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).

Off Treatment 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)

Off Treatment 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**
Off Treatment Date (m) 6962817 DSOTXDT	The date of completion, progression, death, or decision to discontinue therapy. CDASH: DSTERM (6355980) and DSSTDAT (6384212); SDTM: DSSTDTC (No CDE) where DSTERM = "OFF TREATMENT"	DATE
Off Treatment Reason (m) 6936206 DSOTXRCD	Code that represents the reason a participant did not complete treatment. CDASH: DSOTXRCD (6936206); SDTM: DSDECOD (No CDE)	CHARACTER. Use choice list
Off Treatment Other, Specify (m) 6936221 DSDECODX	Text description of another reason a participant did not complete treatment not already specified. CDASH: DSDECODX (6936221); SDTM: DSTERM (No CDE)	CHARACTER

Annotated CRF: Off Treatment 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: Off Treatment CDISC Aligned NCI Standard Template

Mandatary Questions

CRF Question	Value Domain
Off Treatment Date (6962817) **CDE Short Name:** DSOTXDT CDASH: DSTERM (6355980) and DSSTDAT (6384212) SDTM: DSSTDTC (No CDE) where DSTERM = "OFF TREATMENT"	DATE – Maximum Length = 11
Off Treatment Reason (6936206) **CDE Short Name:** DSOTXRCD CDASH: DSOTXRCD (6936206) SDTM: DSDECOD (No CDE)	CHARACTER – Maximum Length = 2 ☐ 01 – Treatment completed per protocol criteria ☐ 02 – Disease progression, relapse during active treatment ☐ 03 – Adverse event/side effects/complications ☐ 04 – Death on Study ☐ 05 – Patient withdrawal/refusal after beginning protocol therapy ☐ 06 – Patient withdrawal/refusal prior to beginning a protocol therapy ☐ 07 – Alternative Therapy ☐ 08 – Patient off-treatment for other complicating disease ☐ 10 – Lost to Follow-up ☐ 11 – Cytogenetic resistance ☐ 12 – Disease progression before active treatment ☐ 13 – No treatment, per protocol criteria ☐ 98 – Other

CRF Question	Value Domain
Off Treatment Other, Specify (6936221) **CDE Short Name:** DSDECODX CDASH: DSDECODX (6936221) SDTM: DSTERM (No CDE)	CHARACTER – Maximum Length = 200