

Manual for the Completion of CDISC Aligned NCI Standard Case Report Form (CRF) Modules

Introduction

In 2006, members of the National Cancer Institute's Center for Biomedical Informatics and Information Technology (NCI CBIIT) in conjunction with the cancer Data Standards Registry and Repository (caDSR) user community initiated a Case Report Form (CRF) harmonization activity. CRFs submitted from the community were reviewed and inventoried. The Harmonization group then reviewed all questions on the CRF and partitioned them into four categories:

- **Mandatory** – A data collection variable that must be on the CRF (e.g., a regulatory requirement (if applicable)).
- **Conditional** – A data collection variable that must be collected on the CRF for specific cases that may be dictated by local or sponsor defined business rules.
- **Optional** – A data collection variable that is available for use if needed. There is no regulatory or business requirement for inclusion of this element on the CRF; if the design and scientific questions posed in the study dictate the need to collect this type of data; this is the element to include on the CRF.
- **Non-harmonized** – A data collection variable that is, by consensus, to primarily belong to a different CRF module or is not belonging to any defined module.

A template form with modules that contain questions or variables representing data to be collected and a companion electronic CRF instruction manual was developed. These CRF modules were vetted and adopted by the caDSR stakeholder community as metadata standards.

Since the original CRFs and manuals were adopted, the Food & Drug Administration (FDA) published guidelines for submission of clinical trial study data using the Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTM) for Investigational New Drug (IND) trials starting after December 2017. In response, NCI CBIIT has aligned the NCI Standard CRF modules with the CDISC data collection standard, Clinical Data Acquisition Standards Harmonization (CDASH) where data is expected to be submitted to FDA in SDTM format.

The instruction manual is a set of directions to guide data collection in each module template. Specific implementation instructions are not present; various groups may wish to implement the contents of a module in a variety of software applications.

The instructions include the field name, description or definition of each field, and any special formatting notes that apply to entries – such as the inclusion of full dates, use of values from a choice list only, etc. Finally, each question (or data item) is noted as Mandatory (m), Conditional (c), or Optional (o).

NCI Standard irRECIST CDISC Aligned NCI Standard Template Module Definitions

Mapping to the CDASH:

This NCI Standard Template Form maps to the following domains in the CDASHIG v2.0 and CDASHIG v2.1 metadata tables:

- TU – Tumor/Lesion Identification (v2.1)
- TR – Tumor/Lesion Results (v2.1)
- RS – Disease Response and Clin Classification (v2.1)
- CO – Comments (v2.0)

Mapping to the SDTM:

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

- TU – Tumor/Lesion Identification (v3.3)
- TR – Tumor/Lesion Results (v3.3)
- RS – Disease Response and Clin Classification (v3.3)
- CO – Comments (v3.3)

NCI Standard irRECIST CDISC Aligned NCI Standard Template Module Template Instructions

Field Descriptions and Instructions

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Target Lesion Present Ind-2 (m) 58514 TGT_LES_PRES_IND-2	a yes/no indicator to ask whether any target (or indicator) lesions are present at baseline or follow-up evaluation, including absence of target lesions by surgical removal. Not for FDA submission	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Non-Target Lesion Indicator (m) 6941894 TUNTRGNY	An indication of whether any non-target lesions are present at a baseline or follow-up evaluation. CDASH: TUORRES (No CDE) where TUTEST (No CDE) = "Non-Target Indicator"; SDTM: TUORRES (6659635) where TUTESTCD (6659640) = "NTIND", TUTEST (6659638)= "Non-Target Indicator"	CHARACTER. Use choice list.
Link ID (m) 6635925 TULNKID	A sequence of characters used as a linkage between related tumor identifier records. CDASH: TULNKID (No CDE); SDTM: TULNKID (6635925)	CHARACTER
Method of Identification (m) 6621680 TUMETHOD	The technique used to administer the tumor identification assessment. CDASH: TUMETHOD (No CDE); SDTM: TUMETHOD (6621680)	CHARACTER. Use choice list.
Tumor Assessment Date (m) 6922524 TRASMDAT	The date of tumor measurement(s) represented in an unambiguous date format (e.g., DD-MON-YYYY). CDASH: TUDAT (No CDE); SDTM: TUDTC (6651955)	DATE
Tumor/Lesion Location Description (m) 6922525 TULOCDSC	Text description of the site in or on the body at which the tumor identification test or result is performed or collected. CDASH: TULOC (No CDE); SDTM: TULOC (6621372)	CHARACTER

