

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, Colorectal 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, Colorectal 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	he date the TNM staging was completed represented in an unambiguous date format (e.g., DD-MON-YYYY). CDASH: No Match; SDTM: No Match	DATE

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Colorectal Cancer AJCC Edition 8 Clinical Tumor T Category (c) 7098186 AJCR201C	<p>Extent of the primary colon and rectal 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.</p> <p>CDASH: No Match; SDTM: RSORRES (6642369) = value of AJCR201C, RSSTRESC (6642356) = value of AJCR201C, RSTESTCD (6620609) = "AJCC201", RSTEST (6620604) = "AJCC2-Primary Tumor (T)", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "COLORECTAL CANCER CLINICAL"; Conditionality Rule: Inclusion based on patient population being studied</p>	CHARACTER. Use choice list.
Colorectal Cancer AJCC Edition 8 Clinical Regional Lymph Node N Category (c) 7098157 AJCR202C	<p>Extent of the regional lymph node involvement for colon and rectal 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</p> <p>CDASH: No Match; SDTM: RSORRES (6642369) = value of AJCR202C, RSSTRESC (6642356) = value of AJCR202C, RSTESTCD (6620609) = "AJCC202", RSTEST (6620604) = "AJCC2-Regional Lymph Node (N)", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "COLORECTAL CANCER CLINICAL"; Conditionality Rule: Inclusion based on patient population being studied</p>	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Colorectal Cancer AJCC Edition 8 Clinical Distant Metastasis M Category (c) 7108780 AJCR203C	Extent of the distant metastasis for colon and rectal 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 AJCR203C, RSSTRESC (6642356) = value of AJCR203C, RSTESTCD (6620609) = "AJCC203", RSTEST (6620604) = "AJCC2-Distant Metastasis (M)", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "COLORECTAL CANCER CLINICAL"; Conditionality Rule: Inclusion based on patient population being studied	CHARACTER. Use choice list.
Colorectal Cancer AJCC Edition 8 Pathologic Tumor T Category (c) 7098018 AJCR201P	Extent of the primary colon and rectal 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 AJCR201P, RSSTRESC (6642356) = value of AJCR201P, RSTESTCD (6620609) = "AJCC201", RSTEST (6620604) = "AJCC2-Primary Tumor (T)", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "COLORECTAL 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
Colorectal Cancer AJCC Edition 8 Pathologic Regional Lymph Node N Category (c) 7097142 AJCR202P	Extent of the regional lymph node involvement for colon and rectal 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 AJCR202P, RSSTRESC (6642356) = value of AJCR202P, RSTESTCD (6620609) = "AJCC202", RSTEST (6620604) = "AJCC2- Regional Lymph Node (N)", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "COLORECTAL 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
Colorectal Cancer AJCC Edition 8 Pathologic Distant Metastasis M Category (c) 7097186 AJCR203P	Extent of the distant metastasis for colon and rectal 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 AJCR203P, RSSTRESC (6642356) = value of AJCR203P, RSTESTCD (6620609) = "AJCC203", RSTEST (6620604) = "AJCC2-Distant Metastasis (M)", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "COLORECTAL CANCER PATHOLOGIC"; Conditionality Rule: Inclusion based on patient population being studied	CHARACTER. Use choice list.
Colorectal Cancer AJCC Edition 8 Group Stage (c) 7098195 AJCR204	Stage group based on the combination of T, N, and M categories and relevant prognostic factors for colon and rectal carcinoma, using AJCC Ed. 8 criteria CDASH: No Match; SDTM: RSORRES (6642369) = value of AJCR204, RSSTRESC (6642356) = value of AJCR204, RSTESTCD (6620609) = "AJCC204", RSTEST (6620604) = "AJCC2-Anatomic Stage", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "COLORECTAL 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, Colorectal 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, Colorectal CDISC Aligned NCI
Standard Template

Mandatory Questions

CRF Question	Value Domain
Date Current Staging Assessment Completed (7110971) CDE Short Name: QSTMNDT <div data-bbox="284 730 769 781" style="border: 1px solid blue; padding: 2px;">CDASH: No Match</div> <div data-bbox="284 814 769 865" style="border: 1px solid red; padding: 2px;">SDTM: No Match</div>	DATE – Maximum Length = 11

