



Therapeutic Area Data Standards User Guide for Lung Cancer

Version 1.0 (Provisional)

Prepared by the
CDISC Lung Cancer Standards Development Team

Notes to Readers

- This is the *provisional* version 1.0 of the Therapeutic Area Data Standards User Guide for Lung Cancer.
- This document is based on CDASHIG v2.0, CDASH Model 1.0, SDTM v1.7 and the SDTM Implementation Guide (SDTMIG v3.3, SDTMIG-MD v1.1, SDTMIG PGx 1.0), ADaM v2.1, and ADaMIG v1.1

Revision History

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See [Appendix E](#) for Representations and Warranties, Limitations of Liability, and Disclaimers.

CONTENTS

1	INTRODUCTION	3
1.1	HOW TO READ THIS DOCUMENT	3
1.2	ORGANIZATION OF THIS DOCUMENT.....	4
1.3	CDASH METADATA AND ANNOTATED CRFs.....	4
1.4	KNOWN ISSUES.....	6
2	OVERVIEW OF LUNG CANCER	7
3	SUBJECT AND DISEASE CHARACTERISTICS.....	9
3.1	DIAGNOSIS	9
3.2	STAGING.....	11
3.3	DISEASE CHARACTERISTICS	12
3.4	PATHOLOGY AND BIOMARKERS	24
3.5	EFFUSION ASSESSMENTS	32
4	DISEASE ASSESSMENTS AND TREATMENTS.....	48
4.1	TREATMENTS FOR LUNG CANCER	48
4.1.1	Medications/Radiotherapy.....	48
4.1.2	Surgeries.....	49
4.2	DISEASE RESPONSE AND TUMOR ASSESSMENTS	49
4.3	QUESTIONNAIRES, RATINGS, AND SCALES	83
4.4	OXYGEN USE.....	84
4.5	TREATMENT OF PLEURAL EFFUSIONS.....	85
5	ANALYSIS DATA.....	86
5.1	ADSL.....	86
5.2	TUMOR DATA OVERVIEW DATASET	88
6	APPENDICES.....	92
	APPENDIX A: LUNG CANCER STANDARDS DEVELOPMENT TEAM	92
	APPENDIX B: GLOSSARY AND ABBREVIATIONS	93
	APPENDIX C: NON-STANDARD VARIABLES.....	95
	APPENDIX D: REFERENCES.....	96
	Works Cited	96
	Further Reading	97
	APPENDIX E: REPRESENTATIONS AND WARRANTIES, LIMITATIONS OF LIABILITY, AND DISCLAIMERS	98

1 Introduction

The Therapeutic Area Data Standards User Guide for Lung Cancer (TAUG-LuCa) was developed under the Coalition for Accelerating Standards and Therapies (CFAST) initiative. This process included collecting input from various stakeholders to ensure the standard is as thorough as possible. A number of volunteers and experts provided resources and input to support the development of this standard. The goal of this initiative is to identify a core set of clinical therapeutic area concepts and endpoints for targeted therapeutic areas and translate them into CDISC standards to improve semantic understanding, support data sharing, and facilitate global regulatory submission. As with all CDISC therapeutic area standards, the purpose of this standard is to describe how to use CDISC standards to represent data pertaining to a targeted therapeutic area—in this case, lung cancer.

This first version (v1.0) of the TAUG-LuCa focuses on clinical trials of drugs to treat non-small cell lung cancer (NSCLC) and small cell lung cancer (SCLC) in subjects with Stage IV or extensive disease.

This document provides advice and examples for Clinical Data Acquisition Standards Harmonization (CDASH), the Study Data Tabulation Model (SDTM), and the Analysis Data Model (ADaM), including:

- guidance on the use of domains and variables;
- sample annotated case report forms (aCRFs);
- examples of SDTM datasets, with text describing the situational context and pointing out records of note; and
- guidance on the use of ADaM.

The biomedical concepts covered in this guide were selected from concepts identified by one or more stakeholders as important, and which were not addressed or were not completely addressed by existing CDISC implementation guides. This user guide does not provide guidance on what data are needed for regulatory submission or approval; it only provides advice on how to represent data in a standard form.

To reiterate: It is important to note that the choice of biomedical concepts included in this user guide is not intended to influence sponsor decisions as to what data to collect. The examples included are intended to show how particular kinds of data can be represented using CDISC standards. This user guide emphasizes that *examples are only examples and should not be over-interpreted*. For guidance on the selection of biomedical concepts and endpoints, please refer to the appropriate clinical and regulatory authorities.

Clinical guidelines, articles, and other works consulted by the team during the creation of this document are referenced where appropriate, using the American Medical Association (AMA) style for citation. For the sources cited in this document and suggestions for further reading, see Appendix D, [References](#).

1.1 How to Read This Document

1. First, read the foundational standards upon which this document is based—CDASH Implementation Guide v2.0, CDASH Model 1.0, SDTM v1.7 and the SDTM Implementation Guides (SDTMIG v3.3, SDTMIG-MD 1.1, and SDTMIG PGx 1.0), ADaM v2.1, and the ADaM Implementation Guide v1.1—to gain some familiarity with data models and the basic rules for how they are implemented. These standards are available at <http://www.cdisc.org/>. Reviewing [SDTM Examples for Oncology Use Cases](#) is also recommended.
2. Next, read the [Introduction to Therapeutic Area Standards](#) and/or take CDISC's free training module [TA001 - Overview of Therapeutic Area User Guides](#) for an understanding of what to expect from this guide.
3. Read this guide all the way through (without skipping any sections) at least once.
4. Finally, revisit any sections of particular interest.

Some things to bear in mind while reading this document:

- This document does not replace or supersede the foundational CDISC standards or their implementation guides, and should not be used as a substitute for any other CDISC standard.
- This document generally does not repeat content already published in another CDISC standard.
- This document is not and does not try to be an exhaustive documentation of every possible kind of data that could be collected in relation to lung cancer.
- The advice and examples presented in this document are influenced by ongoing internal standards development at CDISC. If a modeling approach seems inconsistent with a published standard, it may be a genuine error, but it could also be a reflection of potential or upcoming changes to the standard. Corrections for errors identified after publication can be found on the [Errata for Therapeutic Area Standards](#) for the document.
- As this document ages, parts of it may become outdated. Please bear in mind the release date when contrasting advice and/or modeling in this guide against that in other CDISC standards.
- The examples in this document use CDISC Controlled Terminology where possible, but some values that seem to be controlled terminology may still be under development at the time of publication, or even especially plausible "best-guess" placeholder values. Do not rely on any source other than the CDISC value set in the National Cancer Institute Thesaurus (available at <http://www.cancer.gov/research/resources/terminology/cdisc>) for controlled terminology.
- Draft standards of interest to this document are listed at: [Draft Standards of Interest to Provisional Standards and Documents Undergoing Public Review](#).

All general caveats for therapeutic area (TA) standards given in the [Introduction to Therapeutic Area Standards](#) apply to this document.

1.2 Organization of This Document

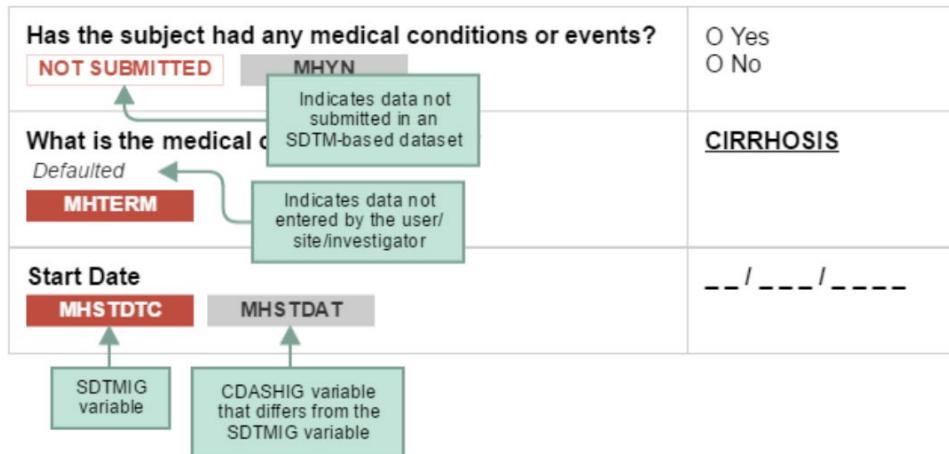
This document is divided into the following sections:

- Section 1, [Introduction](#), provides an overall introduction to the purpose and goals of the TAUG-LuCa.
- Section 2, [Overview of Lung Cancer](#), provides a brief overview of the focus of this document in relation to lung cancer.
- Section 3, [Subject and Disease Characteristics](#), covers data that are usually collected once during a study.
- Section 4, [Disease Assessments and Treatments](#), covers data that are used to evaluate progression. These are usually collected repeatedly during a study, and may be used as or for the derivation of efficacy and/or safety endpoints.
- Section 5, [Analysis Data](#), includes a brief description of endpoints that are described more fully in the Breast Cancer (<https://www.cdisc.org/standards/therapeutic-areas/breast-cancer>) and Prostate Cancer (<https://www.cdisc.org/standards/therapeutic-areas/prostate-cancer>) Therapeutic Area User Guides.
- [Appendices](#) provide additional background material and describe other supplemental material relevant to lung cancer.

1.3 CDASH Metadata and Annotated CRFs

CDASH examples include both metadata tables and sample case report forms (CRFs). Each table of CDASH metadata corresponds to an example annotated CRF (aCRF), built directly from the metadata. The annotations show the variables associated with each field in the context of data collection (CDASH) and submission (SDTM) and are denoted by color. Data that are collected using the same variable name as defined in the SDTMIG are in **RED**. If the CDASHIG variable differs from the one defined in the SDTMIG, the CDASHIG variable is in **GREY**. Data collected but not submitted in SDTM-based datasets are denoted as **NOT SUBMITTED**.

The following figure illustrates how to interpret the annotations.



When implementing CDASH in a denormalized structure, denormalized CDASH variable names are created by the sponsor, when needed. Denormalized CDASH variable names for TAUGs generally use the following naming convention:

<Topic Variable values>_<Qualifier(s)>_<SDTMIG Target>. Sponsors may define their own conventions for creating denormalized CDASH variable names.

Examples:

- DIABP_VSORRES where DIABP is the value for VTESTCD (topic variable): VSORRES is the SDTMIG target.
- DIABP_ARM_RIGHT_VSORRES where DIABP is the value for VTESTCD (topic variable): ARM and RIGHT are values of the SDTM Qualifier variables VSLOC and VSLAT, VSORRES is the SDTMIG target.
- Depression_MHOCCUR where Depression is the value of MHTERM (topic variable): MHOCCUR is the SDTMIG target.

When viewing sample aCRFs, bear in mind that:

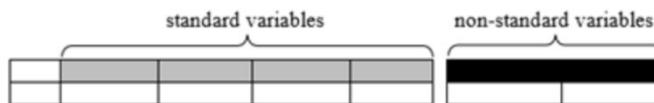
- More information may be found in the CDASH Model and the CDASHIG.
- Example CRFs are provided to illustrate data collection instruments. These are only examples and are not meant to recommend any particular layout over another.
- Example CRFs include instructions for the clinical site regarding how to enter collected information on the CRF.
- Example CRFs are best understood in conjunction with their respective metadata tables and/or the CDASH Domain Metadata Tables.
- Most example CRFs do not include the Highly Recommended header variables. The population of these values is usually determined by the sponsor's data management system.
- Sponsors are responsible for understanding and implementing CDISC Controlled Terminology where applicable.
- CDASH variable names for denormalized variables are examples. Sponsors may use other conventions for creating denormalized CDASH variable names.
- CDASH variable names that are annotated as "NOT SUBMITTED" may be used to contribute towards the population of other appropriate variables when the SDTM-based datasets are created.
- CDASH variables may also be mapped to or used to populate other SDTMIG variables that are not shown.
- Although a CDASH variable usually maps to a single SDTM-based domain, some CRFs may illustrate mapping to multiple variables as indicated by SDTM annotations such as **TUDTC AND TRDTC**. Also, some

CRFs have SDTM variable names separated by "/" which indicates that either SDTMIG variable may be used when creating SDTM datasets.

- The CDASH variables ----NO (e.g., --AENO, --PRNO) are generically annotated as **ASSOCIATED WITH RELATED RECORD VIA RELREC**. These RELREC relationships are sponsor-defined and depend on the actual study and the procedures used by the sponsor to create RELREC.

1.4 Known Issues

Non-standard variables: The TAUG-LuCa has adopted the practices outlined in the proposed SDTMIG Section 8.4.4, Alternative Representation of Non-Standard Variables (available in draft form at <http://wiki.cdisc.org/xUi68AQ>). Accordingly, SDTM-based examples containing sample data requiring the use of a variable outside the standard set of variables included in the SDTM are represented not with Supplemental Qualifier records, but with non-standard variables (NSVs) appended to the end of the parent domain, followed by sample value-level metadata for the NSVs. In order to avoid confusion between standard variables and NSVs, NSVs have been rendered visually distinct, as shown below, with white text on black in the header row, and separated from the standard variables by a small space. Metadata for non-standard variables, from the Define.XML file that would accompany the submission, are tabulated below the example; only those attributes or elements that assist the example are included. (For more information on variable-level metadata in general, see Define-XML v2.0 Sections 4.2 and 5.3.11, available at <https://www.cdisc.org/standards/data-exchange/define-xml>). A list of all NSVs used in this document, and the variable-level metadata that might become normative for the NSVs should they be promoted to standard variables, is included in Appendix C, [Non-Standard Variables](#).



- SDTMIG-PGx recommendations on the reporting of genetic variations were not followed in some examples:** The genetic variations data were not parsed using PFORREF, PFORRES, and PFGENLOC. This parsing approach is recommended, but the non-parsing approach was used to facilitate historical data collected on CRFs. This approach is under discussion within the PGx Team.
- Use of PFGENLOC:** The pf.xpt dataset in Section 3.4, [Pathology and Biomarkers](#), Example 1 makes use of the PFGENLOC variable in a manner that is inconsistent with Example 3 in the same section (and all known published uses) by adding the word "CODON" in front of the numeric position (e.g., "CODON 12"). This decision was made in consultation with the PGx team in an effort to make more explicit the specific feature whose position is described in PFGENLOC. This was deemed particularly necessary in the case of Row 3. The PGx team is currently revising the SDTMIG-PGx and will evaluate and publish more explicit instructions for using this variable as part of v2.0 of that guide.
- NSV naming convention:** In this document, NSV names include the 2-letter domain code before the variable name. Generic NSVs will be denoted as -- + 6-character name. The -- is replaced by the 2-letter domain code when the NSV is used in an actual dataset.
- Treatment regimens:** The strategy used to treat cancer is often a “regimen” that may consist of multiple drugs or of drug treatment combined with radiation and/or surgery. The SDTMIG does not provide clear guidance on how to indicate that multiple treatment modalities comprise a regimen or a product. The modeling of this data is under consideration to be included the Combination Therapy Focus Area User Guide currently being developed and is not part of the TAUG-LuCa.
- Location of the Biospecimen Events and Biospecimen domains:** At the time of this publication, the BE and BS domains reside in the SDTMIG-PGx v1.0. However, these domains can be applied to any collected sample and are not specific to pharmacogenomics/pharmacogenetics. In the future, BE and BS will be moved out of the SDTMIG-PGx and into to the SDTMIG.

2 Overview of Lung Cancer

Worldwide, lung cancer is the leading cause of cancer death in men and the second leading cause in women, with an estimated 1.6 million deaths in 2012 (1.1 million in men and 491,200 in women). However, in developed countries, it is now the leading cause of cancer death in women, surpassing breast cancer.[\[1\]](#)

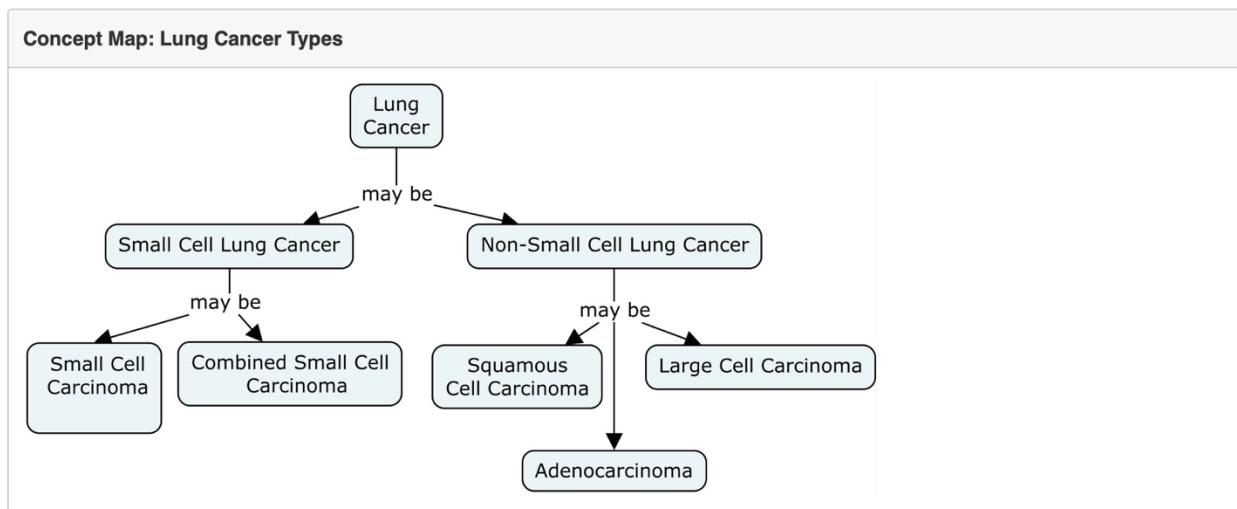
For most patients with lung cancer, current treatments do not cure the cancer.[\[2\]](#) It is a disease in which malignant (cancer) cells form in the tissues of the lung. The 2 main types of lung cancer are non-small cell lung cancer (NSCLC) and small cell lung cancer (SCLC); see the figure below. NSCLC is much more common than SCLC.

The common histologic types of NSCLC are:

- **Squamous cell carcinoma:** Cancer that begins in squamous cells. This is also called epidermoid carcinoma.
- **Large cell carcinoma:** Cancer that may begin in several types of large cells.
- **Adenocarcinoma:** Cancer that begins in the cells that line the alveoli and produce substances such as mucus.

The common histologic types of SCLC are:

- **Small cell carcinoma:** Cancer that usually begins in the large, central bronchi. It sometimes called oat cell cancer, because under a microscope the cells look like oat grains.
- **Combined small cell carcinoma:** A relatively rare type of lung cancer which has components of both SCLC and NSCLC.



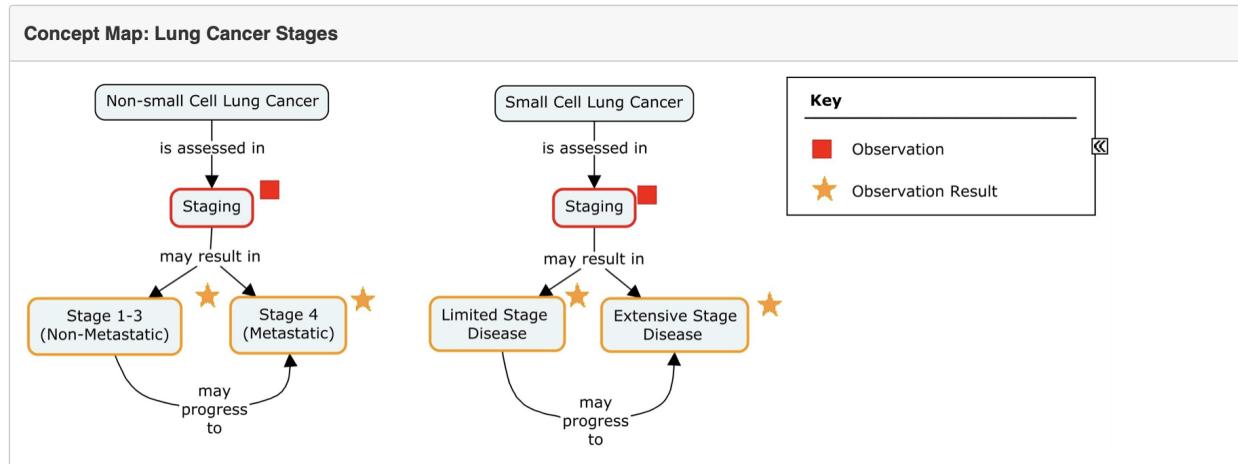
Risk factors for lung cancer include (1) smoking cigarettes, pipes, or cigars, now or in the past; (2) exposure to secondhand smoke, radiation, and asbestos; and (3) living in an area with air pollution.

For the reader unfamiliar with lung cancer, basic information in layman's language can be found at the following websites:

- US National Library of Medicine <https://medlineplus.gov/lungcancer.html>
- National Cancer Institute www.cancer.gov

The following concept map provides a high-level overview of the stages of lung cancer. The stage of cancer describes the extent of the cancer. Each cancer type has a very specific staging definition. Staging in NSCLC is usually performed using the TNM staging system (<https://www.cancer.gov/about-cancer/diagnosis-staging/staging>). Staging in SCLC may be performed using the TNM staging system, but commonly the stages are reported as

Limited Disease (LD) or Extensive Disease (ED) Stage, using either Veterans Administration Lung Study Group (VALG) or International Association for the Study of Lung Cancer (IASLC) criteria.[\[3\]](#)



In Stage IV NSCLC, the cancer has spread to the other lung and/or to lymph nodes; fluid around the lungs or heart; and/or other parts of the body, such as the brain, liver, adrenal gland, kidney, or bone. The lymph nodes, bone, and brain are the most common organs to which lung cancer spreads from the origin in the lung. Stage IV lung cancer is not resectable and surgery is not a treatment option.

In Extensive Disease SCLC, the cancer has spread beyond the lungs (i.e., beyond the lung or the area between the lungs or the lymph nodes above the collarbone) to other places in the body.

3 Subject and Disease Characteristics

Subject and disease characteristics generally include events and activities that may have affected the subject prior to the study. For lung cancer studies, this may include information on the initial diagnosis, staging, and any re-staging performed at study entry, if applicable. Other data may also be collected to describe the subject's disease characteristics including prior treatment information, prior radiation therapy, laboratory, and genetic variations. Sponsors may collect this type of information on a comprehensive case report form (CRF) specifically designed to collect various baseline and disease characteristics. Sponsors are reminded that this type of data should be represented in already defined SDTM domains, based on the type of information being collected.

Smoking history is a well-established risk factor for lung cancer. Other comorbidities such as diseases of cardiovascular, pulmonary and other systems may potentially affect survival and treatment tolerability in patients with malignancies. The SDTMIG provides examples of how smoking history and comorbidities can be represented using CDISC standards, hence no examples will be included in this TAUG.

3.1 Diagnosis

The 2 types of lung cancer are characterized by the cell size of the tumor when viewed under a microscope. The tumor cells of small cell lung cancer (SCLC) appear small and round, whereas non-small cell lung cancer (NSCLC) tumor cells are larger in size. SCLC is a more aggressive cancer than NSCLC.

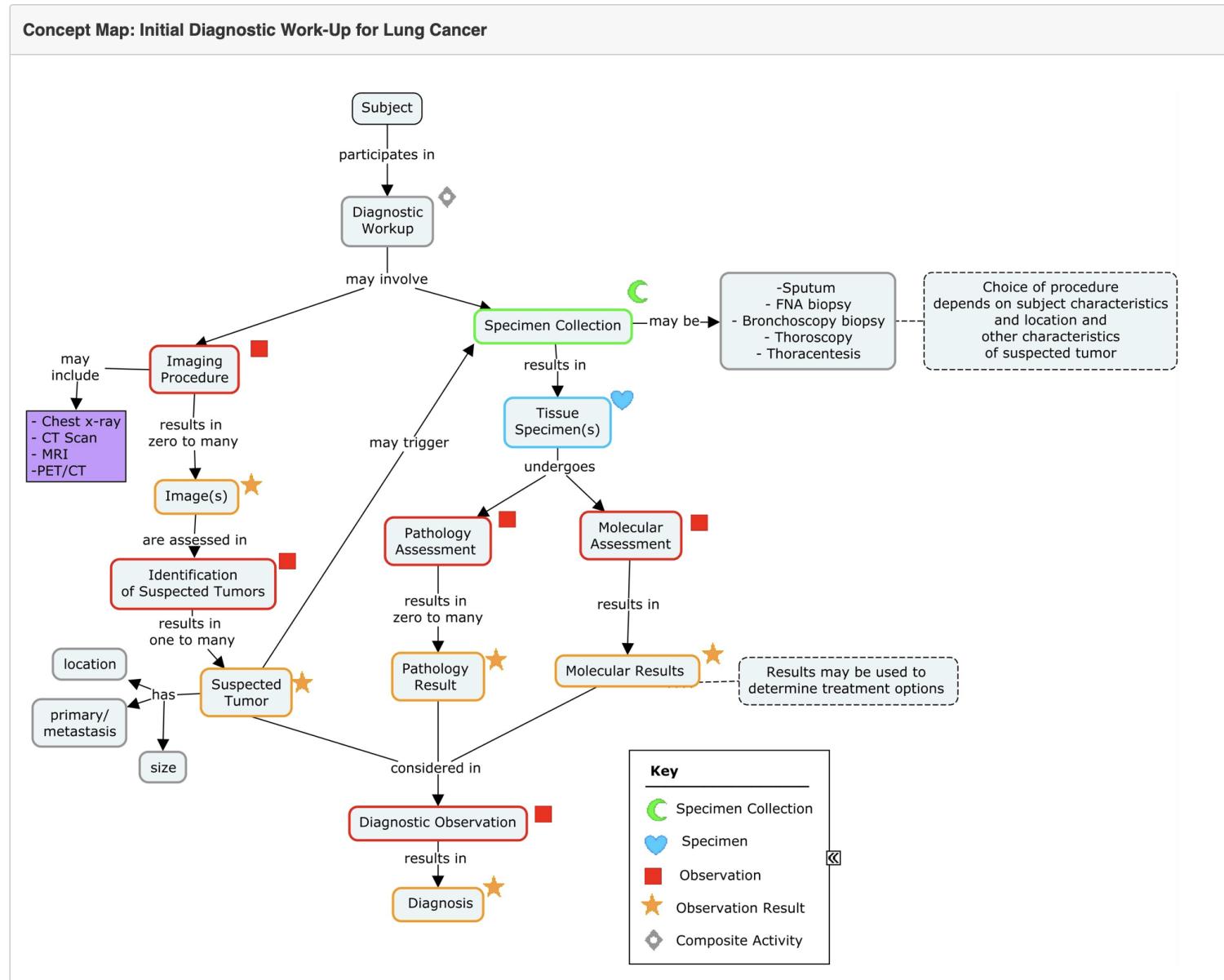
Screening and work-up for lung cancer may include:

- Imaging, such as magnetic resonance imaging (MRI), computed tomography (CT) scan, CT/positron emission tomography (PET) scan, ultrasound, bone scan
- Laboratory testing and molecular work-up (including DNA testing)
- Physical exam and medical history
- Sputum cytology
- Fine-needle aspiration (FNA) biopsy of the lung

For clinical trials, data collected on the initial diagnosis of lung cancer (see below) may include the date of diagnosis and histological findings. Studies in metastatic lung cancer may collect data both on the initial diagnostic and from diagnostic work-ups (including molecular work-up) conducted when the subject enters the study.

For the purposes of the TAUG-LuCa, the definition of *diagnosis* can refer to:

- Confirmation that lung cancer is present.
- Determination on the severity or extent of the lung cancer.



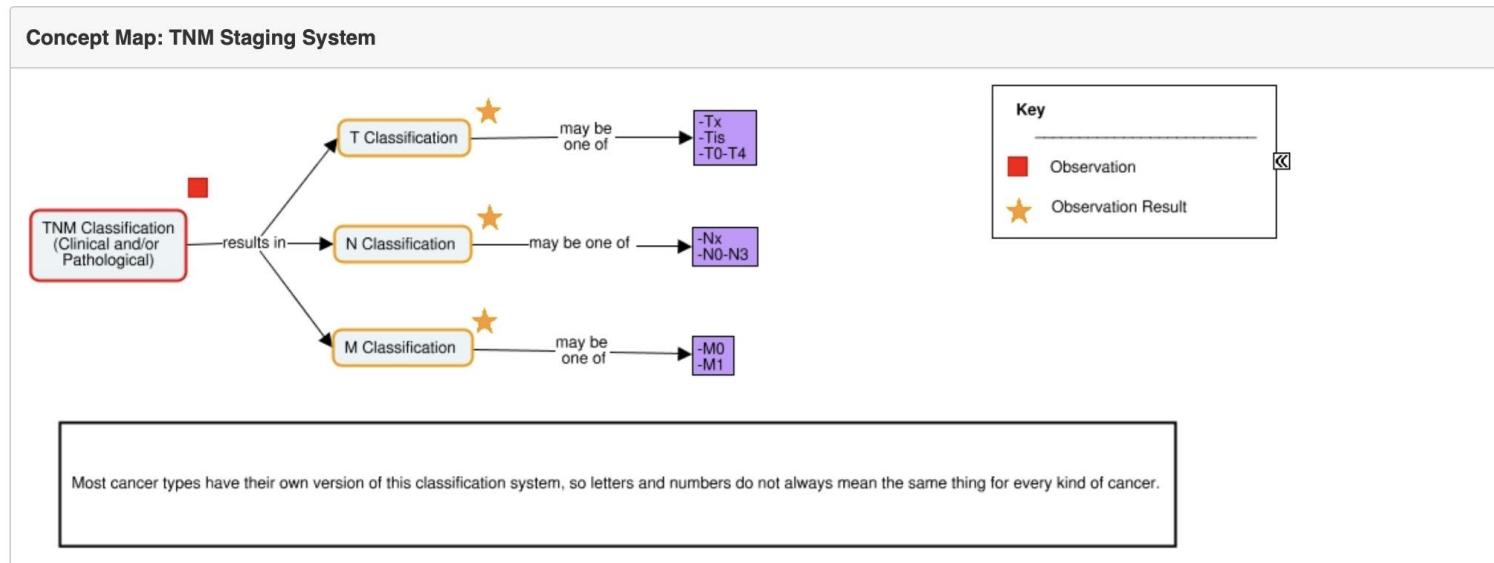
3.2 Staging

When a subject is diagnosed with cancer, cancer staging is performed to determine the severity of the cancer (i.e., size of primary tumor and extent to which the cancer has spread). Assessments used for staging may include imaging (e.g., MRI, CT), lab tests, and other tests or procedures. There are many staging systems. The TNM staging system was developed and is maintained by the American Joint Committee on Cancer (AJCC) and the Union for International Cancer Control (UICC). The TNM staging system is used for many types of cancer. Other staging systems may be used and are specific to a particular type of cancer.

In the TNM system:

- The T refers to the size and extent of the main tumor. The main tumor is usually called the *primary tumor*.
- The N refers to the number of nearby lymph nodes that have cancer.
- The M refers to whether the cancer has metastasized (i.e., the cancer has spread from the primary tumor to other parts of the body).

AJCC staging may be performed before or after treatment. The AJCC has defined prefix designators that may be used to indicate the different points in time that staging may be determined. For example, staging may be determined before any treatment (clinical stage) or after surgery (pathologic stage). As described in the AJCC Cancer Staging Manual,[4] the prefix of *c*, *p*, *yc*, *yp*, *r*, or *a* may be applied to denote the classification of stage. For example, the classification of T, N, and M by pathologic means is denoted by use of a lower-case *p* prefix (*pT*, *pN*, and *pM*). A complete description of and definitions for these prefixes are included in the AJCC Manual. The following concept map illustrates the TNM system for staging.



For many cancers, the TNM values are grouped into less detailed categories called *stages*; these stages are typically denoted as Stage 0 through IV. The appropriate grouping of the TNM values into these fewer detailed categories can be found in the AJCC Cancer Staging Manual.[4] Stage IV NSCLC would typically include any subject with cancer that has metastasized.

TNM staging is typically used in NSCLC lung cancer, whereas the Veterans Administration Lung Study Group (VALG) and the International Association for the Study of Lung Cancer (IASLC) staging systems may be used in SCLC. These SCLC staging systems classify a subject using a 2-category staging system, Limited or Extensive Disease (LD and ED, respectively). Although these systems use the same 2-category staging system, the criteria are not the same. Whereas the VALG definition of LD includes patients with primary tumor and nodal involvement limited to 1 hemithorax, the IASLC criteria recommend that LD should additionally include all patients without distant metastasis.[\[3\]](#)

Example 1 shows how to represent staging in the Disease Response and Clin Classification (RS) domain for SCLC. Section 3.3, [Disease Characteristics](#), provides an additional example of how to model the TNM staging system.

Example 1

This is an example of SCLC staging and shows that this subject, who has SCLC, had a stage of "limited disease" when the VALG staging definitions were used.

Row	STUDYID	DOMAIN	USUBJID	RSSEQ	RSTESTCD	RSTEST	RSCAT	RSSCAT	RSORRES	RSSTRESC	VISITNUM	VISIT	VISITDY	RSDTC	RSDY
1	LC006	RS	5001	1	VALG0101	VALG01-Cancer Stage	VALG	SMALL CELL LUNG CANCER	limited disease	limited disease	1	SCREENING	-10	2014-06-05	-68

3.3 Disease Characteristics

Clinical trial protocols define the population eligible for participation in a given study. At trial entry, disease characteristics relevant to the particular trial are typically collected; these characteristics help to define the study population. Types of characteristics that may be collected include the date of diagnosis, stage of disease, and prior treatments for the disease. In some protocols, information on prognostic factors may also be collected. These prognostic factors are often used in the analysis. Typically in lung cancer trials, information on date(s) of diagnosis of the primary cancer and the date of diagnosis of metastatic disease are collected, as well as staging information, baseline sites of disease, previous surgeries, prior anti-cancer treatments, and response to prior treatments.

Many sponsors collect these disease characteristics and prognostic factors using comprehensive disease characteristic case report form (CRF) modules. Sponsors are reminded that this type of data should not be represented in a sponsor-defined custom disease-characteristic domain, but represented in already defined SDTM domains, based on the type of information being collected.

Example 1

This is an example of disease characteristics and prognostic factors collected in a NSCLC study. In this trial, subjects with advanced disease (defined as having progressed twice after the initial diagnosis of metastases (mets)) were enrolled. The information collected included:

- TNM staging following the AJCC Cancer Staging Manual.[\[4\]](#) The stage at the time of initial diagnosis and at study entry was collected.
- Cancer histology
- Prior surgeries and prior anti-cancer treatments
- History of the disease (date of diagnosis, date of first metastatic disease, and dates of subsequent progressions)
- Baseline sites of disease

The following aCRFs illustrate how to collect this type of data. Some of this data is typically collected on standard CDASH CRFs (e.g., concomitant medications, procedures) which have been described in the CDASHIG and thus are not provided here.

These example CRFs are used to illustrate what may be collected for baseline disease characteristics in a lung cancer clinical trial. This example includes staging information collected using various options and various levels of detail. Sponsors have to decide what data is required for each study.

In this example, the Medical History (MH) CRF was used to collect the date of initial diagnosis and the date of diagnosis of first mets. Sponsors may decide to collect such information using a general MH CRF. Sponsors also may customize this CRF to ask specific questions about each diagnosis (using MHOCCUR; not shown).

Cancer History MHCAT Hidden/pre-populated		CANCER HISTORY
Indicate any cancer medical history. Include the primary cancer diagnosis and metastatic disease diagnosis (if any).	What was medical history term? MHTERM If "Non-Small lung cancer", MIDS = "INIDX" If "Non-small cell lung cancer metastatic", MIDS = "DXMETS"	
Indicate the date of diagnosis.	What is the diagnosis date? MHSTDAT MHSTDTC MIDSDTC	
Event Date Type MHEVDTYP Hidden/pre-populated	DIAGNOSIS	

Order	Question Text	Prompt	CRF Completion Instructions	CDASH Variable	SDTMIG Target Variable	SDTMIG Target Mapping	Controlled Terminology Code List Name	CRF Implementation Notes	Permissible Values	Pre-populated Value	Displayed Query	List Style	Input Type	Hidden
1	What was the category of the medical history?	Cancer History		MHCAT	MHCAT		N/A	Sponsor-defined controlled terminology. This is an example MH CRF used to collect data for a pre-specified category.	N/A	CANCER HISTORY	prompt	N/A	text	hidden
2	What was medical history term?		Indicate any cancer medical history. Include the primary cancer diagnosis and metastatic disease diagnosis (if any).	MHTERM	MHTERM	MHTERM; If "Non-Small lung cancer", MIDS = "INIDX"; If "Non-small cell lung cancer metastatic", MIDS = "DXMETS"	N/A	Sponsors should collect all relevant medical conditions or events, as defined in the protocol.	N/A	N/A	question text	N/A	text	visible
3	What is the diagnosis date?	Diagnosis Date	Indicate the date of diagnosis.	MHSTDAT	MHSTDTC	MHSTDTC; MIDSDTC	N/A	The type of start and/or end date	N/A	N/A	question text	N/A	date	visible
4	What was the event date type?	Event Date Type	Indicate the Event Date Type	MHEVDTYP	MHEVDTYP		N/A	Specifies the aspect of the medical condition or event by which MHSTDTC and/or the MHENDTC is defined. Examples: "DIAGNOSIS," "SYMPTOMS," "RELAPSE," "INFECTION."	N/A	DIAGNOSIS	prompt	N/A	text	hidden

The Baseline Disease CRF was used to collect data such as histology, AJCC stage, date of first progression of mets, and/or date of second progression of mets. These progression dates are not considered as a diagnosis, but rather a response classification, and are represented in the Disease Response and Clinical Classification (RS) domain. CDISC acknowledges Springer for the approval to include the AJCC TNM Staging System 7th Edition (AJCC V7)[\[4\]](#) in the CDISC data standards.

