

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).

Demography 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)
- SC – Subject Characteristics (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)
- SC – Subject Characteristics (v3.3)

Demography 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
Sex Gender Type (m) 7050283 DMSXGEN	Sex of the subject as determined by the investigator. CDASH: SEX (6343385); SDTM: SEX (No CDE)	CHARACTER. Use choice list.
Race (m) 6343384 RACE	An arbitrary classification based on physical characteristics; a group of persons related by common descent or heredity (U.S. Center for Disease Control). CDASH: RACE (6343384); SDTM: RACE (No CDE)	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Date of Birth (m) 6341138 BRTHDAT	A subject's date of birth (with or without the time of birth). The complete Date of Birth is made from the temporal components of Birth Year, Birth Month, Birth Day and Birth Time. CDASH: BRTHDAT (6341138); SDTM: BRTHDTC (No CDE)	DATE
Ethnicity (m) 6338619 ETHNIC	A social group characterized by a distinctive social and cultural tradition maintained from generation to generation, a common history and origin and a sense of identification with the group; members of the group have distinctive features in their way of life, shared experiences and often a common genetic heritage; these features may be reflected in their experience of health and disease. CDASH: ETHNIC (6338619); SDTM: ETHNIC (No CDE)	CHARACTER. Use choice list.
Address Postal Code (c) 7050284 DMZIPCD	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. CDASH: No Match; SDTM: No Match; Conditionality Rule: Requirement for collection is imposed by the trial sponsor.	CHARACTER

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Healthcare Payment Method Type (c) 7050285 DMPAYMTH	The entity, organization, government, corporation, health plan sponsor, or any other financial agent who pays a healthcare provider for the healthcare service rendered to a person or reimburses the cost of the healthcare service. CDASH: No Match; SDTM: No Match; Conditionality Rule: Requirement for collection is imposed by the trial sponsor. Sponsor now stipulates the use of codes with the values.	CHARACTER. Use choice list.
Address Country Name (c) 7050286 DMCNTY	The country from which a person or their biological family had previous residence or past ancestors. CDASH: No Match; SDTM: No Match; Conditionality Rule: Requirement for collection is imposed by the trial sponsor.	CHARACTER
Demographics Form Completion Date (c) 7050287 DMCRFCMP	The date the demographics case report form was completed, represented in an unambiguous date format (e.g., DD-MON-YYYY). CDASH: No Match; SDTM: No Match; Conditionality Rule: Data Collection is done using paper Case Report Forms (CRFs) instead of an Electronic Data Capture system.	DATE

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Centers for Disease Control and Prevention Race Identifier Code (c) 7050288 DMRACDC	The code used for reporting information about race based on the Center for Disease Control and Prevention (CDC) categories.. CDASH: No Match; SDTM: No Match; Conditionality Rule: In the event the sponsor requires the data be collected using the CDC codes, use this CDE instead of 2192199. Do NOT collect both items.	CHARACTER
Centers for Disease Control and Prevention Ethnicity Identifier Code (c) 7050289 DMETHCDC	The code used for reporting information about ethnicity based on the Center for Disease Control and Prevention (CDC) categories. CDASH: No Match; SDTM: No Match; Conditionality Rule: In the event the sponsor requires the data be collected using the CDC codes, use this CDE instead of 2192217. Do NOT collect both items.	CHARACTER
Education Level Subject Characteristics Original Result Summary Category Type (o) 7050290 EDULEVSM	The category summarizing the highest level of education attained by a person. CDASH: EDLEVEL_SCORRES (6421544); SDTM: SCORRES (No CDE) where SCTESTCD = "EDULEVSM"	CHARACTER. Use choice list.
Address Birth Country Type (o) 7050291 NATORIG	The country in which a person was born. CDASH: NATORIG_SCORRES (6421543); SDTM: SCORRES (No CDE) where SCTESTCD = "NATORIG"	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Education Level Subject Characteristics Original Result Summary Type (o) 7050292 EDULEVEL	The highest level of education attained by a person. CDASH: EDLEVEL_SCORRES (6421544); SDTM: SCORRES (No CDE) where SCTESTCD = "EDULEVEL"	CHARACTER. Use choice list.
Enrollment Address Census Tract Code (o) 7050293 CENCUSCD	The 2000 United States Census Bureau's Area Classifications code indicating the census tract of a person's residence. CDASH: No Match; SDTM: SCORRES (No CDE) where SCTESTCD = "CENCUSCD"	CHARACTER
Marital Status Subject Characteristics Original Result Status (o) 7050294 MARISTAT	The self-reported demographic parameter indicating a person's current conjugal status. CDASH: MARISTAT_SCORRES (6421542); SDTM: SCORRES (No CDE) where SCTESTCD = "MARISTAT"	CHARACTER. Use choice list.

