

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).

Staging AJCC Edition 8, Prostate 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:

- RS – Disease Response and Clin Classification (v3.3)

Staging AJCC Edition 8, Prostate 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
TNM Staging System Assessment Date (m) 7110971 QSTMNDT	The date the TNM staging was completed represented in an unambiguous date format (e.g., DD-MON-YYYY). CDASH: No Match; SDTM: No Match	DATE
Prostate Cancer AJCC Edition 8 Clinical Tumor T Category (c) 7104549 AJPR201C	Extent of the primary prostate carcinoma based on information obtained from the date of cancer diagnosis until the start of definitive treatment, or within four months (whichever is shorter), using AJCC Ed. 8 criteria. CDASH: No Match; SDTM: RSORRES (6642369) = value of AJPR201C, RSSTRESC (6642356) = value of AJPR201C, RSTESTCD (6620609) = "AJCC201", RSTEST (6620604) = "AJCC2-Primary Tumor (T)", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "PROSTATE CANCER CLINICAL"; Conditionality Rule: Inclusion based on patient population being studied.	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Prostate Cancer AJCC Edition 8 Clinical Regional Lymph Node N Category (c) 7101989 AJPR202C	Extent of the regional lymph node involvement for prostate carcinoma based on evidence obtained from the date of cancer diagnosis until the start of definitive treatment, or within four months (whichever is shorter), using AJCC Ed. 8 criteria. CDASH: No Match; SDTM: RSORRES (6642369) = value of AJPR202C, RSSTRESC (6642356) = value of AJPR202C, RSTESTCD (6620609) = "AJCC202", RSTEST (6620604) = "AJCC2- Regional Lymph Node (N)", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "PROSTATE CANCER CLINICAL"; Conditionality Rule: Inclusion based on patient population being studied.	CHARACTER. Use choice list.
Prostate Cancer AJCC Edition 8 Clinical Distant Metastasis M Category (c) 7100296 AJPR203C	Extent of the distant metastasis for prostate carcinoma based on information obtained from the date of cancer diagnosis until the start of definitive treatment, or within four months (whichever is shorter), using AJCC Ed. 8 criteria. CDASH: No Match; SDTM: RSORRES (6642369) = value of AJPR203C, RSSTRESC (6642356) = value of AJPR203C, RSTESTCD (6620609) = "AJCC203", RSTEST (6620604) = "AJCC2- Distant Metastasis (M)", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "PROSTATE CANCER CLINICAL"; Conditionality Rule: Inclusion based on patient population being studied.	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Prostate Cancer AJCC Edition 8 Pathologic Tumor T Category (c) 7104559 AJPR201P	Extent of the primary prostate carcinoma based on clinical stage information combined with operative findings, and evidence obtained from pathology review when surgery is the first definitive therapy, using AJCC Ed. 8 criteria. CDASH: No Match; SDTM: RSORRES (6642369) = value of AJPR201P, RSSTRESC (6642356) = value of AJPR201P, RSTESTCD (6620609) = "AJCC201", RSTEST (6620604) = "AJCC2-Primary Tumor (T)", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "PROSTATE CANCER PATHOLOGIC"; Conditionality Rule: Inclusion based on patient population being studied.	CHARACTER. Use choice list.
Prostate Cancer AJCC Edition 8 Pathologic Regional Lymph Node N Category (c) 7101997 AJPR202P	Extent of the regional lymph node involvement for prostate carcinoma based on clinical stage information combined with operative findings, and evidence obtained from pathology review when surgery is the first definitive therapy, using AJCC Ed. 8 criteria. CDASH: No Match; SDTM: RSORRES (6642369) = value of AJPR202P, RSSTRESC (6642356) = value of AJPR202P, RSTESTCD (6620609) = "AJCC202", RSTEST (6620604) = "AJCC2-Regional Lymph Node (N)", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "PROSTATE CANCER PATHOLOGIC"; Conditionality Rule: Inclusion based on patient population being studied.	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Prostate Cancer AJCC Edition 8 Pathologic Distant Metastasis M Category (c) 7104563 AJPR203P	Extent of the distant metastasis for prostate carcinoma based on clinical stage information combined with operative findings, and evidence obtained from pathology review when surgery is the first definitive therapy, using AJCC Ed. 8 criteria. CDASH: No Match; SDTM: RSORRES (6642369) = value of AJPR203P, RSSTRESC (6642356) = value of AJPR203P, RSTESTCD (6620609) = "AJCC203", RSTEST (6620604) = "AJCC2-Distant Metastasis (M)", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "PROSTATE CANCER PATHOLOGIC"; Conditionality Rule: Inclusion based on patient population being studied.	CHARACTER. Use choice list.
Prostate Cancer AJCC Edition 8 Group Stage (c) 7104553 AJPR204	Stage group based on the combination of T, N, and M categories and relevant prognostic factors for prostate carcinoma, using AJCC Ed. 8 criteria. CDASH: No Match; SDTM: RSORRES (6642369) = value of AJPR204, RSSTRESC (6642356) = value of AJPR204, RSTESTCD (6620609) = "AJCC204", RSTEST (6620604) = "AJCC2-Anatomic Stage", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "PROSTATE CANCER"; Conditionality Rule: Inclusion based on patient population being studied.	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
TNM Staging System Assessment Timepoint Type (o) 7110980 QSTMNTYP	The type of TNM staging completed based on their occurrence at a point in time. CDASH: No Match; SDTM: No Match	CHARACTER. Use choice list.

