FDA Submission	CHARACTER
Healthcare Facility Participant Identifier (o) 2746468 HLTHC_FACL_PART_ID	The unique numeric or alphanumeric designation assigned by a healthcare facility used to link to the participant's medical record. Not for FDA Submission	ALPHANUMERIC

Annotated CRF: Registration 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: Registration CDISC Aligned NCI Standard Template

Mandatary Questions

CRF Question	Value Domain
Study Identifier (6380045) **CDE Short Name:** STUDYID CDASH: STUDYID (6380045) SDTM: STUDYID (No CDE)	CHARACTER – Maximum Length = 40
Date of Registration (7068980) **CDE Short Name:** DSREGDT CDASH: DSSTDAT (6384212) where DSTERM (6355980) = "REGISTRATION" SDTM: DSSTDTC where DSTERM = "REGISTRATION", DSDECOD = 'OTHER' and DSCAT = 'OTHER EVENT'	DATE – Maximum Length = 11

Conditional Questions

CRF Question	Value Domain
Was the participant on a prior study with this group? (2746466) **CDE Short Name:** PART_PR_CL_ST_PT_IND CDASH: Not for FDA submission SDTM: Not for FDA submission	CHARACTER – Maximum Length = 7 ☐ No – No ☐ Unknown – Unknown ☐ Yes – Yes
What was the prior study participant identifier? (2822790) **CDE Short Name:** PART_PRIOR_CLSTDY_ID CDASH: Not for FDA submission SDTM: Not for FDA submission	CHARACTER – Maximum Length = 35
Stratification Factors (protocol specific) (7068992) **CDE Short Name:** STRATFCT CDASH: No Match SDTM: TSVAL (No CDE) where TSPARM (No CDE) = "Stratification Factors" and TSPARMCD (No CDE) = "STRATFCT"	CHARACTER – Maximum Length = 200
Participant Subgroup Code (1925) **CDE Short Name:** PT_SUBGRP_CD CDASH: Not for FDA submission SDTM: Not for FDA submission	CHARACTER – Maximum Length = 10
Registering Institution Name (2551737) **CDE Short Name:** 2551668v1.0:2178533v1.0 CDASH: Not for FDA submission SDTM: Not for FDA submission	CHARACTER – Maximum Length = 100

CRF Question	Value Domain
Randomization Date (7068993) **CDE Short Name:** DSRANDT CDASH: DSSTDAT (6384212) where DSTERM (6355980) = "RANDOMIZATION" SDTM: DSSTDTC where DSTERM = "RANDOMIZATION", DSDECOD = 'RANDOMIZED', and DSCAT = 'PROTOCOL MILESTONE'	DATE – Maximum Length = 11

Optional Questions

CRF Question	Value Domain
Registering Institution Code (2003307) **CDE Short Name:** REG_INST_ID_CD CDASH: Not for FDA submission SDTM: Not for FDA submission	CHARACTER – Maximum Length = 10
Treating physician (62749) **CDE Short Name:** TREATING_DR_NAME CDASH: Not for FDA submission SDTM: Not for FDA submission	CHARACTER – Maximum Length = 100
Person Completing Form (2006163) **CDE Short Name:** RSPBLPERSON_NAME CDASH: Not for FDA submission SDTM: Not for FDA submission	CHARACTER – Maximum Length = 100
Person Completing Form, Phone (2175) **CDE Short Name:** RSPBL_PERSON_PH_NUM CDASH: Not for FDA submission SDTM: Not for FDA submission	CHARACTER – Maximum Length = 20
Person Completing Form, Fax (2176) **CDE Short Name:** RSPBL_PERSON_FAX_NUM CDASH: Not for FDA submission SDTM: Not for FDA submission	CHARACTER – Maximum Length = 14

CRF Question	Value Domain
Responsible CRA (2452692) **CDE Short Name:** CRA_RSPBLPERSON_NAME CDASH: Not for FDA submission SDTM: Not for FDA submission	CHARACTER – Maximum Length = 100
CRA phone number (2661003) **CDE Short Name:** CRA_PER_TEL_NUM CDASH: Not for FDA submission SDTM: Not for FDA submission	CHARACTER – Maximum Length = 20
CRA fax number (2661012) **CDE Short Name:** CRA_PERS_FAX_NUM CDASH: Not for FDA submission SDTM: Not for FDA submission	CHARACTER – Maximum Length = 14
Projected Start Date of Treatment (657) **CDE Short Name:** TX_PROJECTED_BEGDT CDASH: Not for FDA submission SDTM: Not for FDA submission	DATE – Maximum Length = 8
Specialist Physician Name (2746480) **CDE Short Name:** SPEC_MD_NM CDASH: Not for FDA submission SDTM: Not for FDA submission	CHARACTER – Maximum Length = 100
Participant Local Identifier (2746468) **CDE Short Name:** HLTHC_FACL_PART_ID CDASH: Not for FDA submission SDTM: Not for FDA submission	ALPHANUMERIC – Maximum Length = 10