

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).

Follow-Up/Survival 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)
- DD – Death Details (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)
- DD – Death Details (v3.3)
- SS – Subject Status (v3.3)

Follow-Up/Survival 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
Follow-Up Vital Status Type (m) 7055151 SURVSTAT	The vital status of a patient during follow-up. CDASH: No Match; SDTM: SSORRES (No CDE) where SSTESTCD = "SURVSTAT" and SSTEST = "Survival Status"	CHARACTER. Use choice list.
Follow-Up Unknown Vital Status Text (o) 7055152 SSVTSTPX	The description of the reason the vital status during follow-up is unknown. CDASH: No Match; SDTM: SSORRES (No CDE) where SSTESTCD = "SURVSTAT" and SSTEST = "Survival Status"	CHARACTER

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Follow-Up Personal Contact Date (o) 7055153 SSFLCTDT	The date follow-up contact occurred, represented in an unambiguous date format (e.g., DD-MON-YYYY). CDASH: No Match; SDTM: SSDTC (6651953) where SSTEESTCD = "SURVSTAT" and SSTEEST = "Survival Status"	DATE
Personal Contact Media Method Type (o) 2006473 PRSN_CNT_TP	The method of communication for direct or indirect interaction between individuals or organizations. Not for FDA submission	ALPHANUMERIC. Use choice list.
Personal Information Obtain Source (o) 3828962 PRSN_INFO_OBT_SRC	A response to indicate where the data, facts or figures about an individual originated. Not for FDA submission	CHARACTER. Use choice list.
Follow-Up Health Information Status (o) 7055156 FLWPSTAT	The status of the patient's health information collected during follow-up. CDASH: No Match; SDTM: SSORRES (No CDE) where SSTEESTCD = "FLWPSTAT" and SSTEEST = "Current follow-up status"	CHARACTER. Use choice list.
Follow-Up Health Status Obtain Indicator (o) 7055157 FLWPIND	The indication whether or not patient health information was obtained during follow-up. CDASH: No Match; SDTM: SSORRES (No CDE) where SSTEESTCD = "FLWPIND" and SSTEEST = "Current follow-up indicator"	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Hospitalization Therapeutic Procedure Attribution Indicator (o) 7055158 HOSPIND	The indication of whether or not the patient was hospitalized due to the therapeutic procedure adverse events. CDASH: No Match; SDTM: SSORRES (No CDE) where SSTESTCD = "HOSPIND" and SSTEST = "Hospitalization indicator"	CHARACTER. Use choice list.
Date of Death (o) 6379836 DTHDAT	Date of death for any subject who died. CDASH: DTHDAT (6379836); SDTM: DSSTDTC (No CDE) where DSTERM = "DEATH"	DATE
Primary Cause of Death Diagnosis Original Result Category (o) 7055159 DDDTHRNC	The high level category that describes the primary reason for a patient death. CDASH: DDRESCAT (6413036) where DDTEST = "Primary Cause of Death Reason Category"; SDTM: DDRESCAT (6658539) where DDTEST = "Primary Cause of Death Reason Category"	CHARACTER. Use choice list.
Primary Cause of Death Diagnosis Original Result Reason (o) 7055160 DDDTHRNC	The description of the primary reason for a patient death. CDASH: DDORRES (6421598) where DDTESTCD = "DIAGPRIM", DDTEST = "Primary Diagnosis"; SDTM: DDORRES (No CDE) where DDTESTCD = "DIAGPRIM", DDTEST = "Primary Diagnosis"	CHARACTER. Use choice list.
Primary Cause of Death (o) 6421593 PRCDTH_DDORRES	Result of the death detail assessment, as originally received or collected. CDASH: DDORRES (6421598) where DDTESTCD = "DIAGPRIM" and DDTEST = "Primary Diagnosis"; SDTM: DDORRES (No CDE) where DDTEST = "Primary Diagnosis"	CHARACTER

