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).

Header 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)

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)

Header 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**
Case Report Form Name (m) 3009034 3009016v1.0:3009019v1.0	The words that uniquely describe the case report form title. Not for FDA submission	CHARACTER
Study Identifier (m) 6380045 STUDYID	A unique identifier for a study. CDASH: STUDYID (6380045); SDTM: STUDYID (No CDE)	CHARACTER
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

Field Name (Partition Status) CDE ID # Short Name	**Definition CDISC Mapping and Instruction**	**Format**
Registering Institution Identification Code (c) 2003307 REG_INST_ID_CD	Code that uniquely identifies the institution where the research participant was registered in a clinical trial. Conditionality Rule: If the Sponsoring organization requests this information for Regulatory reporting, then it MUST be included on the case report form.; Not for FDA submission	CHARACTER
Patient Initials Name (o) 2001039 PT_INITIALS_NAME	The initial letters of the first, middle, and last names of the patient or participant registered on the clinical trial. Enter the initial letters of the first, middle, and last names.; 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. Enter 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
Treatment Current Course Number (o) 2072 TX_CURRENT_CRSE_NUM	the protocol-specific identifier used to indicate the treatment course or cycle the patient is now receiving. Enter the Numeric value assigned to identify a period of protocol activity; a course is comprised of multiple cycles of protocol-dictated activities.; Not for FDA submission	NUMBER

Field Name **(Partition Status)** **CDE ID #** **Short Name**	**Definition** **CDISC Mapping and Instruction**	**Format**
Treating Institution Identifier Code (o) 2481533 RX_INST_ID_CD	Code that uniquely identities the organization providing treatment for a person or study subject. Enter the code that unqiuely identifies all the organizations providing treatment for a participant.; Not for FDA submission	CHARACTER
Patient Multiple Clinical Trials Cooperative Group Identifier Number (o) 2465308 PT_M_CTCOOPGP_ID_NUM	a numeric sequent used to uniquely identify an individual participating in an intergroup clinical protocol. Enter the numeric sequent used to uniquely identify an individual participating in an intergroup clinical protocol.; Not for FDA submission	CHARACTER
Treatment Reporting Period Begin Date (o) 2993 TX_REP_PD_BEGDT	the start date of the reporting interval. Enter the start date of the reporting period.; Not for FDA submission	DATE
Treatment Reporting Period End Date (o) 2992 TX_REP_PD_END_DT	the end date of the reporting interval. Enter the end date of the reporting period.; Not for FDA submission	DATE

Annotated CRF: Header 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: Header CDISC Aligned NCI Standard Template

Mandatary Questions

CRF Question	Value Domain
CRF Name (3009034) **CDE Short Name:** 3009016v1.0:3009019v1.0 CDASH: Not for FDA submission SDTM: Not for FDA submission	CHARACTER – Maximum Length = 100
Study Identifier (6380045) **CDE Short Name:** STUDYID CDASH: STUDYID (6380045) SDTM: STUDYID (No CDE)	CHARACTER – Maximum Length = 40
Study Participant Identifier (6380049) **CDE Short Name:** SUBJID CDASH: SUBJID (6380049) SDTM: SUBJID (No CDE)	CHARACTER – Maximum Length = 40

Conditional 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

Optional Questions

CRF Question	Value Domain
Participant Initials (2001039) **CDE Short Name:** PT_INITIALS_NAME CDASH: Not for FDA submission SDTM: Not for FDA submission	CHARACTER – Maximum Length = 4
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
Current Cycle Number (2072) **CDE Short Name:** TX_CURRENT_CRSE_NUM CDASH: Not for FDA submission SDTM: Not for FDA submission	NUMBER – Maximum Length = 6
Treating Institution (2481533) **CDE Short Name:** RX_INST_ID_CD CDASH: Not for FDA submission SDTM: Not for FDA submission	CHARACTER – Maximum Length = 10
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

CRF Question	Value Domain
Reporting Period Start Date (2993) **CDE Short Name:** TX_REP_PD_BEGDT CDASH: Not for FDA submission SDTM: Not for FDA submission	DATE – Maximum Length = 8
Reporting Period End Date (2992) **CDE Short Name:** TX_REP_PD_END_DT CDASH: Not for FDA submission SDTM: Not for FDA submission	DATE – Maximum Length = 8