

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).

Diagnosis Gross Pathology 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:

- FA – Findings About (v2.0)
- MI – Microscopic Findings (v2.0)

Mapping to the SDTM:

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

- BS – Biospecimen Findings (SDTMIG-PGx v1.0)
- FA – Findings About (v3.3)
- MI – Microscopic Findings (v3.3)
- TR – Tumor/Lesion Results (v3.3)
- PR – Procedures (v3.3)
- TU – Tumor/Lesion Identification (v3.3)

Diagnosis Gross Pathology 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
Gross Pathologic Examination Finding Category (m) 7038784 FAGRPFND	The category of tissue with respect to presence of disease. CDASH: FAORRES (6421467); SDTM: FAORRES (No CDE) where FATESTCD (6651723) = "GRPFND"	CHARACTER. Use choice list.
Neoplasm Margin Involvement Type (c) 7038785 MIMRGINV	The description of disease involvement in the tumor margin. CDASH: MIORRES (6421502); SDTM: MIORRES (No CDE) where MITESTCD (6620591) = "MRGINV"; Conditionality Rule: This CDE is to be included when required by the sponsor.	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Total Gleason Score for Prostate Cancer Finding Score (c) 7038786 MIGLSNSC	The description of prostate tissue based on the combination of cancerous glands and cell morphology represented as a numeric value. CDASH: MIORRES (6421502); SDTM: MIORRES (No CDE) where MITESTCD (6620591) = "CELLDIFF", MITEST = "Cellular Differentiation" and MITSTDTL (6421501) = "GLEASON TOTAL SUM"; Conditionality Rule: This CDE is to be included only in prostate cancer patients.	NUMBER. Use choice list.
Primary Gleason Pattern Finding Category (c) 7038787 MIPGLSSC	The category representing the most prevalent Gleason pattern in a prostate tissue. CDASH: MIORRES (6421502); SDTM: MIORRES (No CDE) where MITESTCD (6620591) = "CELLDIFF", MITEST = "Cellular Differentiation" and MITSTDTL (6421501) = "GLEASON PRIMARY SCORE"; Conditionality Rule: This CDE is to be included only in prostate cancer patients.	NUMBER. Use choice list.
Secondary Gleason Pattern Finding Category (c) 7038788 MISGLSSC	The category representing the second most prevalent Gleason pattern in a prostate tissue. CDASH: MIORRES (6421502); SDTM: MIORRES (No CDE) where MITESTCD (6620591) = "CELLDIFF", MITEST = "Cellular Differentiation" and MITSTDTL (6421501) = "GLEASON SECONDARY SCORE"; Conditionality Rule: This CDE is to be included only in prostate cancer patients.	NUMBER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Residual Neoplasm Gross Pathology Result Type (o) 7038789 MIGRPTHP	The pathologic description of the characteristics of residual tissue specimen. CDASH: MIORRES (6421502); SDTM: MIORRES (No CDE) where MITESTCD (6620591) = "GRPTHP"	CHARACTER. Use choice list.
Metastatic Neoplasm Laterality Name (o) 7038790 LATSPQNM	The name of the metastatic disease located within a structure or the body. CDASH: No Match; SDTM: TULAT (6648992)	CHARACTER. Use choice list.
Neoplasm Weight Value (o) 7038791 SPWEIGHT	The weight of resected neoplasm, represented as a numeric value. CDASH: BSORRES (No CDE); SDTM: BSORRES (No CDE) where BSTESTCD (No CDE) = "SPWEIGHT" and BSTEST (7044691) = "Specimen Weight"	NUMBER