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Secondary Cause of Death Diagnosis Original Result Reason (o) 7055161 DDCNTDTH	The description of the secondary or contributing reason for a patient death. CDASH: DDORRES (6421598) where DDTEST = "Contributing Cause of Death Reason"; SDTM: DDORRES (No CDE) where DDTEST = "Contributing Cause of Death Reason"	CHARACTER. Use choice list.
Secondary Cause of Death (o) 6421594 SECDTH_DDORRES	Result of the death detail assessment, as originally received or collected. CDASH: DDORRES (6421598) where DDTEST = "Contributing Cause of Death Reason"; SDTM: DDORRES (No CDE) where DDTEST = "Contributing Cause of Death Reason"	CHARACTER
ICD-9 CM/PCS Cause of Death Reason Name (o) 7055162 DDRNICD9	The ICD-9 CM/PCS cancer diagnosis that resulted in a patient death. CDASH: No Match; SDTM: No Match, Can be a supplemental qualifier in SDTM	CHARACTER. Use choice list.
ICD-10 CM/PCS Cause of Death Reason Code (o) 7055163 DDRICD10	The ICD-10 CM/PCS cancer diagnosis that resulted in a patient death. CDASH: No Match; SDTM: No Match	NUMBER
Autopsy Performed Indicator (o) 7190202 DDAUTPSY	The indication of whether or not an autopsy was performed. CDASH: DDORRES (6421598) where DDTEST = "Autopsy Indicator", DDTESTCD = "AUTOPIND"; SDTM: DDORRES (No CDE) where DDTEST = "Autopsy Indicator", DDTESTCD = "AUTOPIND"	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Autopsy Finding Availability Indicator (o) 7055165 AUTRIND	The indicator of whether or not the autopsy findings are available. CDASH: DDORRES (6421598) where DDTEST = "Autopsy Result Availability" and DDTESTCD = "AUTRIND"; SDTM: DDORRES (No CDE) where DDTEST = "Autopsy Result Availability" and DDTESTCD = "AUTRIND"	CHARACTER. Use choice list.

Annotated CRF: Follow-Up/Survival 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: Follow-Up/Survival CDISC Aligned NCI Standard Template

Mandatory Questions

CRF Question	Value Domain
<p>Participant vital status (7055151) CDE Short Name: SURVSTAT</p> <p>CDASH: No Match</p> <p>SDTM: SSORRES (No CDE) where SSTEESTCD = "SURVSTAT" and SSTEEST = "Survival Status"</p>	<p>CHARACTER – Maximum Length = 11</p> <ul style="list-style-type: none"><input type="checkbox"/> Alive – Life<input type="checkbox"/> Dead – Death<input type="checkbox"/> Unknown – Unknown<input type="checkbox"/> Unspecified – Unspecified

Optional Questions

CRF Question	Value Domain
<p>Vital status, unknown (7055152) CDE Short Name: SSVTSTPX</p> <p>CDASH: No Match</p> <p>SDTM: SSORRES (No CDE) where SSTESTCD = "SURVSTAT" and SSTEST = "Survival Status"</p>	<p>CHARACTER – Maximum Length = 200</p>
<p>Date of contact (7055153) CDE Short Name: SSFLCTDT</p> <p>CDASH: No Match</p> <p>SDTM: SSDTC (6651953) where SSTESTCD = "SURVSTAT" and SSTEST = "Survival Status"</p>	<p>DATE – Maximum Length = 11</p>

CRF Question	Value Domain
<p>Contact Type (2006473) CDE Short Name: PRSN_CNT_TP</p> <div data-bbox="289 321 769 373" style="border: 1px solid blue; padding: 2px; margin: 10px 0;"> <p>CDASH: Not for FDA submission</p> </div> <div data-bbox="289 407 769 459" style="border: 1px solid red; padding: 2px; margin: 10px 0;"> <p>SDTM: Not for FDA submission</p> </div>	<p>ALPHANUMERIC – Maximum Length = 30</p> <ul style="list-style-type: none"> <input type="checkbox"/> Cell – Cellular Telephone <input type="checkbox"/> Email – E-mail <input type="checkbox"/> Email/Mail/Fax/Etc. (Written correspondence) – Written Correspondence <input type="checkbox"/> Home Cell – Home Mobile Telephone <input type="checkbox"/> Home email – Home E-mail <input type="checkbox"/> Home fax – Home Fax Number <input type="checkbox"/> Home mail – Home Postal Address <input type="checkbox"/> Home phone – Home Telephone Number <input type="checkbox"/> In Clinic – Clinic <input type="checkbox"/> In Person – Visual Contact <input type="checkbox"/> Pager – Pager <input type="checkbox"/> Phone Call – Telephone Number Call <input type="checkbox"/> Regular Mail – Regular Postal Address <input type="checkbox"/> Social media – Internet Social Media <input type="checkbox"/> Text Message – Text Message <input type="checkbox"/> Unknown – Unknown <input type="checkbox"/> Work Cell – Work Mobile Telephone <input type="checkbox"/> Work email – Work E-mail <input type="checkbox"/> Work fax – Work Fax Number <input type="checkbox"/> Work mail – Work Postal Address <input type="checkbox"/> Work phone – Work Telephone Number

