

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).

irRC 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)

irRC 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
Index Lesion Present Indicator (m) 4472278 IDX_LES_IND	The yes/no/unknown response regarding the presence of the largest tumor lesion targeted by therapy. Not for FDA submission	CHARACTER. Use choice list.
Non-Index Lesion Indicator (m) 6922017 NIDXIND	An indication of whether a non-index lesion is present. CDASH: TUORRES (No CDE) where TUTEST (No CDE) = "NON-INDEX LESION Indicator"; SDTM: TUTESTCD (6659640) = "NIDXIND", TUORRES (6659635) = "NON-INDEX LESION Indicator"	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
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
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
New Lesion Indicator (c) 6922023 TUNWLSNY	An indication of whether a new lesion is present. CDASH: TUORRES (No CDE) where TUTEST (No CDE) = "Target 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	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Tumor Location ICD-O-3 Code (c) 6922526 TULOCIC	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. 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.	CHARACTER. Use choice list.
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.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Tumor Long Axis Size Result (c) 6922528 LDIAM	Result of the measurement of the tumor long axis dimension. CDASH: TRORES (No CDE) where TRTEST (No CDE) = "Longest Diameter"; SDTM: TRORES (6642371) where TRTESTCD (6659342) = "LDIAM", TRTEST (6620604) = "Longest Diameter"; Conditionality Rule: Use for Index lesion form; Optional for 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 Index lesion form; Optional for Non-index 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 Index lesion form; Optional for 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 Index lesion form; Optional for Non-index lesion form.	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
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"; SDTM: TRORES (6642371) where TRTESTCD (6659342) = "PDDIAM", TRTEST (6659339) = "Product of diameters"; Conditionality Rule: Use for Index lesion form; Optional for 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 Index lesion form; Optional for Non-index lesion form.	CHARACTER. Use choice list.
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 (6620604) = "Sum of product of diameters"; Conditionality Rule: Use for Index lesion form; Optional for Non-index 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: TRORRESU (No CDE); SDTM: TRORRESU (6619597); Conditionality Rule: Use for Index lesion form; Optional for Non-index lesion form.	CHARACTER. Use choice list.
Index Lesion irRC Measurable Overall Response Category (c) 6928366 IDXORSP	The overall disease response in the largest tumor lesion targeted by therapy using the Immune-Related Response Criteria (irRC). CDASH: RSORRES (No CDE) where RSTEST (No CDE) = "Index lesion overall response", RSCAT (No CDE) = "irRC"; SDTM: RSORRES (6642369) where RSTESTCD (6620609) = "IDXORSP", RSTEST (6620604)= "Index lesion overall response", RSCAT (6659633) = "irRC"; Conditionality Rule: Use on Follow up form to capture the overall response of all Index lesions. Note: Use CDE 6160058 to collect individual index lesion response (log line).	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Non-Index Lesion irRC Non-Measurable Overall Response Category (c) 6930175 NIDXORSP	<p>The overall disease response in individual tumor lesions other than the largest tumor lesion targeted by therapy using the Immune-Related Response Criteria (irRC).</p> <p>CDASH: RSORRES (No CDE) where RSTEST (6620604) = "Non-index lesion overall response", RSCAT = "irRC"; SDTM: RSORRES (6642369) where RSTESTCD (6620609) = "NIDXORSP", RSTEST (6620604) = "Non-index lesion overall response", RSCAT (6659633) = "irRC"; Conditionality Rule: Use on Follow up form to capture the overall response of all Non-target lesions response. Use CDE 6930177 to collect individual non-index lesion response (log line).</p>	CHARACTER. Use choice list.
Index Lesion Response irRC Measurable Response Category (o) 6930176 IDXLRSP	<p>The disease response in the largest tumor lesion targeted by therapy using the Immune-Related Response Criteria (irRC).</p> <p>CDASH: RSORRES (No CDE) where RSTEST (No CDE) = "Index Lesion Response", RSCAT (No CDE) = "irRC"; SDTM: If IDXLRSP (6930176) = "Not done", RSTAT = "NOT DONE" ELSE RSORRES (6642369) where RSTESTCD (6620609) = "IDXLRSP", RSTEST (6620604) = "Index Lesion Response", RSCAT (6659633) = "irRC"</p>	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Non-Index Lesion irRC Non-Measurable Response Category (o) 6930177 NIDXLRSP	<p>The disease response in individual tumor lesions other than the largest tumor lesion targeted by therapy using the Immune-Related Response Criteria (irRC).</p> <p>CDASH: RSORRES (No CDE) where RSTEST (No CDE) = "Non-Index Lesion Response", RSCAT (No CDE) = "irRC"; SDTM: IF NIDXLRSP (6930177) = "Not done", RSTAT (No CDE)= "NOT DONE" ELSE RSORRES (6642369) where RSTESTCD (6620609) = "NIDXLRSP", RSTEST (6620604) = "Non-Index Lesion Response", RSCAT (6659633) = "irRC"</p>	CHARACTER. Use choice list.
Tumor Identification Method (o) 6922532 TUIDMETH	<p>Text description of the technique used to administer the tumor identification assessment.</p> <p>CDASH: TUMETHOD (No CDE); SDTM: TUMETHOD (6621680)</p>	CHARACTER
Overall Lesion Response irRC Measurable Category (o) 6922533 RSOVRRSP	<p>A set of response criteria designed to capture additional response patterns observed with immune therapy beyond those described by Response Evaluation Criteria in Solid Tumors (RECIST) or WHO criteria.</p> <p>CDASH: RSORRES (No CDE) where RSTEST (No CDE) = "Overall Response", RSCAT (No CDE) = "irRC"; SDTM: RSORRES (6642369) where RSTESTCD (6620609)= "OVRLRESP", RSTEST (6620604)= "Overall response", RSCAT (6659633)= "irRC"</p>	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Lesion Best Overall Response irRC Measurable Category (o) 6930636 RSBOVRSP	The best overall disease response recorded from the start until the end of the study treatment taking into account any requirements for confirmation. CDASH: RSTEST (No CDE) = "Best Overall Response", RSCAT (No CDE) = "irRC"; SDTM: If RSBOVRSP (6930636) = "Not done", RSSTAT (6622054) = "NOT DONE" ELSE RSORRES (6642369) where RSTESTCD (6620609) = "BESTRESP", RSTEST = "Best Overall Response", RSCAT = "irRC" STESTCD (6620609) = "RSBOVRSP", RSTEST (6620604) = "Best overall response", RSCAT (6659633) = "irRC"	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: COVAL (6355806); SDTM: COVAL (No CDE) 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