Conditional Questions

CRF Question	Value Domain
<p>Clinical T category (7098186) CDE Short Name: AJCR201C</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 AJCR201C, RSSTRESC (6642356) = value of AJCR201C, RSTESTCD (6620609) = "AJCC201", RSTEST (6620604) = "AJCC2-Primary Tumor (T)", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "COLORECTAL CANCER CLINICAL"</p> </div>	<p>CHARACTER – Maximum Length = 3</p> <ul style="list-style-type: none"> <input type="checkbox"/> T0 – Colorectal Cancer pT0 TNM Finding v8 <input type="checkbox"/> T1 – Colorectal Cancer pT1 TNM Finding v8 <input type="checkbox"/> T2 – Colorectal Cancer pT2 TNM Finding v8 <input type="checkbox"/> T3 – Colorectal Cancer pT3 TNM Finding v8 <input type="checkbox"/> T4 – Colorectal Cancer pT4 TNM Finding v8 <input type="checkbox"/> T4a – Colorectal Cancer pT4a TNM Finding v8 <input type="checkbox"/> T4b – Colorectal Cancer pT4b TNM Finding v8 <input type="checkbox"/> Tis – Colorectal Cancer pTis TNM Finding v8 <input type="checkbox"/> TX – Colorectal Cancer pTX TNM Finding v8
<p>Clinical N category (7098157) CDE Short Name: AJCR202C</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 AJCR202C, RSSTRESC (6642356) = value of AJCR202C, RSTESTCD (6620609) = "AJCC202", RSTEST (6620604) = "AJCC2-Regional Lymph Node (N)", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "COLORECTAL CANCER CLINICAL"</p> </div>	<p>CHARACTER – Maximum Length = 3</p> <ul style="list-style-type: none"> <input type="checkbox"/> N0 – Colorectal Cancer pN0 TNM Finding v8 <input type="checkbox"/> N1 – Colorectal Cancer pN1 TNM Finding v8 <input type="checkbox"/> N1a – Colorectal Cancer pN1a TNM Finding v8 <input type="checkbox"/> N1b – Colorectal Cancer pN1b TNM Finding v8 <input type="checkbox"/> N1c – Colorectal Cancer pN1c TNM Finding v8 <input type="checkbox"/> N2 – Colorectal Cancer pN2 TNM Finding v8 <input type="checkbox"/> N2a – Colorectal Cancer pN2a TNM Finding v8 <input type="checkbox"/> N2b – Colorectal Cancer pN2b TNM Finding v8 <input type="checkbox"/> NX – Colorectal Cancer pNX TNM Finding v8

CRF Question	Value Domain
<p>Clinical M category (7108780) CDE Short Name: AJCR203C</p> <div data-bbox="289 321 769 373" style="border: 1px solid blue; padding: 2px;"> <p>CDASH: No Match</p> </div> <div data-bbox="289 407 769 674" style="border: 1px solid red; padding: 2px;"> <p>SDTM: RSORRES (6642369) = value of AJCR203C, RSSTRESC (6642356) = value of AJCR203C, RSTESTCD (6620609) = "AJCC203", RSTEST (6620604) = "AJCC2-Distant Metastasis (M)", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "COLORECTAL CANCER CLINICAL"</p> </div>	<p>CHARACTER – Maximum Length = 4</p> <ul style="list-style-type: none"> <input type="checkbox"/> cM0 – Colorectal Cancer cM0 TNM Finding v8 <input type="checkbox"/> cM1 – Colorectal Cancer cM1 TNM Finding v8 <input type="checkbox"/> cM1a – Colorectal Cancer cM1a TNM Finding v8 <input type="checkbox"/> cM1b – Colorectal Cancer cM1b TNM Finding v8 <input type="checkbox"/> cM1c – Colorectal Cancer cM1c TNM Finding v8 <input type="checkbox"/> pM1 – Colorectal Cancer pM1 TNM Finding v8
<p>Pathologic T category (7098018) CDE Short Name: AJCR201P</p> <div data-bbox="289 858 769 911" style="border: 1px solid blue; padding: 2px;"> <p>CDASH: No Match</p> </div> <div data-bbox="289 945 769 1211" style="border: 1px solid red; padding: 2px;"> <p>SDTM: RSORRES (6642369) = value of AJCR201P, RSSTRESC (6642356) = value of AJCR201P, RSTESTCD (6620609) = "AJCC201", RSTEST (6620604) = "AJCC2-Primary Tumor (T)", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "COLORECTAL CANCER PATHOLOGIC"</p> </div>	<p>CHARACTER – Maximum Length = 3</p> <ul style="list-style-type: none"> <input type="checkbox"/> T0 – Colorectal Cancer pT0 TNM Finding v8 <input type="checkbox"/> T1 – Colorectal Cancer pT1 TNM Finding v8 <input type="checkbox"/> T2 – Colorectal Cancer pT2 TNM Finding v8 <input type="checkbox"/> T3 – Colorectal Cancer pT3 TNM Finding v8 <input type="checkbox"/> T4 – Colorectal Cancer pT4 TNM Finding v8 <input type="checkbox"/> T4a – Colorectal Cancer pT4a TNM Finding v8 <input type="checkbox"/> T4b – Colorectal Cancer pT4b TNM Finding v8 <input type="checkbox"/> Tis – Colorectal Cancer pTis TNM Finding v8 <input type="checkbox"/> TX – Colorectal Cancer pTX TNM Finding v8