Biospecimen Original Result Unit (o) 7252903 BSORRESU	The unit of measure for the biospecimen measurement or finding as originally received or collected. CDASH: No Match; SDTM: BSORRESU (7252903)	CHARACTER. Use choice list.
Neoplasm Total Volume Value (o) 7038792 SUMVOL	The total volume of tumor, represented as a numeric value. CDASH: No Match; SDTM: TRORRES (6642371) where TRTESTCD (6659342) = "SUMVOL"	NUMBER
Original Units (o) 6619597 TRORRESU	The unit of measure for the result of the tumor results assessment as originally received or collected. CDASH: No Match; SDTM: TRORRESU (6619597)	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Tumor Long Axis Size Result (o) 6922528 LDIAM	Result of the measurement of the tumor long axis dimension. CDASH: No Match; SDTM: TRORES (6642371) where TRTESTCD (6659342) = "LDIAM"	CHARACTER
Original Units (o) 6619597 TRORESU	The unit of measure for the result of the tumor results assessment as originally received or collected. CDASH: No Match; SDTM: TRORESU (6619597)	CHARACTER. Use choice list.
Tumor Short Axis Size Result (o) 6922529 TRSAXIS	Result of the measurement of the tumor short axis dimension. CDASH: No Match; SDTM: TRORES (6642371) where TRTESTCD (6659342) = "LPERP"	CHARACTER
Original Units (o) 6619597 TRORESU	The unit of measure for the result of the tumor results assessment as originally received or collected. CDASH: No Match; SDTM: TRORESU (6619597)	CHARACTER. Use choice list.
Neoplasm Third Greatest Diameter Value (o) 7038795 THRDDIAM	The length of the third dimension/diameter of a tumor that has been measured in a planar direction relative to dimensions 1 and 2, represented as a numeric value. CDASH: No Match; SDTM: TRORES (6642371) where TRTESTCD (6659342) = "THRDDIAM"	NUMBER
Original Units (o) 6619597 TRORESU	The unit of measure for the result of the tumor results assessment as originally received or collected. CDASH: No Match; SDTM: TRORESU (6619597)	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Surgical Margin Finding Status (o) 7038796 MISGMGST	The indication of whether there has been cancer involvement in the surgical margin after tissue removal. CDASH: MIORRES (6421502); SDTM: MIORRES (No CDE) where MITESTCD (6620591) = "SGMGSTAT"	CHARACTER. Use choice list.
Surgical Margin Distance Value (o) 7038797 MIMRGDST	The distance measured between the surgical margin of tissue and the tumor removed during surgery, represented as a numeric value. CDASH: MIORRES (6421502); SDTM: MIORRES (No CDE) where MITESTCD (6620591) = "MRGDST"	NUMBER
Surgical Margin Distance Unit of Measure (o) 7038798 MRGDISU	The unit associated with the distance measured between the surgical margin of tissue and the tumor removed during surgery. CDASH: No Match; SDTM: MIORRESU (6410966) where MITESTCD (6620591) = "MRGDST"	CHARACTER. Use choice list.
Sentinel Lymph Node Lymphadenectomy Performed Indicator (o) 7038799 PRSLNDIS	The indication of whether or not sentinel lymph nodes were removed. CDASH: PROCCUR (6407328) where PRTRT (6411539) = "Sentinel lymph node dissection"; SDTM: PROCCUR (No CDE) where PRTRT (No CDE) = "Sentinel lymph node dissection"	CHARACTER. Use choice list.
Lymph Node Examined Value (o) 7038800 LNCOUNT	The amount of lymph nodes examined, represented as a numeric value. CDASH: No Match; SDTM: TRORRES (6642371) where TRTESTCD (6659342) = "LNCOUNT"	NUMBER

