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, Lung 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, Lung 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

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Lung Cancer AJCC Edition 8 Clinical Tumor T Category (c) 7098765 AJLG201C	Extent of the primary lung cancer 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 AJLG201C, RSSTRESC (6642356) = value of AJLG201C, RSTESTCD (6620609) = "AJCC201", RSTEST (6620604) = "AJCC2-Primary Tumor (T)", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "LUNG CANCER CLINICAL"; Conditionality Rule: Inclusion based on patient population being studied.	CHARACTER. Use choice list.
Lung Cancer AJCC Edition 8 Clinical Regional Lymph Node N Category (c) 7100284 AJLG202C	Extent of the regional lymph node involvement for lung cancer 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 AJLG202C, RSSTRESC (6642356) = value of AJLG202C, RSTESTCD (6620609) = "AJCC202", RSTEST (6620604) = "AJCC2-Regional Lymph Node (N)", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "LUNG 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
Lung Cancer AJCC Edition 8 Clinical Distant Metastasis M Category (c) 7100291 AJLG203C	Extent of the distant metastasis for lung cancer 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 AJLG203C, RSSTRESC (6642356) = value of AJLG203C, RSTESTCD (6620609) = "AJCC203", RSTEST (6620604) = "AJCC2-Distant Metastasis (M)", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "LUNG CANCER CLINICAL"; Conditionality Rule: Inclusion based on patient population being studied.	CHARACTER. Use choice list.
Lung Cancer AJCC Edition 8 Pathologic Tumor T Category (c) 7101993 AJLG201P	Extent of the primary lung cancer 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 AJLG201P, RSSTRESC (6642356) = value of AJLG201P, RSTESTCD (6620609) = "AJCC201", RSTEST (6620604) = "AJCC2-Primary Tumor (T)", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "LUNG 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
Lung Cancer AJCC Edition 8 Pathologic Regional Lymph Node N Category (c) 7101142 AJLG202P	Extent of the regional lymph node involvement for lung cancer 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 AJLG202P, RSSTRESC (6642356) = value of AJLG202P, RSTESTCD (6620609) = "AJCC202", RSTEST (6620604) = "AJCC2-Regional Lymph Node (N)", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "LUNG CANCER PATHOLOGIC"; Conditionality Rule: Inclusion based on patient population being studied.	CHARACTER. Use choice list.
Lung Cancer AJCC Edition 8 Pathologic Distant Metastasis M Category (c) 7101988 AJLG203P	Extent of the distant metastasis for lung cancer 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 AJLG203P, RSSTRESC (6642356) = value of AJLG203P, RSTESTCD (6620609) = "AJCC203", RSTEST (6620604) = "AJCC2-Distant Metastasis (M)", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "LUNG 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
Lung Cancer AJCC Edition 8 Disease Stage (c) 7100295 AJLG204	Stage group based on the combination of T, N, and M categories and relevant prognostic factors for lung cancer, using AJCC Ed. 8 criteria. CDASH: No Match; SDTM: RSORRES (6642369) = value of AJLG204, RSSTRESC (6642356) = value of AJLG204, RSTESTCD (6620609) = "AJCC204", RSTEST (6620604) = "AJCC2-Anatomic Stage", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "LUNG CANCER"; Conditionality Rule: Inclusion based on patient population being studied.	CHARACTER. Use choice list.
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, Lung 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, Lung CDISC Aligned NCI Standard Template

Mandatory Questions

CRF Question	Value Domain
Date Current Staging Assessment Completed (7110971) **CDE Short Name:** QSTMNDT CDASH: No Match SDTM: No Match	DATE – Maximum Length = 11

Conditional Questions

CRF Question	Value Domain
Clinical T category (7098765) **CDE Short Name:** AJLG201C CDASH: No Match SDTM: RSORRES (6642369) = value of AJLG201C, RSSTRESC (6642356) = value of AJLG201C, RSTESTCD (6620609) = "AJCC201", RSTEST (6620604) = "AJCC2-Primary Tumor (T)", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "LUNG CANCER CLINICAL"	CHARACTER – Maximum Length = 4 ☐ T0 – Lung Cancer pT0 TNM Finding v8 ☐ T1 – Lung Cancer pT1 TNM Finding v8 ☐ T1a – Lung Cancer pT1a TNM Finding v8 ☐ T1b – Lung Cancer pT1b TNM Finding v8 ☐ T1c – Lung Cancer pT1c TNM Finding v8 ☐ T1mi – Lung Cancer pT1mi TNM Finding v8 ☐ T2 – Lung Cancer pT2 TNM Finding v8 ☐ T2a – Lung Cancer pT2a TNM Finding v8 ☐ T2b – Lung Cancer pT2b TNM Finding v8 ☐ T3 – Lung Cancer pT3 TNM Finding v8 ☐ T4 – Lung Cancer pT4 TNM Finding v8 ☐ Tis – Lung Cancer pTis TNM Finding v8 ☐ TX – Lung Cancer pTX TNM Finding v8
Clinical N category (7100284) **CDE Short Name:** AJLG202C CDASH: No Match SDTM: RSORRES (6642369) = value of AJLG202C, RSSTRESC (6642356) = value of AJLG202C, RSTESTCD (6620609) = "AJCC202", RSTEST (6620604) = "AJCC2-Regional Lymph Node (N)", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "LUNG CANCER CLINICAL"	CHARACTER – Maximum Length = 2 ☐ N0 – Lung Cancer pN0 TNM Finding v8 ☐ N1 – Lung Cancer pN1 TNM Finding v8 ☐ N2 – Lung Cancer pN2 TNM Finding v8 ☐ N3 – Lung Cancer pN3 TNM Finding v8 ☐ NX – Lung Cancer pNX TNM Finding v8
Clinical M category (7100291) **CDE Short Name:** AJLG203C CDASH: No Match SDTM: RSORRES (6642369) = value of AJLG203C, RSSTRESC (6642356) = value of AJLG203C, RSTESTCD (6620609) = "AJCC203", RSTEST (6620604) = "AJCC2-Distant Metastasis (M)", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "LUNG CANCER CLINICAL"	CHARACTER – Maximum Length = 4 ☐ cM0 – Clinical N category ☐ cM1 – Lung Cancer cM1 TNM Finding v8 ☐ cM1a – Lung Cancer cM1a TNM Finding v8 ☐ cM1b – Lung Cancer cM1b TNM Finding v8 ☐ cM1c – Lung Cancer cM1c TNM Finding v8 ☐ pM1 – Lung Cancer pM1 TNM Finding v8