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
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.
Tumor Prior Radiation Therapy Indicator (o) 6922536 PRPRTIND	An indication of whether radiation therapy was previously administered to the tumor. CDASH: No Match; SDTM: No Match, Can be a supplemental qualifier in SDTM	CHARACTER. Use choice list.
Index and Measurable New Lesion Sum Product Diameter Result (o) 6923721 TUMBDN	The sum of the products of the two largest perpendicular diameters of all index lesions. CDASH: TRORES (No CDE) where TRTEST (No CDE) = "Tumor burden", TRCAT = "irRC"; SDTM: TRORES (6642371) where TRTESTCD (6659342) = "TUMBDN", TRTEST (6659339) = "Tumor burden", TRCAT (No CDE) = "irRC"	CHARACTER
Original Units (o) 6619597 TRORESU	The unit of measure for the result of the tumor results assessment as originally received or collected. CDASH: TRORESU (No CDE); SDTM: TRORESU (6619597)	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Index And Measurable New Lesion Sum Product Percent Result (o) 6923722 TUMBDNC	The percent change in the sum of the two largest perpendicular diameters of all index lesions. CDASH: TRORES (No CDE) where TRTEST (No CDE) = "Tumor burden change", TRCAT (No CDE) = "irRC"; SDTM: TRORES (6642371) where TRTESTCD (6659342) = "TUMBDNC", TRTEST (6659339) = "Tumor burden change", TRCAT (No CDE) = "irRC"	CHARACTER
Original Units (o) 6619597 TRORESU	The unit of measure for the result of the tumor results assessment as originally received or collected. CDASH: TRORESU (No CDE); SDTM: TRORESU (6619597)	CHARACTER. Use choice list.
Overall Response Confirmation Indicator (o) 6923723 RSOVRONY	An indication of whether the derived overall disease response was confirmed. CDASH: No Match; SDTM: No Match, Can be a supplemental qualifier in SDTM	CHARACTER

