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).

Concomitant Medication 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:

- CM – Prior and Concomitant Medications (v2.0)

Mapping to the SDTM:

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

- CM – Prior and Concomitant Medications (v3.3)

Concomitant Medication 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**
Concomitant Medication Name (c) 6400634 CMTRT	Verbatim medication name or treatments (include only treatments with data collection characteristics similar to medications). CDASH: CMTRT (6400634); SDTM: CMTRT (No CDE); Conditionality Rule: In some cases this is not a therapy.	CHARACTER
Concomitant Agent Code (o) 6975007 CMAGTCD	The code that represents the medication name or treatments. CDASH: No Match; SDTM: No Match, Can be a supplemental qualifier in SDTM	NUMBER
Concomitant Meds Active Ingredients (o) 6400636 CMINGRD	Medication Ingredients. CDASH: CMINGRD (6400636); SDTM: No Match, Can be a supplemental qualifier in SDTM	CHARACTER

Field Name **(Partition Status)** **CDE ID #** **Short Name**	**Definition** **CDISC Mapping and Instruction**	**Format**
Concomitant Medication Dose Form Type (o) 6975008 CMDSFMTP	The pharmaceutical dosage form of the concomitant medication. CDASH: CMDOSFRM (6400808); SDTM: CMDOSFRM (No CDE)	CHARACTER. Use choice list.
Concomitant Medication Dose Frequency (o) 6975009 CMCMDSFQ	The frequency doses were given/administered/taken during a specific interval. CDASH: CMDOSFRQ (6401033); SDTM: CMDOSFRQ (No CDE)	CHARACTER. Use choice list.
Concomitant Medication Route of Administration Type Code (o) 6975010 CMROUTTP	The route of administration of the concomitant medication/treatment/therapy. CDASH: CMROUTE (6401132); SDTM: CMROUTE (No CDE)	CHARACTER. Use choice list.
Concomitant Medication Use Indication Reason (o) 6975011 CMUSINRN	The condition, disease, symptom or disorder that the concomitant (non-study) medication/treatment/therapy was used to address or investigate (e.g., why the medication/treatment/therapy was taken or administered). CDASH: CMINDC (6400637); SDTM: CMINDC (No CDE)	CHARACTER. Use choice list.
Concomitant Meds Start Date (o) 6400968 CMSTDAT	The start date when the concomitant medication/treatment/therapy was first taken represented in an unambiguous date format (e.g., DD-MON-YYYY). CDASH: CMSTDAT (6400968); SDTM: CMSTDTC (No CDE)	DATE

Field Name **(Partition Status)** **CDE ID #** **Short Name**	**Definition** **CDISC Mapping and Instruction**	**Format**
Concomitant Meds End Date (o) 6400825 CMENDAT	The date that the subject ended/stopped taking the concomitant medication/treatment/therapy represented in an unambiguous date format (e.g., DD-MON-YYYY). CDASH: CMENDAT (6400825); SDTM: CMENDTC (No CDE)	DATE
Concomitant Meds Dose (o) 6400657 CMDOSE	The dose of medication/treatment (e.g. --TRT) given at one time represented as a numeric value. CDASH: CMDOSE (6400657); SDTM: CMDOSE (No CDE)	NUMBER
Concomitant Medication Dose Unit Code (o) 6983142 CMDSUNCD	The unit associated with the concomitant medication/treatment/therapy taken (e.g., mg in "2mg three times per day"). CDASH: CMDOSU (6400803); SDTM: CMDOSU (No CDE)	CHARACTER. Use choice list.
Any Concomitant Medications Taken (o) 6400632 CMYN	An indication whether or not any (concomitant) medications/treatments/therapies were taken/given. CDASH: CMYN (6400632); SDTM: No Match	CHARACTER. Use choice list.
Concomitant Medication Case Report Form Use Reason (o) 6983152 CMFRMRS	The reason for completion of the concomitant medication case report form. CDASH: No Match; SDTM: No Match	CHARACTER. Use choice list.