Annotated CRF: Staging AJCC Edition 8, Prostate 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: Staging AJCC Edition 8, Prostate CDISC Aligned NCI
Standard Template

Mandatory Questions

CRF Question	Value Domain
Date Current Staging Assessment Completed (7110971) CDE Short Name: QSTMNDT <div style="border: 1px solid blue; padding: 2px; width: fit-content;">CDASH: No Match</div> <div style="border: 1px solid red; padding: 2px; width: fit-content;">SDTM: No Match</div>	DATE – Maximum Length = 11

Conditional Questions

CRF Question	Value Domain
<p>Clinical T category (7104549) CDE Short Name: AJPR201C</p> <div style="border: 1px solid blue; padding: 5px; margin: 10px 0;"> <p>CDASH: No Match</p> </div> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: RSORRES (6642369) = value of AJPR201C, RSSTRESC (6642356) = value of AJPR201C, RSTESTCD (6620609) = "AJCC201", RSTEST (6620604) = "AJCC2-Primary Tumor (T)", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "PROSTATE CANCER CLINICAL"</p> </div>	<p>CHARACTER – Maximum Length = 3</p> <ul style="list-style-type: none"> <input type="checkbox"/> T0 – Prostate Cancer cT0 TNM Finding v8 <input type="checkbox"/> T1 – Prostate Cancer cT1 TNM Finding v8 <input type="checkbox"/> T1a – Prostate Cancer cT1a TNM Finding v8 <input type="checkbox"/> T1b – Prostate Cancer cT1b TNM Finding v8 <input type="checkbox"/> T1c – Prostate Cancer cT1c TNM Finding v8 <input type="checkbox"/> T2 – Prostate Cancer cT2 TNM Finding v8 <input type="checkbox"/> T2a – Prostate Cancer cT2a TNM Finding v8 <input type="checkbox"/> T2b – Prostate Cancer cT2b TNM Finding v8 <input type="checkbox"/> T2c – Prostate Cancer cT2c TNM Finding v8 <input type="checkbox"/> T3 – Prostate Cancer cT3 TNM Finding v8 <input type="checkbox"/> T3a – Prostate Cancer cT3a TNM Finding v8 <input type="checkbox"/> T3b – Prostate Cancer cT3b TNM Finding v8 <input type="checkbox"/> T4 – Prostate Cancer cT4 TNM Finding v8 <input type="checkbox"/> TX – Prostate Cancer cTX TNM Finding v8
<p>Clinical N category (7101989) CDE Short Name: AJPR202C</p> <div style="border: 1px solid blue; padding: 5px; margin: 10px 0;"> <p>CDASH: No Match</p> </div> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: RSORRES (6642369) = value of AJPR202C, RSSTRESC (6642356) = value of AJPR202C, RSTESTCD (6620609) = "AJCC202", RSTEST (6620604) = "AJCC2-Regional Lymph Node (N)", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "PROSTATE CANCER CLINICAL"</p> </div>	<p>CHARACTER – Maximum Length = 2</p> <ul style="list-style-type: none"> <input type="checkbox"/> N0 – Prostate Cancer pN0 TNM Finding v8 <input type="checkbox"/> N1 – Prostate Cancer pN1 TNM Finding v8 <input type="checkbox"/> NX – Prostate Cancer pNX TNM Finding v8