Disease Milestone Instance Name MIDS <small>Hidden/pre-populated</small>	INIDX
Temporal Relation to Milestone Instance RELMIDS RELMIDS where MIDS = "INIDX" and MITESTCD in ("HISTLGY", "GRADE") RELMIDS where MIDS = "INIDX" and RTESTCD = "AJCC104" <small>Hidden/pre-populated</small>	AT TIME OF
Disease Milestone Instance Date/Time MIDSTDTC MIDSTDTC = (MH.MHSTDTC where MH.MIDS = "INIDX")	
Indicate the histology classification at initial diagnosis? HISTOL_MIORRES MIORRES where MITESTCD = "HISTTPC" and MIDS = "INIDX"	<input type="radio"/> Adenocarcinoma, Mixed Subtype <input type="radio"/> Acinar Adenocarcinoma <input type="radio"/> Papillary Adenocarcinoma <input type="radio"/> Bronchioalveolar Carcinoma, Mucinous <input type="radio"/> Bronchioalveolar Carcinoma, Non-Mucinous <input type="radio"/> Solid Pattern Predominant Adenocarcinoma <input type="radio"/> Micropapillary Adenocarcinoma <input type="radio"/> Fetal Adenocarcinoma <input type="radio"/> Mucinous Cystadenocarcinoma <input type="radio"/> Mucinous (Colloid) Adenocarcinoma <input type="radio"/> Signet Ring Adenocarcinoma <input type="radio"/> Clear Cell Adenocarcinoma <input type="radio"/> Adenocarcinoma, Not Otherwise Specified <input type="radio"/> Papillary Squamous Cell Carcinoma <input type="radio"/> Clear Cell Squamous Cell Carcinoma <input type="radio"/> Small Cell Squamous Cell Carcinoma <input type="radio"/> Basaloid Squamous Cell Carcinoma <input type="radio"/> Squamous Cell Carcinoma, Not Otherwise Specified (NOS) <input type="radio"/> Large Cell Carcinoma Other <input type="radio"/> Not Available/Unknown
Indicate the tumor grade. GRADE_MIORRES MIORRES where MITESTCD = "GRADE" and MIDS = "INIDX"	<input type="radio"/> GX: Grade cannot be assessed (undetermined grade) <input type="radio"/> G1: Well differentiated (low grade) <input type="radio"/> G2: Moderately differentiated (intermediate grade) <input type="radio"/> G3: Poorly differentiated (high grade) <input type="radio"/> G4: Undifferentiated (high grade)
Record the AJCC stage. AJCC104_INITDX_RSORRES RSORRES where RTESTCD = "AJCC104" and MIDS = "INITDX"	
Record the AJCC stage. AJCC104_RSORRES RSORRES where RTESTCD = "AJCC104"	
Indicate the VALG stage. VALG_RSORRES RSORRES where RTESTCD = "VALG0101"	<input type="radio"/> Limited disease <input type="radio"/> Extensive disease
Indicate the AJCC T score. AJCC101_RSORRES RSORRES where RTESTCD = "AJCC101"	
Indicate the AJCC N score. AJCC102_RSORRES RSORRES where RTESTCD = "AJCC102"	
Indicate the AJCC M score. AJCC103_RSORRES RSORRES where RTESTCD = "AJCC103"	

CDISC Therapeutic Area Data Standards User Guide for Lung Cancer v1.0 (Provisional)

Order	Question Text	Prompt	CRF Completion Instructions	CDASH Variable	SDTMIG Target Variable	SDTMIG Target Mapping	Controlled Terminology CodeList Name	CRF Implementation Notes	Permissible Values	Pre-populated Value	Displayed Query	List Style	Input Type	Hidden
1	N/A	Disease Milestone Instance Name	N/A	MIDS	MIDS		N/A	Sponsor-defined name of the trial milestone.	N/A	INIDX	prompt	N/A	text	hidden
2	N/A	Temporal Relation to Milestone Instance	N/A	RELMIDS	RELMIDS	RELMIDS where MIDS = "INIDX" and MITESTCD in ("HISTLGY", "GRADE"); RELMIDS where MIDS = "INIDX" and RTESTCD = "AJCC104"	N/A	A sponsor-defined temporal relationship to the associated record.	N/A	AT TIME OF	prompt	N/A	text	hidden
3	N/A	Disease Milestone Instance Date/Time	N/A	MIDSTDTC	MIDSTDTC	MIDSTDTC = (MH.MHSTDTC where MH.MIDS = "INIDX")	N/A	MIDSTDTC is the start date of the defined milestone. In this situation, the MIDSTDTC is the date of Diagnosis.	N/A	N/A	prompt	N/A	text	hidden
4	What was the histology classification at initial diagnosis?	Histological Classification	Indicate the histology classification at initial diagnosis.	HISTOL_MIORRES	MIORRES	MIORRES where MITESTCD = "HISTTPC" and MIDS = "INIDX"	N/A	The classification categories typically will be customized based on the clinical trial.	Adenocarcinoma, Mixed Subtype; Acinar Adenocarcinoma; Papillary Adenocarcinoma; Bronchioloalveolar Carcinoma, Mucinous; Bronchioloalveolar Carcinoma, Non-Mucinous; Solid Pattern Predominant Adenocarcinoma; Micropapillary Adenocarcinoma; Fetal Adenocarcinoma; Mucinous Cystadenocarcinoma; Mucinous (Colloid) Adenocarcinoma; Signet Ring Adenocarcinoma; Clear Cell Adenocarcinoma; Adenocarcinoma, Not Otherwise Specified; Papillary Squamous Cell Carcinoma; Clear Cell Squamous Cell Carcinoma; Small Cell Squamous Cell Carcinoma; Basaloid Squamous Cell Carcinoma; Squamous Cell Carcinoma, Not Otherwise Specified (NOS); Large Cell Carcinoma Other;	N/A	question text	radio	text	visible

Order	Question Text	Prompt	CRF Completion Instructions	CDASH Variable	SDTMIG Target Variable	SDTMIG Target Mapping	Controlled Terminology CodeList Name	CRF Implementation Notes	Permissible Values	Pre-populated Value	Displayed Query	List Style	Input Type	Hidden
									Not Available/Unknown;					
5	What was the Tumor Grade at initial diagnosis?	Tumor Grade	Indicate the tumor grade.	GRADE_MIORRES	MIORRES	MIORRES where MITESTCD = "GRADE" and MIDS = "INIDX"	N/A	If a grading system for a tumor type is not specified, this grading system may be used. Certain cancers have specific grading systems.	GX: Grade cannot be assessed (undetermined grade); G1: Well differentiated (low grade); G2: Moderately differentiated (intermediate grade); G3: Poorly differentiated (high grade); G4: Undifferentiated (high grade);	N/A		radio	text	visible
6	What was the AJCC stage at initial diagnosis?	AJCC Tumor Stage	Record the AJCC stage.	AJCC104_INITDX_RSORRES	RSORRES	RSORRES where RSTESTCD = "AJCC104" and MIDS = "INITDX"	N/A	This is the AJCC test code. See the CDISC website (QRS Standards) for more information on SDTM modeling. INITDX is included in the CDASH variable name to identify which staging is recorded.	N/A	N/A	N/A	text	visible	
7	What was the AJCC stage at study entry?	AJCC Tumor Stage	Record the AJCC stage.	AJCC104_RSORRES	RSORRES	RSORRES where RSTESTCD = "AJCC104"	N/A	This is the AJCC test code. See the CDISC website (QRS Standards) for more information on SDTM modeling.	N/A	N/A	N/A	text	visible	
8	What was the SCLC VALG stage at study entry?	VALG Tumor Stage	Indicate the VALG stage.	VALG_RSORRES	RSORRES	RSORRES where RSTESTCD = "VALG0101"	N/A	A sponsor may also use the IASLC grades.	Limited disease; Extensive disease	N/A		radio	text	visible
9	What was the AJCC T score at study entry?	T score	Indicate the AJCC T score.	AJCC101_RSORRES	RSORRES	RSORRES where RSTESTCD = "AJCC101"	N/A	The sponsor may also collect the T score at initial dx.	N/A	N/A	N/A	text	visible	
10	What was the AJCC N score at study entry?	N Score	Indicate the AJCC N score.	AJCC102_RSORRES	RSORRES	RSORRES where RSTESTCD = "AJCC102"	N/A	The sponsor may also collect the N score at initial dx.	N/A	N/A	N/A	text	visible	
11	What was the AJCC M score at study entry?	M Score	Indicate the AJCC M score.	AJCC103_RSORRES	RSORRES	RSORRES where RSTESTCD = "AJCC103"	N/A	The sponsor may also collect the M score at initial dx.	N/A	N/A	N/A	text	visible	

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The following aCRF is an example of a collection tool for baseline sites of disease. The form illustrates the use of specific Yes/No questions for each site of metastatic disease, as recommended by CDASH. Depending on electronic data capture (EDC) functionality, this may be set up using general question text with repeating rows for each specified disease site (e.g., a table format). Sponsors also may use the approach of checking all the sites of disease that apply.

The method used to evaluate a tumor can be represented (1) only in the SDTMIG TU domain, or (2) in both the SDTMIG Tumor/Lesion Identification (TU) and Procedures (PR) domains. In this example CRF, the method was collected only for the lung site to illustrate the mapping. The method was not included for other sites of disease, to save space.

Sponsors may collect the method used to evaluate the disease site on this CRF, or the sponsor may record all evaluation methods on the PR CRF and only collect the line number for the procedure associated with this evaluation. This line number is typically used to create RELREC; both options are illustrated.

In this example, the dates of diagnosis of lung cancer and the metastatic lung cancer were collected using the MH CRF. The question "Any Metastatic Disease" was used only for data cleaning and eCRF navigation; it was annotated as "Not Submitted."

Indicate if the subject had metastatic disease. If yes, include the appropriate details where indicated on the CRF.	Did the subject have metastatic disease? METYN Not submitted	<input type="radio"/> Yes <input type="radio"/> No
Indicate whether this was a site of metastatic disease. If yes, indicate whether this tumor site will be followed for tumor evaluation during the study.	Was the lung a site of metastatic disease? METIND_LUNG_TUORRES TUORRES where TUTESTCD = "METIND" and TULOC = "LUNG"	<input type="radio"/> Yes <input type="radio"/> No
Record the method/procedure used to evaluate this disease site.	What was the procedure used to evaluate the lung site? METIND_LUNG_TUMETHOD TUMETHOD where TUTESTCD = "METIND" and TULOC = "LUNG"	<input type="text"/> <From METHOD codelist>
Record the identifier for the procedure used to evaluate this site.	What was the procedure line number or ID used to evaluate the lung site? METIND_LUNG_TUPRNO (Associated with related PR record via RELREC)	<input type="text"/>
Indicate whether this was a site of metastatic disease. If yes, indicate whether this tumor site will be followed for tumor evaluation during the study.	Was the liver a site of metastatic disease? METIND_LIVER_TUORRES TUORRES where TULOC = "LIVER" and TUTESTCD = "METIND"	<input type="radio"/> Yes <input type="radio"/> No
Indicate whether this was a site of metastatic disease. If yes, indicate whether this tumor site will be followed for tumor evaluation during the study.	Was the brain a site of metastatic disease? METIND BRAIN TUORRES TUORRES where TULOC = "BRAIN" and TUTESTCD = "METIND"	<input type="radio"/> Yes <input type="radio"/> No
Indicate whether this was a site of metastatic disease. If yes, indicate whether this tumor site will be followed for tumor evaluation during the study.	Was the pleural cavity a site of metastatic disease? METIND_PLEURALCAVITY_TUORRES TUORRES where TULOC = "PLEURAL CAVITY" and TUTESTCD = "METIND"	<input type="radio"/> Yes <input type="radio"/> No

Order	CDASH Variable	Question Text	Prompt	CRF Completion Instructions	SDTMIG Target Variable	SDTMIG Target Mapping	Controlled Terminology CodeList Name	CRF Implementation Notes	Permissible Values	Pre-populated Value	Displayed Query	List Style	Type	Hidden
1	METYN	Did the subject have metastatic disease?	Any Metastatic Disease	Indicate if the subject had metastatic disease. If yes, include the appropriate details where indicated on the CRF.	N/A	N/A	N/A	This was used for data cleaning and eCRF navigation. Because the diagnosis of metastatic disease was assumed to be collected in the MH CRF, this was annotated as not submitted.	Yes; No	N/A	question text	radio	text	visible
2	METIND_LUNG_TUORRES	Was the lung a site of metastatic disease?	Metastatic Site Lung	Indicate whether this was a site of metastatic disease. If yes, indicate whether this tumor site will be followed for tumor evaluation during the study.	TUORRES	TUORRES where TUTESTCD = "METIND" and TULOC = "LUNG"	N/A	This may be collected using a "check all that apply" approach. Sponsor may elect to collect a Yes/No response, or to map these choice to "Y" and "N" when the SDTM datasets are created.	Yes; No	N/A	question text	radio	text	visible
3	METIND_LUNG_TUMETHOD	What was the procedure used to evaluate the lung site?	Method	Record the method/procedure used to evaluate this disease site.	TUMETHOD	TUMETHOD where TUTESTCD = "METIND" and TULOC = "LUNG"	(METHOD)	This item is optional. The method can be represented only in the TU domain or both the TU and PR domains.	N/A	N/A	question text	N/A	text	visible
4	METIND_LUNG_TUPRNO	What was the procedure line number or ID used to evaluate the lung site?	Procedure Line No	Record the identifier for the procedure used to evaluate this site.	N/A	(Associated with related PR record via RELREC)	N/A	The sponsor may collect the method in the procedures domain. This item may be used to create RELREC.	N/A	N/A	question text	N/A	text	visible
5	METIND_LIVER_TUORRES	Was the liver a site of metastatic disease?	Metastatic Site Liver	Indicate whether this was a site of metastatic disease. If yes, indicate whether this tumor site will be followed for tumor evaluation during the study.	TUORRES	TUORRES where TULOC = "LIVER" and TUTESTCD = "METIND"	N/A	This may be collected using a "check all that apply" approach. Sponsor may elect to collect a Yes, No response, or to map these choice to "Y" and "N" when the SDTM datasets are created.	Yes; No	N/A	question text	radio	text	visible
6	METIND_BRAIN_TUORRES	Was the brain a site of metastatic disease?	Metastatic Site Brain	Indicate whether this was a site of metastatic disease. If yes, indicate whether this tumor site will be followed for tumor evaluation during the study.	TUORRES	TUORRES where TULOC = "BRAIN" and TUTESTCD = "METIND"	N/A	This may be collected using a "check all that apply" approach. Sponsor may elect to collect a Yes/No response, or to map these choice to "Y" and "N" when the SDTM datasets are created.	Yes; No	N/A	question text	radio	text	visible
7	METIND_PLEURALCAVITY_TUORRES	Was the pleural cavity a site of metastatic disease?	Metastatic Site Pleural cavity	Indicate whether this was a site of metastatic disease. If yes, indicate whether this tumor site will be followed for tumor evaluation during the study.	TUORRES	TUORRES where TULOC = "PLEURAL CAVITY" and TUTESTCD = "METIND"	N/A	This may be collected using a "check all that apply" approach. Sponsor may elect to collect a Yes/No response, or to map these choice to "Y" and "N" when the SDTM datasets are created.	Yes; No	N/A	question text	radio	text	visible

Examples of SDTM datasets used to represent these disease characteristics and prognostic factors are discussed below. These data were represented in the Concomitant/Prior Medications (CM), Microscopic Findings (MI), PR, TU, and Disease Response and Clinical Classification (RS) domains. The Subject Disease Milestones (SM) and Trial Disease Milestones (TM) domains were also used to define trial milestones relevant to the study. An example of a RELREC dataset is provided following the individual SDTM datasets and illustrates how the domains used to represent data are related.

Diagnosis date, date of first metastatic disease, and dates of first and second progression after diagnosis of metastatic disease were considered important events in the course of the disease and were times at which data of interest for the study were collected, so they were defined as disease milestones. The TM domain is used to define these milestones. The fact that each milestone can occur only once is represented by TMRPT="N".

Row 1: Defines the date of the initial diagnosis of NSCLC as a disease milestone, assigning it the name (MIDSTYPE) "INITIAL DIAGNOSIS".

Row 2: Defines the date of the diagnosis of first metastatic NSCLC as a disease milestone, assigning it the name "METASTATIC DIAGNOSIS".

Rows 3-4: Define the dates of the first and second progressions of the metastatic disease as disease milestones "DIAGNOSIS OF FIRST PROGRESSION" and "DIAGNOSIS OF SECOND PROGRESSION".

Row	STUDYID	DOMAIN	MIDSTYPE	TMDEF	TMRPT
1	LC005	TM	INITIAL DIAGNOSIS	Initial diagnosis of non-small cell lung cancer	N
2	LC005	TM	METASTATIC DIAGNOSIS	Diagnosis of metastatic non-small cell lung cancer	N
3	LC005	TM	DIAGNOSIS OF FIRST PROGRESSION	Date of the first progression of the metastatic non-small cell lung cancer	N
4	LC005	TM	DIAGNOSIS OF SECOND PROGRESSION	Date of the second progression of the metastatic non-small cell lung cancer	N

The SM domain is used to represent the protocol-specified milestones that have been defined in TM for each subject.

Row 1: Shows the date of initial diagnosis of NSCLC for subject 3000. This date was obtained from the MH domain, where the diagnoses dates were represented with MIDS="INITX".

Row 2: Shows the date of the diagnosis of metastatic disease for subject 3000. This date was obtained from the MH domain, where the diagnoses were represented with MIDS="DXMETS".

Rows 3-4: Show the dates of the first progression and second progression after the initial diagnosis of metastatic disease. These dates were obtained from the RS domain, where the Historical PD responses were represented. The MIDS variable links the records.

Row	STUDYID	DOMAIN	USUBJID	SMSEQ	MIDS	MIDSTYPE	SMSTDTC	SMENDTC	SMSTDY	SMENDY
1	LC005	SM	3000	1	INITDX	INITIAL DIAGNOSIS	2012-12-28		-533	
2	LC005	SM	3000	2	DXMETS	METASTATIC DIAGNOSIS	2014-03-14		-92	
3	LC005	SM	3000	3	DXMETPROG	DIAGNOSIS OF FIRST PROGRESSION	2014-06-01		-60	
4	LC005	SM	3000	4	DXMETPROG2	DIAGNOSIS OF SECOND PROGRESSION	2014-09-20		-10	

NSCLC and metastatic NSCLC diagnoses were represented in the MH domain; the dates of diagnosis were represented in MHSTDTC. The value "DIAGNOSIS" in the variable MHEVDTYP was used to indicate that the date in MHSTDTC was the date of diagnosis. The records with MHTERM="Non-small cell lung cancer" or "Non-small cell lung cancer metastatic" are trial disease milestones previously defined in the TM dataset and the variable MIDS is populated. In this study, all subjects had a diagnosis of metastatic disease. In a study with subjects without metastatic disease, the variables MHOCCUR and MHPRESP could be used to indicate whether a subject had metastatic disease. In this study, if the date of the initial diagnosis and the date of metastatic disease were the same, the sponsor included both diagnoses using the same MHSTDTC.

Row 1: Shows the subject's initial diagnosis of NSCLC.

Row 2: Shows the subject's diagnosis of metastatic NSCLC.

Row 3: Shows the subject's diagnosis of NSCLC.

Row 4: Shows that the subject was also diagnosed with metastatic disease on the same date.

Row	STUDYID	DOMAIN	USUBJID	MHSEQ	MHTERM	MHDECOD	MHEVDTYP	MHSTDTC	MHENDTA	MHDY	MIDS
1	LC005	MH	3000	1	NON-SMALL CELL LUNG CANCER	Non-small cell lung cancer	DIAGNOSIS	2012-12-28		-533	INITDX
2	LC005	MH	3000	2	NON-SMALL CELL LUNG CANCER METASTATIC	Non-small cell lung cancer metastatic	DIAGNOSIS	2014-03-14		-92	DXMETS
3	LC005	MH	4001	1	NON-SMALL CELL LUNG CANCER	Non-small cell lung cancer	DIAGNOSIS	2015-01-28		-10	INITDX
4	LC005	MH	4001	2	NON-SMALL CELL LUNG CANCER METASTATIC	Non-small cell lung cancer metastatic	DIAGNOSIS	2015-01-28		-10	DXMETS

The PR domain was used to represent procedures data collected at baseline, including prior surgical procedures and imaging procedures used to evaluate baseline disease sites. MedDRA was used to determine the dictionary-derived name of PRTRT. The imaging PR records for disease site identification are based on sponsor preference. --METHOD in the Findings domain(s) may be sufficient to reflect the procedure used for disease site identification. It is at the sponsor's discretion whether to represent the procedure as both a test method (--METHOD) and related PR record. In this example, the sponsor chose to represent the imaging procedure information using the PR domain.

An example CRF used for collecting data on study procedures is not provided in this TAUG as the representation of this is adequately described in the CDASHIG. Only selected example records are shown for the PR domain below.

Row 1: Shows that the subject had thoracoscopic wedge resection to remove the lung tumor. MedDRA was used to determine the dictionary-derived name of PRTRT.

Row 2: Shows that the subject had a liver resection to remove a secondary tumor in the liver.

Row 3: Shows the subject had a CT scan to evaluate whether there were any tumors in the chest or abdomen at baseline. The sponsor specified the indication for this as a diagnostic procedure.

Row 4: Shows the subject had an MRI to evaluate whether there were any brain tumors. The sponsor specified the indication for this as a diagnostic procedure.

Row	STUDYID	DOMAIN	USUBJID	PRSEQ	PRTRT	PRDECOD	PRINDC	PRLOCT	VISITNUM	VISIT	VISITDY	PRSTDTC	PRLOC1	PRLOC2
1	LC005	PR	3001	1	THORACOSCOPIC WEDGE RESECTION	Lung Wedge Resection	LUNG CANCER STAGE UNSPECIFIED (EXCL METASTATIC TUMORS TO LUNG)	LUNG, RIGHT LOWER LOBE	1	SCREENING	-14	2013-01-01		
2	LC005	PR	3001	2	LIVER RESECTION	Liver Resection	MALIGNANT NEOPLASM OF LIVER, SPECIFIED AS SECONDARY	LIVER	1	SCREENING	-14	2014-01-01		
3	LC005	PR	3007	1	CT SCAN	CT Scan	DIAGNOSTIC PROCEDURE	MULTIPLE	10	BASELINE	1	2016-01-02	CHEST	ABDOMEN
4	LC005	PR	3007	2	MRI	MRI	DIAGNOSTIC PROCEDURE	BRAIN	10	BASELINE	1	2016-01-04		

PR NSV Metadata

Variable	Label	Type	Role	Origin
PRLOC1	Location of Procedure 1	text	Non-Standard Record Qualifier	CRF
PRLOC2	Location of Procedure 2	text	Non-Standard Record Qualifier	CRF

The MI domain is used to represent cancer histology information, as this is part of a pathological examination on the tumor tissue. Note that this example is included in this section rather than Section 3.4, [Pathology and Biomarkers](#), as many sponsors collect this type of data on the Disease Characteristics CRF.

MISPCCND is an expected variable and was included. No information was available on the specimen condition. This represents the histology of the tumor at the initial diagnosis of lung cancer. Since this histology is associated with the disease milestone "INITX", the variables MIDS, RELMIDS and MISTDTC are included.

Row	STUDYID	DOMAIN	USUBJID	MISEQ	MITESTCD	MITEST	MIORRES	MIORRESU	MISTRESC	MISTRESN	MISTRESU	MISPEC	MISPCCND	VISITNUM	VISIT	VISITDY	MIDTC	MIDY
1	LC005	MI	3031	1	HISTTPYC	Histologic Type of Cancer	SOLID PATTERN PREDOMINANT ADENOCARCINOMA		SOLID PATTERN PREDOMINANT ADENOCARCINOMA			TUMOR TISSUE		1	SCREENING	-14		

Subjects may have been treated with anti-cancer therapies before the start of a study. In some cases, the sponsor may collect Best Response (e.g., the best observed tumor response the subject had on the therapy during the treatment period), Reason for Discontinuation, and Date of Progression for all prior therapies. Although the information may be collected on a CM CRF (not included), the data on best response and date of progression are represented in the RS domain. Reason for Discontinuation is represented in the CM domain using the variable CMRSDISC. The example SDTM CM domain shows the data associated with the prior use of Avastin and Docetaxel. Typically, Avastin may be given in combination with other chemotherapy agents, but this is not shown. This subject was initially treated with Avastin and had a partial response, but eventually the subject progressed, and was given Docetaxel (another chemotherapy agent) at the time of progression.

Row	STUDYID	DOMAIN	USUBJID	CMSEQ	CMLNKID	CMTRT	CMDECOD	CMCAT	CMINDC	CMDOSE	CMDOSU	CMDOSFRQ	CMRSDISC	CMSTDTC	CMENDTC
1	LC005	CM	3001	1	CM001	AVASTIN	Bevacizumab	ANTI-CANCER THERAPY	LUNG CANCER	15	mg/kg	EVERY 3 WEEKS	PROGRESSION	2012-03-15	2014-06-01
2	LC005	CM	3001	2	CM002	DOCETAXEL	Docetaxel	ANTI-CANCER THERAPY	LUNG CANCER	75	mg/m ²	EVERY 3 WEEKS	PROGRESSION	2014-06-15	2014-07-01

The RS domain is used to represent any clinical classifications and treatment responses associated with the study. In this example, the pre-study tumor evaluation responses and the AJCC staging information are represented. Illustrated are 2 possible methods for representing pre-study tumor response information. A sponsor may decide to just collect the dates of progression (especially in trials with a heavily pre-treated population). Progression dates are represented in rows 1-2 below. Alternatively, a sponsor may collect Best Response and Date of Progression for each prior anti-cancer therapy. These responses are illustrated in rows 3-5 below. An aCRF for the collection of responses (e.g., Best Response, Date of Progression) for each prior therapy, or the collection of dates of progression are not provided in this TAUG.

Rows 1-2: Show the dates when the subject had the first and second progression of metastatic disease. RSCAT is typically used to define the criteria used; because the criteria used was not known, the value of "UNSPECIFIED" was used. The fact that this is an instance of the disease milestone is represented by the inclusion of MIDS="DXMETPROG1" and "DXMETPROG2". Because these are records for disease milestones, rather than associated records, the variables RELMIDS and MIDSDTC are not needed for these records.

Rows 3-5: Show the best response and the date of progression associated with each prior lung cancer treatment. RSLNKGRP was assigned by the sponsor and used to link the reported response with the corresponding prior therapy record in the CM dataset. The sponsor chose to use RSLNKGRP to link this RS dataset to the CM dataset, since this variable is typically included in the RS domain for oncology studies. Other sponsors may choose to use other variables to link the datasets.

Because the date of the best response was not available for the Avastin treatment, RSDTC is null. The best response for Docetaxel was not reported. The sponsor decided not to include this information in the RS domain.

Row 6: Shows the AJCC overall stage and the TNM staging codes for subject 3002. Because the prefix c is not included, these are assumed to be clinical staging. RSCAT is used to indicate what staging procedure was used and RSSCAT is used to indicate what specific AJCC anatomical site criteria were used for the staging. RSDTC for the AJCC stage at initial diagnosis, was populated with the date of diagnosis of lung cancer. This record is associated with the disease milestone of initial diagnosis, hence the variables MIDS, RELMIDS and MIDSDTC are included. The temporal relationship of this observation (e.g., AT THE TIME OF) to the Disease Milestone Instance Name in MIDS (e.g., INITDX) is provided in the variable RELMIDS. Note that the controlled terminology for RSCAT is specific to AJCC Version 7.

Rows 7-10: Show the AJCC overall stage and the TNM staging codes for subject 3002 at study entry. Because the prefix c is not included, these are assumed to be clinical staging. RSCAT is used to indicate what staging procedure was used and RSSCAT is used to indicate what specific AJCC anatomical site criteria were used for the staging. These records are not associated with the trial defined disease milestones, therefore MIDS, RELMIDS, and MIDSDTC are not populated.

Rows 11-14: Show the AJCC overall stage and the TNM staging codes for subject 3010 at study entry. Because the prefix p is included, these are pathological staging results. RSCAT is used to indicate what staging procedure was used and RSSCAT is used to indicate what specific AJCC anatomical site criteria were used for the staging. Note that the controlled terminology for RSCAT is specific to AJCC Version 7.

Row	STUDYID	DOMAIN	USUBJID	RSSEQ	RSLNKGRP	RSTESTCD	RSTEST	RSCAT	RSSCAT	RSORRES	RSSTRESC	VISITNUM	VISIT	VISITDY	RSDTC	RSDY	RSSTRF	MIDS	RELMIDS	MIDSDTC
1	LC005	RS	3000	1		OVRRESP	Overall Response	UNSPECIFIED		PD	PD	1	SCREENING	-14	2014-06-01	-60		DXMETPROG1		
2	LC005	RS	3000	2		OVRRESP	Overall Response	UNSPECIFIED		PD	PD	1	SCREENING	-14	2014-09-20	-10		DXMETPROG2		
3	LC005	RS	3001	1	CM001	BESTRESP	Best Overall Response	UNSPECIFIED		PR	PR	1	SCREENING	-14			BEFORE			
4	LC005	RS	3001	2	CM001	OVRRESP	Overall Response	UNSPECIFIED		PD	PD	1	SCREENING	-14	2014-06-01	-100		DXMETPROG1		
5	LC005	RS	3001	3	CM002	OVRRESP	Overall Response	UNSPECIFIED		PD	PD	1	SCREENING	-14	2014-07-01	-70		DXMETPROG2		
6	LC005	RS	3002	1		AJCC104	AJCC1-Anatomic Stage	AJCC V7	LUNG	STAGE I	STAGE I	1	SCREENING	-14	2012-12-28	-1103		INITDX	AT TIME OF	2012-12-28
7	LC005	RS	3002	2		AJCC104	AJCC1-Anatomic Stage	AJCC V7	LUNG	STAGE 4	STAGE 4	1	SCREENING	-14	2016-01-02	-3				
8	LC005	RS	3002	3		AJCC101	AJCC1-Primary Tumor (T)	AJCC V7	LUNG	T1	T1	1	SCREENING	-14	2016-01-02	-3				
9	LC005	RS	3002	4		AJCC102	AJCC1-Regional Lymph Nodes (N)	AJCC V7	LUNG	N1	N1	1	SCREENING	-14	2016-01-02	-3				
10	LC005	RS	3002	5		AJCC103	AJCC1-Distant Metastasis (M)	AJCC V7	LUNG	M1	M1	1	SCREENING	-14	2016-01-02	-3				
11	LC005	RS	3010	1		AJCC104	AJCC1-Anatomic Stage	AJCC V7	LUNG	STAGE 4	STAGE 4	1	SCREENING	-14	2015-01-02	-4				
12	LC005	RS	3010	2		AJCC101	AJCC1-Primary Tumor (T)	AJCC V7	LUNG	pT1	pT1	1	SCREENING	-14	2015-01-02	-4				
13	LC005	RS	3010	3		AJCC102	AJCC1-Regional Lymph Nodes (N)	AJCC V7	LUNG	pN1	pN1	1	SCREENING	-14	2015-01-02	-4				
14	LC005	RS	3010	4		AJCC103	AJCC1-Distant Metastasis (M)	AJCC V7	LUNG	pM1	pM1	1	SCREENING	-14	2015-01-02	-4				

In some clinical studies, the location of all existing sites of disease at baseline may be collected. Sponsors may also document that no disease had been found at a specified site. These baseline sites of disease may be used as prognostic factors in the analysis. The TU domain was used to report the information on the sites of disease that were present/absent at baseline. TU would also be used to identify specific tumors that are followed for tumor response evaluation. In order to facilitate review, these records are grouped by assigning TUCAT to "BASELINE DISEASE SITE" and "RESPONSE EVALUATION TUMOR" to distinguish between actual tumors that will be followed throughout the study, and information about baseline sites of disease. TULNKID is an expected variable, and should be included in the dataset. For the baseline sites of disease, TULNKID was not populated in this example because no results are associated with these sites of disease.

Rows 1-3: Show the sites of metastatic disease at baseline. The DTC was the assessment date. A row is included for each site of disease evaluated. The general question about whether the subject had metastatic disease is reported in MH as a diagnosis. TUREFID is used to link to the procedure used to assess this site.

Row 4: Shows that the pleural cavity was not assessed at baseline.

Row 5: Shows the specific tumor being evaluated for tumor response during the study. TULNKID links to the assessments on this tumor that are represented in TR but are not shown.

Row	STUDYID	DOMAIN	USUBJID	TUSEQ	TUREFID	TULNKID	TUTESTCD	TUTEST	TUCAT	TUORRES	TUSTRESC	TUSTAT	TULOC	TULAT	TUMETHOD	TUEVAL	VISITNUM	VISIT	EPOCH	TUDTC	TUDY
1	LC005	TU	3007	1	IMG-001		METIND	Metastatic Tumor Site Indicator	BASELINE DISEASE SITE	Y	Y		LIVER		CT SCAN	INVESTIGATOR	10	BASELINE	BASELINE	2016-01-02	1
2	LC005	TU	3007	2	IMG-002		METIND	Metastatic Tumor Site Indicator	BASELINE DISEASE SITE	N	N		BRAIN		MRI	INVESTIGATOR	10	BASELINE	BASELINE	2016-01-02	1
3	LC005	TU	3007	3	IMG-001		METIND	Metastatic Tumor Site Indicator	BASELINE DISEASE SITE	Y	Y		LYMPH NODE		CONTRAST ENHANCED PET/CT SCAN	INVESTIGATOR	10	BASELINE	BASELINE	2016-01-02	1
4	LC005	TU	3007	4			METIND	Metastatic Tumor Site Indicator	BASELINE DISEASE SITE			NOT DONE	PLEURAL CAVITY			INVESTIGATOR	10	BASELINE	BASELINE	2016-01-02	1
5	LC005	TU	3007	5	IMG-001	T01	TUMIDENT	Tumor Identification	RESPONSE EVALUATION TUMOR	TARGET	TARGET		LUNG	RIGHT		INVESTIGATOR	10	BASELINE	BASELINE	2016-01-02	1

The RELREC dataset shows dataset relationships between the different SDTM domains used to represent the lung cancer disease characteristics and prognostic factors. The disease milestone timing variable MIDS provides a way to link records associated with a particular disease milestone without the need for additional linking via RELREC. Hence, the sponsor did not include RELRECs to reflect the associations between assessments associated with the study defined trial milestones. For example, the AJCC stage at study entry is linked to the date of diagnosis in the MH domain using MIDS="INITDX". The merge keys used to link the related SDTM datasets are null when records are not associated with the defined relationship.

The RELREC table below shows (1) how the prior anti-cancer therapies in the CM domain are related to the multiple historical responses in the RS domain and (2) how the procedures in the PR domain used to assess baseline sites of disease are related to the baseline sites of disease represent in the TU domain. Note that the relationship between the record in the TU domain (row 5) that represented a Tumor Response Evaluation and the associated tumor response assessments in the TR and RS domains is not shown.

Rows 1-2: Show the link between specific therapies in the CM and their associated prior anti-cancer treatment responses, represented in the RS domain. The merge key is blank for the other type of disease classification and responses represented in the RS domain.

Rows 3-4: Show the link between the procedures in the PR used to identify the tumors that are represented in the TU domain. Note that one image may be used to identify multiple tumors. The merge key is blank for the procedures that represented prior lung surgeries.

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	LC005	CM		CMLNKID		ONE	1
2	LC005	RS		RSLNKGRP		MANY	1
3	LC005	PR		PRREFID		ONE	2
4	LC005	TU		TUREFID		MANY	2

3.4 Pathology and Biomarkers

The following table provides limited information on some common tests associated with lung cancer. Readers should consult the literature for decisions on which of these tests would be useful to include in their studies. Study sponsors may seek the guidance of the appropriate regulatory review division if applicable. The College of American Pathologists (CAP), the International Association for the Study of Lung Cancer (IASLC), the Association for Molecular Pathology (AMP), and the American Society of Clinical Oncology (ASCO) are some of the groups that provide recommendations on molecular testing. This table provides only limited information on some common tests associated with lung cancer. This limited information was provided only to help explain the SDTM examples provided in this section. Examples of how to represent other common genetic variations may be found in other TAUGs and the SDTMIG-PGx.

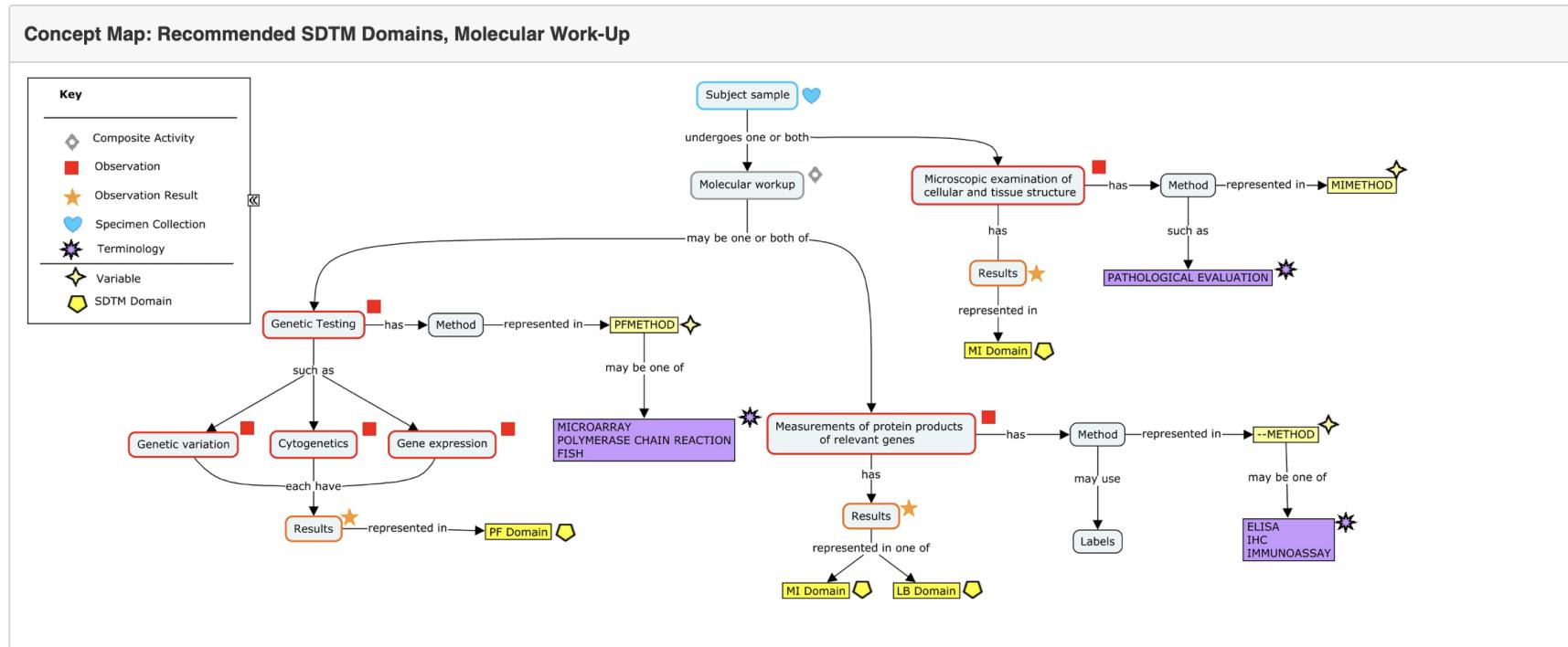
Biomarker	Description
EGFR	<p>For treatment of advanced non-small cell lung cancer (NSCLC), response and outcome to EGFR-TKIs have been demonstrated in most studies to be better predicted by epidermal growth factor receptor (EGFR) mutation testing rather than copy number or immunohistochemistry (IHC).[5] Approximately 90% of these mutations are exon 19 deletions (E746_A750) or exon 21 L858R point mutations.[6] New mutation-specific antibodies for EGFR exon 19 deletions and L858R used in testing mutation using IHC methodology seem to be much more reliable in predicting EGFR mutation status, and these need to be evaluated in future clinical trials.[5]</p> <p>The EGFR E746_A750del mutation arises from the deletion of nucleotides from position 2235-2249 (c.2235_2249del in exon 19), resulting in an in-frame deletion of 5 amino acids (glutamic acid, leucine, arginine, glutamic acid, alanine) from position 746 to 750.</p> <p>Lung cancers caused by mutations in the EGFR are initially responsive to tyrosine kinase inhibitors (TKIs), but the efficacy of these agents is often limited because of the emergence of drug resistance conferred by a second mutation, T790M.[7] Depending on the tumor sites at progression, it can be difficult to obtain tissue for T790M testing. Testing for EGFR T790M in a liquid biopsy using cell-free circulating tumor DNA from a plasma sample can also be a valid approach.[8] Germline T790M mutations, like all germline mutations, can be detected in a variety of subject sample types; tumor DNA is not needed in the case of germline mutations.</p>
MET Protein/MET Gene	<p>The varied mechanisms of mesenchymal–epithelial transition (MET) activation in lung cancer—including over-expression of MET and/or its ligand, hepatocyte growth factor (HGF); genetic alterations to MET (e.g., mutations, amplification, translocation, dysregulated transcription); and impaired degradation of MET—provide an array of potential biomarkers. Mutations in the splice site of MET that result in skipping exon 14[9] may be important in NSCLC. MET gene copy number (GCN) appears to be a good predictive biomarker; the fluorescent in situ hybridization (FISH) MET/chromosome enumeration probe 7 (CEP7) ratio is also a relatively simple primary measure of amplification.[10]</p> <p>MET protein expression can be assessed by IHC methods. The protein expression by IHC methods may be reported as the intensity of the staining using a scoring system (e.g., 0-3+), the percentage of staining, or H scores.</p>
ALK Translocations	<p>Multiple different anaplastic lymphoma kinase (ALK) rearrangements have been described in NSCLC. Automated IHC for ALK expression using a specific clone with ultrasensitive detection-amplification kit may also be used. The clones used may be clone D5F3 and clone 5A4.[11]</p>
ROS1	<p>The presence of a ROS1 rearrangement is detected by FISH with a break-apart probe. FISH testing is not able to discern which particular ROS1 fusion is found. ROS1-IHC (using ROS1 clone D4D6) may also be performed with the FISH method employed only if the IHC method is equivocal. Other testing methods such as reverse transcription polymerase chain reaction (RT-PCR) may be used.</p>
MET Copy Number	<p>The copy number of the MET gene in NSCLC may be of interest.[12] The MET copy number may also be reported as a ratio (MET/CEP7) of the MET copy number to the number of chromosome 7 centromeres—the center point of the chromosome—which allows one to see if MET was amplified in comparison with the chromosome as a whole.[13] Although SNP 6.0 and FISH are methods conventionally used to evaluate MET copy number, other new methods such as droplet digital PCR may be used.</p>
PD-L1	<p>Targeting the PD-1/PD-L1 signaling axis, which when activated leads to T-cell exhaustion and subsequent immune escape by cancer cells, has proven to be an effective therapeutic strategy in lung</p>

Biomarker	Description
	cancer. Several antibodies targeting either PD-1 or PD-L1 have now been FDA-approved in lung cancer and other types of cancer. PD-L1 expression on tumor cells or antigen-presenting cells has been postulated as a biomarker for response to PD-1/PD-L1 inhibitors. However, determining PD-L1 positivity is not standardized; thresholds for PD-L1-positive lung cancer differ based on the antibody and assay used. [14] Recently, with the approval of new drugs targeting PD-1/PD-L1, specific antibodies and scoring criteria have been identified for evaluating this marker using associated companion diagnostics tests.
NSE	Many patients with small cell lung carcinoma will have elevated serum neuron-specific enolase (NSE) concentrations at diagnosis, and the majority of patients with advanced small cell lung cancer (SCLC) will have serum levels above the normal reference range. Serial measurements of serum NSE levels may be useful for monitoring the response to chemotherapy in cases of SCLC.