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Non-Target Lesion irRECIST Response Type (m) 6974586 RSNTRSP	<p>The disease response in a non-target lesion using Immune-related Response Evaluation Criteria In Solid Tumors (irRECIST) criteria.</p> <p>CDASH: RSORRES (No CDE) where RSTEST (No CDE) = "Non-Target Response", RSCAT (No CDE) = "irRECIST"; SDTM: If RSNTRSP (6974586) = "Not done", RSTAT (6622054) = "NOT DONE" ELSE RSORRES (6642369) where RSTESTCD (6620609) = "NTRGRES" and RSTEST (6620604) = "Non-Target Response", RSCAT (6659633) = "irRECIST"</p>	CHARACTER. Use choice list.
New Lesion Indicator (c) 6922023 TUNWLSNY	<p>An indication of whether a new lesion is present.</p> <p>CDASH: TUORRES (No CDE) where TUTEST (No CDE) = "New Lesion Indicator"; SDTM: TUORRES (6659635) where TUTESTCD (6659640) = "NEWLIND", TUTEST (6659638) = "New Lesion Indicator"; Conditionality Rule: This CDE is to be collected as part of follow-up data.</p>	CHARACTER. Use choice list.
Tumor Location ICD-O-3 Code (c) 6922526 TULOCICD	<p>The ICD-O-3 code for the site in or on the body at which the tumor identification test or result is performed or collected.</p> <p>CDASH: No Match; SDTM: No Match, Can be a supplemental qualifier in SDTM; Conditionality Rule: This CDE is to be used for those trials that require collection of the primary tumor location using a ICD-O-3 code.</p>	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Tumor Location SNOMED-CT Code (c) 6922527 TULOCSMD	The SNOMED-CT code for the site in or on the body at which the tumor identification test or result is performed or collected. CDASH: No Match; SDTM: No Match, Can be a supplemental qualifier in SDTM; Conditionality Rule: This CDE is to be used for those trials that require collection of the primary tumor location using a SNOMED-CT code.	CHARACTER
Location of the Tumor/Lesion (c) 6621372 TULOC	The site in or on the body at which the tumor identification test or result is performed or collected. CDASH: TULOC (No CDE); SDTM: TULOC (6621372); Conditionality Rule: This CDE is to be used for those trials that are not using either the SNOMED-CT codes or ICD-O-3 codes to report location of the primary tumor.	CHARACTER. Use choice list.
Tumor Long Axis Size Result (c) 6922528 LDIAM	Result of the measurement of the tumor long axis dimension. CDASH: TRORRES (No CDE) where TRTEST (No CDE) = "Longest Diameter"; SDTM: TRORRES (6642371) where TRTESTCD (6659342) = "LDIAM", TRTEST = 6659339) = "Longest Diameter"; Conditionality Rule: Use for Target lesion form; Optional for Non-target lesion form.	CHARACTER

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Tumor Result Original Unit (c) 7044518 TRORUNIT	The unit of measure for the result of the tumor measurement as originally received or collected. CDASH: TRORESU (No CDE); SDTM: TRORESU (6619597); Conditionality Rule: Use for Target lesion form; Optional for Non-target lesion form.	CHARACTER. Use choice list.
Tumor Short Axis Size Result (c) 6922529 TRSAXIS	Result of the measurement of the tumor short axis dimension. CDASH: TRORES (No CDE) where TRTEST (No CDE) = "Longest Perpendicular"; SDTM: TRORES (6642371) where TRTESTCD (6659342) = "LPERP", TRTEST (6659339) = "Longest Perpendicular"; Conditionality Rule: Use for Target lesion form; Optional for Non-target lesion form.	CHARACTER
Tumor Result Original Unit (c) 7044518 TRORUNIT	The unit of measure for the result of the tumor measurement as originally received or collected. CDASH: TRORESU (No CDE); SDTM: TRORESU (6619597); Conditionality Rule: Conditionality Rule: Use for Target lesion form; Optional for Non-target lesion form.	CHARACTER. Use choice list.
Tumor Sum of Diameters Result (c) 6941900 SUMDIAM	The calculated sum of the diameters (long axis for non-nodal lesions, short axis for nodal lesions) of a tumor. CDASH: TRORES (No CDE) where TRTEST (No CDE) = "Sum of Diameter"; SDTM: TRORES (6642371) where TRTESTCD (6659342) = "SUMDIAM", TRTEST (6659339) = "Sum of Diameter"	CHARACTER