Annotated CRF: Concomitant Medication 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: Concomitant Medication CDISC Aligned NCI Standard Template

Conditional Questions

CRF Question	Value Domain
Concomitant Agent Name (6400634) **CDE Short Name:** CMTRT CDASH: CDASH: CMTRT (6400634) SDTM: CMTRT (No CDE)	CHARACTER – Maximum Length = 200

Optional Questions

CRF Question	Value Domain
Agent Code (6975007) **CDE Short Name:** CMAGTCD CDASH: No Match SDTM: No Match, Can be a supplemental qualifier in SDTM	NUMBER – Maximum Length = 15
Ingredient (6400636) **CDE Short Name:** CMINGRD CDASH: CMINGRD (6400636) SDTM: No Match, Can be a supplemental qualifier in SDTM	CHARACTER – Maximum Length = 200

CRF Question	Value Domain
Formulation (6975008) **CDE Short Name:** CMDSFMTP CDASH: CMDOSFRM (6400808) SDTM: CMDOSFRM (No CDE)	CHARACTER – Maximum Length = 50 ☐ Aerosol – Aerosol Dosage Form ☐ Caplet – Caplet ☐ Capsule – Capsule ☐ Capsule/Liquid-filled – Capsule/Liquid-filled ☐ Capsule/Micronized Powder – Capsule Dosage Form Micronization Powder Dosage Form ☐ Cartridge – Cartridge ☐ Cream – Cream ☐ Depot – Extended Release Depot Dosage Form ☐ Device – Device ☐ Gas – Gas Dosage Form ☐ Gel – Gel Dosage Form ☐ Injection – Injection ☐ Liquid – Liquid ☐ Lotion – Lotion ☐ Ointment – Ointment ☐ Patch – Patch ☐ Powder – Powder ☐ Sachet – Sachet Dosing Unit ☐ Spray – Spray Dosage Form ☐ Suppository – Suppository Dosage Form ☐ Suspension – Suspension Dosage Form ☐ Tablet – Tablet
Frequency (6975009) **CDE Short Name:** CMCMDSFQ CDASH: CMDOSFRQ (6401033) SDTM: CMDOSFRQ (No CDE)	CHARACTER – Maximum Length = 50 List of 42 PVs
Route (6975010) **CDE Short Name:** CMROUTTP CDASH: CMROUTE (6401132) SDTM: CMROUTE (No CDE)	CHARACTER – Maximum Length = 25 List of 39 PVs

CRF Question	Value Domain
Indication (6975011) **CDE Short Name:** CMUSINRN CDASH: CMINDC (6400637) SDTM: CMINDC (No CDE)	CHARACTER – Maximum Length = 50 List of 226 PVs
Start Date (6400968) **CDE Short Name:** CMSTDAT CDASH: CMSTDAT (6400968) SDTM: CMSTDTC (No CDE)	DATE – Maximum Length = 11
Stop Date (6400825) **CDE Short Name:** CMENDAT CDASH: CMENDAT (6400825) SDTM: CMENDTC (No CDE)	DATE – Maximum Length = 11
Dose (6400657) **CDE Short Name:** CMDOSE CDASH: CMDOSE (6400657) SDTM: CMDOSE (No CDE)	NUMBER – Maximum Length = 10
Units of Measure (6983142) **CDE Short Name:** CMDSUNCD CDASH: CMDOSU (6400803) SDTM:d CMDOSU (No CDE)	CHARACTER – Maximum Length = 30 List of 146 PVs
Is the patient taking any concomitant medications (6400632) **CDE Short Name:** CMYN CDASH: CMYN (6400632) SDTM: No Match	CHARACTER – Maximum Length = 2 ☐ N – No ☐ NA – Not Applicable ☐ U – Unknown ☐ Y – Yes

CRF Question	Value Domain
Use (6983152) **CDE Short Name:** CMFRMRS CDASH: No Match SDTM: No Match	CHARACTER – Maximum Length = 50 ☐ Cumulative at end of therapy – Cumulative at completion of therapy ☐ During each protocol treatment administration – Each therapy administration ☐ Specific therapy cycle – Specific therapy cycle