CRF Question	Value Domain
Pathologic T category (7101993) **CDE Short Name:** AJLG201P CDASH: No Match SDTM: RSORRES (6642369) = value of AJLG201P, RSSTRESC (6642356) = value of AJLG201P, RSTESTCD (6620609) = "AJCC201", RSTEST (6620604) = "AJCC2-Primary Tumor (T)", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "LUNG CANCER PATHOLOGIC"	CHARACTER – Maximum Length = 4 ☐ T0 – Lung Cancer pT0 TNM Finding v8 ☐ T1 – Lung Cancer pT1 TNM Finding v8 ☐ T1a – Lung Cancer pT1a TNM Finding v8 ☐ T1b – Lung Cancer pT1b TNM Finding v8 ☐ T1c – Lung Cancer pT1c TNM Finding v8 ☐ T1mi – Lung Cancer pT1mi TNM Finding v8 ☐ T2 – Lung Cancer pT2 TNM Finding v8 ☐ T2a – Lung Cancer pT2a TNM Finding v8 ☐ T2b – Lung Cancer pT2b TNM Finding v8 ☐ T3 – Lung Cancer pT3 TNM Finding v8 ☐ T4 – Lung Cancer pT4 TNM Finding v8 ☐ Tis – Lung Cancer pTis TNM Finding v8 ☐ TX – Lung Cancer pTX TNM Finding v8
Pathologic N category (7101142) **CDE Short Name:** AJLG202P CDASH: No Match SDTM: RSORRES (6642369) = value of AJLG202P, RSSTRESC (6642356) = value of AJLG202P, RSTESTCD (6620609) = "AJCC202", RSTEST (6620604) = "AJCC2-Regional Lymph Node (N)", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "LUNG CANCER PATHOLOGIC"	CHARACTER – Maximum Length = 2 ☐ N0 – Lung Cancer pN0 TNM Finding v8 ☐ N1 – Lung Cancer pN1 TNM Finding v8 ☐ N2 – Lung Cancer pN2 TNM Finding v8 ☐ N3 – Lung Cancer pN3 TNM Finding v8 ☐ NX – Lung Cancer pNX TNM Finding v8
Pathologic M category (7101988) **CDE Short Name:** AJLG203P CDASH: No Match SDTM: RSORRES (6642369) = value of AJLG203P, RSSTRESC (6642356) = value of AJLG203P, RSTESTCD (6620609) = "AJCC203", RSTEST (6620604) = "AJCC2-Distant Metastasis (M)", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "LUNG CANCER PATHOLOGIC"	CHARACTER – Maximum Length = 4 ☐ cM0 – Lung Cancer cM0 TNM Finding v8 ☐ cM1 – Lung Cancer cM1 TNM Finding v8 ☐ pM1 – Lung Cancer pM1 TNM Finding v8 ☐ pM1a – Lung Cancer pM1a TNM Finding v8 ☐ pM1b – Lung Cancer pM1b TNM Finding v8 ☐ mP1c – Lung Cancer pM1c TNM Finding v8

CRF Question	Value Domain
Disease stage (7100295) **CDE Short Name:** AJLG204 CDASH: No Match SDTM: RSORRES (6642369) = value of AJLG204, RSSTRESC (6642356) = value of AJLG204, RSTESTCD (6620609) = "AJCC204", RSTEST (6620604) = "AJCC2-Anatomic Stage", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "LUNG CANCER"	CHARACTER – Maximum Length = 16 ☐ 0 – Stage 0 Lung Cancer AJCC v8 ☐ IA1 – Stage IA1 Lung Cancer AJCC v8 ☐ IA2 – Stage IA2 Lung Cancer AJCC v8 ☐ IA3 – Stage IA3 Lung Cancer AJCC v8 ☐ IB – Stage IB Lung Cancer AJCC v8 ☐ IIA – Stage IIA Lung Cancer AJCC v8 ☐ IIB – Stage IIB Lung Cancer AJCC v8 ☐ IIIA – Stage IIIA Lung Cancer AJCC v8 ☐ IIIB – Stage IIIB Lung Cancer AJCC v8 ☐ IIIC – Stage IIIC Lung Cancer AJCC v8 ☐ IV – Stage IV Lung Cancer AJCC v8 ☐ IVA – Stage IVA Lung Cancer AJCC v8 ☐ IVB – Stage IVB Lung Cancer AJCC v8 ☐ Occult carcinoma – Occult Lung Cancer AJCC v8

Optional Questions

CRF Question	Value Domain
Staging Time Point (7110980) **CDE Short Name:** QSTMNTYP CDASH: No Match SDTM: No Match	CHARACTER – Maximum Length = 18 ☐ Current Diagnosis – Current Diagnosis ☐ Initial Diagnosis – First Diagnosis ☐ Restaging – Restaging ☐ Study Enrollment – Clinical Study Enrollment