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).

Eligibility 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)
- IE – Inclusion/Exclusion Criteria Not Met (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)

Eligibility 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**
Any Inclusion/Exclusion Criteria Findings (m) 6408651 IEYN	Indication whether the subject met all the eligibility requirements for this study at the time the subject was enrolled. CDASH: IEYN (6408651); SDTM: No Match	CHARACTER. Use choice list.
Any Inclusion/Exclusion Criteria Findings (c) 6408651 IEYN	Indication whether the subject met all the eligibility requirements for this study at the time the subject was enrolled. CDASH: IEYN (6408651); SDTM: No Match; Conditionality Rule: The CDE is to be used with the OPEN system for NCI trials or systems where the application eligibility data cannot perform this eligibility function in an automated manner.	CHARACTER. Use choice list.

Field Name **(Partition Status)** **CDE ID #** **Short Name**	**Definition** **CDISC Mapping and Instruction**	**Format**
Eligibility Waiver Indicator (c) 7063880 IEWAIIND	The indication of whether or not an eligibility waiver was granted. CDASH: No Match; SDTM: No Match; Conditionality Rule: Use CDE if the sponsor permits waivers. The value of 'Not Applicable' can be used if needed, otherwise it can be subset out of the value domain.	CHARACTER. Use choice list.
Eligibility Waiver Text (c) 7063881 IEWAIRSN	The reason an eligibility waiver was granted. CDASH: No Match; SDTM: No Match; Conditionality Rule: Use CDE if the sponsor permits waivers.	CHARACTER
Eligibility Waiver Identifier (c) 7063882 IEWAINUM	A unique identifier for granted eligibility waiver. CDASH: No Match; SDTM: No Match; Conditionality Rule: Use CDE if the sponsor permits waivers.	CHARACTER
Clinical Trial Ineligibility Reason (o) 7063883 DSSCRNIE	The reason a patient was not able to participate in a clinical trial. CDASH: DSTERM (6355980) where DSSCAT (6384142) = "Patient Trial Screening Ineligibility Reasons"; SDTM: DSDECOD (No CDE)	CHARACTER. Use choice list.
Clinical Trial Ineligibility Reason Text (o) 7063884 DSIERSNX	The reason a patient was not able to participate in a clinical trial not previously listed. CDASH: DSTERM (6355980) where DSSCAT (6384142) = "Patient Ineligibility Other Specify Text"; SDTM: DSTERM (No CDE) where DSSCAT (No CDE) = "Patient Ineligibility Other Specify Text"	CHARACTER

Field Name **(Partition Status)** **CDE ID #** **Short Name**	**Definition** **CDISC Mapping and Instruction**	**Format**
Eligibility Determination Checklist Version Date (o) 7063885 IEDCVDAT	The date of the eligibility checklist, represented in an unambiguous date format (e.g., DD-MON-YYYY). CDASH: No Match; SDTM: No Match	DATE
Eligibility Determination Date (o) 7063886 IEDTMDAT	The date eligibility for participation in a clinical trial was determined, represented in an unambiguous date format (e.g., DD-MON-YYYY). CDASH: No Match; SDTM: No Match	DATE

Annotated CRF: Eligibility 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: Eligibility CDISC Aligned NCI Standard Template

Mandatary Questions

CRF Question	Value Domain
Is the participant eligible for inclusion on this study (6408651) **CDE Short Name:** IEYN CDASH: IEYN (6408651) SDTM: No Match	CHARACTER – Maximum Length = 2 ☐ N – No ☐ NA – Not Applicable ☐ U – Unknown ☐ Y – Yes

Conditional Questions

CRF Question	Value Domain
Is the participant eligible for inclusion on this study (6408651) **CDE Short Name:** IEYN CDASH: IEYN (6408651) SDTM: No Match	CHARACTER – Maximum Length = 2 ☐ N – No ☐ NA – Not Applicable ☐ U – Unknown ☐ Y – Yes
Was a waiver granted? (7063880) **CDE Short Name:** IEWAIIND CDASH: No Match SDTM: No Match	CHARACTER – Maximum Length = 2 ☐ N – No ☐ NA – Not Applicable ☐ U – Unknown ☐ Y – Yes
Reason for waiver (7063881) **CDE Short Name:** IEWAIRSN CDASH: No Match SDTM: No Match	CHARACTER – Maximum Length = 200
Waiver ID (7063882) **CDE Short Name:** IEWAINUM CDASH: No Match SDTM: No Match	CHARACTER – Maximum Length = 40

Optional Questions

CRF Question	Value Domain
Reason patient not able to participate in trial (7063883) **CDE Short Name:** DSSCRNIE CDASH: DSTERM (6355980) where DSSCAT (6384142) = "Patient Trial Screening Ineligibility Reasons" SDTM: DSDECOD (No CDE)	CHARACTER – Maximum Length = 50 ☐ Did not meet disease criteria – Disease Exclusion Criteria not Met ☐ Did not meet Eligibility Criteria – Ineligible ☐ Had not celebrated their eight birthday at time of enrollment – Child Less Than 8 Years Old at Time of Enrollment ☐ Inability to read English or Spanish – English or Spanish Language Illiterate ☐ Insurance/financial issues – Insurance And/Or Financial Problem ☐ Investigator Decision – Investigator Decision ☐ Logistical and/or transportation issues – Logistical and/or transportation issues ☐ Other health issues – Other Health Problem ☐ Other, specify – Other Specify ☐ Participant Decision – Participant Decision ☐ Prior problems with protocol compliance – Prior Protocol Compliance Problem ☐ Psychosocial conditions that would prevent study compliance – Psychological And Social Condition Block Trial Compliance
Specify reason patient not able to participate in trial (7063884) **CDE Short Name:** DSIERSNX CDASH: DSTERM (6355980) where DSSCAT (6384142) = "Patient Ineligibility Other Specify Text" SDTM: DSTERM (No CDE) where DSSCAT (No CDE) = "Patient Ineligibility Other Specify Text"	CHARACTER – Maximum Length = 200
Checklist Version Date (7063885) **CDE Short Name:** IEDCVDAT CDASH: No Match SDTM: No Match	DATE – Maximum Length = 11

CRF Question	Value Domain
Eligibility Determined Date (7063886) **CDE Short Name:** IEDTMDAT CDASH: No Match SDTM: No Match	DATE – Maximum Length = 11