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Tumor Result Original Unit (c) 7044518 TRORUNIT	The unit of measure for the result of the tumor measurement as originally received or collected. CDASH: TRORESU (No CDE); SDTM: TRORESU (6619597); Conditionality Rule: Use for Target lesion form; Optional for Non-target lesion form.	CHARACTER. Use choice list.
Tumor Product Dimension Result (c) 6922530 PDDIAM	Calculated result obtained by multiplying two perpendicular tumor measurements. CDASH: TRORES (No CDE) where TRTEST (No CDE) = "Product of diameters"(6922528); SDTM: TRORES (6642371) where TRTESTCD (6659342) = "PDDIAM", TRTEST (6659339) = "Product of diameters"; Conditionality Rule: Use for Target or Index lesion form; Optional for Non-target or Non-index lesion form.	CHARACTER
Tumor Result Original Unit (c) 7044518 TRORUNIT	The unit of measure for the result of the tumor measurement as originally received or collected. CDASH: TRORESU (No CDE); SDTM: TRORESU (6619597); Conditionality Rule: Conditionality Rule: Use for Target or Index lesion form; Optional for Non-target or Non-index lesion form.	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Tumor Sum Product Dimension Result (c) 6922531 SUMPDIAM	The sum of the products of the greatest diameter tumor measurements. CDASH: TRORES (No CDE) where TRTEST (No CDE) = "Sum of product of diameters"; SDTM: TRORES (6642371) where TRTESTCD (6659342) = "SUMPDIAM", TRTEST (6659339) = "Sum of product of diameters"; Conditionality Rule: Use for Target or Index lesion form; Optional for Non-target or Non-index lesion form.	CHARACTER
Tumor Result Original Unit (c) 7044518 TRORUNIT	The unit of measure for the result of the tumor measurement as originally received or collected. CDASH: TRORESU (No CDE); SDTM: TRORESU (6619597); Conditionality Rule: Use for Target or Index lesion form; Optional for Non-target or Non-index lesion form.	CHARACTER. Use choice list.
Target Lesion RECIST Overall Response Status (c) 6941946 RSTGORSP	The overall response status for target lesions at a particular time, using Response Evaluation Criteria in Solid Tumors version 1.1 (RECISTv1.1). CDASH: RSORRES (No CDE) where RSTEST (No CDE) = "Target Lesion Overall Response", RSCAT (6659633) = "irRECIST"; SDTM: If TRGORSP (6941946) = "Not done", RSTAT (6622054) = "irRECIST"; Conditionality Rule: Use on Follow up form to capture the overall response of all Target lesions.	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Non-Target Lesion RECIST Overall Response Status (c) 6941951 RSNTORSP	<p>The overall response status for non-target lesions at a particular time, using Response Evaluation Criteria in Solid Tumors version 1.1 (RECISTv1.1).</p> <p>CDASH: RSORRES (No CDE) where RSTEST (No CDE) = "Non-Target Lesion Overall Response", RSCAT (No CDE) = "irRECIST"; SDTM: If NTRGORSP (6941951) = "Not done", RSSTAT (6622054) = "NOT DONE" ELSE RSORRES (6642369) where RSTESTCD (6620609) = "NTRGORSP", RSTEST (6620604) = "Non-Target Lesion Overall Response" and RSCAT (6659633) = "irRECIST"; Conditionality Rule: Use on Follow up form to capture the overall response of all Non-target lesions.</p>	CHARACTER. Use choice list.
Target Lesion irRECIST Type (o) 6944815 RSTGIRRSP	<p>The disease response in a target lesion using the Immune-related Response Evaluation Criteria in Solid Tumors (irRECIST).</p> <p>CDASH: RSORRES (No CDE) where RSTEST (No CDE) = "Target Response", RSCAT (No CDE) = "irRECIST"; SDTM: If RSTGIRRSP (6944815) = "Not Done", RSSTAT (6622054) = "NOT DONE" ELSE RSORRES (6642369) where RSTESTCD (6620609) = "TRGRES", RSTEST (6620604) = "Target Response", RSCAT (6659633) = "irRECIST"</p>	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Lymph Node Indicator (o) 6941959 TRLMNDNY	An indication of whether a lymph node is present. CDASH: TRORES (No CDE) where TRTEST (No CDE) = "Lymph Node Indicator", RSCAT (No CDE) = "irRECIST"; SDTM: TRORES (6642371) where TRTESTCD (6659342) = "LYNDIND", RSCAT (6659633) = "irRECIST"	CHARACTER. Use choice list.
Tumor Measurable Category (o) 6941899 TRMRSCAT	An indication of whether a lesion or lymph node is measurable or non-measurable. CDASH: No Match; SDTM: No Match, Can be a supplemental qualifier in SDTM	CHARACTER. Use choice list.
Baseline Measurable Tumor RECIST Type (o) 6941964 TUBMTRTP	The kind of lesion or lymph node identified at baseline that meets the minimum size requirements as defined in the Response Evaluation Criteria in Solid Tumors version 1.1 (RECISTv1.1). CDASH: TUORRES (No CDE) where TUTEST (No CDE) = "Baseline measurable lesion", RSCAT (No CDE) = "irRECIST"; SDTM: TUORRES (6659635) where TUTESTCD (6659640) = "Baseline measurable lesion", RSCAT (6659633) = "irRECIST"	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Baseline Non-Measurable Tumor RECIST Type (o) 6941965 TUBNMTP	The kind of lesion or lymph node identified at baseline not meeting minimum size requirements as defined in the Response Evaluation Criteria in Solid Tumors version 1.1 (RECISTv1.1). CDASH: TUORRES (No CDE) where TUTEST (No CDE) = "Baseline non-measurable lesion", RSCAT (No CDE) = "irRECIST"; SDTM: TUORRES (6659635) where TUTESTCD (6659640) = "BLNMRLES", TUTEST (6659638) = "Baseline non-measurable lesion", RSCAT (6659633) = "irRECIST"	CHARACTER. Use choice list.
Lesion Overall Response irRECIST Type (o) 6944816 RSOVRSP	The overall disease response in a target, non-target, or new lesion using the Immune-related Response Evaluation Criteria in Solid Tumors (irRECIST). CDASH: RSORRES (No CDE) where RSTEST (No CDE) = "Overall Response", RSCAT (No CDE) = "irRECIST"; SDTM: RSORRES (6642369) where RSTESTCD (6620609) = "OVRLRESP", RSTEST = "Overall Response", RSCAT (6659633) = "irRECIST"	CHARACTER. Use choice list.
Overall Response Duration (o) 6941972 RSOVRDUR	The maximum length of time over which response is maintained, measured from a date when criteria for complete or partial response are met until a date when recurrent or progressive disease is reported. CDASH: No Match; SDTM: No Match, Can be a supplemental qualifier in SDTM	CHARACTER