Annotated CRF: irRC 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: irRC CDISC Aligned NCI Standard Template

Mandatory Questions

CRF Question	Value Domain
<p>Are there any index lesions? (4472278) CDE Short Name: IDX_LES_IND</p> <div style="border: 1px solid blue; padding: 2px; margin: 5px 0;">CDASH: Not for FDA submission</div> <div style="border: 1px solid red; padding: 2px; margin: 5px 0;">SDTM: Not for FDA submission</div>	<p>CHARACTER – Maximum Length = 7</p> <p><input type="checkbox"/> No – No <input type="checkbox"/> Unknown – Unknown <input type="checkbox"/> Yes – Yes</p>
<p>Are there any non-index lesions? (6922017) CDE Short Name: NIDXIND</p> <div style="border: 1px solid blue; padding: 2px; margin: 5px 0;">CDASH: TUORRES (No CDE) where TUTEST (No CDE) = "NON-INDEX LESION Indicator";</div> <div style="border: 1px solid red; padding: 2px; margin: 5px 0;">SDTM: TUTESTCD (6659640) = "NIDXIND", TUORRES (6659635) = "NON-INDEX LESION Indicator"</div>	<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> <div style="border: 1px solid blue; padding: 2px; margin: 5px 0;">CDASH: TULNKID (No CDE)</div> <div style="border: 1px solid red; padding: 2px; margin: 5px 0;">SDTM: TULNKID (6635925)</div>	<p>CHARACTER – Maximum Length = 40</p>
<p>Method of assessment (6621680) CDE Short Name: TUMETHOD</p> <div style="border: 1px solid blue; padding: 2px; margin: 5px 0;">CDASH: TUMETHOD (No CDE)</div> <div style="border: 1px solid red; padding: 2px; margin: 5px 0;">SDTM: TUMETHOD (6621680)</div>	<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>