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Lymph Node Pathologic Finding Outcome (o) 7038801 MILNPATH	The indication of whether there has been cancer involvement in the lymph nodes. CDASH: MIORRES (6421502); SDTM: MIORRES (No CDE) where MITESTCD (6620591) = "LNPATH"	CHARACTER. Use choice list.
Extracapsular Disease or Disorder Indicator (o) 7038802 MIEXCPSD	The indication of whether there has been extracapsular spread of disease. CDASH: MIORRES (6421502); SDTM: MIORRES (No CDE) where MITESTCD (6620591) = "EXCPSD"	CHARACTER. Use choice list.

Annotated CRF: Diagnosis Gross Pathology 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: Diagnosis Gross Pathology CDISC Aligned NCI Standard Template

Mandatory Questions

CRF Question	Value Domain
<p>Gross pathology findings (7038784) CDE Short Name: FAGRPFND</p> <p>CDASH: FAORRES (6421467)</p> <p>SDTM: FAORRES (No CDE) where FATESTCD (6651723) = "GRPFND"</p>	<p>CHARACTER – Maximum Length = 15</p> <ul style="list-style-type: none"><input type="checkbox"/> Abnormal – Abnormal<input type="checkbox"/> Benign – Benign<input type="checkbox"/> Equivocal – Equivocal<input type="checkbox"/> Malignant – Malignant<input type="checkbox"/> Non-malignant– Non-Malignant<input type="checkbox"/> Normal – Normal

Conditional Questions

CRF Question	Value Domain
<p>Margin involvement (7038785) CDE Short Name: MIMRGINV</p> <p>CDASH: MIORRES (6421502)</p> <p>SDTM: MIORRES (No CDE) where MITESTCD (6620591) = "MRGINV"</p>	<p>CHARACTER – Maximum Length = 35</p> <ul style="list-style-type: none"> <input type="checkbox"/> Circumferential – Circumferential Margin <input type="checkbox"/> Distal – Distal Margin <input type="checkbox"/> Non-resectable deep margins – Unresectable Deep Margin <input type="checkbox"/> Other – Other <input type="checkbox"/> Proximal – Proximal Margin
<p>Gleason score (7038786) CDE Short Name: MIGLSNSC</p> <p>CDASH: MIORRES (6421502)</p> <p>SDTM: MIORRES (No CDE) where MITESTCD (6620591) = "CELLDIFF", MITEST = "Cellular Differentiation" and MITSTDTL (6421501) = "GLEASON TOTAL SUM"</p>	<p>NUMBER – Maximum Length = 2</p> <ul style="list-style-type: none"> <input type="checkbox"/> 10 – Gleason Score 10 <input type="checkbox"/> 2 – Gleason Score 2 <input type="checkbox"/> 3 – Gleason Score 3 <input type="checkbox"/> 4 – Gleason Score 4 <input type="checkbox"/> 5 – Gleason Score 5 <input type="checkbox"/> 6 – Gleason Score 6 <input type="checkbox"/> 7 – Gleason Score 7 <input type="checkbox"/> 8 – Gleason Score 8 <input type="checkbox"/> 9 – Gleason Score 9
<p>Gleason score (7038787) CDE Short Name: MIPGLSSC</p> <p>CDASH: MIORRES (6421502)</p> <p>SDTM: MIORRES (No CDE) where MITESTCD (6620591) = "CELLDIFF", MITEST = "Cellular Differentiation" and MITSTDTL (6421501) = "GLEASON PRIMARY SCORE"</p>	<p>NUMBER – Maximum Length = 1</p> <ul style="list-style-type: none"> <input type="checkbox"/> 1 – Gleason Pattern 1 <input type="checkbox"/> 2 – Gleason Pattern 2 <input type="checkbox"/> 3 – Gleason Pattern 3 <input type="checkbox"/> 4 – Gleason Pattern 4 <input type="checkbox"/> 5 – Gleason Pattern 5
<p>Secondary Gleason grade (7038788) CDE Short Name: MISGLSSC</p> <p>CDASH: MIORRES (6421502)</p> <p>SDTM: MIORRES (No CDE) where MITESTCD (6620591) = "CELLDIFF", MITEST = "Cellular Differentiation" and MITSTDTL (6421501) = "GLEASON SECONDARY SCORE"</p>	<p>NUMBER – Maximum Length = 1</p> <ul style="list-style-type: none"> <input type="checkbox"/> 1 – Gleason Pattern 1 <input type="checkbox"/> 2 – Gleason Pattern 2 <input type="checkbox"/> 3 – Gleason Pattern 3 <input type="checkbox"/> 4 – Gleason Pattern 4 <input type="checkbox"/> 5 – Gleason Pattern 5