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Best Overall irRECIST Response Type (o) 6944817 RSBOIRSP	The best overall disease response recorded from the start of the study treatment until the end of treatment using the Immune-related Response Evaluation Criteria in Solid Tumors (irRECIST). CDASH: RSORRES (No CDE) where RSTEST (No CDE) = "Best Overall Response", RSCAT (No CDE) - "irRECIST"; SDTM: RSORRES (6642369) where RSTESTCD (6620609) = "BESTRESP", RSTEST (6620604) = "Best Overall Response", "RSCAT (6659633) = "irRECIST"	CHARACTER. Use choice list.
Comment (o) 6355806 COVAL	A free text comment. CDASH: COVAL (6355806); SDTM: COVAL (No CDE)	CHARACTER
Evaluation Time Point (o) 6964665 RSEVLTP	A point in time that the response evaluation takes place. CDASH: No Match; SDTM: No Match, Can be a supplemental qualifier in SDTM	CHARACTER. Use choice list.
Tumor Imaging Technique Date (o) 6922534 TRIMGDAT	The date of the tumor imaging procedure. CDASH: TUDAT (No CDE); SDTM: TUDTC (6651955)	DATE
Baseline No Disease or Disorder Indicator (o) 6922535 TUNDISNY	An indication of whether there was no measurable or non-measurable disease at baseline. CDASH: No Match; SDTM: No Match, Can be a supplemental qualifier in SDTM	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Total Measured Tumor Burden Result (o) 6944820 TOTBURDN	The total tumor size calculated as the sum of the longest diameters of non-nodal target and new non-nodal measurable lesions and the short axes of nodal target and new nodal measurable lesions. CDASH: TRORRES (No CDE) where TRTEST (No CDE) = "Total measured tumor burden"; SDTM: TRORRES (6642371) where TRTEST (6659339) = "Total measured tumor burden" and TRTESTCD (6659342) = "TOTBURDN"	CHARACTER
Tumor Result Original Unit (o) 7044518 TRORUNIT	The unit of measure for the result of the tumor measurement as originally received or collected. CDASH: TRORRES (No CDE); SDTM: TRORRESU (6619597)	CHARACTER. Use choice list.

Annotated CRF: irRECIST CDISC Aligned NCI Standard Template

This annotated CRF is ONLY used to show CDISC mapping without consideration of the CRF layout. CDASH mapping is in **Blue**, and SDTM mapping is in **Red**.

Form Name: irRECIST CDISC Aligned NCI Standard Template

Mandatory Questions

CRF Question	Value Domain
<p>Are there any target lesions? (58514) CDE Short Name: TGT_LES_PRES_IND-2</p> <p>CDASH: Not for FDA submission</p> <p>SDTM: Not for FDA submission</p>	<p>CHARACTER – Maximum Length = 3</p> <p><input type="checkbox"/> No – No <input type="checkbox"/> Yes – Yes</p>
<p>Are there any non-target lesions? (6941894) CDE Short Name: TUNTRGNY</p> <p>CDASH: TUORRES (No CDE) where TUTEST (No CDE) = "Non-Target Indicator"</p> <p>SDTM: TUORRES (6659635) where TUTESTCD (6659640) = "NTIND", TUTEST (6659638) = "Non-Target Indicator"</p>	<p>CHARACTER – Maximum Length = 2</p> <p><input type="checkbox"/> N – No <input type="checkbox"/> NA – Not Applicable <input type="checkbox"/> U – Unknown <input type="checkbox"/> Y – Yes</p>
<p>Lesion # (6635925) CDE Short Name: TULNKID</p> <p>CDASH: TULNKID (No CDE)</p> <p>SDTM: TULNKID (6635925)</p>	<p>CHARACTER – Maximum Length = 40</p>
<p>Method of assessment (6621680) CDE Short Name: TUMETHOD</p> <p>CDASH: TUMETHOD (No CDE)</p> <p>SDTM: TUMETHOD (6621680)</p>	<p>CHARACTER – Maximum Length = 200</p> <p>List of 388 PVs</p>

CRF Question	Value Domain
<p>Assessment date (6922524) CDE Short Name: TRASMDAT</p> <p>CDASH: TUDAT (No CDE)</p> <p>SDTM: TUDTC (6651955)</p>	<p>DATE – Maximum Length = 11</p>
<p>Description of lesion (6922525) CDE Short Name: TULOCDSC</p> <p>CDASH: TULOC (No CDE)</p> <p>SDTM: TULOC (6621372)</p>	<p>CHARACTER – Maximum Length = 200</p>
<p>Non-target lesion (6974586) CDE Short Name: RSNTRSP</p> <p>CDASH: RSORRES (No CDE) where RSTEST (No CDE) = "Non-Target Response", RSCAT (No CDE) = "irRECIST"</p> <p>SDTM: : If RSNTRSP (6974586) = "Not done", RSTAT (6622054) = "NOT DONE" ELSE RSORRES (6642369) where RSTESTCD (6620609) = "NTRGRESP" and RSTEST (6620604) = "Non-Target Response", RSCAT (6659633) = "irRECIST"</p>	<p>CHARACTER – Maximum Length = 30</p> <ul style="list-style-type: none"> <input type="checkbox"/> irCR – irCR <input type="checkbox"/> irNN – irNN <input type="checkbox"/> irPD – irPD <input type="checkbox"/> Not done – Not done <input type="checkbox"/> Not evaluated – Unevaluable

