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).

Protocol Deviations 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:

- DV – Protocol Deviations (v2.0)

Mapping to the SDTM:

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

- DV – Protocol Deviations (v3.3)

Protocol Deviations 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**
Protocol Deviation Notification Date (c) 2435009 PROT_DEV_NOTIF_DT	Date on which the local study team and/or site PI became aware of the deviation. Study team members may include co-investigators, research nurses, study coordinators, CRAs, CRCs, co-investigators, or data managers at a site. [Manually-curated] Conditionality Rule: Condition is for use in multi-site trials, or when multiple teams may be involved in the conduct of a trial.; Not for FDA submission	DATE
Deviation Start Date (o) 6409584 DVSTDAT	The start date of deviation represented in an unambiguous date format (e.g., DD-MON-YYYY). CDASH: DVSTDAT (6409584); SDTM DVSTDTC (No CDE)	DATE

Field Name **(Partition Status)** **CDE ID #** **Short Name**	**Definition** **CDISC Mapping and Instruction**	**Format**
Protocol Deviation Reported Term (o) 6414219 DVTERM	The reported or pre-specified name of the protocol deviation. CDASH: DVTERM (6414219); SDTM: DVTERM (No CDE)	CHARACTER
Protocol Deviation Severity Type (o) 2740401 PROT_DEV_SEV_TP	A categorization to indicate a level of severity for a protocol deviation. [Manually-curated] Conditionality Rule: Element is required by sponsor.; Not for FDA submission	CHARACTER. Use choice list
Protocol Deviation Category Text (o) 7068996 DVCATX	The grouping of protocol deviations that occurred not previously listed. CDASH: No Match; SDTM: DVCAT (No CDE)	CHARACTER
Treating Physician Or Participating Investigator Name (o) 2740424 TX_MD_PART_INV_NM	Text name for an investigator or physician involved in a study (may be the registering physician or investigator and/or the treating physician for a study participant. [Manually-curated] Not for FDA Submission	CHARACTER
Protocol Deviation Category (o) 7068997 DVCAT	The grouping of protocol deviations that occurred. CDASH: DVCAT (6413029); SDTM: DVCAT (No CDE)	CHARACTER. Use choice list
Protocol Deviation Action Text (o) 2435042 PROT_DEV_ACTION_TXT	The free text field used to describe the corrective actions initiated by the site to address a specific deviation (i.e. patient's care) and/or prevent its recurrence. Not for FDA submission	CHARACTER

Annotated CRF: Protocol Deviations 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: Protocol Deviations CDISC Aligned NCI Standard Template

Conditional Questions

CRF Question	Value Domain
Protocol Deviation Notification Date (2435009) **CDE Short Name:** PROT_DEV_NOTIF_DT CDASH: Not for FDA submission SDTM: Not for FDA submission	DATE – Maximum Length = 8

Optional Questions

CRF Question	Value Domain
Protocol Deviation Occurrence Date (6409584) **CDE Short Name:** DVSTDAT CDASH: DVSTDAT (6409584) SDTM: DVSTDTC (No CDE)	DATE – Maximum Length = 11
Protocol Deviation Description (6414219) **CDE Short Name:** DVTERM CDASH: DVTERM (6414219) SDTM: DVTERM (No CDE)	CHARACTER – Maximum Length = 200
Protocol Deviation Severity Type (2740401) **CDE Short Name:** PROT_DEV_SEV_TP CDASH: Not for FDA Submission SDTM: Not for FDA Submission	CHARACTER – Maximum Length = 8 ☐ Major – Will affect major endpoint data integrity or will have a major impact on participant safety or ethical concerns ☐ Minor – No meaningful effect on data integrity and no meaningful risk to participant safety ☐ Moderate – Potential to affect data integrity or jeopardize participant safety
Protocol Deviation Other Category Descriptive Text (7068996) **CDE Short Name DVCATX** CDASH: No Match SDTM: DVCAT (No CDE)	CHARACTER – Maximum Length = 200
Treating Physician Or Participating Investigator Name (2740424) **CDE Short Name:** TX_MD_PART_INV_NM CDASH: Not for FDA Submission SDTM: Not for FDA Submission	CHARACTER – Maximum Length = 100

CRF Question	Value Domain
Protocol Deviation Category (7068997) **CDE Short Name:** DVCAT CDASH: DVCAT (6413029) SDTM: DVCAT (No CDE)	CHARACTER – Maximum Length = 40 ☐ Concomitant Medications – Concomitant Medications: prohibited concomitant medication was taken or administered ☐ Data Integrity Compromised – Validity and accuracy of the study data is compromised by either mishandling, omitting, or falsifying collected data. ☐ Eligibility not checked – Participant eligibility criteria was not fully verified before starting intervention. ☐ Eligibility waiver – Participant was granted a waiver for violated eligibility criteria before or during trial intervention. ☐ Informed Consent – Informed Consent: not collected or mishandled ☐ Other, specify – Other, specify: deviation does not fit into types listed ☐ Study Procedures – Study Procedures: other study procedures, such as labs, images, missed or out of the window from that described in the protocol ☐ Treatment – Treatment: study drug agent/intervention not given as directed in the protocol
Protocol Deviation Action Text (2435042) **CDE Short Name:** PROT_DEV_ACTION_TXT CDASH: Not for FDA Submission SDTM: Not for FDA Submission	CHARACTER – Maximum Length = 200