BRAF testing using next-generation sequencing technology is commonly performed in Japan. Pro-gastrin-releasing peptide precursor (ProGRP) and carcinoembryonic antigen (CEA) testing may also be used in subjects with SCLC. The specific results are not shown in the provided SDTM examples.

Multiplex (i.e., multigene) panels have been recently developed to efficiently screen many cancer susceptibility genes. The transition from discrete to broad genomic sequencing presents many clinical challenges. The representation of multiplex genetic testing was not included in this TAUG. Readers should refer to the SDTMIG-PGx for updates on modeling these multiplex genetic panels.

The abbreviations and test names given in this section are those commonly used in clinical practice. When constructing standard datasets, consult the current version of CDISC Controlled Terminology (available at <http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/cdisc>) for the values of --TEST and --TESTCD. The domain in which a biomarker is represented depends on the test method (e.g., PF for genetic tests on DNA or RNA specimens; MI for microscopic tests on tissue samples). The following concept map may be useful in resolving questions about where particular tests should be represented in SDTM.



More information on the mutations associated with lung cancer can be found at the My Cancer Genome website (<https://www.mycancergenome.org>). The College of American Pathologists also provides information on lung cancer biomarkers at <http://www.cap.org>.

The following examples represent the results of lung cancer biomarkers. The first 2 examples illustrate genetic variation and gene expression tests when data was provided retrospectively on CRFs (Example 1) and when data was collected using a central lab (Example 2). The published controlled terminology for PFTEST ("Genetic Variation") was used instead of the previously used PFTEST of "Amino Acid." New controlled terminology for PFTEST, "Genetic Rearrangement," was used in these examples instead of "Chromosomal Aberration." This new terminology still has to be approved by the Controlled Terminology team and is subject to change. Example 3 represents information on protein expression determined using IHC methods represented in the MI domain; Example 4 illustrates information on a biomarker that was represented in the Laboratory Test Results (LB) domain.

Example 1

In this example, data was collected on the CRF and assumed to be similar to that provided in the CAP Cancer Protocol Template for Reporting Results of Biomarker Testing of Specimens From Patients With Non-Small Cell Carcinoma (<http://www.cap.org/>). The example illustrates how to represent (1) information on the characteristics of the tissue/biospecimen and (2) subject genetic variations data. Although many sponsors may not collect detailed information on characteristics of the tissue/biospecimen, this information is provided to show how it might be represented.

Tissue/Biospecimen Characteristics

In this trial, the tumor specimen used for testing could have been based on an archival tissue sample, or a fresh tissue sample. The sponsor of this trial tracked the specific tissue/biospecimen used and the location from where the tissue was taken. The BE domain is used to represent data about actions taken that affect or may affect a specimen (e.g., specimen collection, freezing and thawing, aliquoting, transportation). BELOC was populated because the sponsor wanted to track the anatomic location of specimen collection. Note that BELOC is populated only when the subject participates in and is directly affected by the event given in BETERM.

Note that the standard Findings variable --SPEC has been added to this dataset as a non-standard (Events) variable. Because the specimen is not genetic and the subject is human, values for this NSV draw from the SPECTYPE codelist.

- Row 1:** Shows the date that the original fresh sample was collected, represented in BEDTC. The start date of the event represented in BETERM is represented in BESTDTC. In this case, BEDTC and BESTDTC are the same. Because the end date/time of the event is the same as the start date/time for the event, BEENDTC is null. BEENDTC is included in the dataset because it is an expected variable. BELOC is populated as this represents the actual collection of the specimen from the subject.
- Row 2:** Shows the information on the retrieval of the archival sample (BETERM="Retrieval") used for testing. The date the original fresh sample was collected is represented in BEDTC and the start date of the event (retrieval) is represented in BESTDTC. Note that BELOC is not populated because the BETERM of retrieval is not directly associated with the subject.
- Row 3:** Shows the date that the original fresh sample was collected. Again, BELOC is populated as this term is directly associated with the subject. No samples required retrieval for this subject.

Row	STUDYID	DOMAIN	USUBJID	BESEQ	BEREFID	BETERM	BELOC	VISITNUM	VISIT	BEDTC	BESTDTC	BEENDTC	BESPEC
1	LC007	BE	3001	1		Collecting	LUNG, LEFT LOWER LOBE	1	BASELINE	2014-06-05	2014-06-05		Tumor Tissue
2	LC007	BE	3001	2		Retrieval		1	BASELINE	2014-06-05	2015-06-07		Tumor Tissue
3	LC007	BE	3008	1		Collecting	LUNG, RIGHT MIDDLE LOBE	1	BASELINE	2015-07-02	2015-07-02		Tumor Tissue

BE NSV Metadata

Variable	Label	Type	Role	Origin
BESPEC	Specimen Type	text	Non-Standard Variable	CRF

Subject Genetic Variations

The SDTMIG-PGx contains complete recommendations for reporting genetic variations. Briefly, these variant results are usually complex and include information such as the position of a nucleotide (or amino acid or codon, according to the test), its expected value, and its observed value. SDTMIG-PGx v1.0 states that these various pieces of information should be parsed out (e.g., separated) as values in different variables: PFORRES should hold the observed nucleotide; PFORREF (the reference result variable) should hold the expected nucleotide according to the reference sequence; and the variable PFGENLOC should hold the *genetic location*, or position of the nucleotide within the sequence. The PGx team is evaluating this approach for possible simplification in the next version.

The data represented in this example deviate from those specifications in the SDTMIG-PGx v1.0. In this trial, some of the data on genetic variations collected on a CRF may have been historical; some subjects only had information on whether any mutations were detected for each gene of interest, whereas other subjects had information on the actual mutation detected in each gene of interest. The method and the reference sequence were not available. The representation of the genetic variation data in the Pharmacogenomics/Genetics Findings (PF) domain for this example was based on a pragmatic approach. This approach focused on ensuring consistency of the information within the dataset. Note that, in order to save space, not all expected SDTM variables are shown.

When viewing examples, bear in mind that:

- Information on genetic variations was not parsed out using the variables PFORRES, PFORREF, and PFGENLOC. This pragmatic representation of the genetic data is under discussion within the PGx Team and subject to change. Sponsors are urged to discuss such representation with the appropriate regulatory agency.
- The sponsor decided to include the results of the question whether or not a generic variation was detected in the SDTM-based dataset. Some sponsors may decide that when a variation is detected, the question indicating that the variation was detected may not be represented in the SDTM-based dataset because the specific variation is represented. Some sponsors may also choose to exclude any information on variations that were not detected and only list the identified genetic variations.
- PFDTCT is the date of the original specimen collection. PFDY is based on the date of the original sample, not the date the testing was performed. The actual run date of the test may be important because additional testing may be performed on archival samples just prior to enrollment in a study. PFRUNDTC may provide some indirect information on the validity of the results, especially because this is an area of rapidly changing methodology. -- RUNDTC has been proposed as a new core variable to be added to the PF domain, and would be used to represent the date that the sample was analyzed. Because this variable has not yet been approved, it is represented as a non-standard variable (NSV).
- Results are based on actual data collected. When CRFs are used to collect pre-study results, sponsors may allow different formats for reporting the results, in order to accommodate formats that may have been used when the original data was reported by the lab. The protein variation may use single-letter amino acid symbols or 3-letter amino acid symbols. For example, a variation in a protein in which the 12th amino acid is Glycine in the reference sequence and Alanine in the subject's sequence can be represented as either Gly12Ala or G12A. (Both 3-letter and single-letter symbols for amino acids were published in 1983 by a Joint Commission of the International Union of Pure and Applied Chemistry and the International Union of Biochemistry and Molecular Biology.[\[15\]](#)) Many labs report results using either the 3-letter or single-letter amino acid names. The CAP Reporting Template uses the 3-letter abbreviation for reporting some amino acid (protein) names. Because the 3-letter amino acid symbols were used, they are reported in the SDTM variable PFORRES/PFSTRESC; this avoids the manual translation of the data into another format. Sponsors are encouraged to design the data collection instrument using the most appropriate format that avoids any manual translation of data. Sponsors also should provide instructions on what nomenclature to use within a specific clinical trial. HGVS nomenclature may be used to report information regarding DNA, RNA, and protein sequences; these standards were updated in 2017.[\[16\]](#)
- Sponsors may include lists of possible variations as a data entry convenience. Sponsors typically do not consider these lists of possible variations as a pre-specified gene variation. Therefore, any variation chosen from the codelist or written in by the investigator were represented using the same format. PFSTRESC, the standardized result, used the format associated with the collected variation to avoid any manual translation to another format (e.g., p.Gly12Asp to c.35>A).
- Typically for variations that are not pre-specified, PFGENLOC and PFORREF would be populated. PFORREF would be compared with PFORRES to determine if a mutation is present. However, in this case, variations were reported only for subjects with a mutation. Because the data was collected on CRFs, and these fields would have to be manually populated, the sponsor elected not to include these "permissible" variables in the SDTM-based dataset.

- In this study, the sponsor standardized the results in the ADaM dataset to facilitate data analysis. This ADaM dataset is not shown.

Rows 1-3: Subject 3001 had a KRAS mutation detected. Some sponsors may decide not to report this record, and only include the genetic variations. The specific KRAS variation was also provided. This subject also had a genetic variation at Codon 61, but the variation was not specified.

Row 4: Subject 3008 had a genetic variation (D963_splice mutation detected) of the MET gene at exon 14.

Row 5: MET Gene Expression for this subject was represented as Amplification.

Rows 6-7: MET Gene Expression for this subject was represented as Copy Number and Copy Number Ratio.

Row 8: Shows how to represent gene rearrangements of the ALK gene. This was determined using fluorescence in situ hybridization (FISH). The FISH method does not determine what rearrangements were detected; it detects any rearrangement of the gene.

Row 9: Shows that the specific gene rearrangement of the ALK gene, EML4-ALK, was detected in this subject.

Row	STUDYID	DOMAIN	USUBJID	PFSEQ	PFTESTCD	PFTEST	PFGENRI	PFGENTYP	PFCAT	PFORRES	PFGENLOC	PFGENSR	PFSTRESC	PFSTRESN	PFMUTYP	PFNAM	PFMETHOD	VISITNUM	VISIT	PFDTG	PFDY	PFRUNDTC
1	LC007	PF	3001	1	GENVAR	Genetic Variation	KRAS	GENE	MOLECULAR DIAGNOSTIC TESTING	DETECTED			DETECTED		SOMATIC	GENLAB1	POLYMERASE CHAIN REACTION	1	BASELINE	2014-06-05	-365	2015-06-05
2	LC007	PF	3001	2	GENVAR	Genetic Variation	KRAS	GENE	MOLECULAR DIAGNOSTIC TESTING	Gly12Cys	CODON 12		p.Gly12Cys		SOMATIC	GENLAB1	POLYMERASE CHAIN REACTION	1	BASELINE	2014-06-05	-365	2015-06-05
3	LC007	PF	3001	3	GENVAR	Genetic Variation	KRAS	GENE	MOLECULAR DIAGNOSTIC TESTING	Specific codon 61 mutation not stated	CODON 61		DETECTED		SOMATIC	GENLAB1	POLYMERASE CHAIN REACTION	1	BASELINE	2014-06-05	-365	2015-06-05
4	LC007	PF	3008	1	GENVAR	Genetic Variation	MET	GENE	MOLECULAR DIAGNOSTIC TESTING	D963_splice mutation detected		EXON 14	D963_splice mutation detected		SOMATIC	GENLAB3	POLYMERASE CHAIN REACTION	1	BASELINE	2015-07-02	-20	
5	LC007	PF	3008	2	GENEXP	Gene Expression	MET	GENE	MOLECULAR DIAGNOSTIC TESTING	AMPLIFICATION			AMPLIFICATION		SOMATIC	GENLAB3	FISH	1	BASELINE	2015-07-02	-20	
6	LC007	PF	3008	3	COPYNUM	Copy Number	MET	GENE	MOLECULAR DIAGNOSTIC TESTING	3			3	3	SOMATIC	GENLAB3	FISH	1	BASELINE	2015-07-02	-20	
7	LC007	PF	3008	4	CPYNUMRT	Copy Number Ratio	MET/CE7	GENE	MOLECULAR DIAGNOSTIC TESTING	1.21			1.21	1.21	SOMATIC	GENLAB3	FISH	1	BASELINE	2015-07-02	-20	
8	LC007	PF	3010	1	GENREARR	Genetic Rearrangement	ALK	GENE	MOLECULAR DIAGNOSTIC TESTING	POSITIVE			POSITIVE		SOMATIC	GENLAB3	FISH	1	BASELINE	2013-07-02	-12	
9	LC007	PF	3010	2	GENREARR	Genetic Rearrangement	EML4-ALK	GENE	MOLECULAR DIAGNOSTIC TESTING	POSITIVE			POSITIVE		SOMATIC	GENLAB3	PCR	1	BASELINE	2013-07-02	-12	

PF NSV Metadata

Variable	Label	Type	Role	Origin
PFRUNDTC	Run Date	text	Non-Standard Timing Variable	CRF

Example 2

This is an example of how to represent the results of genetic variation and gene expression tests when data is provided by a central lab, specifically information on (1) laboratory kits used for mutation testing, and (2) subject genetic variations data. Although many sponsors may not collect detailed information on the in vitro diagnostics test used, this information is included to illustrate how this might be represented.

Laboratory Kits Used for Genetic Variation Testing

In this example, all subjects were required to have KRAS mutation testing performed using the same test. Hence, the sponsor represented information on the commercially available in vitro diagnostics test used during the study in the SDTM Device domains. Commercially available in vitro diagnostics tests are often used across different laboratories, and have been developed following each country's regulatory guidelines. No other characteristics or properties of the device were represented, as this information was available as part of the package insert for the test. No subject-specific set-up was required (e.g., Device Properties (DO) and Device-In-Use (DU) are not used).

The Device Identification (DI) domain is a special-purpose domain designed for the submission of information that identifies a specific device. The DI domain provides a consistent sponsor-defined variable (SPDEVID) for linking data across domains. DEVTYPE should at a minimum be included in the DI domain. DEVTYPE uses controlled terminology defined using the Global Medical Device Nomenclature (GMDN; see www.gmdnagency.org). Note that this DI domain does not include USUBJID, as this variable represents information on the device itself and is not related to the subject.

The Device-Subject Relationships (DR) domain is used to link each subject to the associated device. This domain is optional and in this situation was not included as it was not needed.

Rows 1-2: Show the assay kit used for the somatic gene mutation detection of the KRAS gene. The assay kit was assigned a sponsor-defined SPDEVID. In order to uniquely identify this kit, rows for DIPARMCD and DIPARM of Device Type and Manufacturer were provided.

Row 3: Shows the trade name associated with this device type. This identifies the specific gene mutation detection system used by the central lab.

Row	STUDYID	DOMAIN	SPDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
1	LC12	DI	KRAS KIT	1	DEVTYPE	Device Type	Somatic Gene Mutation Detection System
2	LC12	DI	KRAS KIT	2	MANUF	Manufacturer	Company X
3	LC12	DI	KRAS KIT	3	TRADENAM	Trade Name	Company X KRAS Mutation Kit
4	LC12	DI	EGFR KIT	1	DEVTYPE	Device Type	Somatic Gene Mutation Detection System
5	LC12	DI	EGFR KIT	2	MANUF	Manufacturer	Company Y
6	LC12	DI	EGFR KIT	3	TRADENAM	Trade Name	Company Y EGFR Mutation Kit V2

Subject Genetic Variations Data

The data represented in this dataset followed the recommendations in SDTMIG-PGx v1.0 (unlike the example where genetic testing information was collected on CRFs). SPDEVID was included to link the information to the specific commercially available in vitro diagnostics test used and described in DI. When SPDEVID is null, the test was not performed by a commercially approved test. PFREFID was populated with the tumor sample reference number.

Row 1: Shows how the genetic variation in the KRAS gene is represented by parsing of "c.34G>T" into the appropriate variables. This indicates that nucleotide 34 has a G changed to a T. PFORREF is "G", PFORRES is "T" and PFGENLOC is "34". The reference genetic sequence was represented in PFREFSEQ.

Row 2: Shows the genetic variation that is a deletion in the EGFR gene in exon 19.

Row 3: Shows that a genetic rearrangement of the ROS1 gene was detected using a FISH method. Because FISH testing is not able to discern which particular ROS1 fusion is found, the actual rearrangement was not available. However, this rearrangement is associated with ROS1 gene, on chromosome 6q22, which is represented in PFGENLOC.

Row 4: Shows the genetic variation of the EGFR (also referred to as L858R) results in an amino acid substitution at position 858 in EGFR, from a leucine (L -Leu) to an arginine (R -Arg).

Rows 5-6: Show genetic variations for EGFR and MET genes using the nucleotide nomenclature.

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	PFSEQ	PFTREFID	PFTESTCD	PFTEST	PFGENR1	PFGENTYP	PFREFSEQ	PFCAT	PFORRES	PFORRESU	PFORREF	PFGENLOC	PFGENSR	PFSTREC	PFNAM	PFSPEC	PFMUTYP	PFMETHOD	VISITNUM	VISIT	PFDTC	PFDY
1	LC12	PF	3001	KRAS KIT	1	SX1001	GENVAR	Genetic Variation	KRAS	GENE	NM_033360.3	MOLECULAR DIAGNOSTIC TESTING	T	G	34	c.34G>T	LAB X	DNA	SOMATIC	POLYMERASE CHAIN REACTION	1	BASELINE	2007-5-05	-295		
2	LC12	PF	3002	EGFR KIT	1	SX1002	GENVAR	Genetic Variation	EGFR	GENE	NM_005228.3	MOLECULAR DIAGNOSTIC TESTING	-	GGAAATTAGAGAAAGC	c.2235_2249	EXON 19	c.2235_2249del15	LAB X	DNA	SOMATIC	POLYMERASE CHAIN REACTION	1	BASELINE	2007-11-05	-83	
3	LC12	PF	3003		1	SX3003	GENREARR	Genetic Rearrangement	ROS1	GENE		MOLECULAR DIAGNOSTIC TESTING	POSITIVE		6q22		POSITIVE	LAB X	DNA	SOMATIC	FISH	1	BASELINE	2007-01-08	-10	
4	LC12	PF	3004	EGFR KIT	1	SX3004	GENVAR	Genetic Variation	EGFR	GENE		MOLECULAR DIAGNOSTIC TESTING	Arg	Leu	858	EXON 21	p.Leu858Arg	LAB X	DNA	SOMATIC	NEXT GENERATION SEQUENCING	1	BASELINE	2007-02-08	-15	
5	LC12	PF	3009	EGFR KIT	1	SX3009	GENVAR	Genetic Variation	EGFR	GENE		MOLECULAR DIAGNOSTIC TESTING	G		T	2573		c.2573T>G	LAB X	DNA	SOMATIC	NEXT GENERATION SEQUENCING	1	BASELINE	2007-03-08	-50
6	LC12	PF	3010		1	SX3010	GENVAR	Genetic Variation	MET	GENE		MOLECULAR DIAGNOSTIC TESTING	G		A	3335		c.3335A>G	LAB X	DNA	SOMATIC	NEXT GENERATION SEQUENCING	1	BASELINE	2007-04-08	-34

Example 3

This is an example of lung cancer biomarkers assessed using IHC methods. The variable MISPCCND is an expected variable and was included in the dataset. No information was available on the specimen condition.

Rows 1-2: Show the test results of the protein expression of ROS1 using an IHC method. The result was negative for subject 1002 and equivocal for subject 1003. This expression amount is used to assess whether ROS1 gene rearrangements may be present. The sponsor represented the clone used in the assay in the NSV ABCLON.

Row 3: Shows the test results of the protein expression of the ALK protein in cell lung carcinoma tissue using an IHC method. The sponsor represented the specific antibody clone used in the assay.

Row 4: Shows the test results of the protein expression associated with the EGFR-L858R gene mutation. This testing was performed using an antibody specific for the detection of this mutation (Antibody Clone 6B6). The antibody is represented in the NSV ABCLON. The MITEST/MITESTCD indicates that this test is associated with a specific mutation/variant. The specific variant/mutation is specified in the NSV MIVARINT.

Row 5: Shows the test results of the protein expression associated with the EGFR-E746-A750del gene mutation. This testing was performed using an antibody specific for the detection of this mutation (Antibody Clone 43B2). The MITEST/MITESTCD indicates that this test is associated with a specific mutation/variant. The specific variant/mutation is specified in the NSV MIVARINT.

Row 6: Shows the PD-L1 protein expression determined by using Tumor Proportion Score (TPS), which is the percentage of viable tumor cells showing partial or complete membrane staining at any intensity. MITSTDTL was used to indicate the scoring method.

Row	STUDYID	DOMAIN	USUBJID	MISEQ	MITESTCD	MITEST	MITSTDTL	MIORRES	MIORRESU	MISTREC	MISTRESN	MISTRESU	MISPEC	MISPCCND	MILOC	MIMETHOD	VISITNUM	VISIT	MIDTC	MIABCLON	MIVARINT
1	LC007	MI	1002	1	ROS1	ROS1		NEGATIVE		NEGATIVE			TUMOR TISSUE		LUNG	IHC	10	BASELINE	2013-05-05	D4D6	
2	LC007	MI	1003	1	ROS1	ROS1		EQUIVOCAL		EQUIVOCAL			TUMOR TISSUE		LUNG	IHC	10	BASELINE	2013-07-08	D4D6	
3	LC007	MI	1005	1	ALK	ALK Protein		POSITIVE		POSITIVE			TUMOR TISSUE		LUNG	IHC	10	BASELINE	2014-07-09	D5F3	
4	LC007	MI	1007	1	EGFRVP	EGFR Variant Protein		NEGATIVE		NEGATIVE			TUMOR TISSUE		LUNG	IHC	10	BASELINE	2015-05-14	6B6	L858R
5	LC007	MI	1007	2	EGFRVP	EGFR Variant Protein		POSITIVE		POSITIVE			TUMOR TISSUE		LUNG	IHC	10	BASELINE	2015-05-14	43B2	E746-A750del
6	LC007	MI	1011	1	PDL1	Programmed Death Ligand 1	TUMOR PROPORTION SCORE	34	%	34	34	%	TUMOR TISSUE		LUNG	IHC	10	BASELINE	2013-07-23		

MI NSV Metadata

Variable	Label	Type	Role	Origin
MIABCLON	Antibody Clone	text	Non-Standard Record Qualifier	CRF
MIVARINT	Protein or Mutation Variant	text	Non-Standard Record Qualifier	CRF

Example 4

This is an example of NSE results that were collected in an SCLC study. NSE may be collected only at baseline, or it may be followed during a trial. This example follows SDTMIG guidelines for the LB domain. Not all expected variables are shown to save space. Other tests (e.g., ProGRP and CEA) may also be collected, but are not shown in the example.

Row	STUDYID	DOMAIN	USUBJID	LBSEQ	LBTESTCD	LBTEST	LBORRES	LBORRESU	LBORNRHI	LBSTRESC	LBSTRESN	LBSTRESU	LBSTNRHI	LBNRIND	LBNAM	LBSPEC	LBMETHOD	VISITNUM	VISIT	VISITDY	LBDTC
1	LUCA10	LB	501	1	NSE	Neuron Specific Enolase	48	ng/mL	16	48	48	ug/L	16	HIGH	VENDOR A	SERUM	IMMUNOFLUORESCENT ASSAY	10	SCREENING	-1	2006-08-01
2	LUCA10	LB	501	2	NSE	Neuron Specific Enolase	57	ng/mL	16	57	57	ug/L	16	HIGH	VENDOR A	SERUM	IMMUNOFLUORESCENT ASSAY	20	WEEK 6	42	2006-10-06
3	LUCA10	LB	501	3	NSE	Neuron Specific Enolase	60	ng/mL	16	60	60	ug/L	16	HIGH	VENDOR A	SERUM	IMMUNOFLUORESCENT ASSAY	30	WEEK 12	84	2007-01-05

3.5 Effusion Assessments

The 2 main fluid compartments of the body are the intracellular and extracellular compartments. The extracellular compartment may be divided into interstitial, intravascular, and transcellular. Transcellular may be referred to as a "third-space compartment"; it consists of those spaces in the body where fluid does not normally collect in large amounts (e.g., the peritoneal, pleural, and pericardial cavities).

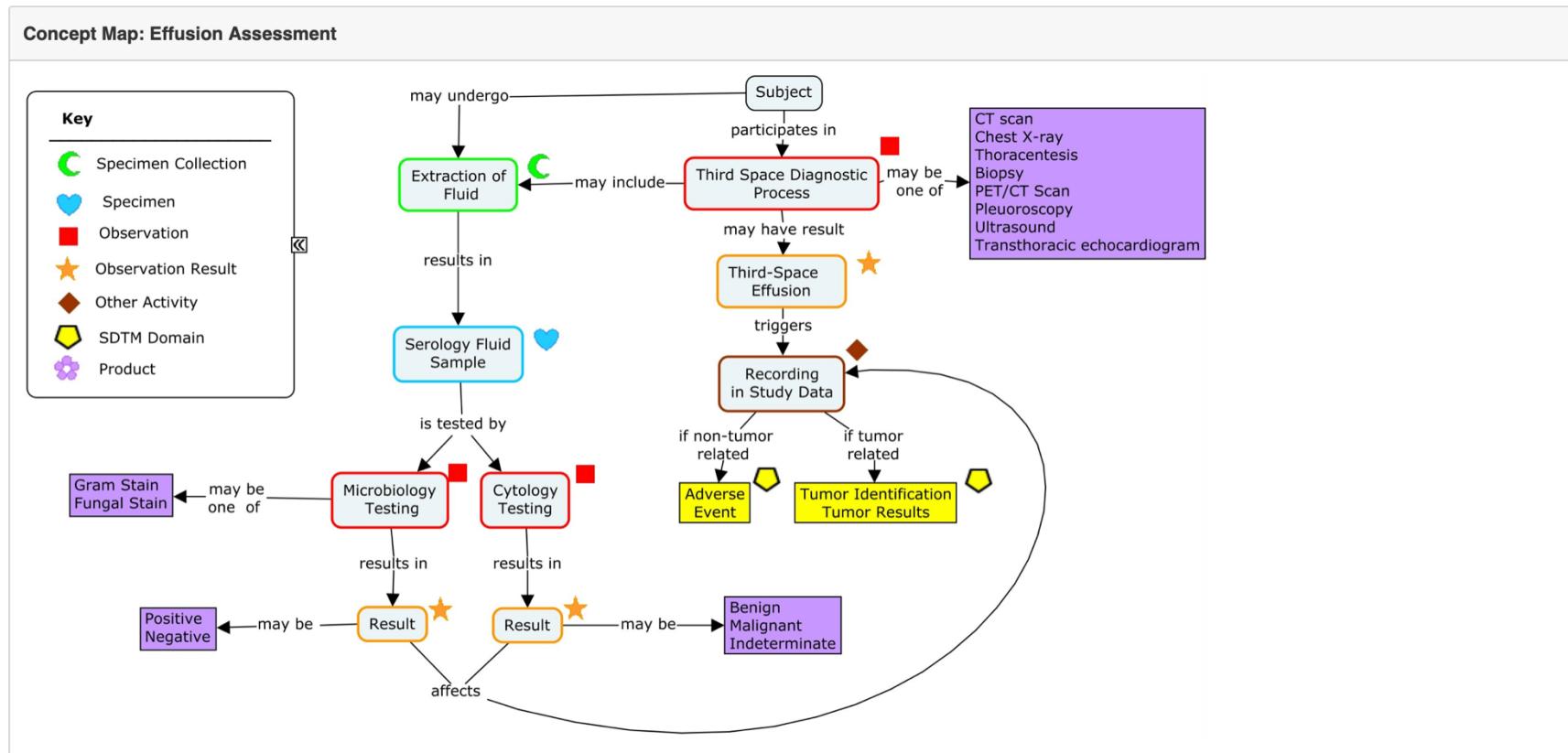
Effusion is the accumulation of serous fluid in a body cavity, particularly around the lungs (pleural cavity), around the heart (pericardial cavity), and in the abdomen (peritoneal cavity). An effusion may be malignant or non-malignant (caused by a condition that is not cancer, e.g., an infection). When effusion is identified, a subject may undergo a procedure to remove a sample of the fluid for testing to help determine the cause of accumulation of fluid.

The pleural cavity is the space between the pleura, a thin layer of tissue that covers the outer surface of each lung and lines the inner wall of the chest cavity. Pleural tissue usually produces a small amount of fluid that helps the lungs move smoothly in the chest while a person is breathing. A pleural effusion is a condition in which an abnormal amount of fluid is collected in the pleural cavity, making it hard to breathe. Malignant pleural effusion is a common problem for patients who have certain cancers (e.g., lung cancer, breast cancer, lymphoma, leukemia). A pleural effusion also may be caused by cancer treatments such as radiation therapy or chemotherapy. Some cancer patients may have conditions such as congestive heart failure, pneumonia, blood clots in the lung, or poor nutrition, which also may lead to pleural effusion.[\[17\]](#)

The pericardial cavity is the space between the two layers of serous pericardium around the heart. This space contains a small amount of fluid that acts to reduce surface tension and facilitates the free movement of the heart. Pericardial effusion is extra fluid that puts pressure on the heart. Pericardial malignant effusions are common in lung cancer, breast cancer, melanoma, lymphoma, and leukemia.[\[17\]](#)

The peritoneal cavity is the space between the wall of the abdomen and the organs contained within the abdomen. Malignant peritoneal effusions are most often caused by cancers of the ovary, uterus, breast, colon, lung, pancreas, and liver.[\[17\]](#)

In lung cancer clinical trials, sponsors often will collect information to assess the presence of any effusions at the start of the study and throughout the study, including any tests performed to determine the cause of the effusion and any treatments (see concept map, below). When the effusion is malignant, this information may be used to assess tumor burden. When the effusion is not malignant, this information may be used to assess the safety of the study treatment.



There are several treatments for effusions. Treatments for pleural effusion may include thoracentesis and pleurodesis. A thoracentesis may be performed to obtain a sample of the fluid for analysis, or it may be performed to treat an effusion by removing the fluid. These procedures typically are represented in the PR domain following the guidelines provided in the SDTMIG. See Section 4.5, [Treatment of Pleural Effusions](#), for an example on representing these types of procedures. A sponsor may decide to either (1) collect the procedure used to assess the pleural effusion on the procedures page and record the associated record identifier on this CRF, or (2) collect the method on this CRF. The PR domain is used to represent the information on when and where the procedure is performed for each subject. However, in the Findings Observation class, the test method may be represented in the --METHOD variable (e.g., electrophoresis, polymerase chain reaction).

At times, the test method overlaps with diagnostic/therapeutic procedures (e.g., ultrasound, MRI, x-ray), which are typically represented in the PR domain. The following is recommended: If timing (start, end, or duration) or an indicator populating --OCCUR, --STAT, or --REASND is collected, then a PR record is created. If only the findings from a procedure are collected, then --METHOD in the Findings Domain(s) may be sufficient to represent the procedure; a related PR record is optional. It is at the sponsor's discretion whether to represent the procedure as both a test method (--METHOD) and a related PR record.

Example 1

This is an example of pleural and pericardial effusion assessments obtained during a lung cancer study. Depending on the study design, a baseline effusion assessment may be conducted, as well as follow-up assessments. In this study, subjects were evaluated for pleural effusion and pericardial effusion at screening, and at all tumor assessment visits. This information was collected on the comprehensive Pleural Cavity Assessment CRF and on the Pericardial Cavity Assessment CRF. The sponsor instructed the investigator to also report relevant information from these assessments on the appropriate CRF: Effusions that were related to the lung cancer were reported on Tumor Evaluation CRFs, and those that were non-cancer related effusions were reported on the Adverse Events CRF.

The following annotated CDASH CRFs illustrate how to collect comprehensive assessments of the pleural and pericardial space. Although this is illustrated using a separate CRF for each cavity, this information may be collected on a single CRF.

This is a sample CRF that illustrates a comprehensive assessment of the pleural cavity. Many sponsors may only collect some of this information. A sponsor may also only report the actual findings on Tumor Evaluation CRFs and/or AE CRFs.

If fluid is evaluated, a separate Serosal Fluid Analysis CRF (not shown) may be completed based on the requested tests on the fluid removed.

The sponsor may decide to either (1) collect the procedure used to assess the pleural effusion on the procedures page and record the associated record identifier (CAVITY_REPRNO) on this CRF, or (2) collect the method (REMTHODn) on this CRF. Both options are illustrated in this CRF.

This CRF assumes that electronic data capture (EDC) navigation will be implemented to ensure appropriate questions based on whether this is a new assessment or an assessment of a previously identified effusion. Some sponsors may prefer to create separate CRFs for the initial effusion cavity assessment and for any follow-up assessments.