Annotated CRF: Demography 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: Demography CDISC Aligned NCI Standard Template

Mandatory Questions

CRF Question	Value Domain
<p>Gender (7050283) CDE Short Name: DMSXGEN</p> <div style="border: 1px solid blue; padding: 2px; margin: 5px 0;">CDASH: SEX (6343385)</div> <div style="border: 1px solid red; padding: 2px; margin: 5px 0;">SDTM: SEX (No CDE)</div>	<p>CHARACTER – Maximum Length = 13</p> <ul style="list-style-type: none"> <input type="checkbox"/> Female – Female Gender <input type="checkbox"/> Intersex – Intersex <input type="checkbox"/> Male – Male Gender <input type="checkbox"/> Not Reported – Not Reported <input type="checkbox"/> Unknown – Unknown <input type="checkbox"/> Unspecified – Unspecified
<p>Race (6343384) CDE Short Name: RACE</p> <div style="border: 1px solid blue; padding: 2px; margin: 5px 0;">CDASH: RACE (6343384)</div> <div style="border: 1px solid red; padding: 2px; margin: 5px 0;">SDTM: RACE (No CDE)</div>	<p>CHARACTER – Maximum Length = 100</p> <ul style="list-style-type: none"> <input type="checkbox"/> AMERICAN INDIAN OR ALASKA NATIVE – American Indian or Alaska Native <input type="checkbox"/> ASIAN – Asian <input type="checkbox"/> BLACK OR AFRICAN AMERICAN – Black or African American <input type="checkbox"/> NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER – Native Hawaiian or Other Pacific Islander <input type="checkbox"/> NOT REPORTED – Not Reported <input type="checkbox"/> UNKNOWN – Unknown <input type="checkbox"/> WHITE – White
<p>Patient's Date of Birth (6341138) CDE Short Name: BRTHDAT</p> <div style="border: 1px solid blue; padding: 2px; margin: 5px 0;">CDASH: BRTHDAT (6341138)</div> <div style="border: 1px solid red; padding: 2px; margin: 5px 0;">SDTM: BRTHDTC (No CDE)</div>	<p>DATE – Maximum Length = 11</p>

CRF Question	Value Domain
<p>Ethnicity (6338619) CDE Short Name: ETHNIC</p> <div data-bbox="285 321 769 373" style="border: 1px solid blue; padding: 2px; margin-bottom: 10px;"> CDASH: ETHNIC (6338619) </div> <div data-bbox="285 407 769 459" style="border: 1px solid red; padding: 2px;"> SDTM: ETHNIC (No CDE) </div>	<p>CHARACTER – Maximum Length = 100</p> <ul style="list-style-type: none"> <input type="checkbox"/> HISPANIC OR LATINO – Hispanic or Latino <input type="checkbox"/> NOT HISPANIC OR LATINO – Not Hispanic or Latino <input type="checkbox"/> NOT REPORTED – Not Reported <input type="checkbox"/> UNKNOWN – Unknown