Conditional Questions

CRF Question	Value Domain
<p>Was the appearance of any new lesions documented? (6922023) CDE Short Name: TUNWLSNY</p> <div data-bbox="287 411 769 520" style="border: 1px solid blue; padding: 2px; margin-bottom: 10px;"> <p>CDASH: TUORRES (No CDE) where TUTEST (No CDE) = "Target Indicator"</p> </div> <div data-bbox="287 558 769 695" 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 – – Unknown</p>
<p>Location of tumor (6922526) CDE Short Name: TULOCICD</p> <div data-bbox="287 831 769 877" style="border: 1px solid blue; padding: 2px; margin-bottom: 10px;"> <p>CDASH: No Match</p> </div> <div data-bbox="287 915 769 993" style="border: 1px solid red; padding: 2px;"> <p>SDTM: No Match, Can be a supplemental qualifier in SDTM</p> </div>	<p>NUMBER – Maximum Length = 7</p> <p>List of 409 PVs</p>
<p>Location of tumor (6922527) CDE Short Name: TULOCMSD</p> <div data-bbox="287 1129 769 1176" style="border: 1px solid blue; padding: 2px; margin-bottom: 10px;"> <p>CDASH: No Match</p> </div> <div data-bbox="287 1213 769 1291" 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 the Tumor/Lesion (6621372) CDE Short Name: TULOC</p> <div data-bbox="287 1430 769 1476" style="border: 1px solid blue; padding: 2px; margin-bottom: 10px;"> <p>CDASH: TULOC (No CDE)</p> </div> <div data-bbox="287 1514 769 1560" 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="289 321 769 436" style="border: 1px solid blue; padding: 5px; margin-bottom: 10px;"> <p>CDASH: TRORES (No CDE) where TRTEST (No CDE) = "Longest Diameter"</p> </div> <div data-bbox="289 468 769 611" style="border: 1px solid red; padding: 5px;"> <p>SDTM: TRORES (6642371) where TRTESTCD (6659342) = "LDIAM", TRTEST (6620604) = "Longest Diameter"</p> </div>	<p>CHARACTER – Maximum Length = 100</p>
<p>Original Units (7044518) CDE Short Name: TRORUNIT</p> <div data-bbox="289 741 769 793" style="border: 1px solid blue; padding: 5px; margin-bottom: 10px;"> <p>CDASH: TRORESU (No CDE)</p> </div> <div data-bbox="289 825 769 877" style="border: 1px solid red; padding: 5px;"> <p>SDTM: TRORESU (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="289 1014 769 1129" style="border: 1px solid blue; padding: 5px; margin-bottom: 10px;"> <p>CDASH: TRORES (No CDE) where TRTEST (No CDE) = "Longest Perpendicular"</p> </div> <div data-bbox="289 1161 769 1304" style="border: 1px solid red; padding: 5px;"> <p>SDTM: TRORES (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="289 1434 769 1486" style="border: 1px solid blue; padding: 5px; margin-bottom: 10px;"> <p>CDASH: TRORESU (No CDE)</p> </div> <div data-bbox="289 1518 769 1570" style="border: 1px solid red; padding: 5px;"> <p>SDTM: TRORESU (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>Product of diameters (6922530) CDE Short Name: PDDIAM</p> <div data-bbox="289 321 769 436" style="border: 1px solid blue; padding: 5px; margin-bottom: 10px;"> <p>CDASH: TRORRES (No CDE) where TRTEST (No CDE) = "Product of diameters"</p> </div> <div data-bbox="289 468 769 611" 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="289 741 769 793" style="border: 1px solid blue; padding: 5px; margin-bottom: 10px;"> <p>CDASH: TRORRESU (No CDE)</p> </div> <div data-bbox="289 825 769 877" 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</p> <p><input type="checkbox"/> mm² – Square Millimeter</p>
<p>Total lesion area (6922531) CDE Short Name: SUMPDIAM</p> <div data-bbox="289 1014 769 1129" style="border: 1px solid blue; padding: 5px; margin-bottom: 10px;"> <p>CDASH: TRORRES (No CDE) where TRTEST (No CDE) = "Sum of product of diameters"</p> </div> <div data-bbox="289 1161 769 1304" style="border: 1px solid red; padding: 5px;"> <p>SDTM: TRORRES (6642371) where TRTESTCD (6659342) = "SUMPDIAM", TRTEST (6620604) = "Sum of product of diameters"</p> </div>	<p>CHARACTER – Maximum Length = 100</p>
<p>Original Units (7044518) CDE Short Name: TRORUNIT</p> <div data-bbox="289 1434 769 1486" style="border: 1px solid blue; padding: 5px; margin-bottom: 10px;"> <p>CDASH: TRORRESU (No CDE)</p> </div> <div data-bbox="289 1518 769 1570" 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</p> <p><input type="checkbox"/> mm² – Square Millimeter</p>