CRF Question	Value Domain
<p>What is the information source? (3828962) CDE Short Name: PRSN_INFO_OBT_SRC</p> <p>CDASH: Not for FDA submission</p> <p>SDTM: Not for FDA submission</p>	<p>CHARACTER – Maximum Length = 100</p> <ul style="list-style-type: none"> <input type="checkbox"/> Adjudication Committee – Adjudication Committee <input type="checkbox"/> Autopsy – Autopsy <input type="checkbox"/> Cancer Registrar – Cancer Registrar <input type="checkbox"/> Death Certificate – Death Certificate <input type="checkbox"/> Family – Family <input type="checkbox"/> Hospice – Hospice <input type="checkbox"/> Medical Record – Medical Record <input type="checkbox"/> Obituaries – Obituary <input type="checkbox"/> Outside medical personnel (Nurse, Physician) – External Medical Personnel <input type="checkbox"/> Participant – Participant <input type="checkbox"/> Site medical personnel (Nurse, Physician) – Study Site Medical Personnel <input type="checkbox"/> SSDI – Social Security Death Index
<p>Current follow-up status (7055156) CDE Short Name: FLWPSTAT</p> <p>CDASH: No Match</p> <p>SDTM: SSORRES (No CDE) where SSTESTCD = "FLWPSTAT" and SSTEST = "Current follow-up status"</p>	<p>CHARACTER – Maximum Length = 200</p> <ul style="list-style-type: none"> <input type="checkbox"/> Active – Present <input type="checkbox"/> Lost – Lost To Follow-up <input type="checkbox"/> Not able to obtain any additional information – Not able to obtain any additional information <input type="checkbox"/> Not Applicable – Not applicable
<p>Were you able to obtain any information about the patient since the last report? (7055157) CDE Short Name: FLWPIND</p> <p>CDASH: No Match</p> <p>SDTM: SSORRES (No CDE) where SSTESTCD = "FLWPIND" and SSTEST = "Current follow-up indicator"</p>	<p>CHARACTER – Maximum Length = 2</p> <ul style="list-style-type: none"> <input type="checkbox"/> N – No <input type="checkbox"/> NA – Not Applicable <input type="checkbox"/> U – Unknown <input type="checkbox"/> Y – Yes

CRF Question	Value Domain
<p>Was the patient hospitalized for any treatment related complications in this report period? (7055158) CDE Short Name: HOSPIND</p> <p style="border: 1px solid blue; padding: 2px;">CDASH: No Match</p> <p style="border: 1px solid red; padding: 2px;">SDTM: SSORRES (No CDE) where SSTESTCD = "HOSPIND" and SSTEST = "Hospitalization indicator"</p>	<p>CHARACTER – Maximum Length = 2</p> <p><input type="checkbox"/> N – No</p> <p><input type="checkbox"/> NA – Not Applicable</p> <p><input type="checkbox"/> U – Unknown</p> <p><input type="checkbox"/> Y – Yes</p>
<p>Date of death (6379836) CDE Short Name: DTHDAT</p> <p style="border: 1px solid blue; padding: 2px;">CDASH: DTHDAT (6379836)</p> <p style="border: 1px solid red; padding: 2px;">SDTM: DSSTDTC (No CDE) where DSTERM = "DEATH"</p>	<p>DATE – Maximum Length = 11</p>
<p>Primary cause (7055159) CDE Short Name: DDDTHRNC</p> <p style="border: 1px solid blue; padding: 2px;">CDASH: DDRESCAT (6413036) where DDTEST = "Primary Cause of Death Reason Category"</p> <p style="border: 1px solid red; padding: 2px;">SDTM: DDRESCAT (6658539) where DDTEST = "Primary Cause of Death Reason Category"</p>	<p>CHARACTER – Maximum Length = 35</p> <p><input type="checkbox"/> Due to non-study treatment – Non-Study Treatment Relationship</p> <p><input type="checkbox"/> Due to other cause – Other Reason</p> <p><input type="checkbox"/> Due to protocol treatment – Therapy-Related Toxicity</p> <p><input type="checkbox"/> Due to secondary primary cancer – Second Primary Malignant Neoplasm</p> <p><input type="checkbox"/> Due to this disease – Primary Disease or Disorder</p> <p><input type="checkbox"/> Unknown – Unknown</p>
<p>Primary cause (7055160) CDE Short Name: DDDTHRN</p> <p style="border: 1px solid blue; padding: 2px;">CDASH: DDORRES (6421598) where DDTESTCD = "DIAGPRIM", DDTEST = "Primary Diagnosis"</p> <p style="border: 1px solid red; padding: 2px;">SDTM: DDORRES (No CDE) where DDTESTCD = "DIAGPRIM", DDTEST = "Primary Diagnosis"</p>	<p>CHARACTER – Maximum Length = 100</p> <p>List of 73 PVs</p>