CRF Question	Value Domain
<p>Pathologic N category (7097142) CDE Short Name: AJCR202P</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 AJCR202P, RSSTRESC (6642356) = value of AJCR202P, RSTESTCD (6620609) = "AJCC202", RSTEST (6620604) = "AJCC2-Regional Lymph Node (N)", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "COLORECTAL CANCER PATHOLOGIC"</p> </div>	<p>CHARACTER – Maximum Length = 3</p> <ul style="list-style-type: none"> <input type="checkbox"/> N0 – Colorectal Cancer pN0 TNM Finding v8 <input type="checkbox"/> N1 – Colorectal Cancer pN1 TNM Finding v8 <input type="checkbox"/> N1a – Colorectal Cancer pN1a TNM Finding v8 <input type="checkbox"/> N1b – Colorectal Cancer pN1b TNM Finding v8 <input type="checkbox"/> N1c – Colorectal Cancer pN1c TNM Finding v8 <input type="checkbox"/> N2 – Colorectal Cancer pN2 TNM Finding v8 <input type="checkbox"/> N2a – Colorectal Cancer pN2a TNM Finding v8 <input type="checkbox"/> N2b – Colorectal Cancer pN2b TNM Finding v8 <input type="checkbox"/> NX – Colorectal Cancer pNX TNM Finding v8
<p>Pathologic M category (7097186) CDE Short Name: AJCR203P</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 AJCR203P, RSSTRESC (6642356) = value of AJCR203P, RSTESTCD (6620609) = "AJCC203", RSTEST (6620604) = "AJCC2-Distant Metastasis (M)", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "COLORECTAL CANCER PATHOLOGIC"</p> </div>	<p>CHARACTER – Maximum Length = 4</p> <ul style="list-style-type: none"> <input type="checkbox"/> cM0 – Colorectal Cancer cM0 TNM Finding v8 <input type="checkbox"/> cM1 – Colorectal Cancer cM1 TNM Finding v8 <input type="checkbox"/> cM1a – Colorectal Cancer cM1a TNM Finding v8 <input type="checkbox"/> cM1b – Colorectal Cancer cM1b TNM Finding v8 <input type="checkbox"/> cM1c – Colorectal Cancer cM1c TNM Finding v8 <input type="checkbox"/> pM1 – Colorectal Cancer pM1 TNM Finding v8

CRF Question	Value Domain
<p data-bbox="245 212 553 239">Disease stage (7098195)</p> <p data-bbox="245 247 589 275">CDE Short Name: AJCR204</p> <div data-bbox="289 323 769 373" style="border: 1px solid blue; padding: 2px; margin: 10px 0;"> <p data-bbox="302 338 526 365">CDASH: No Match</p> </div> <div data-bbox="289 407 769 674" style="border: 1px solid red; padding: 2px; margin: 10px 0;"> <p data-bbox="302 422 748 659">SDTM: RSORRES (6642369) = value of AJCR204, RSSTRESC (6642356) = value of AJCR204, RSTESTCD (6620609) = "AJCC204", RSTEST (6620604) = "AJCC2-Anatomic Stage", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "COLORECTAL CANCER"</p> </div>	<p data-bbox="824 212 1268 239">CHARACTER – Maximum Length = 4</p> <ul style="list-style-type: none"> <li data-bbox="824 260 1341 287"><input type="checkbox"/> 0 – Stage 0 Colorectal Cancer AJCC v8 <li data-bbox="824 302 1325 329"><input type="checkbox"/> I – Stage I Colorectal Cancer AJCC v8 <li data-bbox="824 344 1373 371"><input type="checkbox"/> IIA – Stage IIA Colorectal Cancer AJCC v8 <li data-bbox="824 386 1373 413"><input type="checkbox"/> IIB – Stage IIB Colorectal Cancer AJCC v8 <li data-bbox="824 428 1341 485"><input type="checkbox"/> IIC – Stage IIC Colorectal Cancer AJCC v8 <li data-bbox="824 499 1357 556"><input type="checkbox"/> IIIA – Stage IIIA Colorectal Cancer AJCC v8 <li data-bbox="824 571 1357 627"><input type="checkbox"/> IIIB – Stage IIIB Colorectal Cancer AJCC v8 <li data-bbox="824 642 1357 699"><input type="checkbox"/> IIIC – Stage IIIC Colorectal Cancer AJCC v8 <li data-bbox="824 714 1357 770"><input type="checkbox"/> IVA – Stage IVA Colorectal Cancer AJCC v8 <li data-bbox="824 785 1357 842"><input type="checkbox"/> IVB – Stage IVB Colorectal Cancer AJCC v8 <li data-bbox="824 856 1357 913"><input type="checkbox"/> IVC – Stage IVC Colorectal Cancer AJCC v8

Optional Questions

CRF Question	Value Domain
<p>Staging Time Point (7110980) CDE Short Name: QSTMNTYP</p> <p>CDASH: No Match</p> <p>SDTM: No Match</p>	<p>CHARACTER – Maximum Length = 18</p> <ul style="list-style-type: none"><input type="checkbox"/> Current Diagnosis – Current Diagnosis<input type="checkbox"/> Initial Diagnosis – First Diagnosis<input type="checkbox"/> Restaging – Restaging<input type="checkbox"/> Study Enrollment – Clinical Study Enrollment