CRF Question	Value Domain
<p>Index lesion irRC overall response (6928366) CDE Short Name: IDXORSP</p> <div data-bbox="289 321 769 468" style="border: 1px solid blue; padding: 5px; margin-bottom: 10px;"> <p>CDASH: RSORRES (No CDE) where RSTEST (No CDE) = "Index lesion overall response", RSCAT (No CDE) = "irRC"</p> </div> <div data-bbox="289 499 769 672" style="border: 1px solid red; padding: 5px;"> <p>SDTM: RSORRES (6642369) where RSTESTCD (6620609) = "IDXORSP", RSTEST (6620604) = "Index lesion overall response", RSCAT (6659633) = "irRC"</p> </div>	<p>CHARACTER – Maximum Length = 30</p> <ul style="list-style-type: none"> <input type="checkbox"/> irCR – rCR (Immune-Related Response Criteria) <input type="checkbox"/> irPD – irPD (Immune-Related Response Criteria) <input type="checkbox"/> irPR – irPR (Immune-Related Response Criteria) <input type="checkbox"/> irSD – irSD (Immune-Related Response Criteria)
<p>Non-index lesion overall response (6930175) CDE Short Name: NIDXORSP</p> <div data-bbox="289 804 769 856" style="border: 1px solid blue; padding: 5px; margin-bottom: 10px;"> <p>CDASH: TRORRESU (No CDE)</p> </div> <div data-bbox="289 888 769 940" style="border: 1px solid red; padding: 5px;"> <p>SDTM: TRORRESU (6619597)</p> </div>	<p>CHARACTER – Maximum Length = 30</p> <ul style="list-style-type: none"> <input type="checkbox"/> Absent – Absent <input type="checkbox"/> Stable – Stable <input type="checkbox"/> Unequivocal progression – Unequivocal Progression

Optional Questions

CRF Question	Value Domain
<p>Index lesion (6930176) CDE Short Name: IDXHRSP</p> <div style="border: 1px solid blue; padding: 5px; margin: 10px 0;"> <p>CDASH: RSORRES (No CDE) where RSTEST (No CDE) = "Index Lesion Response", RSCAT (No CDE) = "irRC"</p> </div> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: If IDXHRSP (6930176) = "Not done", RSTAT = "NOT DONE" ELSE RSORRES (6642369) where RSTESTCD (6620609) = "IDXHRSP", RSTEST (6620604) = "Index Lesion Response", RSCAT (6659633) = "irRC"</p> </div>	<p>CHARACTER – Maximum Length = 30</p> <ul style="list-style-type: none"> <input type="checkbox"/> irCR – irCR (Immune-Related Response Criteria) <input type="checkbox"/> irPD – irPD (Immune-Related Response Criteria) <input type="checkbox"/> irPR – irPR (Immune-Related Response Criteria) <input type="checkbox"/> irSD – irSD (Immune-Related Response Criteria) <input type="checkbox"/> NE – Unevaluable <input type="checkbox"/> Not done – Not Done
<p>Non-index lesion (6930177) CDE Short Name: NIDXHRSP</p> <div style="border: 1px solid blue; padding: 5px; margin: 10px 0;"> <p>CDASH: RSORRES (No CDE) where RSTEST (No CDE) = "Non-Index Lesion Response", RSCAT (No CDE) = "irRC"</p> </div> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: IF NIDXHRSP (6930177) = "Not done", RSTAT (No CDE)= "NOT DONE" ELSE RSORRES (6642369) where RSTESTCD (6620609) = "NIDXHRSP", RSTEST (6620604) = "Non-Index Lesion Response", RSCAT (6659633) = "irRC"</p> </div>	<p>CHARACTER – Maximum Length = 30</p> <ul style="list-style-type: none"> <input type="checkbox"/> Absent – Absent <input type="checkbox"/> NE – Unevaluable <input type="checkbox"/> Not done – Not Done <input type="checkbox"/> Stable – Stable <input type="checkbox"/> Unequivocal progression – Unequivocal Progression
<p>Tumor identification method (6922532) CDE Short Name: TUIDMETH</p> <div style="border: 1px solid blue; padding: 5px; margin: 10px 0;"> <p>CDASH: TUMETHOD (No CDE)"</p> </div> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: TUMETHOD (6621680)</p> </div>	<p>CHARACTER – Maximum Length = 200</p>