Indicate whether the subject had any assessments of the pleural cavity. REYN Not submitted	Did the subject have any assessments of the pleural cavity? <input type="radio"/> Yes <input type="radio"/> No <i><From NY codelist></i>
Record the date of the assessment.	What was the date of the pleural cavity assessment? REDAT REDTC
Record the procedures used to assess the pleural cavity on the Procedure CRF and then record the procedure identifier. If multiple methods, record the multiple identifiers using slashes.	What is the identifier for the procedure related to this pleural cavity assessment? CAVITY_REPRNO (Associated with related PR record via RELREC)
Record the method of the examination. If multiple methods, check all that apply.	What was the method used for the examination of the pleural cavity? REMTHODn REMETHOD NSV.REMTHODn <input type="checkbox"/> CT Scan <input type="checkbox"/> MRI <input type="checkbox"/> Chest X-ray <input type="checkbox"/> Ultrasound <input type="checkbox"/> FDG-PET/CT <input type="checkbox"/> Pleuroscopy <input type="checkbox"/> Other <i><From METHOD codelist></i>
If Other is selected for the method, specify.	What was the other method? REMTDOTH REMETHOD

<p>Screening: Indicate whether there was a effusion present (Yes or No). Post-Baseline: Indicate whether 1) this is a new effusion by indicating "Yes" or 2) there is no new effusion observed by indicating "No" or 3) this is an evaluation of a previously identified effusion, by indicating "Previously Identified Effusion".</p>	<p>Did the subject have a pleural effusion?</p> <p>EFFIND_REORRES REORRES where RETESTCD = "EFFIND"</p> <p><input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Previously Identified Effusion</p>
<p>Record the side of the anatomical location of the effusion.</p>	<p>Anatomical Location</p> <p>RELOC Pre-populated</p> <p>PLEURAL CAVITY <i><From LOC codelist></i></p>
<p>If this was reported as a new AE, record the adverse event identifier.</p>	<p>If new effusion, what was the side of the effusion?</p> <p>RELAT</p> <p><input type="radio"/> Right <input type="radio"/> Left <input type="radio"/> Bilateral <i><From LAT codelist></i></p>
<p>Record the procedure to remove the fluid on the Procedures CRF.</p>	<p>If appropriate, what is the identifier for the adverse event(s) associated with this effusion?</p> <p>REAENO (Associated with related AE record via RELREC)</p>
<p>Record the procedure identifier used for the tap.</p>	<p>Has the subject had a procedure to remove the fluid?</p> <p>TAP_PRYN Not submitted</p> <p><input type="radio"/> Yes <input type="radio"/> No</p>
<p>Record the result.</p>	<p>What is the identifier for the procedure used to perform the tap?</p> <p>TAP_REPRNO (Associated with related PR record via RELREC)</p>
<p>Indicate whether there was any evidence of malignancy.</p>	<p>If fluid removed, what was the estimated volume of fluid removed?</p> <p>EFFVOL_REORRES REORRES</p>
<p>Record the evidence description for malignancy, check all that apply.</p>	<p>Unit</p> <p>EFFVOL_REORREU REORRESU Pre-populated</p> <p>ml</p>
<p>Indicate the relative change in size compared to the initial pleural effusion assessment.</p>	<p>If new effusion, was there any evidence of malignancy?</p> <p>MLTIND_REORRES REORRES where RETESTCD = "MLTIND"</p> <p><input type="radio"/> Yes <input type="radio"/> No <i><From NY codelist></i></p>
	<p>If new effusion, what was the description of the malignancy evidence?</p> <p>LEVDD(n)_REORRES REORRES where RETESTCD = "MALEVDD"</p> <p><input type="radio"/> Increased Pleural Thickness <input type="radio"/> Pleural nodularity <input type="radio"/> Diaphragmatic Thickening <input type="radio"/> Positive FDG-PET Uptake</p>
	<p>If previously reported effusion, what was the relative change in size of the pleural effusion?</p> <p>RELSZCHG_REORRES REORRES where RETESTCD = "RELSZCHG"</p> <p><input type="radio"/> Absent <input type="radio"/> Increasing <input type="radio"/> Stable <input type="radio"/> Decreasing</p>

CDISC Therapeutic Area Data Standards User Guide for Lung Cancer v1.0 (Provisional)

Order Number	CDASH Variable	Question Text	Prompt	CRF Completion Instructions	SDTMIG Target Variable	SDTMIG Target Mapping	Controlled Terminology CodeList Name	CRF Implementation Notes	Permissible Values	Pre-Specified Value	Displayed Query	List Style	Input Type	Hidden
1	REYN	Did the subject have any assessments of the pleural cavity? <at screening> <since last visit>	Any Pleural Cavity Assessments	Indicate whether the subject had any assessments of the pleural cavity.			(NY)	General prompt question to be used as a data management tool to verify that missing results are confirmed missing. Typically, this CRF is customized to reflect whether this is a screening/baseline assessment, or a post-baseline assessment.	Yes; No	N/A	question text	radio	text	visible
2	REDAT	What was the date of the pleural cavity assessment?	Pleural Cavity Assessment Date	Record the date of the assessment.	REDC	REDC		A complete date is expected.	N/A	N/A	question text	N/A	date	visible
3	CAVITY_REPRNO	What is the identifier for the procedure related to this pleural cavity assessment?	Procedure Identifier	Record the procedures used to assess the pleural cavity on the Procedure CRF and then record the procedure identifier. If multiple methods, record the multiple identifiers using slashes.		(Associated with related PR record via RELREC)		This does not map directly to an SDTM variable. For the SDTM submission datasets, may be used to create RELREC to link this record with a record in the associated Procedure Domain. This question is used if the procedures are collected on the Procedure CRF.	N/A	N/A	question text	N/A	text	visible
4	REMTHODn	What was the method used for the examination of the pleural cavity?	Method	Record the method of the examination. If multiple methods, check all that apply.	REMETHOD	REMETHOD; NSV.REMTHODn	(METHOD)	This information may be collected when more than one method is possible, and collecting the method used is necessary. If multiple methods, REMETHOD = "MULTIPLE", and NSV REMTHOD1, REMTHOD2, etc., represent each method.	CT Scan; MRI; Chest X-ray; Ultrasound; FDG-PET/CT; Pleuoroscopy; Other	N/A	question text	radio	text	visible
5	REMTDOTH	What was the other method?	Specify	If Other is selected for the method, specify.	RETRT	REMETHOD		REMTDOTH can be used to collect free text values for "Specify Other."	N/A	N/A	question text	N/A	text	visible
6	EFFIND_REORRES	Did the subject have a pleural effusion?	Effusion Indicator	Screening: Indicate whether there was a effusion present (Yes or No). Post-Baseline: Indicate whether 1) this is a new effusion by indicating "Yes" or 2) there is no new effusion observed by indicating "No" or 3) this is an evaluation of a previously identified effusion, by indicating "Previously Identified Effusion".	REORRES	REORRES where RETESTCD = "EFFIND"		Previously identified Effusion responses would not be submitted.	Yes; No; Previously Identified Effusion	N/A	question text	radio	text	visible
7	RELOC	If new effusion, what was the anatomical location of the effusion?	Anatomical Location	Indicate the anatomical location of the effusion.	RELOC	RELOC	(LOC)	This question would only be shown for subjects with a new effusion.	N/A	PLEURAL CAVITY	prompt	N/A	text	visible
8	RELAT	If new effusion, what was the side of the effusion?	Side	Record the side of the anatomical location of the effusion.	RELAT	RELAT	(LAT)	This question would only be shown for subjects with a new pleural effusion.	Right; Left; Bilateral	N/A	question text	radio	text	visible
9	REAENO	If appropriate, what is the identifier for the adverse event(s) associated with this effusion?	Adverse Event Identifier	If this was reported as a new AE, record the adverse event identifier.		(Associated with related AE record via RELREC)		This does not map directly to an SDTM variable. For the SDTM submission datasets, may be used to create RELREC to link this record with a record in the associated Procedure Domain.	N/A	N/A	question text	N/A	text	visible
10	TAP_PRYN	Has the subject had a procedure to remove the fluid?	Any Tap	Record the procedure to remove the fluid on the Procedures CRF.				This does not map to an SDTM variable. Generally prompt question to aid in	Yes; No	N/A	question text	radio	text	visible

Order Number	CDASH Variable	Question Text	Prompt	CRF Completion Instructions	SDTMIG Target Variable	SDTMIG Target Mapping	Controlled Terminology CodeList Name	CRF Implementation Notes	Permissible Values	Pre-Specified Value	Displayed Query	List Style	Input Type	Hidden
								monitoring and data cleaning. This provides verification that fluid was removed.						
11	TAP_REPRNO	What is the identifier for the procedure used to perform the tap?	Procedure Identifier	Record the procedure identifier used for the tap.		(Associated with related PR record via RELREC)		This does not map directly to an SDTM variable. For the SDTM submission datasets, may be used to create RELREC to link this record with a record in the associated Procedure Domain.	N/A	N/A	question text	N/A	text	visible
12	EFFVOL_REORRES	If fluid removed, what was the estimated volume of fluid removed?	Effusion Volume Result	Record the result.	REORRES	REORRES		This is an optional question.	N/A	N/A	question text	N/A	text	visible
13	EFFVOL_REORREU	What was the unit of the result?	Unit	Record the unit.	REORRESU	REORRESU		The unit may be pre-printed on the CRF.	N/A	mL	prompt	N/A	text	visible
14	MLTIND_REORRES	If new effusion, was there any evidence of malignancy?	Malignancy Indicator	Indicate whether there was any evidence of malignancy.	REORRES	REORRES where RETESTCD = "MLTIND"	(NY)		Yes;No;	N/A	question text	radio	text	visible
15	LEVDD(n)_REORRES	If new effusion, what was the description of the malignancy evidence?	Malignant Evidence Description	Record the evidence description for malignancy, check all that apply.	REORRES	REORRES where RETESTCD = "MALEVDD"		Sponsors may decide to collect No/Yes questions for each response. Allow sponsors to repeat the evidence questions as needed, or use check all that apply. Sponsors may use EDC navigation to customize the questions based on the method employed to assess the pleural cavity.	Increased Pleural Thickness; Pleural nodularity; Diaphragmatic Thickening; Positive FDG-PET Uptake;	N/A	question text	radio	text	visible
16	RELSZCHG_REORRES	If previously reported effusion, what was the relative change in size of the pleural effusion?	Relative Size Result	Indicate the relative change in size compared to the initial pleural effusion assessment.	REORRES	REORRES where RETESTCD = "RELSZCHG"		This question would only be shown for assessments on previously identified pleural effusion.	Absent; Increasing; Stable; Decreasing	N/A	question text	radio	text	visible

The following is a sample CRF that illustrates a comprehensive assessment of the pericardial cavity. Many sponsors may only collect some of this information. A sponsor may also only report the actual findings, on Tumor Evaluation CRFs and/or AE CRFs.

If fluid is evaluated, a separate Serosal Fluid Analysis CRF (not shown) may be completed based on the requested tests on the fluid removed.

The sponsor may decide to either (1) collect the procedure used to assess the pericardial effusion on the procedures page and record the associated record identifier (CAVITY_CVPRNO) on this CRF, or (2) collect the method (CVMETHODn) on this CRF. Both options are illustrated in this CRF.

This CRF assumes that EDC navigation will be implemented to ensure appropriate questions based on whether this is a new assessment or an assessment of a previously identified effusion. Some sponsors may prefer to create separate CRFs for the initial effusion cavity assessment and for any follow-up assessments.

Indicate whether the subject had any assessments of the pericardial cavity.	Did the subject have any assessments of the pericardial cavity ?		<input type="radio"/> Yes <input type="radio"/> No <small><From NY codelist></small>
Record the date of the assessment.	Pericardial Cavity Assessment Date		<input type="text"/>
Record the procedures used to assess the pericardial cavity on the Procedure CRF and then record the procedure identifier. If multiple methods, record the multiple identifiers using slashes.	What is the identifier for the procedure related to this pericardial cavity assessment?		<input type="text"/>
Record the method of the examination. If multiple methods, check all that apply.	What was the method used for the examination of the pericardial cavity?		<input type="checkbox"/> CT Scan <input type="checkbox"/> MRI <input type="checkbox"/> Chest X-ray <input type="checkbox"/> Ultrasound <input type="checkbox"/> Other <small><From METHOD codelist></small>
If Other is selected for the method, specify.	What was the other method?		<input type="text"/>
Screening: Indicate whether there was an effusion present (Yes), or there was no effusion present (No) . Post-Baseline: Indicate whether 1) this is a new effusion (Yes) or 2) this is an assessment of a previously reported effusion or 3) there are no new effusions observed (No).	Did the subject have a pericardial effusion?		<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Previously Identified Effusion
If this was reported as a new AE, record the adverse event identifier.	Anatomical Location		<input type="text"/> PERICARDIAL CAVITY <small><From LOC codelist></small>
Record the procedure to remove the fluid on the Procedures CRF.	If appropriate: What is the identifier for the adverse event(s) associated with this pericardial effusion?		<input type="text"/>
Record the procedure identifier used for the tap.	Has the subject had a procedure to remove the fluid?		<input type="radio"/> Yes <input type="radio"/> No
Record the result.	What is the identifier for the procedure used to perform the tap?		<input type="text"/>
Indicate whether there was any evidence of malignancy.	If fluid removed: What was the estimated volume of fluid removed?		<input type="text"/>
Record the evidence description for malignancy, check all that apply.	Unit		mL
Indicate the relative change in size compared to the initial pericardial effusion assessment.	Was there any evidence of malignancy?		<input type="radio"/> Yes <input type="radio"/> No
	What was the description of the evidence?		<input type="checkbox"/> Pericardial Thickening <input type="checkbox"/> Positive FDG-PET Uptake
	If previously reported effusion: What was the relative change in size of the pericardial effusion?		<input type="radio"/> Absent <input type="radio"/> Increasing <input type="radio"/> Stable <input type="radio"/> Decreasing

CDISC Therapeutic Area Data Standards User Guide for Lung Cancer v1.0 (Provisional)

Order Number	TAUG Reference	CDASH Variable	Question Text	Prompt	CRF Completion Instructions	SDTMIG Target Variable	SDTMIG Target Mapping	Controlled Terminology CodeList Name	Implementation Notes	Permissible Values	Pre-populated Value	Displayed Query	List Style	Input Type	Hidden
1	TAUG-LuCa v1.0	CVYN	Did the subject have any assessments of the pericardial cavity <at screening> <since last visit>?	Any Pericardial Cavity Assessments	Indicate whether the subject had any assessments of the pericardial cavity.	N/A	N/A	(NY)	General prompt question to be used as a data management tool to verify that missing results are confirmed missing. Typically, this CRF is customized to reflect whether this is a screening/baseline assessment, or a post-baseline assessment.	Yes; No	N/A	question text	radio	text	visible
2	TAUG-LuCa v1.0	CVDAT	What was the date the pericardial cavity assessment?	Pericardial Cavity Assessment Date	Record the date of the assessment.	CVDTG			A complete date is expected.	N/A	N/A	prompt	N/A	date	visible
3	TAUG-LuCa v1.0	CAVITY_CVPRNO	What is the identifier for the procedure related to this pericardial cavity assessment?	Procedure Identifier	Record the procedures used to assess the pericardial cavity on the Procedure CRF and then record the procedure identifier. If multiple methods, record the multiple identifiers using slashes.	N/A	(Associated with related PR record via RELREC)		This does not map directly to an SDTM variable. For the SDTM submission datasets, may be used to create RELREC to link this record with a record in the associated Procedure Domain. This question is used if the procedures are collected on the Procedure CRF.	N/A	N/A	question text	N/A	text	visible
4	TAUG-LuCa v1.0	CVMETHODn	What was the method used for the examination of the pericardial cavity?	Method	Record the method of the examination. If multiple methods, check all that apply.	CVMETHOD; NSV.CVMETHODn	CVMETHOD; NSV.CVMETHODn	(METHOD)	This information may be collected when more than one method is possible, and collecting the method used is necessary. If multiple methods, CVMETHOD = "MULTIPLE" and NSVs would be used to report each method.	CT Scan; MRI; Chest X-ray; Ultrasound; Other	N/A	question text	checkbox	text	visible
5	TAUG-LuCa v1.0	CVMTDOTH	What was the other method?	Specify	If Other is selected for the method, specify.	CVMETHOD			CVMTDOTH can be used to collect free text values for "Specify Other."	N/A	N/A	question text	N/A	text	visible
6	TAUG-LuCa v1.0	EFFIND_CVORRES	Did the subject have a pericardial effusion?	Effusion Indicator	Screening: Indicate whether there was an effusion present (Yes), or there was no effusion present (No). Post-Baseline: Indicate whether 1) this is a new effusion (Yes) or 2) this is an assessment of a previously reported effusion or 3) there are no new effusions observed (No).	CVORRES	CVORRES where CVTESTCD = "EFFIND"		The response "Previously Identified Effusion" is used only for CRF navigation and data cleaning. The response of "Previously identified Effusion responses" would not be submitted.	Yes; No; Previously Identified Effusion	N/A	question text	radio	text	visible

CDISC Therapeutic Area Data Standards User Guide for Lung Cancer v1.0 (Provisional)

Order Number	TAUG Reference	CDASH Variable	Question Text	Prompt	CRF Completion Instructions	SDTMIG Target Variable	SDTMIG Target Mapping	Controlled Terminology CodeList Name	Implementation Notes	Permissible Values	Pre-populated Value	Displayed Query	List Style	Input Type	Hidden
7	TAUG-LuCa v1.0	CVLOC	What was the anatomical location of the pericardial effusion?	Anatomical Location	Indicate the anatomical location of the effusion.	CVLOC		(LOC)		N/A	PERICARDIAL CAVITY	prompt	N/A	text	visible
8	TAUG-LuCa v1.0	CVAENO	If appropriate: What is the identifier for the adverse event(s) associated with this pericardial effusion?	Adverse Event Identifier	If this was reported as a new AE, record the adverse event identifier.	N/A	(Associated with related AE record via RELREC)		This does not map directly to an SDTM variable. For the SDTM submission datasets, may be used to create RELREC to link this record with a record in the associated Procedure Domain.	N/A	N/A	question text	N/A	text	visible
9	TAUG-LuCa v1.0	TAP_PRYN	Has the subject had a procedure to remove the fluid?	Any Tap	Record the procedure to remove the fluid on the Procedures CRF.				This does not map to an SDTMIG variable General prompt question to aid in monitoring and data cleaning. This provides verification that fluid was removed.	Yes; No	N/A	question text	radio	text	visible
10	TAUG-LuCa v1.0	TAP_CVPRNO	What is the identifier for the procedure used to perform the tap?	Procedure Identifier	Record the procedure identifier used for the tap.	N/A	(Associated with related PR record via RELREC)		This does not map directly to an SDTM variable. For the SDTM submission datasets, may be used to create RELREC to link this record with a record in the associated Procedure Domain.	N/A	N/A	question text	N/A	text	visible
11	TAUG-LuCa v1.0	EFFVOL_CVORRES	If fluid removed: What was the estimated volume of fluid removed?	Effusion Volume Result	Record the result.	CVORRES	CVORRES where CVTESTCD="EFFVOL"		This is an optional question.	N/A	N/A	question text	N/A	text	visible
12	TAUG-LuCa v1.0	EFFVOL_CVORREU	What was the unit of the result?	Unit	Record the unit.	CVORRESU	CVORRESU where CVTESTCD="EFFVOL"		The unit may be pre-printed on the CRF.	N/A	mL	prompt	N/A	text	visible
13	TAUG-LuCa v1.0	MLTIND_CVORRES	Was there any evidence of malignancy?	Malignancy Indicator	Indicate whether there was any evidence of malignancy.	CVORRES	CVORRESU where CVTESTCD="MLTIND"			Yes; No;	N/A	question text	radio	text	visible
14	TAUG-LuCa v1.0	MALEVDD(n)_CVORRES	What was the description of the evidence?	Malignancy Evidence Description	Record the evidence description for malignancy, check all that apply.	CVORRES	CVORRES where CVTESTCD="MALEVDD"		Sponsor may collect this using repeating fields. Sponsor may decide to ask Yes/No questions for each response, instead of Check All That Apply. Sponsor may use EDC navigation to customize the questions based on the method employed to assess the cavity.	Pericardial Thickening; Positive FDG-PET Uptake;	N/A	question text	checkbox	text	visible
15	TAUG-LuCa v1.0	RELSZCHG_CVORRES	If previously reported effusion: What was the relative change in size of the pericardial effusion?	Relative Size Result	Indicate the relative change in size compared to the initial pericardial effusion assessment.	CVORRES	CVORRES where CVTESTCD="RELSZCHG"		This question would only be shown for assessments on previously identified pleural effusion.	Absent; Increasing; Stable; Decreasing	N/A	question text	radio	text	visible

Depending upon the study, some sponsors may elect to collect limited information on the actual assessments used to evaluate effusions. This is illustrated in the following aCRF. An SDTM example dataset is not provided for this CRF; however, the principles used in the SDTM examples provided below would be the same.

This is a sample CRF that illustrates the collection of limited information for effusions. Sponsors would provide instructions to the investigator to report the relevant findings on either the MH, AE, and/or Tumor Evaluation CRFs.

If fluid is evaluated, a separate Serosal Fluid Analysis CRF (not shown) may be completed based on the requested tests on the fluid removed.

The sponsor may decide either to (1) collect the procedure used to assess the effusion on the procedures CRF and record the associated record identifier (--PRNO) on this CRF, or (2) collect the method (--METHODn). Both options are illustrated in this CRF.

This CRF assumes that EDC navigation will be implemented to ensure appropriate questions based on whether this is a new assessment or an assessment of a previously identified effusion. Some sponsors may prefer to create separate CRFs for the initial effusion cavity assessment and for any follow-up assessments.

The CDASH variable names are generic since the effusion results are represented in different domains depending on the location of the effusion. The sponsor would determine the SDTM domain to use based on the response to the question "What was the anatomical location for the effusion assessment?" The Respiratory System Findings (RE) domain is used for PLEURAL CAVITY, the Cardiovascular System Findings (CV) domain is used for PERICARDIAL CAVITY, and the Gastrointestinal Findings (GI) domain is used for PERITONEAL CAVITY. This is an example. Sponsors may, alternatively, choose to create separate forms, one for each of the findings domains: one for respiratory (RE), one for cardiac (CV), and one for gastrointestinal (GI).

Indicate whether the subject had any assessments of the pericardial cavity.	Did the subject have any assessments of the pericardial cavity ? <input type="radio"/> Yes <input type="radio"/> No <i><From NY codelist></i>
Record the date of the assessment.	Pericardial Cavity Assessment Date <input type="text"/> CVDAT <input type="text"/> CVDTG
Record the procedures used to assess the pericardial cavity on the Procedure CRF and then record the procedure identifier. If multiple methods, record the multiple identifiers using slashes.	What is the identifier for the procedure related to this pericardial cavity assessment? <input type="text"/> CAVITY_CVPRNO (Associated with related PR record via RELREC)
Record the method of the examination. If multiple methods, check all that apply.	What was the method used for the examination of the pericardial cavity? <input type="checkbox"/> CVMETHODn <input type="checkbox"/> CVMETHOD <input type="checkbox"/> NSV.CVMETHODn <input type="checkbox"/> CT Scan <input type="checkbox"/> MRI <input type="checkbox"/> Chest X-ray <input type="checkbox"/> Ultrasound <input type="checkbox"/> Other <i><From METHOD codelist></i>
If Other is selected for the method, specify.	What was the other method? <input type="text"/> CMETHODOTH <input type="text"/> CMETHOD
Screening: Indicate whether there was an effusion present (Yes), or there was no effusion present (No) . Post-Baseline: Indicate whether 1) this is a new effusion (Yes) or 2) this is an assessment of a previously reported effusion or 3) there are no new effusions observed (No).	Did the subject have a pericardial effusion? <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Previously Identified Effusion
If this was reported as a new AE, record the adverse event identifier.	Anatomical Location <input type="text"/> CVLOC <i>Pre-populated</i>
Record the procedure to remove the fluid on the Procedures CRF.	If appropriate: What is the identifier for the adverse event(s) associated with this pericardial effusion? <input type="text"/> CVAENO (Associated with related AE record via RELREC)
Record the procedure identifier used for the tap.	Has the subject had a procedure to remove the fluid? <input type="radio"/> Yes <input type="radio"/> No
Record the result.	What is the identifier for the procedure used to perform the tap? <input type="text"/> TAP_CVPRNO (Associated with related PR record via RELREC)
Indicate whether there was any evidence of malignancy.	If fluid removed: What was the estimated volume of fluid removed? <input type="text"/> EFFVOL_CVORRES CVORRES where CVTESTCD="EFFVOL"
Record the evidence description for malignancy, check all that apply.	Unit <input type="text"/> EFFVOL_CVORREU CVORRESU where CVTESTCD="EFFVOL" <i>Pre-populated</i>
Indicate the relative change in size compared to the initial pericardial effusion assessment.	Was there any evidence of malignancy? <input type="radio"/> Yes <input type="radio"/> No
	What was the description of the evidence? <input type="text"/> MALEVDD(n)_CVORRES CVORRES where CVTESTCD="MALEVDD"
	If previously reported effusion: What was the relative change in size of the pericardial effusion? <input type="text"/> RELSZCHG_CVORRES CVORRES where CVTESTCD="RELSZCHG"
	<input type="radio"/> Absent <input type="radio"/> Increasing <input type="radio"/> Stable <input type="radio"/> Decreasing

CDISC Therapeutic Area Data Standards User Guide for Lung Cancer v1.0 (Provisional)

Order Number	CDASH Variable	Question Text	Prompt	CRF Completion Instructions	SDTMIG Target Variable	SDTMIG Target Mapping	Controlled Terminology CodeList Name	CRF Implementation Notes	Permissible Values	Pre-populated Value	Displayed Query	List Style	Input Type	Hidden
1	YN	Did the subject have any assessments for effusions? <at screening> <since last visit>	Any Effusion Assessments	Indicate whether the subject had any assessments of a third space fluid cavity.	N/A	N/A	(NY)	General prompt question to be used as a data management tool to verify that missing results are confirmed missing. Typically, this CRF is customized to reflect whether this is a screening/baseline assessment, or a post-baseline assessment.	Yes; No	N/A	question text	radio	text	visible
2	LOC	What was the anatomical location for the effusion assessment?	Anatomical Location	Indicate the anatomical location of the effusion.	RELOC; CVLOC; GILOC	RELOC/CVLOC/GILOC	(LOC)	This example CRF collects the anatomical location and side of the effusion at all visits to identify the effusion being assessed. Sponsor may use other methods to associate the subsequent effusion assessments with the appropriate cavity. This variable is used to determine which SDTM domain is used to represent the data.	PLEURAL CAVITY; PERICARDIAL CAVITY; PERITONEAL CAVITY;	N/A	question text	radio	text	visible
3	LAT	What was the side for the effusion assessment?	Side	Record the side of the anatomical location of the effusion.	RELAT; CVLAT; GILAT	RELAT/CVLAT/GILAT	(LAT)	This example CRF collects the anatomical location and side of the effusion at all visits to identify the effusion being assessed. Sponsor may use other methods to associate the subsequent effusion assessments with the appropriate cavity.	Right; Left; Bilateral; Not Applicable	N/A	question text	radio	text	visible
4	DAT	What was the date of the effusion assessment?	Effusion Assessment Date	Record the date of the assessment.	REDTC; CVDTc; GIDTC	REDTC/CVDTc/GIDTC	N/A	A complete date is expected.	N/A	N/A	prompt	N/A	date	visible
5	PRNO	What is the identifier for the procedure related to this effusion assessment?	Procedure Identifier	Record the procedures used to assess the effusion on the Procedure CRF and then record the procedure identifier. If multiple methods, record the multiple identifiers using slashes.				This does not map directly to an SDTM variable. For the SDTM submission datasets, may be used to create RELREC to link this record with a record in the associated Procedure Domain. This question is used if the procedures are collected on the Procedure CRF.	N/A	N/A	question text	N/A	text	visible
6	METHODn	What was the method used for	Method	Record the method of the examination. If	REMETHOD; CVMETHOD; GIMETHOD;	REMETHOD/CVMETHOD/GIMETHOD; NSV.REMTHODn/NSV.CVMTHODn/NSV.GIMTHODn	(METHOD)	This information may be collected when more than one method is possible, and	CT Scan; MRI; Chest x-ray;	N/A	question text	checkbox	text	visible

Order Number	CDASH Variable	Question Text	Prompt	CRF Completion Instructions	SDTMIG Target Variable	SDTMIG Target Mapping	Controlled Terminology CodeList Name	CRF Implementation Notes	Permissible Values	Pre-populated Value	Displayed Query	List Style	Input Type	Hidden
		the effusion assessment?		multiple methods, check all that apply.	NSV.REMTHODn; NSV.CVMTHODn; NSV.GIMTHODn			collecting the method used is necessary. If multiple methods, --METHOD = "MULTIPLE" and NSVs would be used to report each method.	Ultrasound; FDG-PET/CT; Pleuroscopy; Other					
7	MTDOOTH	What was the other method?	Specify	If Other is selected for the method, specify.	REMETHOD; CVMETHOD; GIMETHOD	REMETHOD/CVMETHOD/GIMETHOD	N/A	MTDOOTH can be used to collect free text values for "Specify Other."	N/A	N/A	question text	N/A	text	visible
8	EFFIND_ORRES	Did the subject have any effusions?	Effusion Indicator	Screening: Indicate whether there were any effusion present (Yes), or there was no effusions present (No) . Post-Baseline: Indicate whether 1) this is a new effusion (Yes) or 2) this is an assessment of a previously reported effusion or 3) there are no new effusions observed (No)	REORRES; CVORRES; GIORRES	REORRES/CVORRES/GIORRES where RETESTCD/CVTESTCD/GITESTCD = "EFFIND"	N/A	The response "Previously Identified Effusion" is used only for CRF navigation and data cleaning. The response of "Previously identified Effusion responses" would not be submitted.	Yes; No; Previously Identified Effusion	N/A	question text	radio	text	visible
9	AENO	If appropriate: What is the identifier for the adverse event(s) associated with this effusion?	Adverse Event Identifier	If this was reported as a new AE, record the adverse event identifier.	N/A	(Associated with related record via RELREC)	N/A	This does not map directly to an SDTM variable. For the SDTM submission datasets, may be used to create RELREC to link this record with a record in the associated Procedure Domain.	N/A	N/A	question text	N/A	text	visible
10	RELSZCHG_ORRES	If previously reported effusion: What was the relative change in size compared to the initial effusion assessment?	Relative Change Result	Indicate the relative change in size compared to the initial effusion assessment.	REORRES; CVORRES; GIORRES	REORRES/CVORRES/GIORRES where RETESTCD/CVTESTCD/GITESTCD = "RELSZCHG"	N/A	This question would only be shown for assessments on a previously identified effusion.	Absent ; Increasing; Stable; Decreasing	N/A	question text	radio	text	visible

Each third-space fluid assessment result is represented in the appropriate SDTM body system domain. The RE, CV, and GI domains are used to represent effusions in the pleural, pericardial, and peritoneal space, respectively.

The following are examples of the SDTM datasets used to represent the pleural and pericardial effusion assessments obtained during the study. The RE and CV datasets were used by the sponsor to represent the clinical assessment of the pleural and pericardial cavities, respectively. Values for --LOC are populated with the anatomical location of pleural or pericardial cavity, as the actual name of the anatomical location is not included in --TEST. RESPID was used by the sponsor as a merge key in RELREC; this is explained below.

- Rows 1-2:** Show that subject 1001 was diagnosed with a pleural effusion on the right side, which was malignant. This was determined from an evaluation of the pleural cavity evaluated using a hybrid FDG-PET/CT scan. The sponsor elected not to specify the contrast agent used in the SDTM datasets. However, if the contrast agent (deoxy-2-fluorine-18-fluoro-D-glucose) was important, it would be represented in the Procedure Agents (AG) domain.
- Rows 3-4:** Show that there was evidence of increased pleural thickness and positive FDG-PET uptake. REGRPID was used to group questions relating to the evidence of malignancy that was seen using imaging techniques.
- Rows 5-6:** Show the evaluation of the relative size of the pleural cavity at weeks 12 and 24 compared to the initial size assessment at screening.
- Rows 7-8:** Show subject 1006 was diagnosed with a new pleural effusion at week 6. There was no evidence of malignancy.
- Row 9:** Shows that at week 12, the subject's pleural cavity was increased in size from the size noted at the initial diagnosis at week 6 (row 7).
- Row 10:** Shows the volume of the fluid removed. Note this is represented in RE because it is a measure related to the subject's condition; it is not considered to be information about the fluid specimen.

Row	STUDYID	DOMAIN	USUBJID	RESEQ	REGRPID	RESPID	RELNKID	RETESTCD	RETEST	REORRES	REORRESU	RESTRESC	RESTRESN	RESTRESU	RELOC	RELAT	REMETHOD	VISITNUM	VISIT	VISITDY	REDTC	REDY
1	LC001	RE	1001	1				EFFIND	Effusion Indicator	Y		Y			PLEURAL CAVITY	RIGHT	CONTRAST ENHANCED PET/CT SCAN	1	SCREENING	-1	2013-01-13	-11
2	LC001	RE	1001	2	1		PR01	MALIND	Malignancy Indicator	Y		Y			PLEURAL CAVITY	RIGHT	CONTRAST ENHANCED PET/CT SCAN	1	SCREENING	-1	2013-01-13	-11
3	LC001	RE	1001	3	1		PR01	MALEVDD	Malignancy Evidence Description	Increased Pleural Thickness		Increased Pleural Thickness			PLEURAL CAVITY	RIGHT	CONTRAST ENHANCED PET/CT SCAN	1	SCREENING	-1	2013-01-13	-11
4	LC001	RE	1001	4	1		PR01	MALEVDD	Malignancy Evidence Description	Positive FDG-PET Uptake		Positive FDG-PET Uptake			PLEURAL CAVITY	RIGHT	CONTRAST ENHANCED PET/CT SCAN	1	SCREENING	-1	2013-01-13	-11
5	LC001	RE	1001	5			PR01	RELSZCHG	Relative Size Change	DECREASING		DECREASING			PLEURAL CAVITY	RIGHT	CONTRAST ENHANCED PET/CT SCAN	30	WEEK 12	84	2013-03-13	84
6	LC001	RE	1001	6			PR01	RELSZCHG	Relative Size Change	INCREASING		INCREASING			PLEURAL CAVITY	RIGHT	CONTRAST ENHANCED PET/CT SCAN	50	WEEK 24	168	2013-06-13	168
7	LC001	RE	1006	1		AE13	PR14	EFFIND	Effusion Indicator	Y		Y			PLEURAL CAVITY	BILATERAL	CONTRAST ENHANCED PET/CT SCAN	20	WEEK 6	42	2013-10-13	40
8	LC001	RE	1006	2		AE13	PR14	MALIND	Malignancy Indicator	N		N			PLEURAL CAVITY	BILATERAL	CONTRAST ENHANCED PET/CT SCAN	20	WEEK 6	42	2013-10-13	40
9	LC001	RE	1006	3		AE13	PR15	RELSZCHG	Relative Size Change	INCREASING		INCREASING			PLEURAL CAVITY	RIGHT	CONTRAST ENHANCED PET/CT SCAN	30	WEEK 12	84	2013-11-25	83
10	LC001	RE	1006	4		AE13	PR32	EFFVOL	Effusion Volume	40	mL	40	40	mL	PLEURAL CAVITY			30	WEEK 12	84	2013-11-25	83

The following CV dataset shows the absence of a pericardial effusion for subject 1001.

Row	STUDYID	DOMAIN	USUBJID	CVSEQ	CVTESTCD	CVTEST	CVORRES	CVORRESU	CVSTRESC	CVSTRESN	CVSTRESU	CVLOC	CVMETHOD	VISITNUM	VISIT	VISITDY	CVDTC	CVDY
1	LC001	CV	1001	1	EFFIND	Effusion Indicator	N		N			PERICARDIAL CAVITY	TRANSTHORACIC ECHOCARDIOGRAPHY	1	SCREENING	-3	2013-01-13	-8

The following illustrates the dataset relationships between the SDTM domains used to represent the data collected on the comprehensive pleural effusion CRF. Although the AE dataset is not shown above, the investigator reported that subject 1006 had a pleural effusion at week 6; this relationship is shown below. The procedures used for each evaluation were reported in the PR domain (not shown).

The collected CDASH variables --AENO and --PRNO were used by the sponsor to create merge keys to link the related SDTM datasets. --GRPID, --SPID, --REFID, --LNKID, or --LNKGPR are typically used for this purpose. The specific merge key used depends on other dataset relationships that need to be defined for the study. In RELREC, the value in IDVAR must be the name of the key used to merge or join the 2 datasets. In the above example, the --SPID and --LNKID variables are used as the key to identify the related observations. The sponsor used the CDASH --AENO to derive --SPID and --PRNO to derive --LNKID. For example, RESPID="AE13" indicates that this record is associated with the AE with AESPID of "AE13" and RELNKID of "PR15" is linked with the Procedure with PRLNKID of "PR15".

Rows 1-2: Show the link between the reported AEs and the RE assessments associated with these AEs. Because an effusion may be evaluated multiple times during a study, there may be many assessments in RE related to the reported AE.

Rows 3-4: Show the link between the specific procedures used to assess the pleural effusion.

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	LUCA007	AE		AESPID		ONE	1
2	LUCA007	RE		RESPID		MANY	1
3	LUCA007	RE		RELNKID		ONE	2
4	LUCA007	PR		PRLNKID		MANY	2

Example 2

This example shows a subject who was identified via a CT scan as having pleural effusion at screening (CT procedure and the pleural effusion not shown). This subject subsequently underwent a thoracentesis to remove pleural fluid for testing (procedure data not shown). The fluid then underwent a series of tests to assess the presence of malignant cells and signs of infection. As previously noted, the total volume removed from the third-space cavity was not considered a finding associated with the fluid sample. The dates shown in --DTC variables represent the date that pleural fluid was sampled.

Results of the assessment of the pleural fluid sample for the presence of malignant cells are represented in the Laboratory Test Results (LB) domain. Sponsors may report the results as histological grading of cells rather than malignant/non-malignant. This is not shown in the example.

Row	STUDYID	DOMAIN	USUBJID	LBSEQ	LBREFID	LBTESTCD	LBTEST	LBORRES	LBSTRESC	LBSPEC	LBSPCCND	VISITNUM	VISIT	LBDTC
1	LUCA005	LB	1006	1	SPEC1	MLIGCEBC	Malignant Cells, NOS	ABSENT	ABSENT	PLEURAL FLUID		1	SCREENING	2013-01-13

The pleural fluid sample also underwent testing to assess the presence of microorganisms including gram-positive bacteria, gram-negative bacteria, acid-fast bacilli, and fungi. The results of these tests are represented in the Microbiology Specimen (MB) domain.

Rows 1-4: Show that the sample was assessed for the presence of gram-positive bacteria, gram-negative bacteria, acid-fast bacilli, and fungi. When a test is targeting the presence of a particular organism or group of organisms, MBTESTCD/MBTEST is populated with the name of the organism or group of organisms. The variable MBTSTDTL is populated with "DETECTION" to indicate that a detection test is being performed. The corresponding MBORRES value is either ABSENT or PRESENT.

Row 5: Shows the results from additional testing using a microbial culture. When a test is open-ended, the generic MBTESTCD/MBTEST of MCORGIDN/Microbial Organism Identification is used and the variable MBTSTDTL is not populated. After further testing via a microbial culture, only Mycobacterium tuberculosis was identified. If multiple organisms were identified, multiple records would be created so that each organism is represented separately.

Row	STUDYID	DOMAIN	USUBJID	MBSEQ	MBREFID	MBTESTCD	MBTEST	MBTSTDTL	MBORRES	MBSTRESC	MBSPEC	MBMETHOD	VISITNUM	VISIT	MBDTC
1	LUCA005	MB	1006	1	SPEC1	GMPBAC	Gram-Positive Bacteria	DETECTION	ABSENT	ABSENT	PLEURAL FLUID	GRAM STAIN	1	SCREENING	2013-01-13
2	LUCA005	MB	1006	2	SPEC1	GMNBAC	Gram-Negative Bacteria	DETECTION	ABSENT	ABSENT	PLEURAL FLUID	GRAM STAIN	1	SCREENING	2013-01-13
3	LUCA005	MB	1006	3	SPEC1	FUNGI	Fungi	DETECTION	ABSENT	ABSENT	PLEURAL FLUID	LACTOPHENOL BLUE STAIN	1	SCREENING	2013-01-13
4	LUCA005	MB	1006	4	SPEC1	AFB	Acid-Fast Bacilli	DETECTION	PRESENT	PRESENT	PLEURAL FLUID	ACID-FAST STAIN	1	SCREENING	2013-01-13
5	LUCA005	MB	1006	5	SPEC1	MCORGIDN	Microbial Organism Identification		MYCOBACTERIUM TUBERCULOSIS	MYCOBACTERIUM TUBERCULOSIS	PLEURAL FLUID	MICROBIAL CULTURE	1	SCREENING	2013-01-13

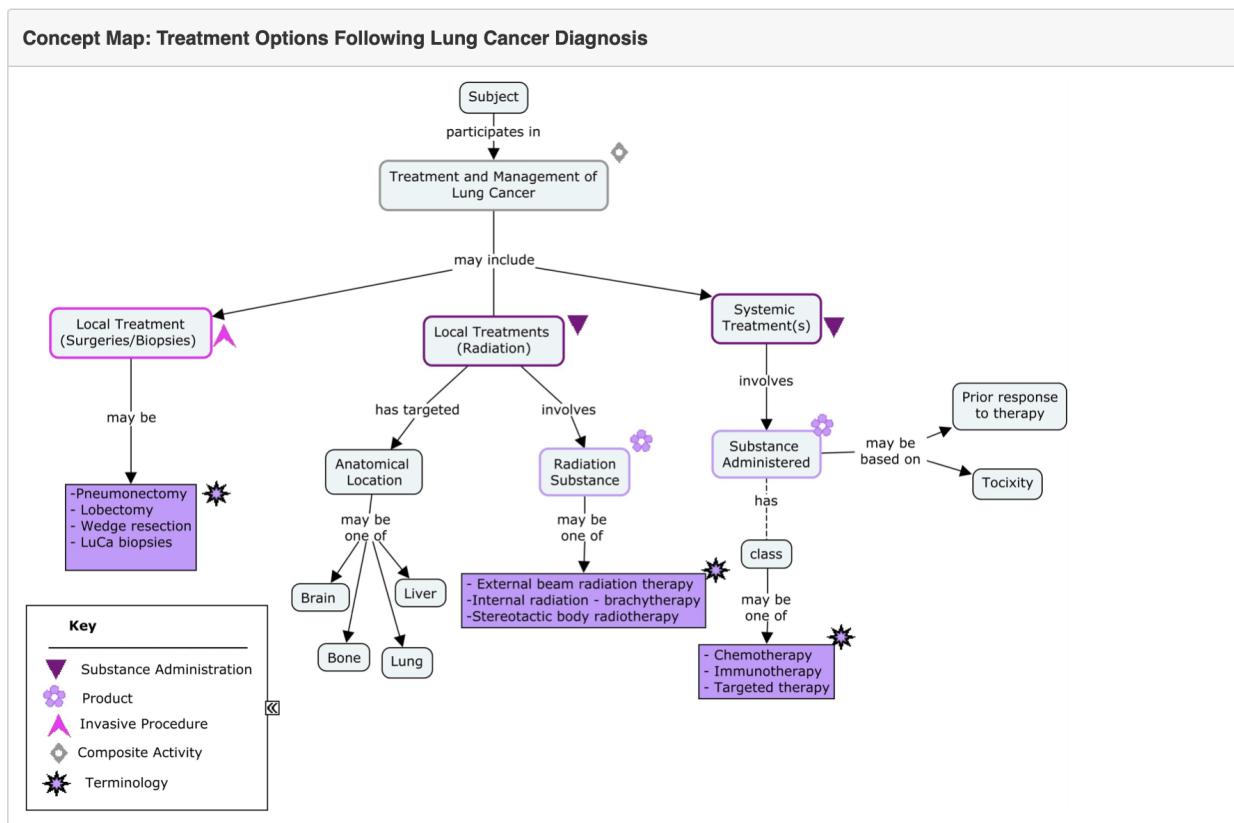
4 Disease Assessments and Treatments

This section generally provides information on data used to evaluate how a subject is progressing over the course of a study that are typically collected multiple times during the study. The following topics are covered in this section:

- Treatments for Lung Cancer
- Disease Response and Tumor Assessments
- Questionnaires, Ratings, and Scales
- Oxygen Use
- Treatment of Pleural Effusions

4.1 Treatments for Lung Cancer

The following concept map shows various treatments for lung cancer. Some treatments target only the anatomic region in which the cancer exists; others operate on a systemic level. In general, types of treatments are sequential, rather than concurrent.