Optional Questions

CRF Question	Value Domain
<p>Gross pathology present (7038789) CDE Short Name: MIGRPTHP</p> <p>CDASH: MIORRES (6421502)</p> <p>SDTM: MIORRES (No CDE) where MITESTCD (6620591) = "GRPTHP"</p>	<p>CHARACTER – Maximum Length = 38</p> <ul style="list-style-type: none"> <input type="checkbox"/> Gross stromal alterations/fibrosis – Gross stromal alterations/fibrosis <input type="checkbox"/> Multifocal discrete masses – Multifocal discrete masses <input type="checkbox"/> None present – None present <input type="checkbox"/> Single discrete mass – Single discrete mass
<p>Laterality (7038790) CDE Short Name: LATSPQNM</p> <p>CDASH: No Match</p> <p>SDTM: TULAT (6648992)</p>	<p>CHARACTER – Maximum Length = 9</p> <ul style="list-style-type: none"> <input type="checkbox"/> Anterior – Anterior <input type="checkbox"/> Bilateral – Bilateral <input type="checkbox"/> Caudal – Caudal <input type="checkbox"/> Contralateral – Contralateral <input type="checkbox"/> Cranial – cranial <input type="checkbox"/> Ipsilateral – Ipsilateral <input type="checkbox"/> Lateral – Lateral <input type="checkbox"/> Left – Left <input type="checkbox"/> Midline – Midline <input type="checkbox"/> Posterior – Posterior <input type="checkbox"/> Right – Right <input type="checkbox"/> Unilateral – Unilateral
<p>Grams resected (7038791) CDE Short Name: SPWEIGHT</p> <p>CDASH: BSORRES (No CDE);</p> <p>SDTM: BSORRES (No CDE) where BSTESTCD (No CDE) = "SPWEIGHT" and BSTEST (7044691) = "Specimen Weight"</p>	<p>NUMBER – Maximum Length = 5</p>
<p>Original Units (7252903) CDE Short Name: BSORRESU</p> <p>CDASH: No Match</p> <p>SDTM: BSORRESU (7252903)</p>	<p>CHARACTER – Maximum Length = 100</p> <ul style="list-style-type: none"> <input type="checkbox"/> g – Gram

CRF Question	Value Domain
<p>Total tumor volume (7038792) CDE Short Name: SUMVOL</p> <p>CDASH: No Match</p> <p>SDTM: TRORES (6642371) where TRTESTCD (6659342) = "SUMVOL"</p>	<p>NUMBER – Maximum Length = 5</p>
<p>Original Units (6619597) CDE Short Name: TRORESU</p> <p>CDASH: No Match</p> <p>SDTM: TRORESU (6619597)</p>	<p>CHARACTER – Maximum Length = 100</p> <p><input type="checkbox"/> mL – Milliliter</p>
<p>Dimension 1 (6922528) CDE Short Name: LDIAM</p> <p>CDASH: No Match</p> <p>SDTM: TRORES (6642371) where TRTESTCD (6659342) = "LDIAM"</p>	<p>CHARACTER – Maximum Length = 100</p>
<p>Original Units (6619597) CDE Short Name: TRORESU</p> <p>CDASH: No Match</p> <p>SDTM: TRORESU (6619597)</p>	<p>CHARACTER – Maximum Length = 100</p> <p><input type="checkbox"/> cm – Centimeter</p>
<p>Dimension 2 (6922529) CDE Short Name: TRSAXIS</p> <p>CDASH: No Match</p> <p>SDTM: TRORES (6642371) where TRTESTCD (6659342) = "LPERP"</p>	<p>CHARACTER – Maximum Length = 100</p>
<p>Original Units (6619597) CDE Short Name: TRORESU</p> <p>CDASH: No Match</p> <p>SDTM: TRORESU (6619597)</p>	<p>CHARACTER – Maximum Length = 100</p> <p><input type="checkbox"/> cm – Centimeter</p>

