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).

Enrollment 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)

Enrollment 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**
Subject Identifier for the Study (m) 6380049 SUBJID	A unique subject identifier within a site and a study. CDASH: SUBJID (6380049); SDTM: SUBJID (No CDE)	CHARACTER
Disposition Event Start Date (m) 6384212 DSSTDAT	The date of the specified protocol milestone (e.g. informed consent, randomization) or disposition event (e.g. study completion or discontinuation) represented in an unambiguous date format (e.g., DD-MON-YYYY). CDASH: DSSTDAT (6384212) where DSTERM (6355980) = "ENROLLMENT"; SDTM: DSSTDTC where DSTERM = "ENROLLMENT", DSDECOD = 'ENTERED INTO TRIAL', and DSCAT = 'PROTOCOL MILESTONE'	DATE

Field Name **(Partition Status)** **CDE ID #** **Short Name**	**Definition** **CDISC Mapping and Instruction**	**Format**
Description of Actual Arm (c) 6618607 ACTARM	The name of the actual arm of a trial or study. CDASH: No Match; SDTM: ACTARM (6618607); Conditionality Rule: Element is required by sponsor.	CHARACTER
Patient Multiple Clinical Trials Cooperative Group Identifier Number (c) 2465308 PT_M_CTCOOPGP_ID_NUM	a numeric sequent used to uniquely identify an individual participating in an intergroup clinical protocol. Conditionality Rule: Element is required by sponsor.; Not for FDA submission	CHARACTER
Protocol Registrar Name (o) 2172 PROT_REG_NAME	The name of the individual responsible for registering a patient for participation in a clinical trial. Not for FDA Submission	CHARACTER

Annotated CRF: Enrollment 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: Enrollment CDISC Aligned NCI Standard Template

Mandatary Questions

CRF Question	Value Domain
Study Participant Identifier (6380049) **CDE Short Name:** SUBJID CDASH: SUBJID (6380049) SDTM: SUBJID (No CDE)	CHARACTER – Maximum Length = 40
Enrollment Date (6384212) **CDE Short Name:** DSSTDAT CDASH: DSSTDAT (6384212) where DSTERM (6355980) = "ENROLLMENT" SDTM: DSSTDTC where DSTERM = "ENROLLMENT", DSDECOD = 'ENTERED INTO TRIAL', and DSCAT = 'PROTOCOL MILESTONE'	DATE – Maximum Length 11

Conditional Questions

CRF Question	Value Domain
Treatment Arm (6618607) **CDE Short Name:** ACTARM CDASH: No Match SDTM: ACTARM (6618607)	CHARACTER – Maximum Length = 200
Intergroup Participant Identifier (2465308) **CDE Short Name:** PT_M_CTCOOPGP_ID_NUM CDASH: Not for FDA submission SDTM: Not for FDA submission	CHARACTER – Maximum Length = 20

Optional Questions

CRF Question	Value Domain
Site Registrar (2172) **CDE Short Name:** PROT_REG_NAME CDASH: Not for FDA Submission SDTM: Not for FDA Submission	CHARACTER – Maximum Length = 100