

# 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).

## Prior Therapies 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)
- PR – Procedures (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)
- PR – Procedures (v3.3)

## Prior Therapies 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 (o) 6400634 CMTRT	Verbatim medication name or treatments (include only treatments with data collection characteristics similar to medications).  CDASH: CMTRT (6400634); SDTM: CMTRT (No CDE)	CHARACTER
Prior Therapy Agent Administered Code (o) 7097657 CMTNCICD	The code that represents the medication/treatment that was administered before protocol therapy.  CDASH: No Match; SDTM: No Match	CHARACTER
Prior Therapy Agent Dose Frequency (o) 7097658 CMPRDSFQ	The frequency doses were administered before protocol therapy.  CDASH: CMDOSFRQ (6401033); SDTM: CMDOSFRQ (No CDE)	CHARACTER. Use choice list.

<b>Field Name (Partition Status) CDE ID # Short Name</b>	<b>Definition CDISC Mapping and Instruction</b>	<b>Format</b>
Prior Therapy Agent Route of Administration Type Code (o) 7097659 CMPRROUT	The route of administration of the medication/treatment that was administered before protocol therapy.  CDASH: CMROUTE (6401132); SDTM: CMROUTE (No CDE)	CHARACTER. Use choice list.
Prior Therapy Last Therapeutic Procedure Administered Date (o) 7097660 PRLTRTDT	The date of the last medication/treatment/therapy that was administered before protocol therapy, represented in an unambiguous date format (e.g., DD-MON-YYYY).  CDASH: No Match; SDTM: No Match	DATE
Intended Procedure Regimen (o) 6421532 PRDOSRGM	The text description of the (intended) schedule or regimen for the procedure.  CDASH: PRDOSRGM (6421532); SDTM: PRDOSRGM (No CDE)	CHARACTER
Prior Therapy Clinical Trial Total Course Administered Number (o) 7097661 AGAGTCSN	The total number of single rounds of medication/treatment treatment that was administered before protocol therapy.  CDASH: No Match; SDTM: No Match	NUMBER
Prior Therapy Total Chemotherapy Treatment Regimen Administered Number (o) 7097665 PRPCRGN	The total number of prior chemotherapy regimens received.  CDASH: No Match; SDTM: No Match	NUMBER
Prior Therapy Administered Type (o) 7097666 PRPRITRT	The therapeutic procedure administered before protocol therapy.  CDASH: PRTRT (6411539); SDTM: PRTRT (No CDE) where PRCAT = "Prior Therapy"	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Prior Therapy Administered Text (o) 7097667 PRPRITRX	The therapeutic procedure administered before protocol therapy not previously listed.  CDASH: PRTRT (6411539); PRTRT (No CDE) where PRCAT = "Prior Therapy"	CHARACTER
Procedure Start Date (o) 6409578 PRSTDAT	The date or start date of when the procedure started or was performed represented in an unambiguous date format (e.g., DD-MON-YYYY).  CDASH: PRSTDAT (6409578); SDTM: PRSTDTC (No CDE)	DATE
Procedure End Date (o) 6409579 PRENDAT	The end date of the procedure represented in an unambiguous date format (e.g., DD-MON-YYYY).  CDASH: PRENDAT (6409579); SDTM: PRENDTC (No CDE)	DATE
Concomitant Meds Dose Description (o) 6400656 CMDSTXT	The dose of medication/treatment taken per administration.  CDASH: CMDSTXT (6400656); SDTM: CMDOSTXT (6631718)	CHARACTER
Prior Therapy Agent Terminology Unit of Measure (o) 7097699 CMPRDOSU	The unit of measure associated with the prior therapy administered.  CDASH: CMDOSU (6400803); SDTM: CMDOSU (No CDE)	CHARACTER. Use choice list.

## Annotated CRF: Prior Therapies 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: Prior Therapies CDISC Aligned NCI Standard Template

Optional Questions

CRF Question	Value Domain
<b>Agent Name (6400634)</b> <b>CDE Short Name: CMTRT</b>  <div style="border: 1px solid blue; padding: 2px; width: fit-content; margin-bottom: 5px;">CDASH: CMTRT (6400634)</div> <div style="border: 1px solid red; padding: 2px; width: fit-content;">SDTM: CMTRT (No CDE)</div>	CHARACTER – Maximum Length = 200
<b>Agent Code (7097657)</b> <b>CDE Short Name: CMTNCICD</b>  <div style="border: 1px solid blue; padding: 2px; width: fit-content; margin-bottom: 5px;">CDASH: No Match</div> <div style="border: 1px solid red; padding: 2px; width: fit-content;">SDTM: No Match</div>	CHARACTER – Maximum Length = 10
<b>Frequency (7097658)</b> <b>CDE Short Name: CMPRDSFQ</b>  <div style="border: 1px solid blue; padding: 2px; width: fit-content; margin-bottom: 5px;">CDASH: CMDOSFRQ (6401033)</div> <div style="border: 1px solid red; padding: 2px; width: fit-content;">SDTM: CMDOSFRQ (No CDE)</div>	CHARACTER – Maximum Length = 50  List of 42 PVs
<b>Route (7097659)</b> <b>CDE Short Name: CMPRROUT</b>  <div style="border: 1px solid blue; padding: 2px; width: fit-content; margin-bottom: 5px;">CDASH: CMROUTE (6401132)</div> <div style="border: 1px solid red; padding: 2px; width: fit-content;">SDTM: CMROUTE (No CDE)</div>	CHARACTER – Maximum Length = 25  List of 39 PVs
<b>Date of Last Treatment (7097660)</b> <b>CDE Short Name: PRLTRTDT</b>  <div style="border: 1px solid blue; padding: 2px; width: fit-content; margin-bottom: 5px;">CDASH: No Match</div> <div style="border: 1px solid red; padding: 2px; width: fit-content;">SDTM: No Match</div>	DATE – Maximum Length = 11