CRF Question	Value Domain
<p>Dimension 3 (7038795) CDE Short Name: THRDDIAM</p> <p>CDASH: No Match</p> <p>SDTM: TRORRES (6642371) where TRTESTCD (6659342) = "THRDDIAM"</p>	<p>NUMBER – Maximum Length = 5</p>
<p>Original Units (6619597) CDE Short Name: TRORRESU</p> <p>CDASH: No Match</p> <p>SDTM: TRORRESU (6619597)</p>	<p>CHARACTER – Maximum Length = 100</p> <p><input type="checkbox"/> cm – Centimeter</p>
<p>Surgical margins (7038796) CDE Short Name: MISGMGST</p> <p>CDASH: MIORRES (6421502);</p> <p>SDTM: MIORRES (No CDE) where MITESTCD (6620591) = "SGMGSTAT"</p>	<p>CHARACTER – Maximum Length = 20</p> <p><input type="checkbox"/> Equivocal – Equivocal</p> <p><input type="checkbox"/> Negative – Negative Finding</p> <p><input type="checkbox"/> Not evaluable – Not evaluable</p> <p><input type="checkbox"/> Positive – Positive Finding</p> <p><input type="checkbox"/> Unknown – Unknown</p>
<p>Margin distance (7038797) CDE Short Name: MIMRGDST</p> <p>CDASH: MIORRES (6421502);</p> <p>SDTM: MIORRES (No CDE) where MITESTCD (6620591) = "MRGDST"</p>	<p>NUMBER – Maximum Length = 5</p>
<p>Margin distance UOM (7038798) CDE Short Name: MRGDISU</p> <p>CDASH: No Match</p> <p>SDTM: MIORRESU (6410966) where MITESTCD (6620591) = "MRGDST"</p>	<p>CHARACTER – Maximum Length = 8</p> <p><input type="checkbox"/> cm – Centimeter</p> <p><input type="checkbox"/> ft – International Foot</p> <p><input type="checkbox"/> m – Meter</p> <p><input type="checkbox"/> mm – Millimeter</p>

CRF Question	Value Domain
<p>Sentinel lymph node dissection (7038799) CDE Short Name: PRSLNDIS</p> <p>CDASH: PROCCUR (6407328) where PRTRT (6411539) = "Sentinel lymph node dissection"</p> <p>SDTM: PROCCUR (No CDE) where PRTRT (No CDE) = "Sentinel lymph node dissection"</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>Number of lymph nodes examined (7038800) CDE Short Name: LNCOUNT</p> <p>CDASH: No Match</p> <p>SDTM: TRORES (6642371) where TRTESTCD (6659342) = "LNCOUNT"</p>	<p>NUMBER – Maximum Length = 5</p>
<p>LN pathologic result (7038801) CDE Short Name: MILNPATH</p> <p>CDASH: MIORRES (6421502)</p> <p>SDTM: MIORRES (No CDE) where MITESTCD (6620591) = "LNPATH"</p>	<p>CHARACTER – Maximum Length = 9</p> <p><input type="checkbox"/> Equivocal – Equivocal</p> <p><input type="checkbox"/> N/A – Not applicable</p> <p><input type="checkbox"/> Negative – Negative</p> <p><input type="checkbox"/> Not Evaluated – Not Evaluated</p> <p><input type="checkbox"/> Positive – Positive</p> <p><input type="checkbox"/> Unknown – Unknown</p>

CRF Question	Value Domain
<p>Extracapsular spread (7038802) CDE Short Name: MIEXCPSD</p> <p style="border: 1px solid blue; padding: 2px; margin: 10px 0;">CDASH: MIORRES (6421502)</p> <p style="border: 1px solid red; padding: 2px; margin: 10px 0;">SDTM: MIORRES (No CDE) where MITESTCD (6620591) = "EXCPSD"</p>	<p>CHARACTER – Maximum Length = 23</p> <ul style="list-style-type: none"> <input type="checkbox"/> Absent – Absent <input type="checkbox"/> Indeterminate – Indeterminate <input type="checkbox"/> No – No <input type="checkbox"/> No source documentation – No source documentation <input type="checkbox"/> Not applicable – Not applicable <input type="checkbox"/> Not available – Not Available <input type="checkbox"/> Not determined – Not Determined <input type="checkbox"/> Not identified – Not Identified <input type="checkbox"/> Not sampled/dissected – Not sampled/dissected <input type="checkbox"/> Present – Present <input type="checkbox"/> Present - extensive – Present - extensive <input type="checkbox"/> Present - minimal – Present - Minimal <input type="checkbox"/> Unknown – Unknown <input type="checkbox"/> Unspecified – Unspecified <input type="checkbox"/> Yes – Yes