Conditional Questions

CRF Question	Value Domain
<p>Was the appearance of any new lesions documented? (6922023) CDE Short Name: TUNWLSNY</p> <div data-bbox="285 411 769 520" style="border: 1px solid blue; padding: 2px; margin-bottom: 10px;"> <p>CDASH: TUORRES (No CDE) where TUTEST (No CDE) = "New Lesion Indicator"</p> </div> <div data-bbox="285 558 769 697" style="border: 1px solid red; padding: 2px;"> <p>SDTM: TUORRES (6659635) where TUTESTCD (6659640) = "NEWLIND", TUTEST (6659638) = "New Lesion Indicator"</p> </div>	<p>CHARACTER – Maximum Length = 2</p> <p><input type="checkbox"/> N – No</p> <p><input type="checkbox"/> NA – Not Applicable</p> <p><input type="checkbox"/> U – Unknown</p> <p><input type="checkbox"/> Y – Yes</p>
<p>Location of tumor (6922526) CDE Short Name: TULOCICD</p> <div data-bbox="285 842 769 894" style="border: 1px solid blue; padding: 2px; margin-bottom: 10px;"> <p>CDASH: No Match</p> </div> <div data-bbox="285 932 769 1010" style="border: 1px solid red; padding: 2px;"> <p>SDTM: No Match, Can be a supplemental qualifier in SDTM</p> </div>	<p>CHARACTER – Maximum Length = 7</p> <p>List of 409 PVs</p>
<p>Location of tumor (6922527) CDE Short Name: TULOC SMD</p> <div data-bbox="285 1140 769 1192" style="border: 1px solid blue; padding: 2px; margin-bottom: 10px;"> <p>CDASH: No Match</p> </div> <div data-bbox="285 1230 769 1308" style="border: 1px solid red; padding: 2px;"> <p>SDTM: No Match, Can be a supplemental qualifier in SDTM</p> </div>	<p>CHARACTER – Maximum Length = 100</p>
<p>Location of tumor (6621372) CDE Short Name: TULOC</p> <div data-bbox="285 1440 769 1493" style="border: 1px solid blue; padding: 2px; margin-bottom: 10px;"> <p>CDASH: TULOC (No CDE)</p> </div> <div data-bbox="285 1530 769 1577" style="border: 1px solid red; padding: 2px;"> <p>SDTM: TULOC (6621372)</p> </div>	<p>CHARACTER – Maximum Length = 200</p> <p>List of 1113 PVs</p>

CRF Question	Value Domain
<p>Long axis (6922528) CDE Short Name: LDIAM</p> <div data-bbox="284 321 771 436" style="border: 1px solid blue; padding: 5px; margin-bottom: 10px;"> <p>CDASH: TRORRES (No CDE) where TRTEST (No CDE) = "Longest Diameter"</p> </div> <div data-bbox="284 468 771 609" style="border: 1px solid red; padding: 5px;"> <p>SDTM: TRORRES (6642371) where TRTESTCD (6659342) = "LDIAM", TRTEST = 6659339 = "Longest Diameter"</p> </div>	<p>CHARACTER – Maximum Length = 100</p>
<p>Original Units (7044518) CDE Short Name: TRORUNIT</p> <div data-bbox="284 741 771 793" style="border: 1px solid blue; padding: 5px; margin-bottom: 10px;"> <p>CDASH: TRORRESU (No CDE)</p> </div> <div data-bbox="284 825 771 877" style="border: 1px solid red; padding: 5px;"> <p>SDTM: TRORRESU (6619597)</p> </div>	<p>CHARACTER – Maximum Length = 20</p> <p><input type="checkbox"/> cm – Centimeter <input type="checkbox"/> mm – Millimeter</p>
<p>Short axis (6922529) CDE Short Name: TRSAXIS</p> <div data-bbox="284 1010 771 1125" style="border: 1px solid blue; padding: 5px; margin-bottom: 10px;"> <p>CDASH: TRORRES (No CDE) where TRTEST (No CDE) = "Longest Perpendicular"</p> </div> <div data-bbox="284 1157 771 1297" style="border: 1px solid red; padding: 5px;"> <p>SDTM: TRORRES (6642371) where TRTESTCD (6659342) = "LPERP", TRTEST (6659339) = "Longest Perpendicular"</p> </div>	<p>CHARACTER – Maximum Length = 100</p>
<p>Original Units (7044518) CDE Short Name: TRORUNIT</p> <div data-bbox="284 1430 771 1482" style="border: 1px solid blue; padding: 5px; margin-bottom: 10px;"> <p>CDASH: TRORRESU (No CDE)</p> </div> <div data-bbox="284 1514 771 1566" style="border: 1px solid red; padding: 5px;"> <p>SDTM: TRORRESU (6619597)</p> </div>	<p>CHARACTER – Maximum Length = 20</p> <p><input type="checkbox"/> cm – Centimeter <input type="checkbox"/> mm – Millimeter</p>