4.1.1 Medications/Radiotherapy

In cancer trials, it is important to collect information on prior anti-cancer therapies (including radiotherapy), and any anti-cancer therapies given after the study drug of interest has been discontinued. Chemotherapy/treatment choice depends on histology (squamous cell carcinoma vs. all others) and molecular profile results (e.g., EGFR, ROS1, ALK, PD-L1 expression).

The collection of data on prior treatments has been described in the SDTMIG. A sponsor would typically include CRF modules for prior treatments of various kinds (e.g., radiation, surgery, anti-cancer). These separate modules would be reflected in PRCAT values such as "PRIOR RADIATION" or "PRIOR SURGERY" and CMCAT values such as "ANTI-CANCER THERAPY." The Breast Cancer Therapeutic Area User Guide (v1.0, Provisional) includes examples on how radiotherapies and prior treatments could be collected. These examples include suggestions on how to determine the number of prior regimens a subject received.

In cancer trials, subjects are often prescribed treatment plans that contain multiple treatment components. These are commonly referred to as "treatment regimens" or "treatment protocols." A regimen is a treatment plan that specifies the dosage, the schedule, and the duration of treatment.[\[18\]](#) Sponsors often collect information about the regimen itself (e.g., start date, end date, best response, reason for discontinuation) as well as information on the individual treatment products within the regimen. In other disease areas, subjects are also treated with a combination of treatments—but these treatments are often administered as a single product which is a combination of several active ingredients. It is difficult to represent the information about treatments which include multiple components in the SDTM domain CM. This topic is applicable to many therapeutic areas and is a known issue. (See Section 1.4, [Known Issues](#)).

4.1.2 Surgeries

In some lung cancer trials, it may be important to collect information on any anti-cancer surgeries performed before or during the study. Types of surgery may include:

- Wedge resection and segmentectomy: removal of cancerous tissue from the lung
- Lobectomy: removal of an entire lobe from the lung
- Pneumonectomy: removal of an entire lung

Video-assisted thoracic surgery (VATS) is a minimally invasive technology used to perform a lobectomy or wedge resection without opening up the chest. This thoracotomy procedure involves inserting a tube with an attached camera (thoroscope). Using images from the camera, the surgeon removes cancerous tissues.

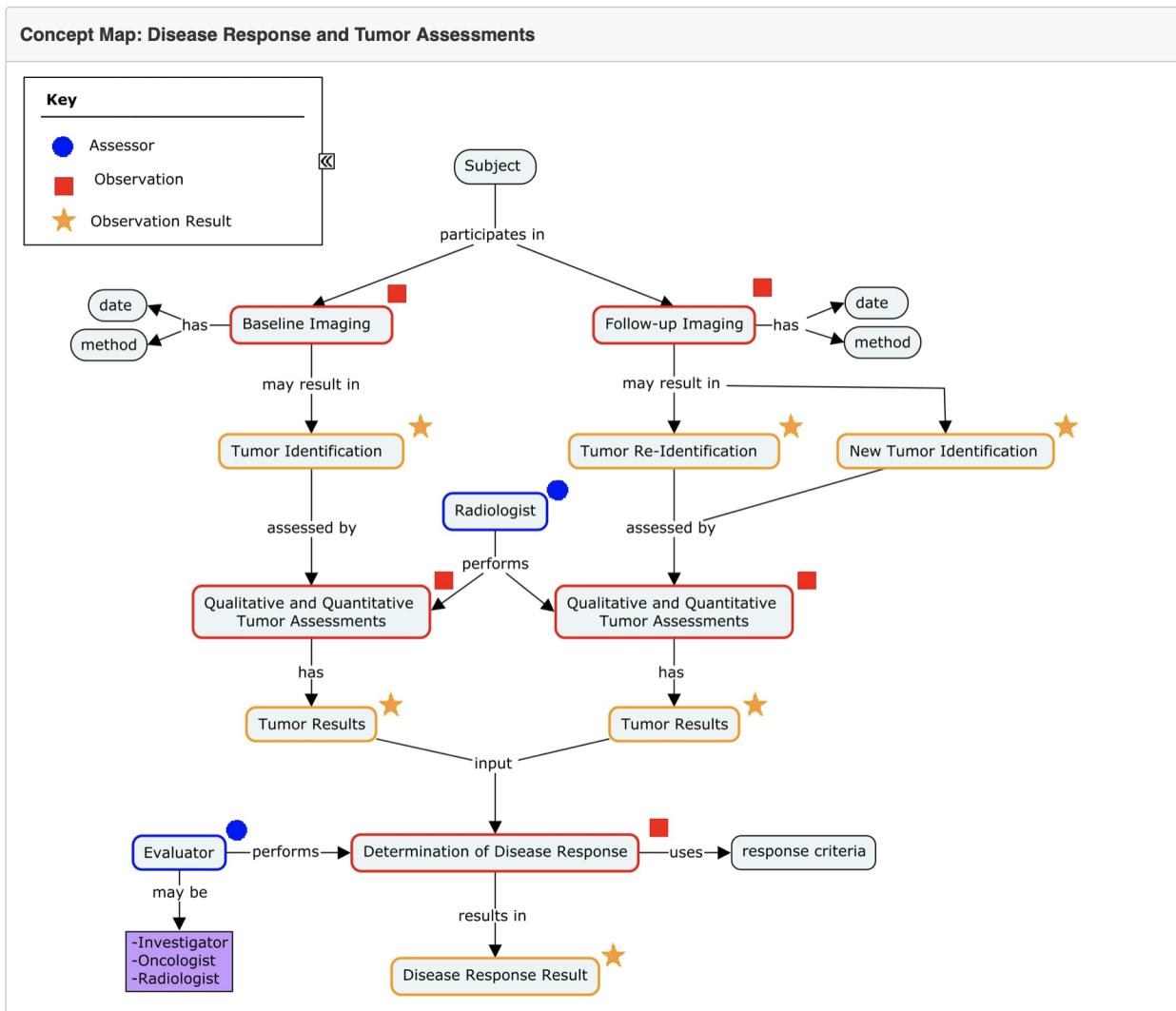
More information may be found at the American Cancer Society: (<https://www.cancer.org/cancer/non-small-cell-lung-cancer/treating/surgery.html>).

4.2 Disease Response and Tumor Assessments

RECIST may be used to assess disease response in metastatic lung cancer clinical trials.[\[19\]](#) In the TAUG-LuCa, RECIST is used as a generic term to refer to the various versions of the RECIST criteria. However, sponsors should always specify which RECIST version was used in a study. The response criteria chosen to assess disease response may also depend on the type of therapy being evaluated. Due to the different response patterns in subjects undergoing anti-cancer immunotherapies, other criteria (e.g., iRECIST) may also be used.

Other Oncology TAUGs (e.g., TAUG-BrCa Section 4.2, Tumor Identification, Assessment, and Disease Response; TAUG-PrCa Section 4.2, Disease Assessments and Response for Metastatic Disease) have provided examples on disease response using RECIST. CDISC Oncology TAUGs are available at <https://www.cdisc.org/standards>. SDTM Examples for Oncology Use Cases are also available, at <https://wiki.cdisc.org/display>.

The TAUG-LuCa shows examples of the iRECIST criteria. The published consensus iRECIST guideline released in March 2017 by the RECIST Working Group Team[\[20\]](#) is intended to standardize the design and collection guidelines for the evaluation of disease in cancer immunotherapy trials. More information on RECIST 1.1 and iRECIST can be found at <http://www.eortc.org/recist>.



Tumor Results referenced in the concept map are based on the response criteria and version used by the sponsor. In iRECIST, the principles used to establish objective tumor response are largely unchanged from RECIST 1.1. When RECIST 1.1 progression is observed, the next scan can either confirm progression, keep the patient in a state of unconfirmed progression, or cause the patient to return to a non-progression response. If the latter occurs, there is a "resetting the bar" which means only that the next observed radiographic progression should again go through a confirmation process. New lesions in iRECIST may be assessed quantitatively as "new lesion targets" (with a sum of diameters that is kept distinct from the sum of diameters of the target lesions seen at baseline) or qualitatively as "new lesion non-targets."

Familiarity with the iRECIST tumor response guidelines is required when reviewing the following examples.

General guidance on managing data pertaining to the identification, monitoring, and assessment of tumors and lesions is covered by three SDTMIG Findings domains: Tumor Identification (TU), Tumor Results (TR), and Disease Response (RS). Consult SDTMIG for specifications, assumptions, and examples for these domain models.

Example 1

This is an example of the collection of data regarding tumor identification, tumor assessment, and tumor response in a lung cancer clinical trial involving immunotherapeutics. In this clinical trial, as recommended by the RECIST Working Group, RECIST 1.1 criteria were used to determine the primary endpoints, and iRECIST response criteria were used to determine endpoints for exploratory analyses.[\[19\]](#)

The following aCRFs are sample CDASH CRFs for studies using iRECIST. When using iRECIST, RECIST criteria are employed until the subject has RECIST PD; subsequent to a RECIST PD, subjects will continue to be followed using iRECIST. This example illustrates how to use combined CRFs to collect the information needed to determine RECIST and iRECIST criteria. Dynamic navigation ensures that the appropriate set of questions is asked depending upon whether the subject had a RECIST PD; for subjects who have not had a RECIST PD, the questions related to iRECIST are not displayed. Similarly, once RECIST PD has occurred, only the questions relevant to iRECIST are displayed.

This CRF was designed to collect information on target lesions identified in trials testing immunotherapeutics. These trials use RECIST 1.1 and iRECIST criteria to define endpoints. Sponsors may decide to (1) collect RECIST and iRECIST on separate CRFs or (2) collect RECIST and iRECIST on a single CRF using dynamic navigation.

Although not illustrated, the CRF layout assumes that dynamic navigation controls would be used to display the RECIST or iRECIST questions based on the category chosen. The CRF questions relating to descriptions of the identified tumors (e.g., TULOC, TULAT) to be followed are typically collected at the initial/baseline visit, and then are not re-collected at subsequent tumor assessments.

This CRF collects longest diameters for non-nodal disease, and short axis for lymph nodal disease. Some sponsors may collect diameter and map to the correct TRTESTCD based on the location of the disease. Refer to the original RECIST paper for detail information on the measurements to be used.

One CDASH variable may need to be mapped to other domains when the SDTM-based datasets are created (e.g., TUDAT would be mapped to TUDTC and TRDTC).

TUCAT may be used by sponsors to categorize tumors that have been identified to be followed during the study for tumor response (e.g., RESPONSE EVALUATION TUMOR), from other information that may be collected about tumor sites at baseline (e.g., baseline sites of disease). Since TUCAT was used in this example to define the category "RESPONSE EVALUATION TUMOR", another CDASH variable ONCRSCAT (Oncology Response Criteria) was included to allow dynamic navigation to the relevant question concerning RECIST or iRECIST.

<p>Category TUCAT Hidden/pre-populated</p> <p>Response Criteria</p> <p>ONCRSCAT Not submitted</p> <p>Indicate whether or not tumors were identified. If tumors were identified, list each tumor and provide the requested information.</p> <p>Sponsor-specified</p> <p>Specify the general (anatomical) location of the tumor.</p> <p>Specify the laterality of the tumor.</p> <p>Specify the directionality of the tumor.</p> <p>Describe additional detail on the exact location of the tumor so that it can be distinguished from other tumors in the same anatomical location.</p>	<p>RESPONSE EVALUATION TUMOR</p> <p><input type="radio"/> RECIST 1.1 <input type="radio"/> iRECIST</p> <p>TUMIDENT_TURORES TURORES where TUTESTCD = "TUMIDENT" Hidden/pre-populated</p> <p>TARGET</p> <p><input type="radio"/> Yes <input type="radio"/> No</p> <p><From NY codelist></p> <p>What was the Tumor ID?</p> <p>TULNKID TULNKID and TRLNKID</p> <p>What was the anatomical location of the tumor identified?</p> <p>TULOC</p> <p>If applicable, what was the laterality of the anatomical location?</p> <p>TULAT</p> <p>If applicable, what was the directionality of the anatomical location?</p> <p>TUDIR</p> <p>If applicable, what is the additional detail about the tumor location?</p> <p>TULOCDTL SUPPTU.QVAL where QNAME = "TULOCDTL"</p>
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Indicate whether this is a tumor that has split from a previous tumor, or is a tumor that has merged with another tumor.	Select if changes to tumor were identified. TUCHANGE If TUCHANGE = "Split", TURORES = "TARGET" where TRTESTCD = "TUSPLIT" If TUCHANGE = "Merged", TURORES = "TARGET" where TRTESTCD = "TUMERGE"	<input type="radio"/> Merged <input type="radio"/> Split <i><From TUTEST codelist></i>
Specify the method used to identify/ evaluate the tumor.	What was the method of evaluation? TUMETHOD TUMETHOD and TRMETHOD	<input type="radio"/> Clinical Exam <input type="radio"/> CT Scan <input type="radio"/> MRI <input type="radio"/> PET/CT Scan <input type="radio"/> PET/MRI Scan <input type="radio"/> Photography <input type="radio"/> Physical Examination <input type="radio"/> Scintigraphy <i><From METHOD codelist></i>
Insert the date of the scan/image/examination (not the date on which it was read, or the visit date).	Procedure Date TUDAT TUDTC and TRDTC	
Indicate who performed the assessment.	What was the role of the person performing the tumor evaluation? TUEVAL TUEVAL and TREVAL	<input type="radio"/> Independent Assessor <input type="radio"/> Investigator <i><From EVAL codelist></i>
Identify the evaluator providing this evaluation.	What is the evaluator identifier? TUEVALID TUEVALID and TREVALID	<input type="radio"/> Radiologist 1 <input type="radio"/> Radiologist 2 <input type="radio"/> Oncologist <i><From MEDEVAL codelist></i>
For non-nodal disease, record the longest diameter of the tumor.	What was the longest diameter of the tumor? LDIAM_TRRORES TRRORES where TRTESTCD = "LDIAM"	<input type="text"/> . <input type="text"/>
	Longest Diameter Unit LDIAM_TRRORESU TRRORESU where TRTESTCD = "LDIAM" Pre-populated	<input type="text"/> mr <i><From UNIT codelist></i>
Check if the tumor is too small to measure.	Longest Diameter Too Small to Measure LDIAM_TRTOOSM_TRRORES TRRORES = "TOO SMALL TO MEASURE" where TRTESTCD = "LDIAM"	<input type="checkbox"/> Diameter Too Small to Measure <i><From NY codelist></i>
For lymph nodes, record the short axis measurement	What was the perpendicular diameter of the tumor? PDIAM_TRORESS TRRORESS where TRTESTCD = "LPERP"	<input type="text"/> . <input type="text"/>
	Perpendicular Diameter Unit PDIAM_TRRORESU TRRORESU where TRTESTCD = "LPERP" Pre-populated	<input type="text"/> mr <i><From UNIT codelist></i>
Check if the lymph node is too small to measure.	Perpendicular Diameter Too Small to Measure PDIAM_TRTOOSM_TRRORES TRRORES = "TOO SMALL TO MEASURE" where TRTESTCD = "LPERP"	<input type="checkbox"/> Diameter Too Small to Measure <i><From NY codelist></i>
If appropriate, denote the tumor as inevaluable.	Tumor Inevaluable TRINEVAL TRSTAT = "NOT DONE" where TRTESTCD = "TUMSTATE"	<input type="checkbox"/> Inevaluable
Indicate the reason why the tumor was inevaluable.	If the tumor was Inevaluable, what was the reason? TRREASND TRREASND where TRSTAT = "NOT DONE" and TRESTCD = "TUMSTATE"	<input type="radio"/> Lesion or Background Change that Prevents Evaluation <input type="radio"/> Focal Intervention <input type="radio"/> Poor Scan Quality <input type="radio"/> Insufficient Images/Anatomy <input type="radio"/> Inconsistent Modality <input type="radio"/> Site Error <input type="radio"/> Other
For nodal tumors only, denote whether the node is pathological or non-pathological.	What was the nodal state? LNSTAT_TRRORES TRRORES where TRTESTCD = "LNSTATE"	<input type="radio"/> Pathological <input type="radio"/> Non-Pathological

CDISC Therapeutic Area Data Standards User Guide for Lung Cancer v1.0 (Provisional)

Order Number	CDASH Variable Name	Question Text	Prompt	Case Report Form Completion Instructions	SDTMIG Target Variable	SDTM Target Mapping	Controlled Terminology CodeList Name	CRF Implementation Notes	Permissible Values	Pre-populated Value	Displayed Query	List Style	Input Type	Hidden
1	TUCAT	What is the category of the [tumor/lesion] identification?	Category	Record the Tumor Identification category, if not pre-printed on the CRF.	TUCAT		N/A	Sponsor-defined Controlled Terminology. This would most commonly be either a heading, or a pre-printed category value on the CRF and not a question to which the site would provide an answer. If a question is asked, the response would typically be a sponsor-defined codelist. If the form is laid out as a grid, then words such as "Category" can be included as the column header.	N/A	RESPONSE EVALUATION TUMOR	prompt	N/A	text	hidden
2	ONCRSCAT	What is the Response Criteria being used at this assessment?	Response Criteria	N/A	N/A	N/A	N/A	Since there are separate codelists used for categorizations of records about oncology response criteria (ONCRCAT), this CDASH variable was created for use in Oncology trials to identify the response criteria being used in a study. While this field is not typically captured on a CRF, it should be displayed clearly on the CRF. Most often pre-defined, instructional text to orient the data entry staff to appropriate cancer response criteria. Collect if multiple types/versions are active in a single study/database . The codelist may be extended for other cancer response systems (e.g., IWG, IMWG, etc.).	RECIST 1.1; iRECIST	N/A	prompt	radio	text	visible
3	TUMIDENT_TUORRES	What type of tumors are being identified as defined by the criteria being employed?	Tumor Type According to Criteira	Record or select which type of tumor is being evaluated, as defined by the criteria.	TUORRES	TUORRES where TUTESTCD = "TUMIDENT"	N/A	Although this field is not typically captured on a CRF, it should be displayed clearly on the CRF and/or the EDC system. When TUTESTCD = "TUMIDENT" (Tumor Identification), values of TUORRES will be: TARGET, NON-TARGET, NEW TARGET, NEW NON-TARGET.	N/A	TARGET	prompt	N/A	text	hidden
4	TUYN	Were target tumors identified?	Any target tumors	Indicate whether or not tumors were identified. If tumors were identified, list each tumor and provide the requested information.	N/A	N/A	(NY)	This is intended to be used as a data management tool to verify that missing tumor evaluations are confirmed missing. If "Yes", a record is created in the SDTMIG TU domain for each tumor identified.	Yes; No	N/A	question text	radio	text	visible
5	TULNKID	What was the Tumor ID?	Tumor ID	Sponsor-specified	TULNKID	TULNKID and TRLNKID	N/A	This variable is used to provide a unique code for each identified tumor in order to link records across related domains (TU and TR). TULNKID and TRLNKID are expected to be the same across datasets. The values of TULNKID are compound values that may carry the following information: an indication of the role (or assessor) providing the data records when it is someone other than the principal investigator; an indication of whether the data record is for a target, non-target, or new tumor; and an indication of whether the tumor has	N/A	N/A	question text	N/A	text	visible

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								split or merged. Sponsors may develop their own conventions for identifying tumors						
6	TULOC	What was the anatomical location of the tumor identified?	Location	Specify the general (anatomical) location of the tumor.	TULOC		(LOC)	When anatomical location is broken down and collected as distinct pieces of data that when combined provide the exact location information (e.g. laterality /directionality) then the additional anatomical location qualifiers should be used. The first (TULOC) should follow controlled terminology, which will enable consistency across sites. Laterality (TULAT) and Directionality (TUDIR) should also be available for entry if more explicit detail can be provided. A location detail text field (TULOCDTL) is conditional for entry (i.e., can be left blank) and allows the study site to specify the lesion in its own terms or can be used to distinguish tumors within the same location if TULAT and/or TUDIR is not sufficient. Finally, Presentation Type is conditional for truly non-measurable lesions that are difficult to characterize with Location.	LUNG, LEFT UPPER LOBE; LUNG, RIGHT UPPER LOBE; LUNG, LEFT LOWER LOBE; LUNG, RIGHT LOWER LOBE; LUNG, LEFT MIDDLE LOBE; LUNG, RIGHT MIDDLE LOBE;	N/A	question text	radio	text	visible
7	TULAT	If applicable, what was the laterality of the anatomical location?	Laterality	Specify the laterality of the tumor.	TULAT		(LAT)	See TULOC	RIGHT; LEFT; BILATERAL	N/A	question text	radio	text	visible
8	TUDIR	If applicable, what was the directionality of the anatomical location?	Directionality	Specify the directionality of the tumor.	TUDIR		(DIR)	See TULOC	ANTERIOR; POSTERIOR	N/A	question text	radio	text	visible
9	TULOCCTL	if applicable, what is the additional detail about the tumor location?	Location Detail	Describe additional detail on the exact location of the tumor so that it can be distinguished from other tumors in the same anatomical location.	SUPPTU.QVAL	SUPPTU.QVAL where QNAM = "TULOCCTL"	N/A	Use if TULOC and TULAT and/or TUDIR values cannot provide uniqueness from other tumor records. TULOCCTL is not meant to replace TULOC, TULAT, and/or TUDIR or serve as the free-text description field for TULOC (e.g., Location, Other). May also be useful if sponsor collects cancer antigens or tumor markers as Non-Target Lesions. See TULOC.	N/A	N/A	question text	N/A	text	visible
10	TUCHANGE	Select if changes to tumor were identified.	Changes to Tumor Identified	Indicate whether this is a tumor that has split from a previous tumor, or is a tumor that has merged with another tumor.	N/A	If TUCHANGE = "Split", TUORRES = "TARGET" where TUTESTCD = "TUSPLIT"; If TUCHANGE = "Merged", TUORRES = "TARGET" where TUTESTCD = "TUMERGE"	(TUTEST)	Sponsors must consider how to identify both split and merged tumors in the fields TULNKID and TULOCCTL. Possible conventions for use in TULNKID are: T04.1 = the first "child" tumor split from the fourth target tumor T04.2 = the second "child" tumor split from the fourth target tumor, etc. T02/T03 = the tumor merged from the second and third target tumor or picking one of the original tumors as the	Merged; Split	N/A	question text	radio	text	visible

CDISC Therapeutic Area Data Standards User Guide for Lung Cancer v1.0 (Provisional)

Order Number	CDASH Variable Name	Question Text	Prompt	Case Report Form Completion Instructions	SDTMIG Target Variable	SDTM Target Mapping	Controlled Terminology CodeList Name	CRF Implementation Notes	Permissible Values	Pre-populated Value	Displayed Query	List Style	Input Type	Hidden
								primary tumor, including the sum of the merged tumors in a single record TULOCCTL should include sufficient free text description of the split or merged tumors to permit unequivocal identification. See SDTM oncology examples for alternative methods for representing Split and Merge tumors.						
11	TUMETHOD	What was the method of evaluation?	Method of Evaluation	Specify the method used to identify/ evaluate the tumor.	TUMETHOD	TUMETHOD and TRMETHOD	(METHOD)	The METHOD codelist provides submission values using most commonly known/generally recognized terms. The values will represent the method generically, not the product of the method (e.g. photograph). Sponsors may customize or restrict the list of values per response criteria or protocol needs. At a minimum, the primary method of identification should be entered and is expected to be consistent throughout the study; recording secondary methods is at the discretion of the sponsor.	Clinical Exam; CT Scan; MRI; PET/CT Scan; PET/MRI Scan; Photography; Physical Examination; Scintigraphy	N/A	question text	radio	text	visible
12	TUDAT	What was the date of the procedure?	Procedure Date	Insert the date of the scan/image/examination (not the date on which it was read, or the visit date).	TUDTC	TUDTC and TRDTC	N/A	Insert the date of the scan/image/examination on which the evaluation was based (not the date on which it was read, or the visit date). Date should align with the primary method.	N/A	N/A	prompt	N/A	date	visible
13	TUEVAL	What was the role of the person performing the tumor evaluation?	Evaluator	Indicate who performed the assessment.	TUEVAL	TUEVAL and TREVAL	(EVAL)	Collect if multiple evaluators are used in the study (may be omitted if the investigator is always the evaluator); values should follow controlled terminology.	Independent Assessor; Investigator	N/A	question text	radio	text	visible
14	TUEVALID	What is the evaluator identifier?	Evaluator Identifier	Identify the evaluator providing this evaluation.	TUEVALID	TUEVALID and TREVALID	(MEDEVAL)	Collect if multiple evaluators with the same value of TUEVAL are used in the study; values should follow controlled terminology.	Radiologist 1; Radiologist 2; Oncologist	N/A	question text	radio	text	visible
15	LDIAM_TRORRES	What was the longest diameter of the tumor?	Longest Diameter	For non-nodal disease, record the longest diameter of the tumor.	TRORRES	TRORRES where TRTESTCD = "LDIAM"	N/A	Target lesions should have measurements. Some sponsors opt to record measurements for new lesions and, more rarely, non-target lesions. Leverage diameter/diameter unit as appropriate per study needs.	N/A	N/A	question text	N/A	float	visible
16	LDIAM_TRORRESU	What were the units for the longest diameter?	Longest Diameter Unit	N/A	TRORRESU	TRORRESU where TRTESTCD = "LDIAM"	(UNIT)	Usually the unit of the test is pre-defined on the CRF.	N/A	mm	prompt	N/A	text	visible
17	LDIAM_TRTOOSM_TRORRES	Check if the longest diameter was too small to measure.	Longest Diameter Too Small to Measure	Check if the tumor is too small to measure.	TRORRES	TRORRES = "TOO SMALL TO MEASURE" where TRTESTCD = "LDIAM"	(NY)	This field can be used to record that tumors are too small to measure. Note that with some assessment criteria (e.g., RECIST), a default value (e.g., 5mm) may be used in the calculation to determine response. As an alternative, the fact that a tumor is too small to measure can be recorded in TRREASND.	Diameter Too Small to Measure	N/A	prompt	checkbox	text	visible

CDISC Therapeutic Area Data Standards User Guide for Lung Cancer v1.0 (Provisional)

Order Number	CDASH Variable Name	Question Text	Prompt	Case Report Form Completion Instructions	SDTMIG Target Variable	SDTM Target Mapping	Controlled Terminology CodeList Name	CRF Implementation Notes	Permissible Values	Pre-populated Value	Displayed Query	List Style	Input Type	Hidden
18	PDIAM_TRORESS	What was the perpendicular diameter of the tumor?	Perpendicular Diameter	For lymph nodes, record the short axis measurement	TRRRES	TRRRES where TRTESTCD = "LPERP"	N/A	Target lesions should have measurements. Some sponsors opt to record measurements for new lesions and, more rarely, non-target lesions. Leverage diameter/diameter unit as appropriate per study needs.	N/A	N/A	question text	N/A	float	visible
19	PDIAM_TRORRESU	What were the units for the perpendicular diameter?	Perpendicular Diameter Unit	N/A	TRORRESU	TRORRESU where TRTESTCD = "LPERP"	(UNIT)	Usually the unit of the test is pre-defined on the CRF.	N/A	mm	prompt	N/A	text	visible
20	PDIAM_TRTOOSM_TRORRES	Check if the perpendicular diameter was too small to measure.	Perpendicular Diameter Too Small to Measure	Check if the lymph node is too small to measure.	TRRRES	TRRRES = "TOO SMALL TO MEASURE" where TRTESTCD = "LPERP"	(NY)	This field can be used to record that tumors are too small to measure. Note that with some assessment criteria (e.g., RECIST), a default value (e.g., 5mm) may be used in the calculation to determine response. As an alternative, the fact that a tumor is too small to measure can be recorded in TRREASND.	Diameter Too Small to Measure	N/A	prompt	N/A	text	visible
21	TRINEVAL	Check if the tumor was inevaluable.	Tumor Inevaluable	If appropriate, denote the tumor as inevaluable.	TRSTAT	TRSTAT = "NOT DONE" where TRTESTCD = "TUMSTATE"	N/A	This is intended to be used as a data management tool to verify that inevaluable tumor evaluations are denoted at a specific evaluation. Inevaluable may also be collected as a No/Yes question based on sponsor preference.	Inevaluable	N/A	prompt	N/A	text	visible
22	TRREASND	If the tumor was Inevaluable, what was the reason?	If Tumor is inevaluable, Reason Not Done	Indicate the reason why the tumor was inevaluable.	TRREASND	TRREASND where TRSTAT = "NOT DONE" and TRESTCD = "TUMSTATE"	N/A	The pre-specified terms are simply examples of REASND collected terms to encourage standardized terminology (as opposed to free-text). "Lesion or Background Change that Prevents Evaluation" makes it hard to measure the lesion and will include cavitation, fibrosis, necrosis; for example, a lung metastasis develops pneumonia around it, so the edges are concealed. "Poor Scan Quality" indicates that the full anatomy was scanned but could not be evaluated due to low quality (e.g., no/poor IV contrast, motion present). "Insufficient Images/Anatomy" indicates that the lesion anatomy is incomplete, crucial anatomy is out of field of view, or a key scan slice is not taken. "Inconsistent Modality" denotes a change in assessment/technique that prevents lesion evaluation (e.g., using a different machine or changes in the use of contrast). "Focal Intervention" (e.g., focal radiation, ablation, excision) is selected if the lesion can no longer be evaluated for the effects of the trial therapy based on a concomitant procedure. For example, surgically removing a large tumor in a trial where the trial therapy is only systemic; the radiologist/oncologist can	Lesion or Background Change that Prevents Evaluation; Focal Intervention; Poor Scan Quality; Insufficient Images/Anatomy; Inconsistent Modality; Site Error; Other	N/A	question text	radio	text	visible

Order Number	CDASH Variable Name	Question Text	Prompt	Case Report Form Completion Instructions	SDTMIG Target Variable	SDTM Target Mapping	Controlled Terminology CodeList Name	CRF Implementation Notes	Permissible Values	Pre-populated Value	Displayed Query	List Style	Input Type	Hidden
								no longer make meaningful comparisons before/after surgery. The sponsor may elect to concatenate the response "Inevaluable" with the collected reason not done.						
23	LNSTAT_TRORRES	What was the nodal state?	Nodal State	For nodal tumors only, denote whether the node is pathological or non-pathological.	TRORRES	TRORRES where TRTESTCD = "LNSTATE"	N/A	Per RECIST 1.1, lymph nodes merit special mention since they are normal anatomical structures which may be visible by imaging even if not involved by tumor. Pathological vs. non-pathological lymph nodes have different documentation expectations; refer to the RECIST 1.1 criteria.	Pathological; Non-Pathological	N/A	question text	N/A	text	visible

The following CRF was designed to collect information on non-target lesions identified in trials testing immunotherapeutics. These trials use RECIST 1.1 and iRECIST criteria to define endpoints. Sponsors may decide to (1) collect RECIST and iRECIST on separate CRFs or (2) collect RECIST and iRECIST on a single CRF.

Although not illustrated, the CRF layout assumes that dynamic navigation controls would be used to display the RECIST or iRECIST questions based on the category chosen. The CRF questions relating to descriptions of the identified tumors (e.g., TULOC, TULAT) to be followed are typically collected at the initial/baseline visit, and then are not re-collected at subsequent tumor assessments.

One CDASH variable may need to be mapped to other domains when the SDTM-based datasets are created (e.g., TUDAT would be mapped to TUDTC and TRDTC).

TUCAT may be used by sponsors to categorize tumors that have been identified to be followed during the study for tumor response (e.g., RESPONSE EVALUATION TUMOR), from other information that may be collected about tumor sites at baseline (e.g., baseline sites of disease). Since TUCAT was used in this example to define the category "RESPONSE EVALUATION TUMOR", another CDASH variable ONCRSCAT (Oncology Response Criteria) was included to allow dynamic navigation to the relevant question concerning RECIST or iRECIST.