CRF Question	Value Domain
<p><b>Regimen Name (6421532)</b>  <b>CDE Short Name: PRDOSRGM</b></p> <p>CDASH: PRDOSRGM (6421532)</p> <p>SDTM: PRDOSRGM (No CDE)</p>	<p>CHARACTER – Maximum Length = 200</p>
<p><b>Total # of Courses Received (7097661)</b>  <b>CDE Short Name: [CDE short name]</b></p> <p>CDASH: No Match</p> <p>SDTM: No Match</p>	<p>NUMBER – Maximum Length = 10</p>
<p><b>Total Number of Prior Chemotherapy Regimens (7097665)</b>  <b>CDE Short Name: PRPCRGN</b></p> <p>CDASH: No Match</p> <p>SDTM: No Match</p>	<p>NUMBER – Maximum Length = 10</p>

**Prior Therapy Type (7097666)**

**CDE Short Name: PRPRITRT**

CDASH: PRTRT (6411539)

SDTM: PRTRT (No CDE) where  
PRCAT = "Prior Therapy"

CHARACTER – Maximum Length = 100

- Anti-retroviral therapy – Agents administered to control the replication and/or spread of viruses
- Antisense – Treatment with an agent that prevents or impairs the translation of the genetic message for production of a specific protein
- Bone marrow transplant – High dose chemotherapy combined with transplantation of bone marrow cells
- Chemotherapy (NOS) – Non-systemic chemotherapy treatment or chemotherapy not described by Chemotherapy Single Agent Systemic or Multi-Agent Systemic
- Chemotherapy multiple agents systemic – Systemic chemotherapy with a regimen containing multiple agents
- Chemotherapy non-cytotoxic – Prior therapy with agents that are not known to cause damage to cycling cells
- Chemotherapy single agent systemic – Systemic chemotherapy with a single agent regimen
- Drug and/or Immunotherapy – Drug and/or Immunotherapy
- Gene transfer – Treatment of human disease by gene transfer
- Hematopoietic Stem Cell Transplantation – Hematopoietic Stem Cell Transplantation
- Hormonal therapy – Cancer therapy which incorporates hormonal manipulation
- Image Directed Local Therapy – Image Directed Local Therapy
- No prior therapy – No previous exposure to drug (NOS)
- Oncolytic virotherapy – Anticancer treatment with a live, replication-competent virus
- Prior therapy NOS – Prior Therapy (NOS)
- Radiation therapy – Radiation Therapy
- Surgery – Surgery
- Therapeutic Device – Therapeutic Medical Device
- Therapy (NOS) – Therapy NOS
- Vaccine – Substance or group of substances administered to induce the

CRF Question	Value Domain
	immune system to recognize and destroy tumors or microorganisms
<p><b>Prior Therapy Other Administration (7097667)</b>  <b>CDE Short Name:</b> PRPRITRX</p> <p>CDASH: PRTRT (6411539)</p> <p>SDTM: PRTRT (No CDE) where PRCAT = "Prior Therapy"</p>	<p>CHARACTER – Maximum Length = 200</p>
<p><b>Start Date (6409578)</b>  <b>CDE Short Name:</b> PRSTDAT</p> <p>CDASH: PRSTDAT (6409578)</p> <p>SDTM: PRSTDTC (No CDE)</p>	<p>DATE – Maximum Length = 11</p>
<p><b>Stop Date (6409579)</b>  <b>CDE Short Name:</b> PRENDAT</p> <p>CDASH: PRENDAT (6409579)</p> <p>SDTM: PRENDTC (No CDE)</p>	<p>DATE – Maximum Length = 11</p>
<p><b>Dose (6400656)</b>  <b>CDE Short Name:</b> CMDSTXT</p> <p>CDASH: CMDSTXT (6400656)</p> <p>SDTM: CMDOSTXT (6631718)</p>	<p>CHARACTER – Maximum Length = 200</p>
<p><b>Units of Measure (7097699)</b>  <b>CDE Short Name:</b> CMPRDOSU</p> <p>CDASH: CMDOSU (6400803)</p> <p>SDTM: CMDOSU (No CDE)</p>	<p>CHARACTER – Maximum Length = 100</p> <p>List of 750 PVs</p>