CRF Question	Value Domain
<p>Sum of diameters (6941900) CDE Short Name: SUMDIAM</p> <div data-bbox="284 321 771 436" style="border: 1px solid blue; padding: 5px; margin-bottom: 10px;"> <p>CDASH: TRORRES (No CDE) where TRTEST (No CDE) = "Sum of Diameter"</p> </div> <div data-bbox="284 468 771 609" style="border: 1px solid red; padding: 5px;"> <p>SDTM: TRORRES (6642371) where TRTESTCD (6659342) = "SUMDIAM", TRTEST (6659339) = "Sum of Diameter"</p> </div>	<p>CHARACTER – Maximum Length = 100</p>
<p>Original Units (7044518) CDE Short Name: TRORUNIT</p> <div data-bbox="284 741 771 793" style="border: 1px solid blue; padding: 5px; margin-bottom: 10px;"> <p>CDASH: TRORRESU (No CDE)</p> </div> <div data-bbox="284 825 771 877" style="border: 1px solid red; padding: 5px;"> <p>SDTM: TRORRESU (6619597)</p> </div>	<p>CHARACTER – Maximum Length = 20</p> <p><input type="checkbox"/> cm – Centimeter <input type="checkbox"/> mm – Millimeter</p>
<p>Product of diameters (6922530) CDE Short Name: PDDIAM</p> <div data-bbox="284 1010 771 1125" style="border: 1px solid blue; padding: 5px; margin-bottom: 10px;"> <p>CDASH: TRORRES (No CDE) where TRTEST (No CDE) = "Product of diameters"(6922528)</p> </div> <div data-bbox="284 1157 771 1297" style="border: 1px solid red; padding: 5px;"> <p>SDTM: TRORRES (6642371) where TRTESTCD (6659342) = "PDDIAM", TRTEST (6659339) = "Product of diameters"</p> </div>	<p>CHARACTER – Maximum Length = 100</p>
<p>Original Units (7044518) CDE Short Name: TRORUNIT</p> <div data-bbox="284 1430 771 1482" style="border: 1px solid blue; padding: 5px; margin-bottom: 10px;"> <p>CDASH: TRORRESU (No CDE)</p> </div> <div data-bbox="284 1514 771 1566" style="border: 1px solid red; padding: 5px;"> <p>SDTM: TRORRESU (6619597)</p> </div>	<p>CHARACTER – Maximum Length = 20</p> <p><input type="checkbox"/> cm² – Square Centimeter <input type="checkbox"/> mm² – Square Millimeter</p>

CRF Question	Value Domain
<p>Sum of product of diameters (6922531) CDE Short Name: SUMPDIAM</p> <div style="border: 1px solid blue; padding: 5px; margin: 10px 0;"> <p>CDASH: TRORRES (No CDE) where TRTEST (No CDE) = "Sum of product of diameters"</p> </div> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: TRORRES (6642371) where TRTESTCD (6659342) = "SUMPDIAM", TRTEST (6659339) = "Sum of product of diameters"</p> </div>	<p>CHARACTER – Maximum Length = 100</p>
<p>Original Units (7044518) CDE Short Name: TRORUNIT</p> <div style="border: 1px solid blue; padding: 5px; margin: 10px 0;"> <p>CDASH: TRORRESU (No CDE)</p> </div> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: TRORRESU (6619597)</p> </div>	<p>CHARACTER – Maximum Length = 20</p> <ul style="list-style-type: none"> <input type="checkbox"/> cm² – Square Centimeter <input type="checkbox"/> mm² – Square Millimeter
<p>Target lesion overall response (6941946) CDE Short Name: RSTGORSP</p> <div style="border: 1px solid blue; padding: 5px; margin: 10px 0;"> <p>CDASH: RSORRES (No CDE) where RSTEST (No CDE) = "Target Lesion Overall Response", RSCAT (6659633) = "irRECIST"</p> </div> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: If TRGORSP (6941946) = "Not done", RSTAT (6622054) = "irRECIST"</p> </div>	<p>CHARACTER – Maximum Length = 20</p> <ul style="list-style-type: none"> <input type="checkbox"/> CR – Complete Remission <input type="checkbox"/> NE – Unevaluable <input type="checkbox"/> Not all evaluated – Not All Tumors Evaluated <input type="checkbox"/> Not done – Not Done <input type="checkbox"/> PD – Progressive Disease <input type="checkbox"/> PR – Partial Remission <input type="checkbox"/> SD – Stable Disease
<p>Non-target lesion overall response (6941951) CDE Short Name: RSNTORSP</p> <div style="border: 1px solid blue; padding: 5px; margin: 10px 0;"> <p>CDASH: RSORRES (No CDE) where RSTEST (No CDE) = "Non-Target Lesion Overall Response", RSCAT (No CDE) = "irRECIST"</p> </div> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: If NTRGORSP (6941951) = "Not done", RSSTAT (6622054) = "NOT DONE" ELSE RSORRES (6642369) where RSTESTCD (6620609) = "NTRGORSP", RSTEST (6620604) = "Non-Target Lesion Overall Response" and RSCAT (6659633) = "irRECIST"</p> </div>	<p>CHARACTER – Maximum Length = 20</p> <ul style="list-style-type: none"> <input type="checkbox"/> CR – Complete Remission <input type="checkbox"/> NE – Unevaluable <input type="checkbox"/> Non-CR/non-PD – Non Complete Response/Non Progressive Disease <input type="checkbox"/> Not all evaluated – Not All Tumors Evaluated <input type="checkbox"/> Not done – Not Done <input type="checkbox"/> PD – Progressive Disease <input type="checkbox"/> Unequivocal PD – Unequivocal Progressive Disease