<p>Indicate whether or not non-target tumors were identified. If non-target tumors identified, list each non-target tumor and provide the requested information.</p> <p>Sponsor-specified</p> <p>Specify the general (anatomical) location of the tumor.</p> <p>Specify the laterality of the tumor.</p> <p>Specify the directionality of the tumor.</p> <p>Describe additional detail on the exact location of the tumor so that it can be distinguished from other tumors in the same anatomical location.</p> <p>For truly non-measurable lesions (as defined by RECIST 1.1) specify the lesion presentation type.</p> <p>Specify the method used to identify/ evaluate the tumor.</p>	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="padding: 5px;">Category TUCAT Hidden/pre-populated</td> <td style="padding: 5px;">Response Criteria ONCRSCAT Not submitted</td> <td style="padding: 5px;">RESPONSE EVALUATION TUMOR <input type="radio"/> RECIST 1.1 <input type="radio"/> iRECIST <i><From ONCRSCAT codelist></i> </td> </tr> <tr> <td colspan="2" style="padding: 5px;">Tumor Type According to Criteria TUMIDENT_TUORRES TUORRES where TUTESTCD = "TUMIDENT" Hidden/pre-populated</td> <td style="padding: 5px;">Non-Target <input type="radio"/> Yes <input type="radio"/> No <i><From NY codelist></i> </td> </tr> <tr> <td colspan="2" style="padding: 5px;">Were non-target tumors identified? TUYN Not submitted</td> <td style="padding: 5px;"></td> </tr> <tr> <td colspan="2" style="padding: 5px;">What was the Tumor ID? TULNKID TULNKID and TRLNKID</td> <td style="padding: 5px;"></td> </tr> <tr> <td colspan="2" style="padding: 5px;">What was the anatomical location of the tumor? TULOC</td> <td style="padding: 5px;"> <input type="radio"/> LUNG, LEFT UPPER LOBE <input type="radio"/> LUNG, RIGHT UPPER LOBE <input type="radio"/> LUNG, LEFT LOWER LOBE <input type="radio"/> LUNG, RIGHT LOWER LOBE <input type="radio"/> LUNG, LEFT MIDDLE LOBE <input type="radio"/> LUNG, RIGHT MIDDLE LOBE <i><From LOC codelist></i> </td> </tr> <tr> <td colspan="2" style="padding: 5px;">If applicable, what was the laterality of the anatomical location? TULAT</td> <td style="padding: 5px;"> <input type="radio"/> RIGHT <input type="radio"/> LEFT <input type="radio"/> BILATERAL <i><From LAT codelist></i> </td> </tr> <tr> <td colspan="2" style="padding: 5px;">If applicable, what was the directionality of the anatomical location? TUDIR</td> <td style="padding: 5px;"> <input type="radio"/> ANTERIOR <input type="radio"/> POSTERIOR <i><From DIR codelist></i> </td> </tr> <tr> <td colspan="2" style="padding: 5px;">If applicable, what is the additional detail about the tumor location? TULOCCTL SUPPTU.QVAL where SUPPTU.QNAM = "TULOCCTL"</td> <td style="padding: 5px;"></td> </tr> <tr> <td colspan="2" style="padding: 5px;">For truly non-measurable lesions, What was the lesion presentation type? TUPRTYP SUPPTU.QVAL where SUPPTU.QNAM = "TUPRTYP"</td> <td style="padding: 5px;"> <input type="radio"/> Ascites <input type="radio"/> Effusion <input type="radio"/> Leptomeningeal Disease <input type="radio"/> Complex Cystic <i><From DSPRTYP codelist></i> </td> </tr> <tr> <td colspan="2" style="padding: 5px;">What was the method of evaluation? TUMETHOD TUMETHOD and TRMETHOD</td> <td style="padding: 5px;"> <input type="radio"/> Clinical Exam <input type="radio"/> CT Scan <input type="radio"/> MRI <input type="radio"/> PET/CT Scan <input type="radio"/> PET/MRI Scan <input type="radio"/> Photography <input type="radio"/> Physical Examination <input type="radio"/> Scintigraphy <i><From METHOD codelist></i> </td> </tr> </table>	Category TUCAT Hidden/pre-populated	Response Criteria ONCRSCAT Not submitted	RESPONSE EVALUATION TUMOR <input type="radio"/> RECIST 1.1 <input type="radio"/> iRECIST <i><From ONCRSCAT codelist></i>	Tumor Type According to Criteria TUMIDENT_TUORRES TUORRES where TUTESTCD = "TUMIDENT" Hidden/pre-populated		Non-Target <input type="radio"/> Yes <input type="radio"/> No <i><From NY codelist></i>	Were non-target tumors identified? TUYN Not submitted			What was the Tumor ID? TULNKID TULNKID and TRLNKID			What was the anatomical location of the tumor? TULOC		<input type="radio"/> LUNG, LEFT UPPER LOBE <input type="radio"/> LUNG, RIGHT UPPER LOBE <input type="radio"/> LUNG, LEFT LOWER LOBE <input type="radio"/> LUNG, RIGHT LOWER LOBE <input type="radio"/> LUNG, LEFT MIDDLE LOBE <input type="radio"/> LUNG, RIGHT MIDDLE LOBE <i><From LOC codelist></i>	If applicable, what was the laterality of the anatomical location? TULAT		<input type="radio"/> RIGHT <input type="radio"/> LEFT <input type="radio"/> BILATERAL <i><From LAT codelist></i>	If applicable, what was the directionality of the anatomical location? TUDIR		<input type="radio"/> ANTERIOR <input type="radio"/> POSTERIOR <i><From DIR codelist></i>	If applicable, what is the additional detail about the tumor location? TULOCCTL SUPPTU.QVAL where SUPPTU.QNAM = "TULOCCTL"			For truly non-measurable lesions, What was the lesion presentation type? TUPRTYP SUPPTU.QVAL where SUPPTU.QNAM = "TUPRTYP"		<input type="radio"/> Ascites <input type="radio"/> Effusion <input type="radio"/> Leptomeningeal Disease <input type="radio"/> Complex Cystic <i><From DSPRTYP codelist></i>	What was the method of evaluation? TUMETHOD TUMETHOD and TRMETHOD		<input type="radio"/> Clinical Exam <input type="radio"/> CT Scan <input type="radio"/> MRI <input type="radio"/> PET/CT Scan <input type="radio"/> PET/MRI Scan <input type="radio"/> Photography <input type="radio"/> Physical Examination <input type="radio"/> Scintigraphy <i><From METHOD codelist></i>
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CDISC Therapeutic Area Data Standards User Guide for Lung Cancer v1.0 (Provisional)

Insert the date of the scan/image/ examination (not the date on which it was read, or the visit date).	What was the date of evaluation? TUDAT TUDTC and TRDT	<input type="text"/>
Indicate who performed the assessment.	What was the role of the person performing the tumor evaluation? TUEVAL TUEVAL and TREVAL	<input type="radio"/> Independent Assessor <input type="radio"/> Investigator <small><From EVAL codelist></small>
Identify the evaluator providing this evaluation.	What is the evaluator identifier? TUEVALID TUEVALID and TREVALID	<input type="radio"/> Radiologist 1 <input type="radio"/> Radiologist 2 <input type="radio"/> Oncologist <small><From MEDEVAL codelist></small>
If initial non-target assessment, denote the tumor state as PRESENT. If followup-assessment, indicate the current tumor state.	What was the tumor state using RECIST 1.1 criteria? TUMSTATE_RECIST_TRORRES TRORRES where TRTESTCD = "TUMSTATE"	<input type="radio"/> ABSENT <input type="radio"/> PRESENT <input type="radio"/> ENLARGEMENT FROM NADIR <small><From TRPROPRS codelist></small>
If initial non-target assessment, denote the tumor state as PRESENT. If followup-assessment, indicate the current tumor state.	What was the tumor state using iRECIST criteria? TUMSTATE_IRECIST_TRORRES TRORRES where TRTESTCD = "TUMSTATE"	<input type="radio"/> ABSENT <input type="radio"/> PRESENT <input type="radio"/> ENLARGEMENT FROM NADIR <input type="radio"/> FURTHER ENLARGEMENT FROM NADIR <small><From TRPROPRS codelist></small>
If appropriate, denote the tumor as inevaluable.	Check if the tumor was inevaluable. TRINEVAL TRSTAT= "NOT DONE" where TRTESTCD = "TUMSTATE"	<input type="checkbox"/> Inevaluable
Indicate the reason why the tumor was inevaluable.	If the tumor was inevaluable, what was the reason? TRREASND TRREASND where TRSTAT = "NOT DONE" and TRTESTCD = "TUMSTATE"	<input type="radio"/> Lesion or Background Change that Prevents Evaluation <input type="radio"/> Focal Intervention <input type="radio"/> Poor Scan Quality <input type="radio"/> Insufficient Images/Anatomy <input type="radio"/> Inconsistent Modality <input type="radio"/> Site Error <input type="radio"/> Other
For lymph node tumors only, denote whether the node is pathological or non-pathological.	What was the lymph node state? TRLNSTAT TRORRES where TRTESTCD = "LNSTATE"	<input type="radio"/> Pathological <input type="radio"/> Non-Pathological

Order Number	CDASH Variable Name	Question Text	Prompt	Case Report Form Completion Instructions	SDTMIG Target Variable	SDTMIG Target Mapping	Controlled Terminology CodeList Name	CRF Implementation Notes	Permissible Values	Pre-populated Value	Displayed Query	List Style	Input Type	Hidden
1	TUCAT	What is the category of the [tumor/lesion] identification?	Category	Record the Tumor Identification category, if not pre-printed on the CRF.	TUCAT		N/A	Sponsor-defined Controlled Terminology. This would most commonly be either an heading, or a pre-printed category value on the CRF and not a question to which the site would provide an answer. If a question is asked, the response would typically be a sponsor-defined codelist. If the form is laid out as a grid, then words such	N/A	RESPONSE EVALUATION TUMOR	prompt	N/A	text	hidden

Order Number	CDASH Variable Name	Question Text	Prompt	Case Report Form Completion Instructions	SDTMIG Target Variable	SDTMIG Target Mapping	Controlled Terminology CodeList Name	CRF Implementation Notes	Permissible Values	Pre-populated Value	Displayed Query	List Style	Input Type	Hidden
								as "Category" can be included as the column header.						
2	ONCRSCAT	What is the Response Criteria being used?	Response Criteria	N/A	N/A	N/A	(ONCRSCAT)	Since there are separate codelists used for categorizations of records about oncology response criteria (ONCRCAT), this CDASH variable was created for use in Oncology trials to identify the response criteria being used in a study. While this field is not typically captured on a CRF, it should be displayed clearly on the CRF. Most often pre-defined, instructional text to orient the data entry staff to appropriate cancer response criteria. Collect if multiple types/versions are active in a single study/database. The codelist may be extended for other cancer response systems (e.g., IWG, IMWG, etc.).	RECIST 1.1; iRECIST	N/A	prompt	N/A	text	visible
3	TUMIDENT_TUORRES	What type of tumors are being identified as defined by the criteria being employed?	Tumor Type According to Criteria	Record or select which type of tumor is being evaluated, as defined by the criteria.	TUORRES	TUORRES where TUTESTCD = "TUMIDENT"		Although this field is not typically captured on a CRF, it should be displayed clearly on the CRF and/or the EDC system. When TUTESTCD=TUMIDENT (Tumor Identification), values of TUORRES will be: TARGET, NON-TARGET, NEW_BONE LESION or NEW BONE LESION.	N/A	Non-Target	prompt	N/A	text	hidden
4	TUYN	Were non-target tumors identified?	Any new non-target tumors	Indicate whether or not non-target tumors were identified. If non-target tumors identified, list each non-target tumor and provide the requested information.	N/A	N/A	(NY)	This is intended to be used as a data management tool to verify that missing tumor evaluations are confirmed missing. If "Yes", a record is created in the SDTMIG TU domain for each tumor identified. Typically, tumor type/class would be Target, Non-Target, New, Bone Tumor, or New Bone Tumor.	Yes; No	N/A	question text	radio	text	visible
5	TULNKID	What was the Tumor ID?	Tumor ID	Sponsor-specified	TULNKID	TULNKID and TRLNKID	N/A	This variable is used to provide a unique code for each identified tumor in order to link records across related domains (TU and TR). TULNKID and TRLNKID are expected to be the same across datasets. The values of TULNKID are compound values that may carry the following information: an indication of the role (or assessor) providing the data records when it is someone other than the principal investigator; and an indication of whether the data record is for a target, non-target, or new tumor; and an indication of whether the tumor has split or merged. Sponsors may develop their own conventions for identifying tumors.	N/A	N/A	question text	N/A	text	visible
6	TULOC	What was the anatomical	Location	Specify the general (anatomical)	TULOC		(LOC)	When anatomical location is broken down and collected as distinct pieces of data that, when combined, provide the exact location	LUNG, LEFT UPPER LOBE;	N/A	question text	radio	text	visible

CDISC Therapeutic Area Data Standards User Guide for Lung Cancer v1.0 (Provisional)

Order Number	CDASH Variable Name	Question Text	Prompt	Case Report Form Completion Instructions	SDTMIG Target Variable	SDTMIG Target Mapping	Controlled Terminology CodeList Name	CRF Implementation Notes	Permissible Values	Pre-populated Value	Displayed Query	List Style	Input Type	Hidden
		location of the tumor?		location of the tumor.				information (e.g. laterality/directionality), then the additional anatomical location qualifiers should be used. The first (TULOC) should follow controlled terminology, which will enable consistency across sites. Laterality (TULAT) and Directionality (TUDIR) should also be available for entry if more explicit detail can be provided. A location detail text field (TULOCCTL) is conditional for entry (i.e., can be left blank) and allows the study site to specify the lesion in its own terms; it also can be used to distinguish tumors within the same location if TULAT and/or TUDIR is not sufficient. Finally, Presentation Type is conditional for truly non-measurable lesions that are difficult to characterize with Location.	LUNG, RIGHT UPPER LOBE; LUNG, LEFT LOWER LOBE; LUNG, RIGHT LOWER LOBE; LUNG, LEFT MIDDLE LOBE; LUNG, RIGHT MIDDLE LOBE					
7	TULAT	If applicable, what was the laterality of the anatomical location?	Laterality	Specify the laterality of the tumor.	TULAT		(LAT)	See TULOC	RIGHT; LEFT; BILATERAL	N/A	question text	radio	text	visible
8	TUDIR	If applicable, what was the directionality of the anatomical location?	Directionality	Specify the directionality of the tumor.	TUDIR		(DIR)	See TULOC	ANTERIOR; POSTERIOR	N/A	question text	radio	text	visible
9	TULOCCTL	If applicable, what is the additional detail about the tumor location?	Location Detail	Describe additional detail on the exact location of the tumor so that it can be distinguished from other tumors in the same anatomical location.	SUPPTU.QVAL	SUPPTU.QVAL where SUPPTU.QNAM = "TULOCCTL"	N/A	Use if TULOC and TULAT and/or TUDIR values cannot provide uniqueness from other tumor records. TULOCCTL is not meant to replace TULOC, TULAT, and/or TUDIR or serve as the free-text description field for TULOC (e.g., Location, Other). May also be useful if sponsor collects cancer antigens or tumor markers as Non-Target Lesions. See TULOC.	N/A	N/A	question text	N/A	text	visible
10	TUPRTYP	For truly non-measurable lesions, What was the lesion presentation type?	Tumor or Lesion Presentation Type	For truly non-measurable lesions (as defined by RECIST 1.1) specify the lesion presentation type.	SUPPTU.QVAL	SUPPTU.QVAL where SUPPTU.QNAM = "TUPRTYP"	(DSPRTYP)	Used for non-target or new lesions only. Truly non-measurable is defined as described in the RECIST 1.1 paper section 3.1.2.	Ascites; Effusion; Leptomeningeal Disease; Complex Cystic	N/A	question text	radio	text	visible
11	TUMETHOD	What was the method of evaluation?	Method of Evaluation	Specify the method used to identify/ evaluate the tumor.	TUMETHOD	TUMETHOD and TRMETHOD	(METHOD)	The METHOD code list provides submission values using most commonly known/generally recognized terms. The values will represent the method generically, not the product of the method (e.g., photograph). Sponsors may customize or restrict the list of values per response criteria or protocol needs. At a	Clinical Exam; CT Scan; MRI; PET/CT Scan; PET/MRI Scan; Photography; Physical Examination; Scintigraphy	N/A	question text	radio	text	visible

CDISC Therapeutic Area Data Standards User Guide for Lung Cancer v1.0 (Provisional)

Order Number	CDASH Variable Name	Question Text	Prompt	Case Report Form Completion Instructions	SDTMIG Target Variable	SDTMIG Target Mapping	Controlled Terminology CodeList Name	CRF Implementation Notes	Permissible Values	Pre-populated Value	Displayed Query	List Style	Input Type	Hidden
								minimum, the primary method of identification should be entered and is expected to be consistent throughout the study; recording secondary methods is at the discretion of the sponsor.						
12	TUDAT	What was the date of evaluation?	Procedure Date	Insert the date of the scan/image/examination (not the date on which it was read, or the visit date).	TUDTC	TUDTC and TRDTC	N/A	Insert the date of the scan/image/examination on which the evaluation was based (not the date on which it was read, or the visit date). Dates should align with the primary method.	N/A	N/A	question text	N/A	date	visible
13	TUEVAL	What was the role of the person performing the tumor evaluation?	Evaluator	Indicate who performed the assessment.	TUEVAL	TUEVAL and TREVAL	(EVAL)	Collect if multiple evaluators are used in the study (may be omitted if the investigator is always the evaluator); values should follow controlled terminology.	Independent Assessor; Investigator	N/A	question text	radio	text	visible
14	TUEVALID	What is the evaluator identifier?	Evaluator Identifier	Identify the evaluator providing this evaluation.	TUEVALID	TUEVALID and TREVALID	(MEDEVAL)	Collect if multiple evaluators with the same value of TUEVAL are used in the study; values should follow controlled terminology.	Radiologist 1; Radiologist 2; Oncologist	N/A	question text	radio	text	visible
15	TUMSTATE_RECIST_TRORRES	What was the tumor state using RECIST 1.1 criteria?	Tumor State	If initial non-target assessment, denote the tumor state as PRESENT. If followup-assessment, indicate the current tumor state.	TRORRES; TRTESTCD; TRTEST	TRORRES where TRTESTCD = "TUMSTATE"	(TRPROPRS)	When CRFs are designed for the initial new tumor identification and subsequent assessments, the code list may be subsetted as needed. If a tumor is noted as inevaluable at a specific evaluation, this variable may be blank.	ABSENT; PRESENT; ENLARGEMENT FROM NADIR	N/A	question text	radio	text	visible
16	TUMSTATE_iRECIST_TRORRES	What was the tumor state using iRECIST criteria?	Tumor State	If initial non-target assessment, denote the tumor state as PRESENT. If followup-assessment, indicate the current tumor state.	TRORRES; TRTESTCD; TRTEST	TRORRES where TRTESTCD = "TUMSTATE"	(TRPROPRS)	When CRFs are designed for the initial new tumor identification and subsequent assessments, the code list may be subsetted as needed. If a tumor is noted as inevaluable at a specific evaluation, this variable may be blank.	ABSENT; PRESENT; ENLARGEMENT FROM NADIR; FURTHER ENLARGEMENT FROM NADIR	N/A	question text	radio	text	visible
17	TRINEVAL	Check if the tumor was inevaluable.	Tumor Inevaluable?	If appropriate, denote the tumor as inevaluable.	TRSTAT	TRSTAT = "NOT DONE" where TRTESTCD = "TUMSTATE"	N/A	This is intended to be used as a data management tool to verify that inevaluable tumor evaluations are denoted at a specific evaluation. Inevaluable may also be collected as a No/Yes question based on sponsor preference.	Inevaluable	N/A	question text	checkbox	text	visible
18	TRREASND	If the tumor was inevaluable, what was the reason?	If Tumor is inevaluable,	Indicate the reason why the	TRREASND	TRREASND where TRSTAT = "NOT DONE" and	N/A	The pre-specified terms are simply examples of REASND collected terms to encourage	Lesion or Background Change that Prevents Evaluation; Focal	N/A	question text	radio	text	visible

Order Number	CDASH Variable Name	Question Text	Prompt	Case Report Form Completion Instructions	SDTMIG Target Variable	SDTMIG Target Mapping	Controlled Terminology CodeList Name	CRF Implementation Notes	Permissible Values	Pre-populated Value	Displayed Query	List Style	Input Type	Hidden		
			Reason Not Done	tumor was inevaluable.		TRTESTCD = "TUMSTATE"		standardized terminology (as opposed to free-text). "Lesion or Background Change that Prevents Evaluation" makes it hard to measure the lesion and will include cavitation, fibrosis, necrosis; for example, a lung metastasis develops pneumonia around it, so the edges are concealed. "Poor Scan Quality" indicates that the full anatomy was scanned but could not be evaluated due to low quality (e.g., no/poor IV contrast or motion present). "Insufficient Images/Anatomy" indicates that the lesion anatomy is incomplete, crucial anatomy is out of field of view, or a key scan slice is not taken. "Inconsistent Modality" denotes a change in assessment/technique that prevents lesion evaluation (e.g., using a different machine, changes in the use of contrast). "Focal intervention" (e.g., focal radiation, ablation, excision) is selected if the lesion can no longer be evaluated for the effects of the trial therapy based on a concomitant procedure. For example, surgically removing a large tumor in a trial where the trial therapy is only systemic; the radiologist/oncologist can no longer make meaningful comparisons before/after surgery. The sponsor may elect to concatenate the response "Inevaluable" with the collected reason not done.	Intervention; Poor Scan Quality; Insufficient Images/Anatomy; Inconsistent Modality; Site Error; Other							
19	TRLNSTAT	What was the lymph node state?	Lymph Node State	For lymph node tumors only, denote whether the node is pathological or non-pathological.	TRRRES; TRTESTCD; TRTEST	TRRRES where TRTESTCD = "LNSTATE"	N/A	Per RECIST 1.1, lymph nodes merit special mention because they are normal anatomical structures which may be visible by imaging even if not involved by tumor. Pathological vs. non-pathological lymph nodes have different documentation expectations; refer to the RECIST 1.1 criteria.	Pathological; Non-Pathological	N/A	question text	radio	text	visible		

The following CRF was designed to collect information on new tumors/lesions identified in trials testing immunotherapeutics. These trials use RECIST 1.1 and iRECIST criteria to define endpoints. Sponsors may decide to (1) collect RECIST and iRECIST on separate CRFs or (2) collect RECIST and iRECIST on a single CRF using dynamic navigation.

Although not illustrated, the CRF layout assumes that dynamic navigation controls would be used to display the RECIST or iRECIST questions based on the category chosen using the CDASH variable ONCRSCAT. The leading questions on the CRF would also be used to control dynamic navigation.

The question "Was this an assessment on a previously identified new lesion?" is used to navigate to the question that relates to either a newly identified lesion, or a lesion that has been previously identified. The CRF collects tumor identification information for a newly identified lesion, or it collects an assessment of the already identified lesions.

This CRF collects longest diameters for non-nodal disease, and short axis for lymph nodal disease. Some sponsors may collect diameter and map to the correct TRTESTCD based on the location of the disease. Refer to the original RECIST paper for detail information on measurements to be used.

One CDASH variable may need to be mapped to other domains when the SDTM-based datasets are created (e.g., TUDAT would be mapped to TUDTC and TRDTC).

TUCAT may be used by sponsors to categorize tumors that have been identified to be followed during the study for tumor response (e.g., RESPONSE EVALUATION TUMOR), from other information that may be collected about tumor sites at baseline (e.g., baseline sites of disease). Since TUCAT was used in this example to define the category "RESPONSE EVALUATION TUMOR", another CDASH variable ONCRSCAT (Oncology Response Criteria) was included to allow dynamic navigation to the relevant question concerning RECIST or iRECIST.

	Category TUCAT Hidden/pre-populated	RESPONSE EVALUATION TUMOR
Indicate what Response Criteria are being used at this assessment.	ONCRSCAT Not submitted	<input type="radio"/> RECIST 1.1 <input type="radio"/> iRECIST <small><From ONCRSCAT codelist></small>
Indicate whether this is an assessment of a previously identified new lesion.	TUPLEYN Not submitted	<input type="radio"/> Yes <input type="radio"/> No <small><From NY codelist></small>
Indicate whether or not new tumors were identified. If new tumors identified, list each new tumor and provide the requested information.	TUYN Not submitted	<input type="radio"/> Yes <input type="radio"/> No <small><From NY codelist></small>
Record or select which type of new tumor is being evaluated as defined by the criteria.	TUMIDENT_TUORRES TUORRES where TUTESTCD = "TUMIDENT"	<input type="radio"/> NEW TARGET TUMOR <input type="radio"/> NEW NON-TARGET TUMOR
Sponsor-specified	TULNKID TULNKID and TRLNKID	<input type="text"/>
Specify the general (anatomical) location of the tumor.	TULOC	<input type="radio"/> LUNG, LEFT UPPER LOBE <input type="radio"/> LUNG, RIGHT UPPER LOBE <input type="radio"/> LUNG, LEFT LOWER LOBE <input type="radio"/> LUNG, RIGHT LOWER LOBE <input type="radio"/> LUNG, LEFT MIDDLE LOBE <input type="radio"/> LUNG, RIGHT MIDDLE LOBE <small><From LOC codelist></small>
Specify the laterality of the tumor.	TULAT	<input type="radio"/> BILATERAL <input type="radio"/> RIGHT <input type="radio"/> LEFT: <small><From LAT codelist></small>
Specify the directionality of the tumor.	TUDIR	<input type="radio"/> ANTERIOR <input type="radio"/> POSTERIOR <small><From DIR codelist></small>

Describe additional detail on the exact location of the tumor so that it can be distinguished from other tumors in the same anatomical location.	<p>If applicable, what is the additional detail about the tumor location?</p> <p>TULOCCTL SUPPTU.QVAL where QNAM = "TULOCCTL"</p>	
Specify the truly non-measurable lesion presentation type.	<p>What was the tumor presentation type of the non-measurable disease?</p> <p>TUPRTYP SUPPTU.QVAL where QNAM = "TUPRTYP"</p>	<input type="radio"/> Ascites <input type="radio"/> Effusion <input type="radio"/> Leptomeningeal Disease <input type="radio"/> Complex Cystic <p style="text-align: right;"><i><From DSPRTYP codelist></i></p>
Indicate whether this is a tumor that has split from a previous tumor, or is a tumor that has merged with another tumor.	<p>Select if changes to tumor were identified.</p> <p>TUCHANGE IF TUCHANGE = "Split", TUORRES = "TARGET" where TUTESTCD = "TUSPLIT" IF TUCHANGE = "Merged", TUORRES = "TARGET" where TUTESTCD = "TUMERGE"</p>	<input type="radio"/> Merged <input type="radio"/> Split <p style="text-align: right;"><i><From TUTEST codelist></i></p>
Specify the method used to identify/evaluate the tumor.	<p>What was the method of evaluation?</p> <p>TUMETHOD TUMETHOD and TRMETHOD</p>	<input type="radio"/> CT Scan <input type="radio"/> PET/CT Scan <input type="radio"/> PET/MRI Scan <input type="radio"/> Photography <input type="radio"/> Physical Examination <input type="radio"/> X-Ray <p style="text-align: right;"><i><From METHOD codelist></i></p>
Insert the date of the scan/image/examination (not the date on which it was read, or the visit date).	<p>What was the date of evaluation?</p> <p>TUDAT TUDTC and TRDT</p>	
Indicate who performed the assessment.	<p>What was the role of the person performing the tumor evaluation?</p> <p>TUEVAL TUEVAL and TREVAL</p>	<input type="radio"/> Independent Assessor <input type="radio"/> Investigator <p style="text-align: right;"><i><From EVAL codelist></i></p>
Identify the evaluator providing this evaluation.	<p>What is the evaluator identifier?</p> <p>TUEVALID TUEVALID and TREVAL</p>	<input type="radio"/> Radiologist 1 <input type="radio"/> Radiologist 2 <input type="radio"/> Oncologist <p style="text-align: right;"><i><From MEDEVAL codelist></i></p>
For non-nodal disease, record the longest diameter of the tumor.	<p>What was the longest diameter of the tumor?</p> <p>LDIAM_TRORRES TRORRES where TRTESTCD = "LDIAM"</p>	
Check if the longest diameter is too small to measure.	<p>What were the units for the longest diameter?</p> <p>LDIAM_TRORRESU TRORRESU where TRTESTCD = "LDIAM" Pre-populated</p>	<input type="checkbox"/> mr <p style="text-align: right;"><i><From UNIT codelist></i></p>
	<p>Check if the longest diameter was too small to measure.</p> <p>LDIAM_TRTOOSM_TRORRES TRORRES = "TOO SMALL TO MEASURE" where TRTESTCD = "LDIAM"</p>	<input type="checkbox"/> Diameter Too Small to Measure <p style="text-align: right;"><i><From NY codelist></i></p>

For lymph nodes, record the short axis measurement	<p>For lymph nodes, what was the short axis diameter?</p> <p>PDIAM_TRORRES TRORRES where TRTESTCD = "LPERP"</p> <p>Perpendicular Diameter Unit</p> <p>PDIAM_TRORRESU TRORRESU where TRTESTCD = "LPERP" Pre-populated</p>	<input type="text"/>	
		mr	<From UNIT codelist>
Check if the short axis tumor is too small to measure.	<p>Check if the short axis diameter was too small to measure.</p> <p>PDIAM_TROOSM_TRORRES TRORRES = "TOO SMALL TO MEASURE" where TRTESTCD = "LPERP"</p>	<input type="checkbox"/> Short Axis Diameter Too Small to Measure	<From NY codelist>
If new- non-target tumor, denote the tumor state as PRESENT. If followup-assessment, indicate the current tumor state.	<p>What was the tumor state?</p> <p>TUMSTATE_RECIST_TRORRES TRORRES where TRTESTCD = "TUMSTATE"</p>	<input type="radio"/> PRESENT <input type="radio"/> ABSENT <input type="radio"/> ENLARGEMENT FROM NADIR	<From TRPROPRS codelist>
If new- non-target tumor, denote the tumor state as PRESENT. If followup-assessment, indicate the current tumor state	<p>What was the tumor state?</p> <p>TUMSTATE_IRECIST_TRORRES TRORRES where TRTESTCD = "TUMSTATE"</p>	<input type="radio"/> PRESENT <input type="radio"/> ABSENT <input type="radio"/> ENLARGEMENT FROM NADIR <input type="radio"/> FURTHER ENLARGEMENT FROM NADIR	<From TRPROPRS codelist>
If appropriate, denote the tumor as inevaluable.	<p>Check if the tumor was inevaluable.</p> <p>TRINEVAL TRSTAT = "NOT DONE" where TRTESTCD = "TUMSTATE"</p>	<input type="checkbox"/> Inevaluable	
Indicate the reason why the tumor was inevaluable.	<p>If the tumor was Inevaluable, what was the reason?</p> <p>TRREASND TRREASND where TRSTAT = "NOT DONE" and TRTESTCD = "TUMSTATE"</p>	<input type="radio"/> Lesion or Background Change that Prevents Evaluation <input type="radio"/> Focal Intervention <input type="radio"/> Poor Scan Quality <input type="radio"/> Insufficient Images/Anatomy <input type="radio"/> Inconsistent Modality <input type="radio"/> Site Error <input type="radio"/> Other	
For lymph node tumors only, denote whether the node is pathological or non-pathological.	<p>What was the lymph node state?</p> <p>TRLNSTAT TRORRES where TRTESTCD = "LNSTATE"</p>	<input type="radio"/> Pathological <input type="radio"/> Non-Pathological	

CDISC Therapeutic Area Data Standards User Guide for Lung Cancer v1.0 (Provisional)

Order Number	CDASH Variable Name	Question Text	Prompt	Case Report Form Completion Instructions	SDTMIG Target Variable	SDTMIG Target Mapping	Controlled Terminology CodeList Name	CRF Implementation Notes	Permissible Values	Pre-populated Value	Displayed Query	List Style	Input Type	Hidden
1	TUCAT	What is the category of the [tumor/lesion] identification?	Category	Record the Tumor Identification category, if not pre-printed on the CRF.	TUCAT		N/A	Sponsor-defined Controlled Terminology. This would most commonly be either a heading, or a pre-printed category value on the CRF and not a question to which the site would provide an answer. If a question is asked, the response would typically be a sponsor-defined codelist. If the form is laid out as a grid, then words such as "Category" can be included as the column header.	N/A	RESPONSE EVALUATION TUMOR	prompt	N/A	text	hidden
2	ONCRSCAT	What is the Response Criteria being used for this assessment?	Response Criteria	Indicate what Response Criteria are being used at this assessment.	N/A	N/A	(ONCRSCAT)	Since there are separate codelists used for categorizations of records about oncology response criteria (ONCRSCAT), this CDASH variable was created for use in Oncology trials to identify the response criteria being used in a study. While this field is not typically captured on a CRF, it should be displayed clearly on the CRF. Most often pre-defined, instructional text to orient the data entry staff to appropriate cancer response criteria. Collect if multiple types/versions are active in a single study/database . The codelist may be extended for other cancer response systems (e.g., IWG, IMWG, etc.).	RECIST 1.1 ; iRECIST	N/A	prompt	radio	text	visible
3	TUPLEYN	Was this an assessment on a previously identified new lesion?	Assessment on Previous New Lesion	Indicate whether this is an assessment of a previously identified new lesion.	N/A	N/A	(NY)	This is intended to be used as a data management tool to implement dynamic navigation to the questions related to the assessments of new lesions.	Yes; No	N/A	question text	radio	text	visible
4	TUYN	Were new tumors identified?	Any new tumors	Indicate whether or not new tumors were identified. If new tumors identified, list each new tumor and provide the requested information.	N/A	N/A	(NY)	This is intended to be used as a data management tool to verify that missing tumor evaluations are confirmed missing. If "Yes", a record is created in the SDTMIG TU domain for each tumor identified. Once new tumors have been identified, they are followed at all subsequent assessment visits.	Yes; No	N/A	question text	radio	text	visible
5	TUMIDENT_TUORRES	What type of new tumors are being identified as defined by the criteria being employed?	Tumor Type According to Criteria	Record or select which type of new tumor is being evaluated as defined by the criteria.	TUORRES; TUTEST; TUTESTCD	TUORRES where TUTESTCD = "TUMIDENT"	N/A	This field was captured on this CRF, and used for EDC navigation. The TULNKID is used to distinguish each new tumor identified. The TUCAT will indicate new lesions identified prior to RECIST PD, and New Lesion Identified after RECIST PD.	NEW TARGET TUMOR; NEW NON-TARGET TUMOR;	N/A	question text	radio	text	visible
6	TULNKID	What was the Tumor ID?	Tumor ID	Sponsor-specified	TULNKID	TULNKID and TRLNKID	N/A	This variable is used to provide a unique code for each identified tumor in	N/A	N/A	question text	N/A	text	visible

Order Number	CDASH Variable Name	Question Text	Prompt	Case Report Form Completion Instructions	SDTMIG Target Variable	SDTMIG Target Mapping	Controlled Terminology CodeList Name	CRF Implementation Notes	Permissible Values	Pre-populated Value	Displayed Query	List Style	Input Type	Hidden
								order to link records across related domains (TU and TR). TULNKID and TRLNKID are expected to be the same across datasets. The values of TULNKID are compound values that may carry the following information: an indication of the role (or assessor) providing the data records when it is someone other than the principal investigator; an indication of whether the data record is for a target, non-target, or new tumor; and an indication of whether the tumor has split or merged. Sponsors may develop their own conventions for identifying tumors.						
7	TULOC	What was the anatomical location of the tumor identified?	Location	Specify the general (anatomical) location of the tumor.	TULOC		(LOC)	When anatomical location is broken down and collected as distinct pieces of data that when combined provide the exact location information (e.g., laterality /directionality), then the additional anatomical location qualifiers should be used. The first (TULOC) should follow controlled terminology, which will enable consistency across sites. Laterality (TULAT) and Directionality (TUDIR) should also be available for entry if more explicit detail can be provided. A location-detail text field (TULOCDTL) is conditional for entry (i.e., can be left blank) and allows the study site to specify the lesion in its own terms or can be used to distinguish tumors within the same location if TULAT and/or TUDIR is not sufficient. Finally, Presentation Type is conditional for truly non-measurable lesions that are difficult to characterize with Location.	LUNG, LEFT UPPER LOBE; LUNG, RIGHT UPPER LOBE; LUNG, LEFT LOWER LOBE; LUNG, RIGHT LOWER LOBE; LUNG, LEFT MIDDLE LOBE; LUNG, RIGHT MIDDLE LOBE;	N/A	question text	radio	text	visible
8	TULAT	If applicable, what was the laterality of the anatomical location?	Laterality	Specify the laterality of the tumor.	TULAT		(LAT)	See TULOC	BILATERAL; RIGHT; LEFT;	N/A	question text	radio	text	visible
9	TUDIR	If applicable, what was the directionality of the anatomical location?	Directionality	Specify the directionality of the tumor.	TUDIR		(DIR)	See TULOC	ANTERIOR; POSTERIOR;	N/A	question text	radio	text	visible
10	TULOCDTL	If applicable, what is the additional detail	Location Detail	Describe additional detail on the exact location of the tumor so that it can be	SUPPTU.QVAL	SUPPTU.QVAL where QNAM = "TULOCDTL"	N/A	Use if TULOC and TULAT and/or TUDIR values cannot provide uniqueness from other tumor records.	N/A	N/A	question text	N/A	text	visible

CDISC Therapeutic Area Data Standards User Guide for Lung Cancer v1.0 (Provisional)

Order Number	CDASH Variable Name	Question Text	Prompt	Case Report Form Completion Instructions	SDTMIG Target Variable	SDTMIG Target Mapping	Controlled Terminology CodeList Name	CRF Implementation Notes	Permissible Values	Pre-populated Value	Displayed Query	List Style	Input Type	Hidden
		about the tumor location?		distinguished from other tumors in the same anatomical location.				TULOCCTL is not meant to replace TULOC, TULAT, and/or TUDIR or to serve as the free-text description field for TULOC (e.g., Location, Other). May also be useful if sponsor collects cancer antigens or tumor markers as Non-Target Lesions. See TULOC.						
11	TUPRTYP	What was the tumor presentation type of the non-measurable disease?	Tumor or Lesion Presentation Type	Specify the truly non-measurable lesion presentation type.	SUPPTU.QVAL where QNAM = "TUPRTYP"	(DSPRTYP)	Used for non-target tumors only.	Ascites; Effusion; Leptomeningeal Disease; Complex Cystic	N/A	question text	radio	text	visible	
12	TUCHANGE	Select if changes to tumor were identified.	Changes to Tumor Identified	Indicate whether this is a tumor that has split from a previous tumor, or is a tumor that has merged with another tumor.	TUORRES; TUTESTCD; TUTEST	If TUCHANGE = "Split", TUORRES = "TARGET" where TUTESTCD = "TUSPLIT"; If TUCHANGE = "Merged", TUORRES = "TARGET" where TUTESTCD = "TUMERGE"	(TUTEST)	Sponsors must consider how to identify both split and merged tumors in the fields TULNKID and TULOCCTL. Possible conventions for use in TULNKID are: T04.1 = the first "child" tumor split from the fourth target tumor T04.2 = the second "child" tumor split from the fourth target tumor, etc. T02/T03 = the tumor merged from the second and third target tumor. Or, picking one of the original tumors as the primary tumor, including the sum of the merged tumors in a single record. TULOCCTL should include sufficient free-text description of the split or merged tumors to permit unequivocal identification. See SDTM oncology examples for alternative methods for representing Split and Merge tumors.	Merged; Split	N/A	question text	radio	text	visible
13	TUMETHOD	What was the method of evaluation?	Method of Evaluation	Specify the method used to identify/evaluate the tumor.	TUMETHOD	TUMETHOD and TRMETHOD	(METHOD)	The METHOD codelist provides submission values using most commonly known/generally recognized terms. The values will represent the method generically, not the product of the method (e.g., photograph). Sponsors may customize or restrict the list of values per response criteria or protocol needs. At a minimum, the primary method of identification should be entered and is expected to be consistent throughout the study; recording secondary methods is at the discretion of the sponsor.	CT Scan; PET/CT Scan; PET/MRI Scan; Photography; Physical Examination; X-Ray	N/A	question text	radio	text	visible
14	TUDAT	What was the date of evaluation?	Procedure Date	Insert the date of the scan/image/examination (not the date on which it was read, or the visit date).	TUDTC	TUDTC and TRDTC	N/A	Insert the date of the scan/image/examination on which the evaluation was based (not the date on which it was read, or the visit date).	N/A	N/A	question text	N/A	date	visible

CDISC Therapeutic Area Data Standards User Guide for Lung Cancer v1.0 (Provisional)

Order Number	CDASH Variable Name	Question Text	Prompt	Case Report Form Completion Instructions	SDTMIG Target Variable	SDTMIG Target Mapping	Controlled Terminology CodeList Name	CRF Implementation Notes	Permissible Values	Pre-populated Value	Displayed Query	List Style	Input Type	Hidden
								Date should align with the primary method.						
15	TUEVAL	What was the role of the person performing the tumor evaluation?	Evaluator	Indicate who performed the assessment.	TUEVAL	TUEVAL and TREVAL	(EVAL)	Collect if multiple evaluators are used in the study (may be omitted if the investigator is always the evaluator); values should follow controlled terminology.	Independent Assessor; Investigator	N/A	question text	radio	text	visible
16	TUEVALID	What is the evaluator identifier?	Evaluator Identifier	Identify the evaluator providing this evaluation.	TUEVALID	TUEVALID and TREVAL	(MEDEVAL)	Collect if multiple evaluators with the same value of TUEVAL are used in the study; values should follow controlled terminology.	Radiologist 1; Radiologist 2; Oncologist	N/A	question text	radio	text	visible
17	LDIAM_TRORRES	What was the longest diameter of the tumor?	Longest Diameter	For non-nodal disease, record the longest diameter of the tumor.	TRORRES; TRTESTCD; TRTEST	TRORRES where TRTESTCD = "LDIAM"	N/A	When using iRESIST, new non-nodal Target lesions should have measurements.	N/A	N/A	question text	N/A	text	visible
18	LDIAM_TRORRESU	What were the units for the longest diameter?	Longest Diameter Unit	N/A	TRORRESU	TRORRESU where TRESTCD = "LDIAM"	(UNIT)	Usually, the unit of the test is pre-defined on the CRF.	N/A	mm	question text	N/A	text	visible
19	LDIAM_TRTOOSM_TRORRES	Check if the longest diameter was too small to measure.	Longest Diameter Too Small to Measure	Check if the longest diameter is too small to measure.	TRORRES; TRTESTCD; TRTEST	TRORRES = "TOO SMALL TO MEASURE" where TRTESTCD = "LDIAM"	(NY)	This field can be used to record that tumors are too small to measure. Note that with some assessment criteria (e.g., RECIST), a default value (e.g., 5mm) may be used in the calculation to determine response. As an alternative, the fact that a tumor is too small to measure can be recorded in TRREASND.	Diameter Too Small to Measure	N/A	question text	checkbox	text	visible
20	PDIAM_TRORRES	For lymph nodes, what was the short axis diameter?	Perpendicular Diameter	For lymph nodes, record the short axis measurement	TRORRES; TRTESTCD; TRTEST	TRORRES where TRTESTCD = "LPERP"	N/A	When using IRESIST, new nodal tumors lesions should have short axis measurements	N/A	N/A	question text	N/A	text	visible
21	PDIAM_TRORRESU	What were the units for the short axis diameter?	Perpendicular Diameter Unit	N/A	TRORRESU	TRORRESU where TRTESTCD = "LPERP"	(UNIT)	Usually, the unit of the test is pre-defined on the CRF.	N/A	mm	prompt	N/A	text	visible
22	PDIAM_TRTOOSM_TRORRES	Check if the short axis diameter was too small to measure.	Perpendicular Diameter Too Small to Measure	Check if the short axis tumor is too small to measure.	TRORRES; TRTESTCD; TRTEST	TRORRES = "TOO SMALL TO MEASURE" where TRTESTCD = "LPERP"	(NY)	This field can be used to record that tumors are too small to measure. Note that with some assessment criteria (e.g., RECIST), a default value (e.g., 5mm) may be used in the calculation to determine response. As an alternative, the fact that a tumor is too small to measure can be recorded in TRREASND.	Short Axis Diameter Too Small to Measure	N/A	question text	checkbox	text	visible
23	TUMSTATE_RECIST_TRORRES	What was the tumor state?	Tumor State	If new- non-target tumor, denote the tumor state as PRESENT. If followup-	TRORRES; TRTESTCD; TRTEST	TRORRES where TRTESTCD = "TUMSTATE"	(TRPROPRS)	When CRFs are designed for the initial new tumor identification and	PRESENT; ABSENT;	N/A	question text	radio	text	visible

CDISC Therapeutic Area Data Standards User Guide for Lung Cancer v1.0 (Provisional)

Order Number	CDASH Variable Name	Question Text	Prompt	Case Report Form Completion Instructions	SDTMIG Target Variable	SDTMIG Target Mapping	Controlled Terminology CodeList Name	CRF Implementation Notes	Permissible Values	Pre-populated Value	Displayed Query	List Style	Input Type	Hidden
				assessment, indicate the current tumor state.				subsequent assessments, the codelist may be subsetted as needed. New non-target lesions may not require any measurements and can be categorized as "present" when first identified. If a tumor is noted as inevaluable at a specific evaluation, this variable may be blank.	ENLARGEMENT FROM NADIR;					
24	TUMSTATE_IRECIST_TRORRES	What was the tumor state?	Tumor State	If new- non-target tumor, denote the tumor state as PRESENT. If followup-assessment, indicate the current tumor state	TRORRES; TRTESTCD; TRTEST	TRORRES where TRTESTCD = "TUMSTATE"	(TRPROPRS)	When CRFs are designed for the initial new tumor identification, and subsequent assessments, the codelist may be subsetted as needed. If a tumor is noted as inevaluable at a specific evaluation, this variable may be blank.	PRESENT; ABSENT; ENLARGEMENT FROM NADIR; FURTHER ENLARGEMENT FROM NADIR	N/A	question text	radio	text	visible
25	TRINEVAL	Check if the tumor was inevaluable.	Tumor Inevaluable?	If appropriate, denote the tumor as inevaluable.	TRSTAT	TRSTAT = "NOT DONE" where TRTESTCD = "TUMSTATE"	N/A	This is intended to be used as a data management tool to verify that inevaluable tumor evaluations are denoted at a specific evaluation. Inevaluable may also be collected as a No/Yes question based on sponsor preference.	Inevaluable	N/A	question text	checkbox	text	visible
26	TRREASND	If the tumor was Inevaluable, what was the reason?	If Tumor is inevaluable, Reason Not Done	Indicate the reason why the tumor was inevaluable.	TRREASND	TRREASND where TRSTAT = "NOT DONE" and TRTESTCD = "TUMSTATE"	N/A	The pre-specified terms are simply examples of REASND collected terms to encourage standardized terminology (as opposed to free-text). "Lesion or Background Change that Prevents Evaluation" makes it hard to measure the lesion and will include cavitation, fibrosis, necrosis; for example, a lung metastasis develops pneumonia around it, so the edges are concealed. "Poor Scan Quality" indicates that the full anatomy was scanned but could not be evaluated due to low quality (e.g., no/poor IV contrast or motion present). "Insufficient Images/Anatomy" indicates that the lesion anatomy is incomplete, crucial anatomy is out of field of view, or a key scan slice is not taken. "Inconsistent Modality" denotes a change in assessment/technique that prevents lesion evaluation (e.g., using a different machine, changes in the use of contrast). "Focal intervention" (e.g., focal radiation, ablation, excision) is selected if the lesion can no longer be evaluated for the effects of the trial therapy based on a concomitant procedure. For	Lesion or Background Change that Prevents Evaluation; Focal Intervention; Poor Scan Quality; Insufficient Images/Anatomy; Inconsistent Modality; Site Error; Other	N/A	question text	radio	text	visible

Order Number	CDASH Variable Name	Question Text	Prompt	Case Report Form Completion Instructions	SDTMIG Target Variable	SDTMIG Target Mapping	Controlled Terminology CodeList Name	CRF Implementation Notes	Permissible Values	Pre-populated Value	Displayed Query	List Style	Input Type	Hidden
								example, surgically removing a large tumor in a trial where the trial therapy is only systemic; the radiologist/oncologist can no longer make meaningful comparisons before/after surgery. The sponsor may elect to concatenate the response "Inevaluable" with the collected reason not done.						
27	TRLNSTAT	What was the lymph node state?	Lymph Node State	For lymph node tumors only, denote whether the node is pathological or non-pathological.	TRORRES; TRTESTCD; TRTEST	TRORRES where TRTESTCD = "LNSTATE"	N/A	Per RECIST 1.1, lymph nodes merit special mention because they are normal anatomical structures which may be visible by imaging even if not involved by tumor. Pathological vs. non-pathologic lymph nodes have different documentation expectations; refer to the RECIST 1.1 criteria.	Pathological; Non-Pathological	N/A	question text	radio	text	visible

This CRF was designed to collect information on tumor response in trials testing immunotherapeutics. These trials use RECIST 1.1 and iRECIST criteria to define endpoints. Sponsors may decide to (1) collect RECIST and iRECIST on separate CRFs or (2) collect RECIST and iRECIST on a single CRF using dynamic navigation.