Conditional Questions

CRF Question	Value Domain
<p>ZIP Code (7050284) CDE Short Name: DMZIPCD</p> <p>CDASH: No Match</p> <p>SDTM: No Match</p>	<p>CHARACTER – Maximum Length = 15</p>
<p>Payment Method (7050285) CDE Short Name: DMPAYMTH</p> <p>CDASH: No Match</p> <p>SDTM: No Match</p>	<p>CHARACTER – Maximum Length = 50</p> <ul style="list-style-type: none"> <input type="checkbox"/> Managed Care/Medicare – Managed Care/Medicare <input type="checkbox"/> Medicaid – Medicaid <input type="checkbox"/> Medicaid and Medicare – Medicare And Medicaid <input type="checkbox"/> Medicare – Medicare <input type="checkbox"/> Medicare and Private Insurance – Medicare And Private Insurance <input type="checkbox"/> Military or Veterans Sponsored, NOS – Military Or Veterans Sponsored Insurance, Not Otherwise Specified <input type="checkbox"/> Military Sponsored (Including CHAMPUS & TriCare) – Military Insurance <input type="checkbox"/> No Means of Payment (No Insurance) – No Insurance <input type="checkbox"/> Other – Other <input type="checkbox"/> Private Insurance – Private Insurance <input type="checkbox"/> Self-Pay (No Insurance) – Self Payment <input type="checkbox"/> State Supplemental Health Insurance – State Supplemental Health Insurance <input type="checkbox"/> Unknown – Unknown <input type="checkbox"/> Veterans Sponsored – Veterans Administration Sponsor Insurance
<p>Country of Residence (7050286) CDE Short Name: DMCNTRY</p> <p>CDASH: No Match</p> <p>SDTM: No Match</p>	<p>CHARACTER – Maximum Length = 200</p>

CRF Question	Value Domain
<p>Date Completed (7050287) CDE Short Name: DMCRFCMP</p> <p>CDASH: No Match</p> <p>SDTM: No Match</p>	<p>DATE – Maximum Length = 11</p>
<p>CDC Race Code (7050288) CDE Short Name: DMRACDC</p> <p>CDASH: No Match</p> <p>SDTM: No Match</p>	<p>CHARACTER – Maximum Length = 6</p>
<p>CDC Ethnicity Code (7050289) CDE Short Name: DMETHCDC</p> <p>CDASH: No Match</p> <p>SDTM: No Match</p>	<p>CHARACTER – Maximum Length = 6</p>

Optional Questions

CRF Question	Value Domain
<p>Highest Education Level (7050290) CDE Short Name: EDULEVSM</p> <div style="border: 1px solid blue; padding: 5px; margin: 10px 0;"> <p>CDASH: EDLEVEL_SCORRES (6421544)</p> </div> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: SCORRES (No CDE) where SCTESTCD = "EDULEVSM"</p> </div>	<p>CHARACTER – Maximum Length = 44</p> <ul style="list-style-type: none"> <input type="checkbox"/> Bachelor's Degree – Bachelor's Degree <input type="checkbox"/> Doctoral degree or professional degree – Professional Doctorate or Doctorate Degree <input type="checkbox"/> Grade School – Grade School <input type="checkbox"/> Graduate or professional degree – Graduation Or Professional Degree <input type="checkbox"/> High school graduate (including equivalency) – High School Completion or General Equivalency Diploma (GED) Completion <input type="checkbox"/> Master's Degree – Master's Degree <input type="checkbox"/> No formal education – No Formal Schooling <input type="checkbox"/> Not high school graduate – Not High School Graduate <input type="checkbox"/> Some college or associate degree – Some College or Associates Degree
<p>Country of Birth (7050291) CDE Short Name: NATORIG</p> <div style="border: 1px solid blue; padding: 5px; margin: 10px 0;"> <p>CDASH: NATORIG_SCORRES (6421543)</p> </div> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: SCORRES (No CDE) where SCTESTCD = "NATORIG"</p> </div>	<p>CHARACTER – Maximum Length = 55</p> <ul style="list-style-type: none"> <input type="checkbox"/> Other country – Other country <input type="checkbox"/> Other country, specify – OTHER COUNTRY, SPECIFY <input type="checkbox"/> USA – USA <input type="checkbox"/> USA, specify the 2 letter State code, eg NY– USA, SPECIFY THE 2 LETTER STATE CODE, EG NY