Optional Questions

CRF Question	Value Domain
<p>Target lesion (6944815) CDE Short Name: RSTGIRRSP</p> <div style="border: 1px solid blue; padding: 5px; margin: 10px 0;"> <p>CDASH: RSORRES (No CDE) where RSTEST (No CDE) = "Target Response", RSCAT (No CDE) = "irRECIST"</p> </div> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: If RSTGIRRSP (6944815) = "Not Done", RSSTAT (6622054) = "NOT DONE" ELSE RSORRES (6642369) where RSTESTCD (6620609) = "TRGRES", RSTEST (6620604) = "Target Response", RSCAT (6659633) = "irRECIST"</p> </div>	<p>CHARACTER – Maximum Length = 30</p> <ul style="list-style-type: none"> <input type="checkbox"/> irCR – irCR <input type="checkbox"/> irPD – irPD <input type="checkbox"/> irPR – irPR <input type="checkbox"/> irSD – irSD <input type="checkbox"/> Not done – Not Done <input type="checkbox"/> Not evaluated – Unevaluable
<p>Baseline: Target and Non-Target Lymph Node Lesion (6941959) CDE Short Name: TRLMNDNY</p> <div style="border: 1px solid blue; padding: 5px; margin: 10px 0;"> <p>CDASH: TRORRES (No CDE) where TRTEST (No CDE) = "Lymph Node Indicator", RSCAT (No CDE) = "irRECIST"</p> </div> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: TRORRES (6642371) where TRTESTCD (6659342) = "LYNDIND", RSCAT (6659633) = "irRECIST"</p> </div>	<p>CHARACTER – Maximum Length = 2</p> <ul style="list-style-type: none"> <input type="checkbox"/> N – No <input type="checkbox"/> NA – Not Applicable <input type="checkbox"/> U – Unknown <input type="checkbox"/> Y – Yes
<p>Measurable/non-measurable (6941899) CDE Short Name: TRMRSCAT</p> <div style="border: 1px solid blue; padding: 5px; margin: 10px 0;"> <p>CDASH: No Match</p> </div> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: No Match, Can be a supplemental qualifier in SDTM</p> </div>	<p>CHARACTER – Maximum Length = 14</p> <ul style="list-style-type: none"> <input type="checkbox"/> Measurable – Measurable <input type="checkbox"/> Non-measurable – Non-Measurable

CRF Question	Value Domain
<p>Baseline measurable lesion type (6941964) CDE Short Name: TUBMTRTP</p> <div style="border: 1px solid blue; padding: 5px; margin: 10px 0;"> <p>CDASH: TUORRES (No CDE) where TUTEST (No CDE) = "Baseline measurable lesion", RSCAT (No CDE) = "irRECIST"</p> </div> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: TUORRES (6659635) where TUTESTCD (6659640) = "Baseline measurable lesion", RSCAT (6659633) = "irRECIST"</p> </div>	<p>CHARACTER – Maximum Length = 50</p> <ul style="list-style-type: none"> <input type="checkbox"/> Bone lesions – Bone Lesion <input type="checkbox"/> Brain lesions – Brain Lesion <input type="checkbox"/> Cystic lesions – Cystic Lesion <input type="checkbox"/> Lesions with prior local treatment – Lesion With Prior Local Therapy <input type="checkbox"/> Malignant lymph node – Malignant Lymph Node <input type="checkbox"/> Tumor lesions – Neoplasm Lesion
<p>Baseline non-measurable lesion type (6941965) CDE Short Name: TUBNMTP</p> <div style="border: 1px solid blue; padding: 5px; margin: 10px 0;"> <p>CDASH: TUORRES (No CDE) where TUTEST (No CDE) = "Baseline non-measurable lesion", RSCAT (No CDE) = "irRECIST"</p> </div> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: TUORRES (6659635) where TUTESTCD (6659640) = "BLNMRLES", TUTEST (6659638) = "Baseline non-measurable lesion", RSCAT (6659633) = "irRECIST"</p> </div>	<p>CHARACTER – Maximum Length = 50</p> <ul style="list-style-type: none"> <input type="checkbox"/> Abdominal masses – Abdominal Mass <input type="checkbox"/> Abdominal organomegaly – Abdominal Organomegaly <input type="checkbox"/> Ascites – Ascites <input type="checkbox"/> Bone lesions – Bone Lesion <input type="checkbox"/> Cystic lesions – Cyst Lesion <input type="checkbox"/> Inflammatory breast disease – Inflammatory Breast Disease or Disorder <input type="checkbox"/> Leptomeningeal disease – Leptomeninges Disease or Disorder <input type="checkbox"/> Lesions with prior local treatment – Lesion With Prior Local Therapy <input type="checkbox"/> Lymphangitic involvement of skin or lung – Involvement Skin Lung Lymphatic System <input type="checkbox"/> Malignant lymph node – Malignant Lymph Node <input type="checkbox"/> Pleural or pericardial effusion – Pericardial or pleural effusions <input type="checkbox"/> Tumor lesions – Neoplasm Lesion