Although not illustrated, the CRF layout assumes that dynamic navigation controls would be used to display the RECIST or iRECIST questions based on the category chosen.

The denormalized CDASH variable names used are only examples of CDASH variable names that can be used within a denormalized data structure. The variable names used were sponsor-defined.

<p>Subjects are followed using RECIST criteria until RECIST PD is observed. After a RECIST PD has been reported, subjects are followed using iRECIST.</p> <p>Indicate whether or not response was collected.</p> <p>If the response was not collected, indicate why.</p> <p>Indicate who performed the assessment.</p> <p>Identify the evaluator providing this evaluation.</p> <p>Indicate whether a new lesion was identified at this assessment based on RECIST 1.1 criteria.</p> <p>Indicate whether new lesion(s) was identified at this assessment based on iRECIST criteria. Note, do not consider new lesions that have previously been identified.</p> <p>Indicate the response assessment for target lesions using the RECIST 1.1 criteria.</p>	<p>What was the response criteria used to determine response at this assessment?</p> <p>RSCAT</p> <p>Was the response assessment performed?</p> <p>RSUPERF If "No", RSSTAT = "NOT DONE" where RSTESTCD = "OVRLRESP"</p> <p>Why was the response assessment not performed?</p> <p>RSREASND RSREASND where RSTESTCD = "OVRLRESP"</p> <p>Evaluator</p> <p>RSEVAL</p> <p>What is the evaluator identifier?</p> <p>RSEVALID</p> <p>Was a new lesion detected at this assessment?</p> <p>NLESIN_RECIST_RSORRES</p> <p>RSORRES where RSTESTCD = "NEWLIN" and RSCAT = "RECIST 1.1"</p> <p>Was a new lesion detected at this assessment?</p> <p>NLESIND_IRECIST_RSORRES</p> <p>RSORRES where RSTESTCD = "NEWLIND" and RSCAT = "IRECIST"</p> <p>What was the Target Response?</p> <p>TRGRESP_RECIST_RSORRES</p> <p>RSORRES where RSTESTCD = "TRGRESP" and RSCAT = "RECIST 1.1"</p>	<p><input type="radio"/> RECIST <input type="radio"/> iRECIST</p> <p><input type="radio"/> Yes <input type="radio"/> No</p> <p style="text-align: right;"><i><From NY codelist></i></p> <p><input type="radio"/> Not Imaged <input type="radio"/> Patient Refusal <input type="radio"/> Site Error <input type="radio"/> Other</p> <p><input type="radio"/> Independent Assessor <input type="radio"/> Investigator</p> <p style="text-align: right;"><i><From EVAL codelist></i></p> <p><input type="radio"/> Radiologist 1 <input type="radio"/> Radiologist 2 <input type="radio"/> Oncologist</p> <p style="text-align: right;"><i><From MEDEVAL codelist></i></p> <p><input type="radio"/> Yes <input type="radio"/> No</p> <p style="text-align: right;"><i><From NY codelist></i></p> <p><input type="radio"/> Yes <input type="radio"/> No</p> <p style="text-align: right;"><i><From NY codelist></i></p> <p><input type="radio"/> Complete Response (CR) <input type="radio"/> Partial Response (PR) <input type="radio"/> Stable Disease (SD) <input type="radio"/> Progressive Disease (PD) <input type="radio"/> Not Evaluable (NE) <input type="radio"/> Not Applicable</p>
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CDISC Therapeutic Area Data Standards User Guide for Lung Cancer v1.0 (Provisional)

Indicate the response assessment for target lesions using the iRECIST criteria.	<p>What was the Target Response?</p> <p>TRGRESP_IRECIST_RSORRES</p> <p>RSORRES where RSTESTCD = "TRGRESP" and RSCAT = "IRECIST"</p> <p><input type="radio"/> Complete Response (iCR) <input type="radio"/> Partial Response (iPR) <input type="radio"/> Stable Disease (iSD) <input type="radio"/> Unconfirmed Progressive Disease (iUPD) <input type="radio"/> Confirmed Progressive Disease (ICPD) <input type="radio"/> Not Evaluable (NE) <input type="radio"/> Not Applicable</p>
Insert the date of the procedure associated with target response.	<p>What was the date of procedure for the Target Response (e.g., scan date)?</p> <p>TRGRESP_RSDAT RSDTC</p>
Indicate the response assessment for non-target lesions using RECIST 1.1 criteria.	<p>What was the Non-Target Response?</p> <p>NTRGRESP_RECIST_RSORRES</p> <p>RSORRES where RSTESTCD = "NTRGRESP" and RSCAT = "RECIST 1.1"</p> <p><input type="radio"/> Complete Response (CR) <input type="radio"/> Non Complete Response/Non Progressive Disease (NON-CR/NON-PD) <input type="radio"/> Progressive Disease (PD) <input type="radio"/> Not Evaluable (NE) <input type="radio"/> Not Applicable</p>
Indicate the response assessment for non-target lesions using iRECIST criteria.	<p>What was the Non-Target Response?</p> <p>NTRGRESP_IRECIST_RSORRES</p> <p>RSORRES where RSTESTCD = "NTRGRESP" and RSCAT = "IRECIST"</p> <p><input type="radio"/> Complete Response (iCR) <input type="radio"/> Non Complete Response/Non Unconfirmed Progressive Disease (NON-iCR/NON-iUPD) <input type="radio"/> Unconfirmed Progressive Disease (iUPD) <input type="radio"/> Confirmed Progressive Disease (ICPD) <input type="radio"/> Not Evaluable (NE) <input type="radio"/> Not Applicable</p> <p style="text-align: right;"><i><From ONCRSR codelist></i></p>
Insert the date of the procedure associated with the non-target response.	<p>What was the date of procedure for the Non-Target Response (e.g., scan date)?</p> <p>NTRGRESP_RSDAT RSDTC</p>
Indicate whether new lesions (target or non-target) previously identified had a worsening, as defined by IRECIST.	<p>Was there a worsening in previously identified new lesions?</p> <p>NEWLWIND_IIECIST_RSORRES</p> <p>RSORRES where RSTESTCD = "NEWLWIND" and RSCAT = "IRECIST"</p> <p><input type="radio"/> Yes <input type="radio"/> No</p> <p style="text-align: right;"><i><From NY codelist></i></p>
Indicate the overall response assessment using RECIST 1.1 criteria.	<p>What was the overall response?</p> <p>OVRLRESP_RECIST_RSORRES</p> <p>RSORRES where RSTESTCD = "OVRLRESP" and RSCAT = "RECIST 1.1"</p> <p><input type="radio"/> Complete Response (CR) <input type="radio"/> Partial Response (PR) <input type="radio"/> Stable Disease (SD) <input type="radio"/> Non Complete Response/Non Progressive Disease (NON-CR/NON-PD) <input type="radio"/> Progressive Disease (PD) <input type="radio"/> Not Evaluable (NE)</p> <p style="text-align: right;"><i><From ONCRSR codelist></i></p>

Indicate the overall response assessment using iRECIST criteria.

What was the overall response?	<input type="radio"/> Complete Response (iCR) <input type="radio"/> Partial Response (iPR) <input type="radio"/> Stable Disease (iSD) <input type="radio"/> Non Complete Response/Non Progressive Disease (NON-iCR/NON-iUPD) <input type="radio"/> Unconfirmed Progressive Disease (iUPD) <input type="radio"/> Confirmed Progressive Disease (iCPD) <input type="radio"/> Not Evaluable (NE)
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<From ONCRSR codelist>

Record the date of the procedure associated with the overall response.

What was the date of procedure for the overall response (e.g., scan date)?	<input type="text"/>
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OVRLDAT_RSDAT

RSDTC

Indicate the best overall response assessment.

What was the best overall response?	<input type="radio"/> Complete Response (CR) <input type="radio"/> Partial Response (PR) <input type="radio"/> Stable Disease (SD) <input type="radio"/> Non Complete Response/Non Progressive Disease (NON-CR/NON-PD) <input type="radio"/> Progressive Disease (PD) <input type="radio"/> Not Evaluable (NE)
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<From ONCRSR codelist>

Indicate the best overall response assessment.

What was the best overall response?	<input type="radio"/> Complete Response (iCR) <input type="radio"/> Partial Response (iPR) <input type="radio"/> Stable Disease (iSD) <input type="radio"/> Non Complete Response/Non Progressive Disease (NON-iCR/NON-iUPD) <input type="radio"/> Unconfirmed Progressive Disease (iUPD) <input type="radio"/> Confirmed Progressive Disease (iCPD) <input type="radio"/> Not Evaluable (NE)
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<From ONCRSR codelist>

Insert the date of the procedure associated with the best overall response.

What was the date of procedure for the best overall response (e.g., scan date)?	<input type="text"/>
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BESTDAT_RSDAT

RSDTC

Indicate whether or not symptomatic deterioration is observed.

Did the patient experience symptomatic deterioration?	<input type="radio"/> Yes <input type="radio"/> No
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<From NY codelist>

Insert the date on which symptomatic deterioration was observed.

Symptomatic Deterioration Date	<input type="text"/>
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SYMPTDAT_RSDAT

RSDTC

Insert the name of the vendor performing the response assessments.

What was the vendor name?	<input type="text"/>
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RSNAM

CDISC Therapeutic Area Data Standards User Guide for Lung Cancer v1.0 (Provisional)

Order Number	CDASH Variable Name	Question Text	Prompt	Case Report Form Completion Instructions	SDTMIG Target Variable	SDTMIG Target Mapping	Controlled Terminology CodeList Name	CRF Implementation Notes	Permissible Values	Pre-populated Value	Displayed Query	List Style	Input Type	Hidden
1	RSCAT	What was the response criteria used to determine response at this assessment?	Response Category	Subjects are followed using RECIST criteria until RECIST PD is observed. After a RECIST PD has been reported, subjects are followed using iRECIST.	RSCAT	RSCAT		Collect if multiple types/versions are active in a single study/database; otherwise information should be distinguished somewhere on a form (table name, title, tab). The appropriate category must be associated with all responses when the SDTM-based datasets are created.	RECIST; iRECIST	N/A	question text	radio	text	visible
2	RSUPERF	Was the response assessment performed?	Response Assessment Status	Indicate whether or not response was collected.	RSSTAT	If "No", RSSTAT = "NOT DONE" where RSTESTCD = "OVRLRESP"	(NY)	This may be implemented for an entire response paradigm (i.e., RSTESTCD=OVRLRESP).	Yes; No	N/A	question text	radio	text	visible
3	RSREASND	Why was the response assessment not performed?	Reason Response Assessment Not Performed	If the response was not collected, indicate why.	RSREASND	RSREASND where RSTESTCD = "OVRLRESP"	N/A	The pre-specified terms are simply examples of REASND collected terms.	Not Imaged; Patient Refusal; Site Error; Other	N/A	question text	radio	text	visible
4	RSEVAL	What was the role of the person performing the response assessment?	Evaluator	Indicate who performed the assessment.	RSEVAL	RSEVAL	(EVAL)	EVAL codelist has more elements than included in this table, but the remainder are usually not be used in this context.	Independent Assessor; Investigator	N/A	prompt	radio	text	visible
5	RSEVALID	What is the evaluator identifier?	Evaluator Identifier	Identify the evaluator providing this evaluation.	RSEVALID	RSEVALID	(MEDEVAL)	When multiple assessors play the role identified in RSEVAL, values of RSEVALID will attribute a row of data to a particular assessor. MEDEVAL codelist has more elements than included in this table, but the remainder would not typically be used in this context.	Radiologist 1; Radiologist 2; Oncologist	N/A	question text	radio	text	visible
6	NLESIN_RECIST_RSORRES	Was a new lesion detected at this assessment?	New Lesion	Indicate whether a new lesion was identified at this assessment based on RECIST 1.1 criteria.	RSORRES; RSTEST; RSTESTCD	RSORRES where RSTESTCD = "NEWLIN" and RSCAT = "RECIST 1.1"	(NY)	NLESIND was considered a response-related category, similar to the other components of RECIST. This question is used to explain a RECIST response of PD, when the other response categories are non-PD.	Yes; No	N/A	question text	radio	text	visible
7	NLESIND_IRECIST_RSORRES	Was a new lesion detected at this assessment?	New Target Lesion	Indicate whether new lesion(s) was identified at this assessment based on iRECIST criteria. Note, do not consider new lesions that have previously been identified.	RSORRES; RSTEST; RSTESTCD	RSORRES where RSTESTCD = "NEWLIND" and RSCAT = "iRECIST"	(NY)	New Lesion Indicator = "Y" indicates that a new lesion was identified at this assessment. This indicator would be "N" if no new lesions were identified at this assessment. This does not consider whether other new lesions had been previously detected.	Yes; No	N/A	question text	radio	text	visible
8	TRGRESP_RECIST_RSORRES	What was the Target Response?	Target Response	Indicate the response assessment for	RSORRES; RSTEST; RSTESTCD	RSORRES where RSTESTCD =	N/A	Generally collected in the CRF if efficacy endpoint requires such specificity and supportive data are available in the source.	Complete Response (CR); Partial Response (PR); Stable Disease (SD); Progressive	N/A	question text	radio	text	visible

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				target lesions using the RECIST 1.1 criteria.		"TRGRESP" and RSCAT = "RECIST 1.1"			Disease (PD); Not Evaluable (NE); Not Applicable					
9	TRGRESP_IRECIST_RSORRES	What was the Target Response?	Target Response	Indicate the response assessment for target lesions using the iRECIST criteria.	RSORRES; RSTEST; RTESTCD	RSORRES where RTESTCD = "TRGRESP" and RSCAT = "IRECIST"	N/A	Generally collected in the CRF if efficacy endpoint requires such specificity and supportive data are available in the source.	Complete Response (iCR); Partial Response (iPR); Stable Disease (iSD); Unconfirmed Progressive Disease (iUPD); Confirmed Progressive Disease (iCPD); Not Evaluable (NE); Not Applicable	N/A	question text	radio	text	visible
10	TRGRESP_RSDAT	What was the date of procedure for the Target Response (e.g., scan date)?	Date of Procedure for Target Response (e.g., scan date)	Insert the date of the procedure associated with target response.	RSDTC	RSDTC	N/A	RSDAT is typically derived from the dates of scans/ images/physical exams, which may be performed on different dates. Sponsors should determine which convention to use for populating the date of the response assessment. Examples are: (1) Earliest date of any assessment contributing to the response assessment; (2) Most frequent date on which assessments are performed; (3) Latest date of any assessment if the response is beneficial (earliest date otherwise)	N/A	N/A	question text	N/A	date	visible
11	NTRGRESP_RECIST_RSORRES	What was the Non-Target Response?	Non-target Response	Indicate the response assessment for non-target lesions using RECIST 1.1 criteria.	RSORRES; RSTEST; RTESTCD	RSORRES where RTESTCD = "NTRGRESP" and RSCAT = "RECIST 1.1"	N/A	Generally collected in the CRF if efficacy endpoint requires such specificity and supportive data are available in the source. Patients with target plus non-target disease have a different allowable set of values than patients with non-target disease only. Refer to RECIST 1.1 criteria. Please note that Unequivocal PD is considered synonymous with PD and should be recorded accordingly.	Complete Response (CR); Non Complete Response/Non Progressive Disease (NON-CR/NON-PD); Progressive Disease (PD); Not Evaluable (NE); Not Applicable	N/A	question text	radio	text	visible
12	NTRGRESP_IRECIST_RSORRES	What was the Non-Target Response?	Non-target Response	Indicate the response assessment for non-target lesions using iRECIST criteria.	RSORRES; RSTEST; RTESTCD	RSORRES where RTESTCD = "NTRGRESP" and RSCAT = "IRECIST"	(ONCRSR)	Generally collected in the CRF if efficacy endpoint requires such specificity and supportive data are available in the source. Patients with target plus non-target disease have a different allowable set of values than patients with non-target disease only. Refer to iRECIST criteria.	Complete Response (iCR); Non Complete Response/Non Unconfirmed Progressive Disease (NON-iCR/NON-iUPD); Unconfirmed Progressive Disease (iUPD); Confirmed Progressive Disease (iCPD); Not Evaluable (NE); Not Applicable	N/A	question text	radio	text	visible
13	NTRGRESP_RSDAT	What was the date of procedure for the Non-Target Response (e.g., scan date)?	Non-target Response Date (e.g., scan date)	Insert the date of the procedure associated with the non-target response.	RSDTC		N/A	RSDAT is typically derived from the dates of scans/ images/physical exams, which may be performed on different dates. Sponsors should determine which convention to use for populating the date of the response assessment. Examples are: (1) Earliest date of any assessment contributing to the response assessment; (2) Most frequent date on which assessments	N/A	N/A	question text	radio	date	visible

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								are performed; (3) Latest date of any assessment if the response is beneficial (earliest date otherwise)						
14	NEWLWIND_IIECIST_RSORRES	Was there a worsening in previously identified new lesions?	New Non-Target Lesion Worsening	Indicate whether new lesions (target or non-target) previously identified had a worsening, as defined by IRECIST.	RSORRES; RSTEST; RTESTCD	RSORRES where RTESTCD = "NEWLWIND" and RSCAT = "IRECIST"	(NY)	This indicator is used to indicate worsening in either new target lesions or new non-target lesions. New target lesions worsening would be based on the sum of the diameters of the new lesions, whereas worsening of new non-target lesions shows enlargements or further enlargements. The data in TR indicates what kind of worsening was seen.	Yes; No	N/A	question text	radio	text	visible
15	OVRLRESP_RECIST_RSORRES	What was the overall response?	Overall Response	Indicate the overall response assessment using RECIST 1.1 criteria.	RSORRES; RTESTCD; RTEST	RSORRES where RTESTCD = "OVRLRESP" and RSCAT = "RECIST 1.1"	(ONCRSR)	Collected at the appropriate visit in which assessments are performed. Non-CR/Non-PD is limited value for patients with non-target disease only, as including this population is protocol-specific.	Complete Response (CR); Partial Response (PR); Stable Disease (SD); Non Complete Response/Non Progressive Disease (NON-CR/NON-PD); Progressive Disease (PD); Not Evaluable (NE)	N/A	question text	radio	text	visible
16	OVRLRESP_IRECIST_RSORRES	What was the overall response?	Overall Response	Indicate the overall response assessment using iRECIST criteria.	RSORRES; RTESTCD; RTEST	RSORRES where RTESTCD = "OVRLRESP" and RSCAT = "IRECIST"	(ONCRSR)	Collected at the appropriate visit in which assessments are performed. Non-CR/Non-PD is limited value for patients with non-target disease only, as including this population is protocol-specific.	Complete Response (iCR); Partial Response (iPR); Stable Disease (iSD); Non Complete Response/Non Progressive Disease (NON-iCR/NON-iUPD); Unconfirmed Progressive Disease (iUPD); Confirmed Progressive Disease (iCPD); Not Evaluable (NE)	N/A	question text	radio	text	visible
17	OVRLDAT_RSDAT	What was the date of procedure for the overall response (e.g., scan date)?	Overall Response Date (e.g., scan date)	Record the date of the procedure associated with the overall response.	RSDTC	RSDTC	N/A	RSDAT is typically derived from the dates of scans/ images/physical exams, which may be performed on different dates. Sponsors should determine which convention to use for populating the date of the response assessment. Examples are: (1) Earliest date of any assessment contributing to the response assessment; (2) Most frequent date on which assessments are performed; (3) Latest date of any assessment if the response is beneficial (earliest date otherwise)	N/A	N/A	question text	radio	date	visible
18	BESTRESP_RECIST_RSORRES	What was the best overall response?	Best Overall Response	Indicate the best overall response assessment.	RSORRES; RSTEST; RTESTCD	RSORRES where RTESTCD = "BESTRESP" and RSCAT = "RECIST 1.1"	(ONCRSR)	This question is meant to represent independent evaluation that is collected in a CRF. In these circumstances, this question could appear on a separate form (i.e., completed one time, rather than visit-dependent). This result is most typically derived (and therefore not collected in the CRF), but in cases of third-party data providers or unique radiology agreements, independent evaluation of best overall response may be recorded in the CRF. Determined once all the data for the patient is known.	Complete Response (CR); Partial Response (PR); Stable Disease (SD); Non Complete Response/Non Progressive Disease (NON-CR/NON-PD); Progressive Disease (PD); Not Evaluable (NE)	N/A	question text	radio	text	visible

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Order Number	CDASH Variable Name	Question Text	Prompt	Case Report Form Completion Instructions	SDTMIG Target Variable	SDTMIG Target Mapping	Controlled Terminology CodeList Name	CRF Implementation Notes	Permissible Values	Pre-populated Value	Displayed Query	List Style	Input Type	Hidden
19	BESTRESP_IRECIST_RSORRES	What was the best overall response?	Best Overall Response	Indicate the best overall response assessment.	RSORRES; RSTEST; RSTESTCD	RSORRES where RSTESTCD = "BESTRESP" AND RSCAT = "IRECIST"	(ONCRSR)	This question is meant to represent independent evaluation that is collected in a CRF. In these circumstances, this question could appear on a separate form (i.e., completed one time, rather than visit-dependent). This result is most typically derived (and therefore not collected in the CRF), but in cases of third-party data providers or unique radiology agreements, independent evaluation of best overall response may be recorded in the CRF. Determined once all the data for the patient is known.	Complete Response (iCR); Partial Response (iPR); Stable Disease (iSD); Non Complete Response/Non Progressive Disease (NON-iCR/NON-iUPD); Unconfirmed Progressive Disease (iUPD); Confirmed Progressive Disease (iCPD); Not Evaluable (NE)	N/A	question text	radio	text	visible
20	BESTDAT_RSDAT	What was the date of procedure for the best overall response (e.g., scan date)?	Best Overall Response Date (e.g., scan date)	Insert the date of the procedure associated with the best overall response.	RSDTC	RSDTC	N/A	RSDAT is typically derived from the dates of scans/ images/physical exams, which may be performed on different dates. Sponsors should determine which convention to use for populating the date of the response assessment. Examples are: (1) Earliest date of any assessment contributing to the response assessment; (2) Most frequent date on which assessments are performed; (3) Latest date of any assessment if the response is beneficial (earliest date otherwise)	N/A	N/A	question text	N/A	date	visible
21	SYMPTDTR_RSORRES	Did the patient experience symptomatic deterioration?	Symptomatic Deterioration	Indicate whether or not symptomatic deterioration is observed.	RSORRES; RSTEST; RSTESTCD	RSORRES where RSTESTCD = "SYMPTDTR"	(NY)	Collect for non-objective progression in the symptoms of the disease in accordance with the efficacy parameters; recommend to collect Symptomatic Deterioration on the Response CRF but maybe collected on a separate Clinical Assessment, Symptomatic Disease, or Disease Symptom Status eCRF to include a detailed description as text (i.e., increased shortness of breath, increased weakness, worsening of performance status) or link to the associated AEs.	Yes; No	N/A	question text	radio	text	visible
22	SYMPTDAT_RSDAT	What was the date of symptomatic deterioration?	Symptomatic Deterioration Date	Insert the date on which symptomatic deterioration was observed.	RSDTC	RSDTC	N/A	Date associated with the non-objective progression in the symptoms of the disease; may be the start date of associated AE(s)	N/A	N/A	prompt	N/A	date	visible
23	RSNAM	What was the vendor name?	Vendor Name	Insert the name of the vendor performing the response assessments.	RSNAM	RSNAM	N/A	Do not collect if "Investigator" is the only source of response data. If the data come from a single external source, this maybe noted in the protocol or vendor specifications rather than collected.	N/A	N/A	question text	N/A	text	visible

Example 2

This is an example of the representation of iRECIST tumor data in the appropriate domains. The sponsor also adjudicated the tumor data. This adjudicate data is not shown, but --EVAL was populated with "INVESTIGATOR". If only investigator evaluations were performed in the study, TUEVAL may be removed.

In this trial, the sponsor requested that subjects have a complete evaluation to determine any sites of metastatic disease at screening prior to enrollment. The investigator then identified what tumors were to be evaluated for tumor response.

Because baseline sites of disease were represented by the sponsor in TU (following the example presented in Section 3.3, [Disease Characteristics](#)), the sponsor decided it was necessary to explicitly introduce categories to distinguish baseline sites of disease and tumor lesions used for assessment of tumor response. Although TUCAT previously had not been included in the TU domain for cancer studies, TUCAT was used to distinguish the tumors/lesions used for tumor evaluations and the sites of disease that were collected at trial entry.

Tumors to be followed to evaluate response were identified at baseline using RECIST 1.1 criteria. Once RECIST 1.1 PD was observed, the subjects were followed using iRECIST criteria. --LNKGRP has been used to organize the individual lesion assessments, where A(n) is used to represent the assessments (e.g., A2, A3). TRLNKID is used to link the assessments to the identified tumor in TU. No new lesions/tumors were identified for this subject during the study.

Rows 1-5: Show whether there is any metastatic disease in that site. The DTC was the assessment date. A row is included for each site of disease evaluated.

Rows 6-9: Show the target tumors that were identified at study entry and followed during the study for the evaluation of tumor response. TUCAT is used to indicate that these tumors are used for the study response evaluations.

Row 10: Shows the non-target tumor identified at study entry. Note that TUPRTYP was used to describe that the non-target lesion was a pleural effusion.

Row	STUDYID	DOMAIN	USUBJID	TUSEQ	TUREFID	TULNKID	TUTESTCD	TUTEST	TUCAT	TURORES	TUSTRESC	TULOC	TULAT	TUMETHOD	TUEVAL	EPOCH	VISITNUM	VISIT	TUDTC	TUDY	TUPRTYP
1	LC007	TU	40070	1	IMG-001		METIND	Metastatic Tumor Site Indicator	BASELINE DISEASE SITE	Y	Y	LIVER		CT SCAN	INVESTIGATOR	SCREEN	1	SCREEN	2010-01-01	1	
2	LC007	TU	40070	2	IMG-002		METIND	Metastatic Tumor Site Indicator	BASELINE DISEASE SITE	N	N	BRAIN		MRI	INVESTIGATOR	SCREEN	1	SCREEN	2010-01-01	1	
3	LC007	TU	40070	3	IMG-003		METIND	Metastatic Tumor Site Indicator	BASELINE DISEASE SITE	N	N	BONE		SCINTIGRAPHY	INVESTIGATOR	SCREEN	1	SCREEN	2010-01-01	1	
4	LC007	TU	40070	4	IMG 001		METIND	Metastatic Tumor Site Indicator	BASELINE DISEASE SITE	Y	Y	ADRENAL GLAND		CT SCAN	INVESTIGATOR	SCREEN	1	SCREEN	2010-01-01	1	
5	LC007	TU	40070	5	IMG 001		METIND	Metastatic Tumor Site Indicator	BASELINE DISEASE SITE	Y	Y	LUNG		CT SCAN	INVESTIGATOR	SCREEN	1	SCREEN	2010-01-01	1	
6	LUCA007	TU	40070	6	IMG-00001	T01	TUMIDENT	Tumor Identification	RESPONSE EVALUATION TUMOR	TARGET	TARGET	LIVER		CT SCAN	INVESTIGATOR	SCREEN	1	SCREEN	2010-01-01	1	
7	LUCA007	TU	40070	7	IMG-00001	T02	TUMIDENT	Tumor Identification	RESPONSE EVALUATION TUMOR	TARGET	TARGET	LIVER		CT SCAN	INVESTIGATOR	SCREEN	1	SCREEN	2010-01-01	1	
8	LUCA007	TU	40070	8	IMG-00001	T03	TUMIDENT	Tumor Identification	RESPONSE EVALUATION TUMOR	TARGET	TARGET	ADRENAL GLAND		CT SCAN	INVESTIGATOR	SCREEN	1	SCREEN	2010-01-01	1	
9	LUCA007	TU	40070	9	IMG-00001	T04	TUMIDENT	Tumor Identification	RESPONSE EVALUATION TUMOR	TARGET	TARGET	LUNG	RIGHT	CT SCAN	INVESTIGATOR	SCREEN	1	SCREEN	2010-01-01	1	
10	LUCA007	TU	40070	10	IMG-00001	NT01	TUMIDENT	Tumor Identification	RESPONSE EVALUATION TUMOR	NON-TARGET	NON-TARGET	PLEURAL CAVITY		CT SCAN	INVESTIGATOR	SCREEN	1	SCREEN	2010-01-01	1	EFFUSION

TU NSV Metadata

Variable	Label	Type	Role	Origin
TUPRTYP	Tumor Presentation Type	text	Non-Standard Record Qualifier	CRF

TR is used to report the assessments of each lesion. RECIST 1.1 and iRECIST use essentially the same tumor assessments for target and non-target lesions, but these are evaluated differently when the response is determined. In addition, iRECIST follows new lesions differently than RECIST 1.1; thus, a study that uses iRECIST may have assessments in TR that would not be needed for a study that uses only RECIST. The assessments of non-target tumors are similar whether RECIST 1.1 or iRECIST is used, although the non-target tumor state uses a different set of responses for RECIST 1.1 and iRECIST. TR does not include the name of the criteria used in TRCAT to avoid unnecessary duplication of results for each lesion. In this example, the investigator continued the subject on treatment after RECIST 1.1 PD was observed at assessment 2 (A2). At the third assessment (A3), iRECIST progression was confirmed, and no further assessments of the subject's tumors were performed.

Rows 1-12: Show the evaluation of the tumors at assessment 1 and assessment 2. These evaluations were performed as described by RECIST 1.1. Note that the Tumor State result is based on RECIST 1.1.

Rows 13-18: Show the evaluation of the subject at assessment 3. Note that the Tumor State result is based on iRECIST. Problem executing proxy for macro 'expand'. Check the log.RS is used to represent tumor responses. Because tumor response is determined based on the criteria being used, RSCAT is populated with the appropriate response criteria name. In the following example, all response assessments for a subject prior to the RECIST PD used RECIST 1.1 criteria. At the time of the RECIST PD, the sponsor started the collection of tumor response according to iRECIST. Hence, at the assessment where RECIST 1.1 PD was observed, both the RECIST tumor response and the iRECIST tumor response are provided. Although this sponsor collected both RECIST 1.1 and iRECIST at the assessment where RECIST PD was observed (A2), some sponsors may elect to "derive" the iRECIST response at this RECIST PD assessment. The iRECIST tumor response at the first iRECIST assessment will always be identical to RECIST 1.1, except that the terminology used to report progression will be iUPD. All subsequent tumor response assessments were performed using iRECIST only.

Row	STUDYID	DOMAIN	USUBJID	TRSEQ	TRGRPID	TRREFID	TRLNKID	TRLNKGRP	TRTESTCD	TRTEST	TRRRES	TRRRESU	TRSTRESC	TRSTRESN	TRSTRESU	TRMETHOD	TREVAL	VISITNUM	VISIT	EPOCH	TRDTG	TRDY
1	LUCA007	TR	40070	1	TARGET	IMG-00001	T01	A1	LDIAM	Longest Diameter	24	mm	24	24	mm	CT SCAN	INVESTIGATOR	1	SCREEN	SCREEN	2010-01-01	1
2	LUCA007	TR	40070	2	TARGET	IMG-00001	T02	A1	LDIAM	Longest Diameter	21	mm	21	21	mm	CT SCAN	INVESTIGATOR	1	SCREEN	SCREEN	2010-01-01	1
3	LUCA007	TR	40070	3	TARGET	IMG-00001	T03	A1	LDIAM	Longest Diameter	32	mm	32	32	mm	CT SCAN	INVESTIGATOR	1	SCREEN	SCREEN	2010-01-01	1
4	LUCA007	TR	40070	4	TARGET	IMG-00001	T04	A1	LDIAM	Longest Diameter	23	mm	23	23	mm	CT SCAN	INVESTIGATOR	1	SCREEN	SCREEN	2010-01-01	1
5	LUCA007	TR	40070	5	NON-TARGET	IMG-00001	NT01	A1	TUMSTATE	Tumor State	PRESENT		PRESENT			CT SCAN	INVESTIGATOR	1	SCREEN	SCREEN	2010-01-01	1
6	LUCA007	TR	40070	6	TARGET	IMG-00001		A1	SUMDIAM	Sum of Diameter	100	mm	100	100	mm	CT SCAN	INVESTIGATOR	1	SCREEN	SCREEN	2010-01-01	1
7	LUCA007	TR	40070	7	TARGET	IMG-00002	T01	A2	LDIAM	Longest Diameter	45	mm	45	45	mm	CT SCAN	INVESTIGATOR	2	WEEK 6	TREATMENT	2010-02-15	45
8	LUCA007	TR	40070	8	TARGET	IMG-00002	T02	A2	LDIAM	Longest Diameter	30	mm	30	30	mm	CT SCAN	INVESTIGATOR	2	WEEK 6	TREATMENT	2010-02-15	45
9	LUCA007	TR	40070	9	TARGET	IMG-00002	T03	A2	LDIAM	Longest Diameter	32	mm	32	32	mm	CT SCAN	INVESTIGATOR	2	WEEK 6	TREATMENT	2010-02-15	45
10	LUCA007	TR	40070	10	TARGET	IMG-00002	T04	A2	LDIAM	Longest Diameter	23	mm	23	23	mm	CT SCAN	INVESTIGATOR	2	WEEK 6	TREATMENT	2010-02-15	45
11	LUCA007	TR	40070	11	NON-TARGET	IMG-00002	NT01	A2	TUMSTATE	Tumor State	PRESENT		PRESENT			CT SCAN	INVESTIGATOR	2	WEEK 6	TREATMENT	2010-02-15	45
12	LUCA007	TR	40070	12	TARGET	IMG-00002		A2	SUMDIAM	Sum of Diameter	130	mm	130	130	mm	CT SCAN	INVESTIGATOR	2	WEEK 6	TREATMENT	2010-02-15	45
13	LUCA007	TR	40070	13	TARGET	IMG-00003	T01	A3	LDIAM	Longest Diameter	50	mm	50	50	mm	CT SCAN	INVESTIGATOR	3	WEEK 12	TREATMENT	2010-03-31	89
14	LUCA007	TR	40070	14	TARGET	IMG-00003	T02	A3	LDIAM	Longest Diameter	33	mm	33	33	mm	CT SCAN	INVESTIGATOR	3	WEEK 12	TREATMENT	2010-03-31	89
15	LUCA007	TR	40070	15	TARGET	IMG-00003	T03	A3	LDIAM	Longest Diameter	32	mm	32	32	mm	CT SCAN	INVESTIGATOR	3	WEEK 12	TREATMENT	2010-03-31	89
16	LUCA007	TR	40070	16	TARGET	IMG-00003	T04	A3	LDIAM	Longest Diameter	23	mm	23	23	mm	CT SCAN	INVESTIGATOR	3	WEEK 12	TREATMENT	2010-03-31	89
17	LUCA007	TR	40070	17	NON-TARGET	IMG-00003	NT01	A3	TUMSTATE	Tumor State	PRESENT		PRESENT			CT SCAN	INVESTIGATOR	3	WEEK 12	TREATMENT	2010-03-31	89
18	LUCA007	TR	40070	18	TARGET			A3	SUMDIAM	Sum of Diameter	138	mm	138	138	mm	CT SCAN	INVESTIGATOR	3	WEEK 12	TREATMENT	2010-03-31	89

RS is used to represent tumor responses. Because tumor response is determined based on the criteria being used, RSCAT is populated with the appropriate response criteria name. In the following example, all response assessments for a subject prior to the RECIST PD used RECIST 1.1 criteria. At the time of the RECIST PD, the sponsor started the collection of tumor response according to iRECIST. Hence, at the assessment where RECIST 1.1 PD was observed, both the RECIST tumor response and the iRECIST tumor response are provided. Although this sponsor collected both RECIST 1.1 and iRECIST at the assessment where RECIST PD was observed (A2), some sponsors may elect to "derive" the iRECIST response at this RECIST PD assessment. The iRECIST tumor response at the first iRECIST assessment will always be identical to RECIST 1.1, except that the terminology used to report progression will be iUPD. All subsequent tumor response assessments were performed using iRECIST only.

