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).

Participant Identification CDISC Aligned NCI Standard Template Module Definitions

Mapping to the CDASH:

Not for FDA submission

Mapping to the SDTM:

Not for FDA submission

Participant Identification 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
Person Family/Last Name (c) 2179591 PERSON_FAMILY_NM	A means of identifying an individual by using a word or group of words indicating a person's last (family) name. Synonym = Last Name, Surname. Conditionality Rule: Conditionality rests on the local organization's need to capture name as a unique identifier; this item will never be exchanged.; Not for FDA submission	CHARACTER
Person Given/First Name (c) 2179589 PERSON_FIRST_NM	A word or group of words indicating a person's first (personal or given) name; the name that precedes the surname. Synonym = Given Name. Conditionality Rule: Conditionality rests on the local organization's need to capture name as a unique identifier; this item will never be exchanged.; Not for FDA submission	CHARACTER

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Person Middle Name (o) 2179590 PERSON_MIDDLE_NM	A means of identifying an individual by using a word or group of words indicating a person's middle name. Not for FDA submission	CHARACTER
Individual Genealogy Suffix Code (o) 2006475 INDIV_GENEAL_TXT_NM	Text term to represent an individual's position in a family lineage or pedigree. Not for FDA submission	CHARACTER. Use choice list.
Person Address Name (o) 62587 PERSON_ADDR_NAME	the address or postal information for a person. Not for FDA submission	CHARACTER
Address City Name (o) 2179601 ADDR_CITY_NM	A component of an address that specifies a location by identification of a city, town, or village. Not for FDA submission	CHARACTER
Address State Name Address State Name (o) 2179603 ADDR_STATE_NM	Address State Name_The name that represents a principal administrative subdivision of the United States, Canada, and Mexico. Not for FDA submission	CHARACTER. Use choice list.
Address Postal Code Identifier (o) 2179606 ADDR_POSTAL_CD	The string of characters used to identify the five-digit Zone Improvement Plan (ZIP) code and the four-digit extension code (if available) that represents the geographic segment that is a subunit of the ZIPcode, assigned by the U.S. Postal Service to a geographic location to facilitate mail delivery; or the postal zone specific to the country, other than the U.S., where the mail is delivered. Not for FDA submission	CHARACTER

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Telephone Number Type (o) 2179594 TELEPHONE_NUM_TYPE_TXT	The text that uniquely identifies a telecommunications connection by a location or by a specific device. Not for FDA submission	ALPHANUMERIC. Use choice list.
Telephone Number (o) 2179593 TELEPHONE_NUM	The number that identifies a particular telephone connection [Explanatory comment: The preferred format for telephone number is +CCC(AAA)LLLLLLLL/XXXXX where +CCC is the country code, (AAA) is the area code, LLLLLLLL is the local code and XXXXX is the extension number. Partial numbers may be filled from the left, e.g., + (AAA)LLLLLLLL/XXXXX (country code unknown or not necessary), + ( )LLLLLLLL/, (country code, area code, and extension unknown or not necessary), etc.] Not for FDA submission	ALPHANUMERIC
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. Not for FDA submission	CHARACTER

Annotated CRF: Participant Identification 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: Participant Identification CDISC Aligned NCI Standard Template

Conditional Questions

CRF Question	Value Domain
Participant Last Name (2179591) **CDE Short Name:** PERSON_FAMILY_NM CDASH: Not for FDA submission SDTM: Not for FDA submission	CHARACTER – Maximum Length = 100
Participant First Name (2179589) **CDE Short Name:** PERSON_FIRST_NM CDASH: Not for FDA submission SDTM: Not for FDA submission	CHARACTER – Maximum Length = 100

Optional Questions

CRF Question	Value Domain
Participant Middle Name (2179590) **CDE Short Name:** PERSON_MIDDLE_NM CDASH: Not for FDA submission SDTM: Not for FDA submission	CHARACTER – Maximum Length = 100
Person Name Suffix (2006475) **CDE Short Name:** INDIV_GENEAL_TXT_NM CDASH: Not for FDA submission SDTM: Not for FDA submission	CHARACTER – Maximum Length = 4 ☐ I – First ☐ II – Second: C49463 ☐ III – Third ☐ IV – Fourth ☐ Jr. – Junior ☐ Sr. – Senior
Street Address (62587) **CDE Short Name:** PERSON_ADDR_NAME CDASH: Not for FDA submission SDTM: Not for FDA submission	CHARACTER – Maximum Length = 100
Participant City (2179601) **CDE Short Name:** ADDR_CITY_NM CDASH: Not for FDA submission SDTM: Not for FDA submission	ALPHANUMERIC – Maximum Length = 30
State (2179603) **CDE Short Name:** ADDR_STATE_NM CDASH: Not for FDA submission SDTM: Not for FDA submission	ALPHANUMERIC – Maximum Length = 30 List of 105 PVs

CRF Question	Value Domain
Participant Postal Code (2179606) **CDE Short Name:** ADDR_POSTAL_CD CDASH: Not for FDA submission SDTM: Not for FDA submission	CHARACTER – Maximum Length = 15
Telephone Number Type (2179594) **CDE Short Name:** TELEPHONE_NUM_TYPE_TXT CDASH: Not for FDA submission SDTM: Not for FDA submission	ALPHANUMERIC – Maximum Length = 22 ☐ Cellular – Cellular Telephone ☐ Facsimile – Facsimile Machine ☐ Home – Home ☐ Mobile Telephone – Mobile Telephone ☐ Modem – Modem Device Component ☐ Pager – Pager ☐ Work – Worksite: C17556
Participant Phone (2179593) **CDE Short Name:** TELEPHONE_NUM CDASH: Not for FDA submission SDTM: Not for FDA submission	ALPHANUMERIC – Maximum Length = 25
Participant Initials (2001039) **CDE Short Name:** PT_INITIALS_NAME CDASH: Not for FDA submission SDTM: Not for FDA submission	CHARACTER – Maximum Length = 4