CRF Question	Value Domain
<p>Overall response (6944816) CDE Short Name: RSOVRSP</p> <div data-bbox="285 321 769 468" style="border: 1px solid blue; padding: 5px; margin-bottom: 10px;"> <p>CDASH: RSORRES (No CDE) where RSTEST (No CDE) = "Overall Response", RSCAT (No CDE) = "irRECIST"</p> </div> <div data-bbox="285 499 769 674" style="border: 1px solid red; padding: 5px;"> <p>SDTM: RSORRES (6642369) where RSTESTCD (6620609) = "OVRLRESP", RSTEST = "Overall Response", RSCAT (6659633) = "irRECIST"</p> </div>	<p>CHARACTER – Maximum Length = 30</p> <ul style="list-style-type: none"> <input type="checkbox"/> irCR – irCR <input type="checkbox"/> irND – irND <input type="checkbox"/> irNE – irNE <input type="checkbox"/> irNN – irNN <input type="checkbox"/> irPD – irPD <input type="checkbox"/> irPR – irPR <input type="checkbox"/> irSD – irSD
<p>Overall response duration (6941972) CDE Short Name: RSOVRDUR</p> <div data-bbox="285 810 769 863" style="border: 1px solid blue; padding: 5px; margin-bottom: 10px;"> <p>CDASH: No Match</p> </div> <div data-bbox="285 894 769 976" style="border: 1px solid red; padding: 5px;"> <p>SDTM: No Match, Can be a supplemental qualifier in SDTM</p> </div>	<p>CHARACTER – Maximum Length = 200</p>
<p>Best overall response (6944817) CDE Short Name: RSBOIRSP</p> <div data-bbox="285 1108 769 1255" style="border: 1px solid blue; padding: 5px; margin-bottom: 10px;"> <p>CDASH: RSORRES (No CDE) where RSTEST (No CDE) = "Best Overall Response", RSCAT (No CDE) = "irRECIST"</p> </div> <div data-bbox="285 1287 769 1461" style="border: 1px solid red; padding: 5px;"> <p>SDTM: RSORRES (6642369) where RSTESTCD (6620609) = "BESTRESP", RSTEST (6620604) = "Best Overall Response", "RSCAT (6659633) = "irRECIST"</p> </div>	<p>CHARACTER – Maximum Length = 30</p> <ul style="list-style-type: none"> <input type="checkbox"/> irCR – irCR <input type="checkbox"/> irND – irND <input type="checkbox"/> irNE – irNE <input type="checkbox"/> irNN – irNN <input type="checkbox"/> irPD – irPD <input type="checkbox"/> irPR – irPR <input type="checkbox"/> irSD – irSD
<p>Comment (6355806) CDE Short Name: COVAL</p> <div data-bbox="285 1591 769 1644" style="border: 1px solid blue; padding: 5px; margin-bottom: 10px;"> <p>CDASH: COVAL (6355806)</p> </div> <div data-bbox="285 1675 769 1728" style="border: 1px solid red; padding: 5px;"> <p>SDTM: COVAL (No CDE)</p> </div>	<p>CHARACTER – Maximum Length = 200</p>

CRF Question	Value Domain
<p>Time point (6964665) CDE Short Name: RSEVLTP</p> <p>CDASH: No Match</p> <p>SDTM: No Match, Can be a supplemental qualifier in SDTM</p>	<p>CHARACTER – Maximum Length = 100</p> <p>List of 700 PVs</p>
<p>Date of imaging (6922534) CDE Short Name: TRIMGDAT</p> <p>CDASH: TUDAT (No CDE)</p> <p>SDTM: TUDTC (6651955)</p>	<p>DATE – Maximum Length = 11</p>
<p>No disease at baseline (6922535) CDE Short Name: TUNDISNY</p> <p>CDASH: No Match</p> <p>SDTM: No Match, Can be a supplemental qualifier in SDTM</p>	<p>CHARACTER – Maximum Length = 2</p> <p><input type="checkbox"/> N – No</p> <p><input type="checkbox"/> NA – Not Applicable</p> <p><input type="checkbox"/> U – Unknown</p> <p><input type="checkbox"/> Y – Yes</p>
<p>Total measured tumor burden (6944820) CDE Short Name: TOTBURDN</p> <p>CDASH: TRORRES (No CDE) where TRTEST (No CDE) = "Total measured tumor burden"</p> <p>SDTM: TRORRES (6642371) where TRTEST (6659339) = "Total measured tumor burden" and TRTESTCD (6659342) = "TOTBURDN"</p>	<p>CHARACTER – Maximum Length = 100</p>
<p>Original Units (7044518) CDE Short Name: TRORUNIT</p> <p>CDASH: TRORRESU (No CDE)</p> <p>SDTM: TRORRESU (6619597)</p>	<p>CHARACTER – Maximum Length = 20</p> <p><input type="checkbox"/> cm – Centimeter</p> <p><input type="checkbox"/> mm – Millimeter</p>