CRF Question	Value Domain
<p>Clinical M category (7100296) CDE Short Name: AJPR203C</p> <div style="border: 1px solid blue; padding: 5px; margin: 10px 0;">CDASH: No Match</div> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;"> SDTM: RSORRES (6642369) = value of AJPR203C, RSSTRESC (6642356) = value of AJPR203C, RSTESTCD (6620609) = "AJCC203", RSTEST (6620604) = "AJCC2-Distant Metastasis (M)", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "PROSTATE CANCER CLINICAL" </div>	<p>CHARACTER – Maximum Length = 4</p> <ul style="list-style-type: none"> <input type="checkbox"/> cM0 – Prostate Cancer cM0 TNM Finding v8 <input type="checkbox"/> cM1 – Prostate Cancer cM1 TNM Finding v8 <input type="checkbox"/> cM1a – Prostate Cancer cM1a TNM Finding v8 <input type="checkbox"/> cM1b – Prostate Cancer cM1b TNM Finding v8 <input type="checkbox"/> cM1c – Prostate Cancer cM1c TNM Finding v8 <input type="checkbox"/> pM1 – Prostate Cancer pM1 TNM Finding v8
<p>Pathologic T category (7104559) CDE Short Name: AJPR201P</p> <div style="border: 1px solid blue; padding: 5px; margin: 10px 0;">CDASH: No Match</div> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;"> SDTM: RSORRES (6642369) = value of AJPR201P, RSSTRESC (6642356) = value of AJPR201P, RSTESTCD (6620609) = "AJCC201", RSTEST (6620604) = "AJCC2-Primary Tumor (T)", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "PROSTATE CANCER PATHOLOGIC" </div>	<p>CHARACTER – Maximum Length = 3</p> <ul style="list-style-type: none"> <input type="checkbox"/> T2 – Prostate Cancer pT2 TNM Finding v8 <input type="checkbox"/> T3 – Prostate Cancer pT3 TNM Finding v8 <input type="checkbox"/> T3a – Prostate Cancer pT3a TNM Finding v8 <input type="checkbox"/> T3b – Prostate Cancer pT3b TNM Finding v8 <input type="checkbox"/> T4 – Prostate Cancer pT4 TNM Finding v8
<p>Pathologic N category (7101997) CDE Short Name: AJPR202P</p> <div style="border: 1px solid blue; padding: 5px; margin: 10px 0;">CDASH: No Match</div> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;"> SDTM: RSORRES (6642369) = value of AJPR202P, RSSTRESC (6642356) = value of AJPR202P, RSTESTCD (6620609) = "AJCC202", RSTEST (6620604) = "AJCC2-Regional Lymph Node (N)", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "PROSTATE CANCER PATHOLOGIC" </div>	<p>CHARACTER – Maximum Length = 2</p> <ul style="list-style-type: none"> <input type="checkbox"/> N0 – Prostate Cancer pN0 TNM Finding v8 <input type="checkbox"/> N1 – Prostate Cancer pN1 TNM Finding v8 <input type="checkbox"/> NX – Prostate Cancer pNX TNM Finding v8

