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).

Equipment CDISC Aligned NCI Standard Template Module Definitions

Mapping to the CDASH:

N/A

Mapping to the SDTM:

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

- DE – Device Events (SDTMIG for Medical Devices v1.1)
- DI – Device Identifiers (SDTMIG for Medical Devices v1.1)
- DO – Device Properties (SDTMIG for Medical Devices v1.1)

Equipment 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**
Diagnostic, Therapeutic, or Research Equipment Medical Device Model Name (m) 7068998 DIMUMODL	The model name of the diagnostic, therapeutic or research equipment model used during a clinical trial. CDASH: No Match; SDTM: DIVAL (6356049) where DIPARM (No CDE) = "Model Identifier" and DIPARMCD (No CDE) = "MODEL"	CHARACTER
Diagnostic, Therapeutic, or Research Equipment Manufacturer Name (m) 7068999 DIMUFNAM	The name of the manufacturer of diagnostic, therapeutic or research equipment model used during a clinical trial. CDASH: No Match; SDTM: DIVAL (6356049) where DIPARM (No CDE) = "Trade Name" and DIPARMCD (No CDE) = "TRADENAM"	CHARACTER

Field Name (Partition Status) CDE ID # Short Name	**Definition CDISC Mapping and Instruction**	**Format**
Diagnostic, Therapeutic, or Research Equipment Serial Number Identifier (o) 7069000 DISERLN	A unique identifier assigned a single unit of diagnostic, therapeutic or research equipment used during a clinical trial. CDASH: No Match; SDTM: DIVAL (6356049) where DIPARM (No CDE) = "Serial Number" and DIPARMCD (No CDE) = "SERIAL"	CHARACTER
Diagnostic, Therapeutic, or Research Equipment Software Version Text (o) 7069001 SFTWRVER	The description of the specific form or variant of software used with the diagnostic, therapeutic or research equipment. CDASH: No Match; SDTM: DOORRES (7165850) where DOTESTCD (No CDE) = "SFTWRVER"	CHARACTER
Diagnostic, Therapeutic, or Research Equipment Station Name (o) 7069002 DISTANAM	The name of the location of diagnostic, therapeutic or research equipment used during a clinical trial. CDASH: No Match; SDTM: DIVAL (6356049) where DIPARM (No CDE) = "Station Name" and DIPARMCD (No CDE) = "STATION"	CHARACTER
Sponsor Device Identifier (o) 6785137 SPDEVID	A sponsor-defined sequence of characters used to identify, name, or characterize a device. CDASH: No Match; SDTM: SPDEVID (6785137)	CHARACTER
Diagnostic, Therapeutic, or Research Equipment Clinical Study Sponsor Requirement Negation Qualifying Text (o) 7069004 DENQULRN	The description of the reason diagnostic, therapeutic or research equipment did meet the sponsor's requirements. CDASH: No Match; SDTM: No Match	CHARACTER

Field Name **(Partition Status)** **CDE ID #** **Short Name**	**Definition** **CDISC Mapping and Instruction**	**Format**
Diagnostic, Therapeutic, or Research Equipment Clinical Study Sponsor Requirement Qualifiying Date (o) 7069005 DESCQLDT	The date diagnostic, therapeutic or research equipment met the sponsor's requirements for use in a clinical trial. CDASH: No Match; SDTM: DESTDTC (No CDE) where DETERM (No CDE) = "Scanner Qualification"	Date
Diagnostic, Therapeutic, or Research Equipment Daily Quality Control Indicator (o) 7069006 DESCQCNY	The indication of whether or not if daily quality assurance assessments were performed on the diagnostic, therapeutic or research equipment. CDASH: No Match; SDTM: If Yes, DETERM (No CDE) = "Daily scanner QC run on date of study"	CHARACTER. Use choice list
Diagnostic, Therapeutic, or Research Equipment Clinical Study Sponsor Requirement Qualifiying Indicator (o) 7069007 DESCQULF	The indication of whether or not diagnostic, therapeutic or research equipment met the sponsor's requirements for use in a clinical trial. CDASH: No Match; SDTM: If Yes, DETERM (No CDE) ='The scanner used for this study been qualified by sponsor'	CHARACTER. Use choice list

Annotated CRF: Equipment 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: Equipment CDISC Aligned NCI Standard Template

Mandatary Questions

CRF Question	Value Domain
Manufacturer's Model Name (7068998) **CDE Short Name:** DIMUMODL CDASH: No Match SDTM: DIVAL (6356049) where DIPARM (No CDE) = "Model Identifier" and DIPARMCD (No CDE) = "MODEL"	CHARACTER – Maximum Length = 200
Manufacturer Name (7068999) **CDE Short Name:** DIMUFNAM CDASH: No Match SDTM: DIVAL (6356049) where DIPARM (No CDE) = "Trade Name" and DIPARMCD (No CDE) = "TRADENAM"	CHARACTER – Maximum Length = 200

Optional Questions

CRF Question	Value Domain
Device Serial Number (7069000) **CDE Short Name:** DISERLN CDASH: No Match SDTM: DIVAL (6356049) where DIPARM (No CDE) = "Serial Number" and DIPARMCD (No CDE) = "SERIAL"	CHARACTER – Maximum Length = 40
Software Version(s) (7069001) **CDE Short Name:** SFTWRVER CDASH: No Match SDTM: DOORRES (7165850) where DOTESTCD (No CDE) = "SFTWRVER"	CHARACTER – Maximum Length = 200
Station Name (7069002) **CDE Short Name:** DISTANAM CDASH: No Match SDTM: DIVAL (6356049) where DIPARM (No CDE) = "Station Name" and DIPARMCD (No CDE) = "STATION"	CHARACTER – Maximum Length = 200
Equipment ID (6785137) **CDE Short Name:** SPDEVID CDASH: No Match SDTM: SPDEVID (6785137)	CHARACTER – Maximum Length = 40
Reason a non-qualified scanner was used for this study (7069004) **CDE Short Name:** DENQULRN CDASH: No Match SDTM: No Match	CHARACTER – Maximum Length = 200

CRF Question	Value Domain
Scanner Qualification Date (7069005) **CDE Short Name:** DESCQLDT CDASH: No Match SDTM: DESTDTC (No CDE) where DETERM (No CDE) = "Scanner Qualification"	Date – Maximum Length = 11
Daily scanner QC run on date of study? (7069006) **CDE Short Name:** DESCQCNY CDASH: No Match SDTM: If Yes, DETERM (No CDE) = "Daily scanner QC run on date of study"	CHARACTER – Maximum Length = 2 ☐ N – No ☐ NA – Not Applicable ☐ U – Unknown ☐ Y – Yes
Has the scanner used for this study been qualified by sponsor? (7069007) **CDE Short Name:** DESCQULF CDASH: No Match SDTM: If Yes, DETERM (No CDE) ='The scanner used for this study been qualified by sponsor'	CHARACTER – Maximum Length = 2 ☐ N – No ☐ NA – Not Applicable ☐ U – Unknown ☐ Y – Yes