In this example, RS was modeled to include the New Lesion Indicator test for both RECIST 1.1 and iRECIST, and the New Lesion Worsening Indicator test for iRECIST. In previous Oncology TAUGs, these indicator tests were not included in RS, but have been added after further consideration. It is important to note that in RECIST 1.1 any new lesion is considered progression and no further tumor evaluations are performed. However, in iRECIST tumor evaluations are performed after the appearance of a new lesion until confirmed progression is reported.

- Rows 1-4:** Show the responses associated with assessment 2 based on RECIST criteria. Because this subject had an overall response of PD, the subject would continue in the study, but be followed using the iRECIST criteria. Note that the New Lesion Indicator test was included in RS to facilitate the review of the data. This allows the reviewer to easily determine what criteria was used to evaluate a subject as having an overall response of PD.
- Rows 5-8:** Show the responses associated with assessment 2 based on iRECIST criteria, wherein the subject's overall response is iUPD. At this assessment, only the New Lesions Indicator Test is represented; at this assessment there would by definition be no new prior lesions to worsen.
- Rows 9-10:** Show Target and Non-Target response for assessment 2. At assessment 3, only the iRECIST response is provided because the subject had RECIST PD at assessment 2.
- Rows 11-12:** Show the New Lesion Indicator and New Lesion Worsening Indicator results. The New Lesion Indicator test represents the presence of any new lesion that was not present at prior assessments. The New Lesion Worsening Indicator represents the state of new lesions that were identified at previous assessments. The New Lesion Worsening Indicator is used to represent worsening in either new target or new non-target lesions. Worsening in New Target Lesion is based on the sum of the diameters of new target lesions, whereas worsening in new non-target lesions is based on enlargements or further enlargements. The data in TR provide support for the Indicator test values. Both the New Lesion Indicator and the New Lesion Worsening Indicator tests would be included in all subsequent assessments.
- Row 13:** Shows the overall response associated with assessment 3.

Row	STUDYID	DOMAIN	USUBJID	RSSEQ	RSLNKGRP	RSTESTCD	RSTEST	RSCAT	RSORRES	RSSTRESC	RSEVAL	VISITNUM	VISIT	EPOCH	RSDTC	RSDY
1	LUCA007	RS	40070	1		TRGRESP	Target Response	RECIST 1.1	PD	PD	INVESTIGATOR	2	WEEK 6	TREATMENT	2010-02-15	45
2	LUCA007	RS	40070	2		NTRGRESP	Non-Target Response	RECIST 1.1	NON-CR/NON-PD	NON-CR/NON-PD	INVESTIGATOR	2	WEEK 6	TREATMENT	2010-02-15	45
3	LUCA007	RS	40070	3		NEWLIND	New Lesion Indicator	RECIST 1.1	N	N	INVESTIGATOR	2	WEEK 6	TREATMENT	2010-02-15	45
4	LUCA007	RS	40070	4	A2	OVRLRESP	Overall Response	RECIST 1.1	PD	PD	INVESTIGATOR	2	WEEK 6	TREATMENT	2010-02-15	45
5	LUCA007	RS	40070	5		TRGRESP	Target Response	iRECIST	iUPD	iUPD	INVESTIGATOR	2	WEEK 6	TREATMENT	2010-02-15	45
6	LUCA007	RS	40070	6		NTRGRESP	Non-Target Response	iRECIST	NON-iCR/NON-iUPD	NON-iCR/NON-iUPD	INVESTIGATOR	2	WEEK 6	TREATMENT	2010-02-15	45
7	LUCA007	RS	40070	7		NEWLIND	New Lesion Indicator	iRECIST	N	N	INVESTIGATOR	2	WEEK 6	TREATMENT	2010-02-15	45
8	LUCA007	RS	40070	8	A2	OVRLRESP	Overall Response	iRECIST	iUPD	iUPD	INVESTIGATOR	2	WEEK 6	TREATMENT	2010-02-15	45
9	LUCA007	RS	40070	9		TRGRESP	Target Response	iRECIST	iCPD	iCPD	INVESTIGATOR	3	WEEK 12	TREATMENT	2010-03-31	89
10	LUCA007	RS	40070	10		NTRGRESP	Non-Target Response	iRECIST	NON-iCR/NON-iUPD	NON-iCR/NON-iUPD	INVESTIGATOR	3	WEEK 12	TREATMENT	2010-03-31	89
11	LUCA007	RS	40070	11		NEWLIND	New Lesion Indicator	iRECIST	N	N	INVESTIGATOR	3	WEEK 12	TREATMENT	2010-03-31	89
12	LUCA007	RS	40070	12		NEWLWIND	New Lesion Worsening Indicator	iRECIST	N	N	INVESTIGATOR	3	WEEK 12	TREATMENT	2010-03-31	89
13	LUCA007	RS	40070	13	A3	OVRLRESP	Overall Response	iRECIST	iCPD	iCPD	INVESTIGATOR	3	WEEK 12	TREATMENT	2010-03-31	89

This is an example of the dataset relationships between the SDTM domains.

Rows 1-2: Show the link between the identified tumor in TU and the tumor results in TR.

Rows 3-4: Show the link between the specific procedures in PR and their associated assessments in TU.

Rows 5-6: Show the link between the specific procedures in PR and their associated assessments in TR.

Rows 7-8: Show the link between the tumor results in TR at each assessment with the overall response at each assessment in RS.

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	LUCA007	TU		TULNKID		ONE	1
2	LUCA007	TR		TRLNKID		MANY	1
3	LUCA007	PR		PRREFID		ONE	2
4	LUCA007	TU		TUREFID		MANY	2
5	LUCA007	PR		PRREFID		ONE	3
6	LUCA007	TR		TRREFID		MANY	3
7	LUCA007	TR		TRLNKGRP		MANY	4
8	LUCA007	RS		RSLNKGRP		ONE	4

4.3 Questionnaires, Ratings, and Scales

Lung cancer studies may use measures which assess symptoms or a particular symptom, such as functional status (i.e., ability to perform functions of daily living) or health-related quality of life.

Questionnaires, Ratings, and Scales (QRS) are maintained as stand-alone guides on the CDISC website at <https://www.cdisc.org/foundational/qrs>. The following table lists assessments that are being pursued as potential supplements as part of the development work for TAUG-LuCa. Supplements may or may not be finalized at the time of publication of this user guide, and depend on copyright approval where applicable. CDISC cannot produce supplements for copyrighted measures without the express permission of the copyright holder.

Sponsors should refer to the QRS link above if a measure of interest is not included in the table, as it may have been developed for another therapeutic area, and new measures are implemented on an ongoing basis by the CDISC QRS Terminology and Standards Development subteams. See CDISC COP 001 at <https://www.cdisc.org/about/bylaws> for details on implementing or requesting development of standards for SDTM-based submissions.

Full Name and Abbreviation	Copyright Permission Status	Supplement Status
AJCC TNM Staging System 7th Edition (AJCC V7)	Granted	Supplement in progress
Eastern Cooperative Oncology Group Performance Status (ECOG)	Public domain	Done
European Organisation for the Research and Treatment of Cancer Quality of Life Questionnaire - Core 30 Version 3.0 (EORTC QLQ-C30 Version 3.0)	Granted	Terminology in progress
European Organisation for the Research and Treatment of Cancer Quality of Life Questionnaire - Palliative Care Version 1.0 (EORTC QLQ-C15-PAL Version 1.0)	Granted	Terminology in progress

Full Name and Abbreviation	Copyright Permission Status	Supplement Status
European Organisation for the Research and Treatment of Cancer Quality of Life Questionnaire - Lung Cancer (EORTC QLQ-LC13)	Granted	Terminology in progress
European Quality of Life Five Dimension Three Level Scale (EQ-5D-3L)	Granted	Done
European Quality of Life Five Dimension Five Level Scale (EQ-5D-5L)	Granted	Done
Functional Assessment of Chronic Illness Therapy (FACIT)-Dyspnea 10 Item Short Form (FACIT-DYSPNEA SF)	Granted	Supplement in progress
Functional Assessment of Chronic Illness Therapy (FACIT)-Dyspnea Scale 33 Item Bank (FACIT-DYSPNEA LF)	Granted	Supplement in progress
International Association for the Study of Lung Cancer (IASLC) Staging System	Requested	
Karnofsky Performance Status Scale (KPS Scale)	Public domain	Done
Lung Cancer Symptom Scale (LCSS)	To be requested	
Non-Small Cell Lung Cancer Symptom Assessment Questionnaire (NSCLC-SAQ)	Granted	Supplement in progress
Veterans Administration Lung Study Group (VALG)	Public domain	Supplement in progress

4.4 Oxygen Use

Oxygen therapy is a treatment to relieve the shortness of breath that can be caused by lung cancer. A typical oxygen prescription will include how much is needed, and how often. Different types of breathing devices are used (e.g., nasal cannula, oxygen mask). If information on the devices used to administer oxygen therapy is collected, this information would be represented as described in the SDTM Implementation Guide for Medical Devices (SDTMIG-MD).

Example 1

This is an example of a study where information on oxygen use was collected, including the amount and schedule of oxygen administered as well as the place of administration. Oxygen therapy may have been administered continuously or may have been administered only during the night.

- Row 1:** Shows the subject was receiving nocturnal oxygen therapy at home (represented using the NSV CMSETTNG). The therapy started after the start of the study and was ongoing at the end of the study. CMDOSFREQ was used to represent continuous use during the night. CMDOSRGM was used to represent the regimen (nightly).
- Row 2:** Shows the subject received oxygen therapy continuously at home (represented using the NSV CMSETTNG). The therapy started before (CMSTRTPPT) the date of collection (CMSTTPT) and was ongoing at the end of the study.

Row	STUDYID	DOMAIN	USUBJID	CMSEQ	CMTRT	CMDECOD	CMINDC	CMDOSE	CMDOSU	CMDOSFRQ	CMDOSRGM	CMSTDTC	CMSTRTP	CMSTTP	CMENRF	CMSETTNG
1	LC008	CM	5001	1	Oxygen Therapy	Oxygen	LUNG CANCER	2	L/min	CONTINUOUS	NIGHTLY	2014-06-14			ONGOING	HOME
2	LC008	CM	5501	1	Oxygen Therapy	Oxygen	LUNG CANCER	4	L/min	CONTINUOUS			BEFORE	2016-06-01	ONGOING	HOME

CM NSV Metadata

Variable	Label	Type	Role	Origin
CMSETTNG	Setting of Event, Intervention, Finding	text	Non-Standard Record Qualifier	CRF

4.5 Treatment of Pleural Effusions

Patients with malignancy in the pleural cavity often have recurring pleural effusions. Pleurodesis may be performed to prevent recurrence of these pleural effusions. Pleurodesis is used to get the 2 layers of the pleural lung lining to stick together, thus obliterating the space between the layers so that fluid (water, blood, or pus) cannot build up between them. Pleurodesis is commonly accomplished by draining the pleural fluid, when present, followed by either mechanical abrasion or an installation of a chemical irritant in the pleural space. Three chemical agents are often used: doxycycline, bleomycin, and talc.[\[21,22\]](#) Picibanil (Streptococcus pyogenes), named OK-432, and doxorubicin have shown efficacy for controlling malignant pleural effusions caused by lung cancer.[\[23\]](#)

A pleurectomy is a surgical procedure that removes part of the pleura. It may be performed to treat pleural effusions, although it is more commonly performed as a palliative treatment for malignant mesothelioma.[\[24\]](#)

Example 1

This is an example of a study collecting information on treatments for pleural effusions. In this study, data on any procedures used to treat pleural effusions were collected, whether prior to the study or during the study.

Row 1: Subject 5001 had a pleurodesis before the start of the study. The exact date of the procedure was not included in the investigator's records.

Row 2: Subject 5501 had a pleurectomy during the study due to recurrent pleural effusions.

Row	STUDYID	DOMAIN	USUBJID	PRSEQ	PRTTRT	PRDECOD	PRINDC	PRSTDTC	PRSTRF
1	LC008	PR	5001	1	Pleurodesis	Pleurodesis	PLEURAL EFFUSION		BEFORE
2	LC008	PR	5501	2	Pleurectomy	Pleurectomy	PLEURAL EFFUSION	2016-08-23	

5 Analysis Data

Lung cancer studies which are based on solid tumors have endpoints similar to those described in the TAUG-Breast Cancer v1.0 (<https://www.cdisc.org/standards/therapeutic-areas/breast-cancer>) and TAUG-Prostate Cancer v1.0 (<https://www.cdisc.org/standards/therapeutic-areas/prostate-cancer>). Descriptions of these endpoints and methodologies for creating the ADaM datasets to support these analyses will not be repeated in the TAUG-Lung Cancer v1.0.

Disease characteristics used for prognostic stratification or covariates may be included in the ADaM Subject-level Analysis Dataset (ADSL). Examples of disease characteristics that might be included in ADSL include mutation, gene expression, and protein expression as determined by immunohistochemistry (IHC).

5.1 ADSL

The ADSL contains subject characteristics and covariates that are important for analyses. The ADSL dataset contains 1 record per subject, regardless of the type of clinical trial design. Which variables to include in a trial-specific ADSL depends on the trial design and data collection, patient population, and primary objectives of the trial. Some of the basic variables included in most ADSL datasets are sex, race, age, age groups, ethnicity, geographic region, population flags, and treatment information. Also typically included are dates and status flags associated with important disposition events (e.g. trial completion status, completion of therapy, the reason for discontinuation, death), and important dates (e.g., date of randomization, date/time of first and last dose of treatment, date of treatment discontinuation). Prior treatment history and baseline measures related to weight, body mass index, and other indication-specific measurements are also often included in ADSL.

Example 1

An example ADSL dataset and variable metadata are provided below.

ADSL Dataset Metadata

Dataset	Description	Class	Structure	Purpose	Keys	Location	Documentation
ADSL	Subject-Level Analysis Dataset	SUBJECT LEVEL ANALYSIS DATASET	One record per subject	Analysis	STUDYID, USUBJID	ADSL.xpt	ADSL.SAS/SAP

ADSL Variable Metadata

Variable Name	Variable Label	type	Codelist/Controlled Terms	Source/Derivation/Comment
STUDYID	Study Identifier	text		DM.STUDYID
USUBJID	Unique Subject Identifier	text		DM.USUBJID
SUBJID	Subject Identifier for the Study	text		DM.SUBJID
SITEID	Study Site Identifier	text		DM.SITEID
AGE	Age	integer		DM.AGE
AGEU	Age Units	text	YEARS	DM.AGEU

Variable Name	Variable Label	type	Codelist/Controlled Terms	Source/Derivation/Comment
SEX	Sex	text	M,F	DM.SEX
RACE	Race	text		DM.RACE
SAFFL	Safety Population Flag	text	Y,N	Y if TRTSDT is not null, otherwise N
EFFFL	Efficacy Population Flag	text	Y,N	Y if the subject has at least one post-baseline response assessment
ARM	Description of Planned Arm	text		DM.ARM
TRT01P	Planned Treatment for Period 01	text		DM.ARM
TRTSDT	Date of First Exposure to Treatment	date		DM.RFXSTDTC
TRTEDT	Date of Last Exposure to Treatment	date		DM.RFXENDTC
EOSSTT	End of Study Status	text		Looking at DS.EPOCH="FOLLOW-UP": COMPLETED is DS.DSDECOD="COMPLETED", else DISCONTINUED if DS.DSDECOD is not missing, otherwise "ONGOING"
EOSDT	End of Study Date	date		Looking at DS.EPOCH="FOLLOW-UP": DS.DSSTDTC
DCSREAS	Reason for Discontinuation from Study	text		Looking at DS.EPOCH="FOLLOW-UP": DS.DSDECOD where DS.DSDECOD not equal "COMPLETED"
EOTSTT	End of Treatment Status	text		Looking at DS.EPOCH="TREATMENT": COMPLETED is DS.DSDECOD="COMPLETED", else "DISCONTINUED" if DS.DSDECOD is not missing, otherwise "ONGOING"
DCTREAS	Reason for Discontinuation of Treatment	text		Looking at DS.EPOCH="TREATMENT": DS.DSDECOD where DS.DSDECOD not equal "COMPLETED"
RANDDT	Date of Randomization	date		DS.DSSTDTC where DS.DSDECOD="RANDOMIZED"

The following is an example of a generic ADSL dataset.

STUDYID	USUBJID	SUBJID	SITEID	AGE	AGEU	SEX	RACE	SAFFL	EFFFL	ARM	TRT01P	TRTSDT	TRTEDT	EOSSTT	EOSDT	DCSREAS	EOTSTT	DCTREAS	RANDDT
LUCA007	40070	070	40	64	YEARS	M	WHITE	Y	Y	Drug A	Drug A	2017-04-12	2017-08-15	DISCONTINUED	2017-08-31	LACK OF EFFICACY	COMPLETED		2017-04-10
LUCA007	40071	071	40	58	YEARS	M	WHITE	Y	Y	Drug B	Drug B	2017-05-02	2018-01-15	COMPLETED	2018-06-09		COMPLETED		2017-04-29
LUCA007	41072	072	41	71	YEARS	F	ASIAN	Y	Y	Drug B	Drug B	2017-06-30	2017-07-25	DISCONTINUED	2017-07-28	LOST TO FOLLOW UP	DISCONTINUED	ADVERSE EVENT	2017-06-29
LUCA007	41073	073	41	50	YEARS	M	WHITE	Y	Y	Drug A	Drug A	2017-07-18	2018-05-31	COMPLETED	2018-07-12		COMPLETED		2017-07-14

5.2 Tumor Data Overview Dataset

Reviewers of tumor evaluation data collected in clinical trials often find it helpful to review tumor measurements and tumor responses together.

Example 1

This is an example of a dataset created by a sponsor to aid a reviewer in visualizing tumor evaluation data represented in the SDTM TU, TR, and RS domains. The example ADVIEW dataset shown is relatively simple; more complex situations may require revisions to this approach. The metadata specification table describes what data from these 3 SDTM domains were included in the dataset. A sponsor could include other data as needed (e.g., TUREFID, TRSTRESU).

The variable names in the metadata specification table include both ADSL variables and the original SDTM variable names. This dataset would be considered an ADAM OTHER, because it does not follow any of the other defined ADaM data structures. However, because the dataset did follow ADaM fundamental principles—clear and unambiguous metadata, traceability (not shown), and so on—the prefix for the example dataset is AD. Had the dataset *not* followed ADaM principles, the dataset name may have been named AXVIEW—in which case the class would have been left blank. The naming convention for SDTM variables was used to provide context to the data location in the source datasets. A description of the data context is provided in the Description column. Note that other naming conventions could be considered to give more meaningful variable names and labels, rather than using the standard SDTM domain variable names.

ADVIEW Dataset Metadata

Dataset	Description	Class	Structure	Purpose	Keys	Location	Documentation
ADVIEW	Response Data Details Dataset	ADAM OTHER	One record per subject per evaluator per visit per assessment	Analysis	STUDYID, USUBJID, --EVAL, VISIT, --LNKID, --TEST	ADVIEW.xpt	ADVIEW.SAS

ADVIEW Metadata Specifications

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Source/Derivation	Comment
STUDYID	Study Identifier	text		ADSL.STUDYID	
USUBJID	Unique Subject Identifier	text		ADSL.USUBJID	
EFFFL	Efficacy Population Flag	text	Y, N	ADSL.EFFFL	
TRT01P	Planned Treatment for Period 01	text	TREAT A; TREAT B	ADSL.TRT01P	Set to DM.ARM
TRTSDT	Date of First Exposure to Treatment	text		ADSL.TRTSDT	
TRTEDT	Date of Last Exposure to Treatment	text		ADSL.TRTEDT	
TUEVAL	Evaluator	text	(EVAL)	TU.TUEVAL	TUEVAL was used in the join with TU with TR. If only one evaluator was used in a trial, this variable may not be used.

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Source/Derivation	Comment
TREVAL	Evaluator	text	(EVAL)	TR.TREVAL	TREVAL was used in the join with TR with RS. If only one evaluator was used in a trial, this variable may not be used.
RSEVAL	Evaluator	text	(EVAL)	RS.RSEVAL	TREVAL was used in the join with TR with RS. If only one evaluator was used in a trial, this variable may not be used.
VISITNUM (TR,RS)	Visit Number	integer		TR.VISITNUM; RS.VISITNUM	The value of VISITNUM was the value from the source in either the TR or the RS domain.
TRLNKGRP	Record Grouping	text		TR.TULNKGRP	This column indicates the assessment number associated with each record. TRLNKGRP was populated onto all the tumor measurement records. These --LNKGRP variables associated the records with tumor assessment results with those with tumor response results. This relationship was defined in the RELREC dataset included in the iRECIST example.
RSLNKGRP	Record Grouping	text		RS.TRLNKGRP	This column indicates the assessment number associated with each record. RSLNKGRP was populated onto all the Response assessments, unlike in the RS dataset where the RSLNKGRP was only populated on the record for overall response. These --LNKGRP variables associated the records with tumor assessment results with those with tumor response results. This relationship was defined in the RELREC dataset included in the iRECIST example.
TULNKID	Tumor ID	text		TU.TULNKID	TULNKID and TRLNKID were primary keys used in the join between TU and TR. This relationship was defined in the RELREC dataset included in the iRECIST example.
TRLNKID	Tumor ID	text		TR.TRLNKID	TULNKID and TRLNKID were primary keys used in the join between TU and TR. This relationship was defined in the RELREC dataset included in the iRECIST example.
TUSTRESC	Type of Tumor	text		TU.TUSTRESC	Each type of tumor (e.g., TARGET) identified in TUSTRESC was joined to the associated tumor measurements reported in TR using TULINKID and TRLINKID.
TULOC	Tumor Location	text	(LOC)	TU.TULOC	The location of the tumor identified in TULOC was joined to the tumor measurements in TR using TULINKID and TRLINKID.
TRTEST	Type of Tumor Measurement	text		TR.TRTEST	Rows were created for each tumor and each measurement type (e.g., longest diameter) in TR.
TRSTRESC	Tumor Measurement Result	text		TR.TRSTRESC	The tumor result measurement as represented in TRSTRESC. The unit of the measurement result may be added to the view. In this example, the units were not shown.
RSCAT	Response Criteria	text		RS.RSCAT	The variable RSCAT was included in the rows added for each type of response assessment (e.g., Target, Non-Target) to indicate what criteria were used to determine the response (e.g., RECIST, iRECIST).
RSTEST	Type of Response Assessment	text		RS.RSTEST	Rows were added for each type of response assessment (e.g., Target, Non-Target) performed for each criteria used.
RSSTRESC	Response Result	text		RS.RSSTREC	The tumor response evaluation as represented in RSTRESC.
TRDTC	Date of Assessment	text		TR.TRDTC	TRDTC was the date of the scan/image/physical exam used for the tumor assessment. TRDTC does not represent the date that the image was read, nor does it represent the VISIT date.
RSDTC	Date of Assessment	text		RS.RSDTC	RSDTC was the date of the tumor response assessment. Sponsors typically provide specific directions to investigators on how to populate this date.
TRDY	Study Day	integer		TR.TRDY	TRDY was the study day of the scan/image/physical exam used for the tumor assessment, measured as integer days.

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Source/Derivation	Comment
RSDY	Study Day	integer		RS.RSDY	RSDY was the study day of the assessment, measured as integer days.

This example ADVIEW dataset was created by a sponsor; it is based on the SDTM TU, TR, and RS domains used in Section 4.2, [Disease Response and Tumor Assessments](#), Example 2.

- Rows 1-6:** Show the tumor measurements reported in TR at visit 1 with the tumors/lesion identification information from TU joined onto these TR records using TULNKID, and TRLNKID. The information from TU includes TUSTRESC, which is the tumor classification type, and TULOC, which is the location of that tumor reported in TU. Note that the records in TR corresponding to the derived sum of the longest diameter have no join with the TU domain; these records are simply added and placed in sort order using VISIT. TRLNKGRP and RSLNKGRP indicate this was the information for assessment 1.
- Rows 7-12:** Show the tumor measurements reported in TR at visit 2 with the tumors/lesion identification information from TU joined onto these TR records using TULNKID, and TRLNKID. The information from TU includes TUSTRESC, which is the tumor classification type, and TULOC, which is the location of that tumor reported in TU. Note that the records in TR corresponding to the derived sum of the longest diameter have no join with the TU domain; these records are simply added and placed in sort order using VISIT. TRLNKGRP and RSLNKGRP indicate this was the information for assessment 2.
- Rows 13-16:** Show the tumor responses reported in RS at visit 2 using RECIST criteria. These records are simply added and placed in sort order using VISIT. To facilitate review, the TRLNKGRP/RSLNKGRP value "A2" (assessment 2) was populated onto all the Response assessments, unlike in the RS dataset where the RSLNKGRP is only populated on the record for overall response.
- Rows 17-20:** Show the tumor responses reported in RS at visit 2 using iRECIST criteria. These records are simply added and placed in sort order using VISIT. To facilitate review, the TRLNKGRP/RSLNKGRP value "A2" (assessment 2) was populated onto all the Response assessments, unlike in the RS domain where the RSLNKGRP is only populated on the record for overall response.
- Rows 21-26:** Show the tumor measurements reported in TR at visit 3 (with the tumors/lesion identified information from TU merged onto these TR records using TULNKID and TRLNKID. The information from TU includes TUSTRESC, which is the tumor classification type, and TULOC, which is the location of that tumor reported in TU. Note that the records in TR corresponding to the derived sum of the longest diameter have no join with the TU domain; these records are simply added and placed in sort order using VISIT. TRLNKGRP and RSLNKGRP indicate this was the information for assessment 3
- Rows 27-31:** Show the tumor response reported in RS at visit 3 using iRECIST criteria. These records are simply added and placed in sort order using VISIT. To facilitate review, in the column TRLNKGRP /RSLNKGRP, the value of "A3" (assessment 3) was populated onto all the Response assessments, unlike in the RS domain where the RSLNKGRP is only populated on the record for overall response.

CDISC Therapeutic Area Data Standards User Guide for Lung Cancer v1.0 (Provisional)

Row	STUDYID	USUBJID	EFFFL	TRT01P	TRTSDT	TRTEDT	TUEVAL	TREVAL	RSEVAL	VISITNUM (TR,RS)	TRLNKGRP	RSLNKGRP	TULNKID	TRLNKID	TUSTRESC	TULOC	TRTEST	TRSTRESC	RSCAT	RSTEST	RSSTRESC	TRDTC	RSDTC	TRDY	RSDY
1	LUCA007	40070	Y	TREAT A	2017-04-12	2017-08-15	INVESTIGATOR	INVESTIGATOR		1	A1		T01	T01	TARGET	LIVER	Longest Diameter	24				2010-01-01		1	
2	LUCA007	40070	Y	TREAT A	2017-04-12	2017-08-15	INVESTIGATOR	INVESTIGATOR		1	A1		T02	T02	TARGET	LIVER	Longest Diameter	21				2010-01-01		1	
3	LUCA007	40070	Y	TREAT A	2017-04-12	2017-08-15	INVESTIGATOR	INVESTIGATOR		1	A1		T03	T03	TARGET	ADRENAL GLAND	Longest Diameter	32				2010-01-01		1	
4	LUCA007	40070	Y	TREAT A	2017-04-12	2017-08-15	INVESTIGATOR	INVESTIGATOR		1	A1		T04	T04	TARGET	LUNG	Longest Diameter	23				2010-01-01		1	
5	LUCA007	40070	Y	TREAT A	2017-04-12	2017-08-15	INVESTIGATOR	INVESTIGATOR		1	A1		NT01	NT01	NON-TARGET	PLEURAL CAVITY	Tumor State	PRESENT				2010-01-01		1	
6	LUCA007	40070	Y	TREAT A	2017-04-12	2017-08-15	INVESTIGATOR	INVESTIGATOR		1	A1				TARGET		Sum of Diameter	100				2010-01-01		1	
7	LUCA007	40070	Y	TREAT A	2017-04-12	2017-08-15	INVESTIGATOR	INVESTIGATOR		2	A2		T01	T01	TARGET	LIVER	Longest Diameter	45				2010-02-15		45	
8	LUCA007	40070	Y	TREAT A	2017-04-12	2017-08-15	INVESTIGATOR	INVESTIGATOR		2	A2		T02	T02	TARGET	LIVER	Longest Diameter	30				2010-02-15		45	
9	LUCA007	40070	Y	TREAT A	2017-04-12	2017-08-15	INVESTIGATOR	INVESTIGATOR		2	A2		T03	T03	TARGET	ADRENAL GLAND	Longest Diameter	32				2010-02-15		45	
10	LUCA007	40070	Y	TREAT A	2017-04-12	2017-08-15	INVESTIGATOR	INVESTIGATOR		2	A2		T04	T04	TARGET	LUNG	Longest Diameter	23				2010-02-15		45	
11	LUCA007	40070	Y	TREAT A	2017-04-12	2017-08-15	INVESTIGATOR	INVESTIGATOR		2	A2		NT01	NT01	NON-TARGET	PLEURAL CAVITY	Tumor State	PRESENT WITHOUT UNEQUIVOCAL PROGRESSION				2010-02-15		45	
12	LUCA007	40070	Y	TREAT A	2017-04-12	2017-08-15	INVESTIGATOR	INVESTIGATOR		2	A2				TARGET		Sum of Diameter	130				2010-02-15		45	
13	LUCA007	40070	Y	TREAT A	2017-04-12	2017-08-15		INVESTIGATOR		2		A2							RECIST	Target Response	PD	2010-02-15		45	
14	LUCA007	40070	Y	TREAT A	2017-04-12	2017-08-15		INVESTIGATOR		2		A2							RECIST	Non-target Response	NON-CR/NON-UPD	2010-02-15		45	
15	LUCA007	40070	Y	TREAT A	2017-04-12	2017-08-15		INVESTIGATOR		2		A2							RECIST	New Lesion Indicator	N	2010-02-15		45	
16	LUCA007	40070	Y	TREAT A	2017-04-12	2017-08-15		INVESTIGATOR		2		A2							RECIST	Overall Response	PD	2010-02-15		45	
17	LUCA007	40070	Y	TREAT A	2017-04-12	2017-08-15		INVESTIGATOR		2		A2							iRECIST	Target Response	iUPD	2010-02-15		45	
18	LUCA007	40070	Y	TREAT A	2017-04-12	2017-08-15		INVESTIGATOR		2		A2							iRECIST	Non-target Response	NON-ICR/NON-iUPD	2010-02-15		45	
19	LUCA007	40070	Y	TREAT A	2017-04-12	2017-08-15		INVESTIGATOR		2		A2							iRECIST	New Lesion Indicator	N	2010-02-15		45	
20	LUCA007	40070	Y	TREAT A	2017-04-12	2017-08-15		INVESTIGATOR		2		A2							iRECIST	Overall Response	iUPD	2010-02-15		45	
21	LUCA007	40070	Y	TREAT A	2017-04-12	2017-08-15		INVESTIGATOR		3	A3		T01		TARGET	LIVER	Longest Diameter	50				2010-03-31		89	
22	LUCA007	40070	Y	TREAT A	2017-04-12	2017-08-15		INVESTIGATOR		3	A3		T02		TARGET	LIVER	Longest Diameter	33				2010-03-31		89	
23	LUCA007	40070	Y	TREAT A	2017-04-12	2017-08-15		INVESTIGATOR		3	A3		T03		TARGET	ADRENAL GLAND	Longest Diameter	32				2010-03-31		89	
24	LUCA007	40070	Y	TREAT A	2017-04-12	2017-08-15		INVESTIGATOR		3	A3		T04		TARGET	LUNG	Longest Diameter	23				2010-03-31		89	
25	LUCA007	40070	Y	TREAT A	2017-04-12	2017-08-15		INVESTIGATOR		3	A3		NT01		NON-TARGET	PLEURAL CAVITY	Tumor State	PRESENT - NO ENLARGEMENT FROM NADIR				2010-03-31		89	
26	LUCA007	40070	Y	TREAT A	2017-04-12	2017-08-15		INVESTIGATOR		3	A3				TARGET		Sum of Diameter	138				2010-03-31		89	
27	LUCA007	40070	Y	TREAT A	2017-04-12	2017-08-15		INVESTIGATOR		3		A3							iRECIST	Target Response	iCPD	2010-03-31		89	
28	LUCA007	40070	Y	TREAT A	2017-04-12	2017-08-15		INVESTIGATOR		3		A3							iRECIST	Non-target Response	NON-ICR/NON-iUPD	2010-03-31		89	
29	LUCA007	40070	Y	TREAT A	2017-04-12	2017-08-15		INVESTIGATOR		3		A3							iRECIST	New Lesion Indicator	N	2010-03-31		89	
30	LUCA007	40070	Y	TREAT A	2017-04-12	2017-08-15		INVESTIGATOR		3		A3							iRECIST	New Lesion Worsening Indicator	N	2010-03-31		89	
31	LUCA007	40070	Y	TREAT A	2017-04-12	2017-08-15		INVESTIGATOR		3		A3							iRECIST	Overall Response	iCPD	2010-03-31		89	

6 Appendices

Appendix A: Lung Cancer Standards Development Team

Name	Institution/Organization
Amy Palmer, Team Lead	CDISC
Alana St. Clair, Team Lead	CDISC
Dana Booth	CDISC
Carl Dmuchowski	Astellas
Nate Freimark	The Griesser Group
Chris Kaiser	Eli Lilly
Elizabeth Langevin	Takeda
Bess LeRoy	CDISC
Kathleen Mellars	CDISC
Erin Muhlbradt	NCI EVS
David Neubauer	Syneos Health
Anh Nguyen	Abbvie
Diane Wold	CDISC

Appendix B: Glossary and Abbreviations

aCRF	Annotated CRF
ADaM	Analysis Data Model
ADaMIG	ADaM Implementation Guide
ADSL	ADaM Subject Level Analysis Dataset
AJCC	American Joint Committee on Cancer
AMA	American Medical Association
Biomedical concept	A high-level building block of clinical research and/or healthcare information that encapsulates lower level implementation details like variables and terminologies.
CDASH	Clinical Data Acquisition Standards Harmonization Project
CDISC	Clinical Data Interchange Standards Consortium
CEA	Carcinoembryonic antigen
CEP	Chromosome enumeration probe
CFAST	Coalition for Accelerating Standards and Therapies
Collected	“Collected” refers to information that is recorded and/or transmitted to the sponsor. This includes data entered by the site on CRFs/eCRFs as well as vendor data such as core lab data. This term is a synonym for “captured.”
Controlled terminology	A finite set of values that represent the only allowed values for a data item. These values may be codes, text, or numeric. A codelist is one type of controlled terminology.
CRF	Case report form (sometimes called a "case record form"). A printed, optical, or electronic document designed to record all required information to be reported to the sponsor for each trial subject.
CT	Computed tomography (scan)
DNA	Deoxyribonucleic acid
Domain	A collection of observations with a topic-specific commonality about a subject.
eCRF	Electronic CRF
ED	Extensive Disease (stage)
EDC	Electronic data capture
EGFR	Epidermal growth factor receptor
FISH	Fluorescent in situ hybridization
FNA	Fine-needle aspiration
Foundational standards	Used to refer to the suite of CDISC standards that describe the clinical study protocol (Protocol), design (Study Design), data collection (CDASH), laboratory work (Lab), analysis (ADaM), and data tabulation (SDTM and SEND). See http://www.cdisc.org/ for more information on each of these clinical data standards.
GCN	Gene copy number
GMDN	Global Medical Device Nomenclature
HGF	Hepatocyte growth factor
IASLC	International Association for the Study of Lung Cancer
IHC	Immunohistochemistry

LD	Limited Disease (stage)
MedDRA	Medical Dictionary for Regulatory Activities: A global standard medical terminology designed to supersede other terminologies (e.g., COSTART, ICD9) used in the medical product development process.
MET	Mesenchymal-epithelial transition
MRI	Magnetic resonance imaging
NCI EVS	National Cancer Institute (NCI) Enterprise Vocabulary Services
NIH	National Institutes of Health
NSCLC	Non-small cell lung cancer
NSE	Neuron-specific enolase
NSV	Non-standard variable
Patient	A recipient of medical treatment
PCR	Polymerase chain reaction
PET	Positron emission tomography (scan)
PRO	Patient-reported outcome
ProGRP	Pro-gastrin-releasing peptide precursor
RECIST/iRECIST	Response Evaluation Criteria In Solid Tumors: Guidelines for Response Criteria for use in trials testing immunotherapeutics
ROS1	Receptor tyrosine kinase (encoded by the gene ROS1)
RT-PCR	RT-PCR (Reverse transcription polymerase chain reaction)
SCLC	Small cell lung cancer
SDS	Submission data standards; also the name of the team that maintains the SDTM and SDTMIG
SDTM	Study Data Tabulation Model
SDTMIG	SDTM Implementation Guide (for Human Clinical Trials)
SHARE	Shared Health and Clinical Research Electronic Library. CDISC's metadata repository.
Subject	A participant in a study
TAUG	Therapeutic Area Data Standards User Guide
TKI	Tyrosine kinase inhibitor
UICC	Union for International Cancer Control
VALG	Veterans Administration Lung Study Group
VATS	Video-assisted thoracic surgery

Appendix C: Non-Standard Variables

The following table lists the non-standard variables used in this document, and gives their parent domain and variable-level metadata.

Parent Domain	Variable	Label	SAS Data Type	XML Data Type	Codelist/Controlled Terms ^a	Role	Description	Notes
BE	--SPEC	Specimen Type	Char	text	(SPECTYPE)	Non-Standard Record Qualifier		Controlled Terminology for the --SPEC variable in Findings domains may be used.
CM	--SETTING	Setting of Event, Intervention, Finding	Char	text	(SETTING)	Non-Standard Record Qualifier	The environment/setting where the event, intervention, or finding occurred.	Can use the SETTING (Environmental Setting) codelist
TU	--LOCDTL	Location Details	Char	text	N/A	Non-Standard Record Qualifier	Further Detail used to describe the exact anatomical location	
PR	--LOC1	Location of Procedure 1	Char	text	(LOC)	Non-Standard Record Qualifier	Location relevant to the intervention.	Used when multiple locations are relevant.
PR	--LOC2	Location of Procedure 2	Char	text	(LOC)	Non-Standard Record Qualifier	Location relevant to the intervention.	Used when multiple locations are relevant.
PF	--RUNDTA	Run Date	Char	date		Non-Standard Timing Variable	The actual run date of the assay	
MI	--ABCLON	Antibody Clone	Char	text		Non-Standard Record Qualifier	The antibody clone used in the assay.	Indicates the specific antibody clone used for the test.
MI	--VARINT	Protein or Mutation Variant	Char	text		Non-Standard Record Qualifier	The specific protein variant or mutation being assessed.	
TU	--PRTYP	Tumor or Lesion Presentation Type	Char	text		Non-Standard Record Qualifier		

^aParentheses indicates CDISC/NCI codelist.

Appendix D: References

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