CRF Question	Value Domain
<p>Pathologic M category (7104563) CDE Short Name: AJPR203P</p> <div style="border: 1px solid blue; padding: 5px; margin: 10px 0;"> <p>CDASH: No Match</p> </div> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: RSORRES (6642369) = value of AJPR203P, RSSTRESC (6642356) = value of AJPR203P, RSTESTCD (6620609) = "AJCC203", RSTEST (6620604) = "AJCC2-Distant Metastasis (M)", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "PROSTATE CANCER PATHOLOGIC"</p> </div>	<p>CHARACTER – Maximum Length = 4</p> <ul style="list-style-type: none"> <input type="checkbox"/> cM0 – Prostate Cancer cM0 TNM Finding v8 <input type="checkbox"/> cM1 – Prostate Cancer cM1 TNM Finding v8 <input type="checkbox"/> pM1 – Prostate Cancer pM1 TNM Finding v8 <input type="checkbox"/> pM1a – Prostate Cancer pM1a TNM Finding v8 <input type="checkbox"/> pM1b – Prostate Cancer pM1b TNM Finding v8 <input type="checkbox"/> pM1c – Prostate Cancer pM1c TNM Finding v8
<p>Disease stage (7104553) CDE Short Name: AJPR204</p> <div style="border: 1px solid blue; padding: 5px; margin: 10px 0;"> <p>CDASH: No Match</p> </div> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: RSORRES (6642369) = value of AJPR204, RSSTRESC (6642356) = value of AJPR204, RSTESTCD (6620609) = "AJCC204", RSTEST (6620604) = "AJCC2-Anatomic Stage", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "PROSTATE CANCER"</p> </div>	<p>CHARACTER – Maximum Length = 4</p> <ul style="list-style-type: none"> <input type="checkbox"/> I – Stage I Prostate Cancer AJCC v8 <input type="checkbox"/> IIA – Stage IIA Prostate Cancer AJCC v8 <input type="checkbox"/> IIB – Stage IIB Prostate Cancer AJCC v8 <input type="checkbox"/> IIC – Stage IIC Prostate Cancer AJCC v8 <input type="checkbox"/> IIIA – Stage IIIA Prostate Cancer AJCC v8 <input type="checkbox"/> IIIB – Stage IIIB Prostate Cancer AJCC v8 <input type="checkbox"/> IIIC – Stage IIIC Prostate Cancer AJCC v8 <input type="checkbox"/> IVA – Stage IVA Prostate Cancer AJCC v8 <input type="checkbox"/> IVB – Stage IVB Prostate Cancer AJCC v8

Optional Questions

CRF Question	Value Domain
<p data-bbox="240 262 617 294">Staging Time Point (7110980)</p> <p data-bbox="240 300 621 331">CDE Short Name: QSTMNTYP</p> <div data-bbox="289 380 769 432" style="border: 1px solid blue; padding: 2px; margin: 10px 0;">CDASH: No Match</div> <div data-bbox="289 464 769 516" style="border: 1px solid red; padding: 2px; margin: 10px 0;">SDTM: No Match</div>	<p data-bbox="818 262 1284 294">CHARACTER – Maximum Length = 18</p> <ul style="list-style-type: none"><li data-bbox="818 342 1328 373"><input type="checkbox"/> Current Diagnosis – Current Diagnosis<li data-bbox="818 384 1263 415"><input type="checkbox"/> Initial Diagnosis – First Diagnosis<li data-bbox="818 426 1141 457"><input type="checkbox"/> Restaging – Restaging<li data-bbox="818 468 1263 531"><input type="checkbox"/> Study Enrollment – Clinical Study Enrollment