CRF Question	Value Domain
<p>Primary cause, other (6421593) CDE Short Name: PRCDTH_DDORRES</p> <div data-bbox="289 321 769 436" style="border: 1px solid blue; padding: 5px; margin-bottom: 10px;"> <p>CDASH: DDORRES (6421598) where DDTESTCD = "DIAGPRIM" and DDTEST = "Primary Diagnosis"</p> </div> <div data-bbox="289 468 769 548" style="border: 1px solid red; padding: 5px;"> <p>SDTM: DDORRES (No CDE) where DDTEST = "Primary Diagnosis"</p> </div>	<p>CHARACTER – Maximum Length = 200</p>
<p>Contributing cause (7055161) CDE Short Name: DDCNTDTH</p> <div data-bbox="289 682 769 793" style="border: 1px solid blue; padding: 5px; margin-bottom: 10px;"> <p>CDASH: DDORRES (6421598) where DDTEST = "Contributing Cause of Death Reason"</p> </div> <div data-bbox="289 825 769 936" style="border: 1px solid red; padding: 5px;"> <p>SDTM: DDORRES (No CDE) where DDTEST = "Contributing Cause of Death Reason"</p> </div>	<p>CHARACTER – Maximum Length = 100</p> <p>List of 73 PVs</p>
<p>Contributing cause, other (6421594) CDE Short Name: SECDTH_DDORRES</p> <div data-bbox="289 1071 769 1182" style="border: 1px solid blue; padding: 5px; margin-bottom: 10px;"> <p>CDASH: DDORRES (6421598) where DDTEST = "Contributing Cause of Death Reason"</p> </div> <div data-bbox="289 1213 769 1325" style="border: 1px solid red; padding: 5px;"> <p>SDTM: DDORRES (No CDE) where DDTEST = "Contributing Cause of Death Reason"</p> </div>	<p>CHARACTER – Maximum Length = 200</p>
<p>Cause of Death (ICD-9) (7055162) CDE Short Name: DDRNICD9</p> <div data-bbox="289 1459 769 1509" style="border: 1px solid blue; padding: 5px; margin-bottom: 10px;"> <p>CDASH: No Match</p> </div> <div data-bbox="289 1541 769 1621" style="border: 1px solid red; padding: 5px;"> <p>SDTM: No Match, can be a supplemental qualifier in SDTM</p> </div>	<p>CHARACTER – Maximum Length = 40</p> <p>List of 73 PVs</p>
<p>Cause of Death (ICD-10) (7055163) CDE Short Name: DDRICD10</p> <div data-bbox="289 1753 769 1803" style="border: 1px solid blue; padding: 5px; margin-bottom: 10px;"> <p>CDASH: No Match</p> </div> <div data-bbox="289 1835 769 1885" style="border: 1px solid red; padding: 5px;"> <p>SDTM: No Match</p> </div>	<p>NUMBER – Maximum Length = 15</p>

CRF Question	Value Domain
<p>Was autopsy performed? (7190202) CDE Short Name: DDAUTPSY</p> <div style="border: 1px solid blue; padding: 5px; margin: 10px 0;"> <p>CDASH: DDORRES (6421598) where DDTEST = "Autopsy Indicator", DDTESTCD = "AUTOPIND"</p> </div> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: DDORRES (No CDE) where DDTEST = "Autopsy Indicator", DDTESTCD = "AUTOPIND"</p> </div>	<p>CHARACTER – Maximum Length = 2</p> <ul style="list-style-type: none"> <input type="checkbox"/> N – No <input type="checkbox"/> NA – Not Applicable <input type="checkbox"/> U – Unknown <input type="checkbox"/> Y – Yes
<p>Autopsy results available (7055165) CDE Short Name: AUTRIND</p> <div style="border: 1px solid blue; padding: 5px; margin: 10px 0;"> <p>CDASH: DDORRES (6421598) where DDTEST = "Autopsy Result Availability" and DDTESTCD = "AUTRIND"</p> </div> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: DDORRES (No CDE) where DDTEST = "Autopsy Result Availability" and DDTESTCD = "AUTRIND"</p> </div>	<p>CHARACTER – Maximum Length = 2</p> <ul style="list-style-type: none"> <input type="checkbox"/> N – No <input type="checkbox"/> NA – Not Applicable <input type="checkbox"/> U – Unknown <input type="checkbox"/> Y – Yes