CRF Question	Value Domain
<p>Highest Education Level (7050292) CDE Short Name: EDULEVEL</p> <div style="border: 1px solid blue; padding: 5px; margin: 10px 0;"> <p>CDASH: EDLEVEL_SCORRES (6421544)</p> </div> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: SCORRES (No CDE) where SCTESTCD = "EDULEVEL"</p> </div>	<p>CHARACTER – Maximum Length = 50</p> <ul style="list-style-type: none"> <input type="checkbox"/> 10th Grade – 10th Grade <input type="checkbox"/> 11th Grade – 11th Grade <input type="checkbox"/> 12th Grade No Diploma – 12th Grade <input type="checkbox"/> 1st Grade – 1st Grade <input type="checkbox"/> 2nd Grade – 2nd Grade <input type="checkbox"/> 3rd Grade – 3rd Grade <input type="checkbox"/> 4th Grade – 4th Grade <input type="checkbox"/> 5th Grade – 5th Grade <input type="checkbox"/> 6th Grade – 6th Grade <input type="checkbox"/> 7th Grade – 7th Grade <input type="checkbox"/> 8th Grade – 8th Grade <input type="checkbox"/> 9th Grade – 9th Grade <input type="checkbox"/> Academic Doctorate Degree – Academic Doctorate Degree Completion <input type="checkbox"/> Associate Degree – Associate Academic Degree Completion <input type="checkbox"/> Bachelor Degree – Bachelor's Degree Completion <input type="checkbox"/> Don't Know – Don't Know/Refused <input type="checkbox"/> General Equivalency Diploma – General Equivalency Diploma <input type="checkbox"/> High School Graduate – High School Graduate <input type="checkbox"/> Kindergarten – Kindergarten Completion <input type="checkbox"/> Master's Degree – Master's Degree Completion <input type="checkbox"/> No Formal Schooling – Never Attended <input type="checkbox"/> Preschool – Preschool Completion <input type="checkbox"/> Professional Doctorate Degree – Professional Doctorate Degree Completion <input type="checkbox"/> Refused – Refused <input type="checkbox"/> Some College, No Degree – Some College <input type="checkbox"/> VoTech Program – Vocational Degree

CRF Question	Value Domain
<p>Census Tract Code at Enrollment (7050293) CDE Short Name: CENCUSCD</p> <div data-bbox="289 321 769 373" style="border: 1px solid blue; padding: 2px; margin-bottom: 10px;"> <p>CDASH: No Match</p> </div> <div data-bbox="289 407 769 489" style="border: 1px solid red; padding: 2px;"> <p>SDTM: SCORRES (No CDE) where SCTESTCD = "CENCUSCD"</p> </div>	<p>CHARACTER – Maximum Length = 15</p>
<p>Marital Status (7050294) CDE Short Name: MARISTAT</p> <div data-bbox="289 621 769 703" style="border: 1px solid blue; padding: 2px; margin-bottom: 10px;"> <p>CDASH: MARISTAT_SCORRES (6421542)</p> </div> <div data-bbox="289 737 769 819" style="border: 1px solid red; padding: 2px;"> <p>SDTM: SCORRES (No CDE) where SCTESTCD = "MARISTAT"</p> </div>	<p>CHARACTER – Maximum Length = 100</p> <ul style="list-style-type: none"> <input type="checkbox"/> ANNULLED – Annulled <input type="checkbox"/> DIVORCED – Divorced <input type="checkbox"/> DOMESTIC PARTNER – Domestic Partner <input type="checkbox"/> INTERLOCUTORY – Interlocutory Marital Status <input type="checkbox"/> LEGALLY SEPARATED – Separated <input type="checkbox"/> MARRIED – Married <input type="checkbox"/> NEVER MARRIED – Never Married <input type="checkbox"/> POLYGAMOUS – PVM Polygamous <input type="checkbox"/> SEPARATED – Separated <input type="checkbox"/> WIDOWED – Widowed