CRF Question	Value Domain
<p>Overall response (6922533) CDE Short Name: RSOVRRSP</p> <div data-bbox="289 321 769 468" style="border: 1px solid blue; padding: 5px; margin-bottom: 10px;"> <p>CDASH: RSORRES (No CDE) where RSTEST (No CDE) = "Overall Response", RSCAT (No CDE) = "irRC"</p> </div> <div data-bbox="289 499 769 672" style="border: 1px solid red; padding: 5px;"> <p>SDTM: RSORRES (6642369) where RSTESTCD (6620609)= "OVRLRESP", RSTEST (6620604)= "Overall response", RSCAT (6659633)= "irRC"</p> </div>	<p>CHARACTER – Maximum Length = 30</p> <ul style="list-style-type: none"> <input type="checkbox"/> irCR – irCR (Immune-Related Response Criteria) <input type="checkbox"/> irPD – irPD (Immune-Related Response Criteria) <input type="checkbox"/> irPR – irPR (Immune-Related Response Criteria) <input type="checkbox"/> irSD – irSD (Immune-Related Response Criteria)
<p>Best overall response (6930636) CDE Short Name: RSBOVRSP</p> <div data-bbox="289 804 769 915" style="border: 1px solid blue; padding: 5px; margin-bottom: 10px;"> <p>CDASH: RSTEST (No CDE) = "Best Overall Response", RSCAT (No CDE) = "irRC"</p> </div> <div data-bbox="289 947 769 1276" style="border: 1px solid red; padding: 5px;"> <p>SDTM: If RSBOVRSP (6930636) = "Not done", RSSTAT (6622054) = "NOT DONE" ELSE RSORRES (6642369) where RSTESTCD (6620609) = "BESTRESP", RSTEST = "Best Overall Response", RSCAT = "irRC" RSTESTCD (6620609)= "RSBOVRSP", RSTEST (6620604) = "Best overall response", RSCAT (6659633)= "irRC"</p> </div>	<p>CHARACTER – Maximum Length = 30</p> <ul style="list-style-type: none"> <input type="checkbox"/> irCR – irCR (Immune-Related Response Criteria) <input type="checkbox"/> irPD – irPD (Immune-Related Response Criteria) <input type="checkbox"/> irPR – irPR (Immune-Related Response Criteria) <input type="checkbox"/> irSD – irSD (Immune-Related Response Criteria) <input type="checkbox"/> NE – Unevaluable <input type="checkbox"/> Not done – Not Done
<p>Comment (6355806) CDE Short Name: COVAL</p> <div data-bbox="289 1409 769 1457" style="border: 1px solid blue; padding: 5px; margin-bottom: 10px;"> <p>CDASH: COVAL (6355806)</p> </div> <div data-bbox="289 1493 769 1541" style="border: 1px solid red; padding: 5px;"> <p>SDTM: COVAL (No CDE)</p> </div>	<p>CHARACTER – Maximum Length = 200</p>
<p>Time point (6964665) CDE Short Name: RSEVLTP</p> <div data-bbox="289 1682 769 1730" style="border: 1px solid blue; padding: 5px; margin-bottom: 10px;"> <p>CDASH: No Match</p> </div> <div data-bbox="289 1766 769 1843" style="border: 1px solid red; padding: 5px;"> <p>SDTM: No Match, Can be a supplemental qualifier in SDTM</p> </div>	<p>CHARACTER – Maximum Length = 100</p> <p>List of 700 PVs</p>

CRF Question	Value Domain
<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>Previously irradiated (6922536) CDE Short Name: PRPRTIND</p> <p>CDASH: No Match</p> <p>SDTM: No Match, Can be a supplemental qualifier in SDTM</p>	<p>CHARACTER – Maximum Length = 30</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>irRC tumor burden (6923721) CDE Short Name: TUMBDN</p> <p>CDASH: TRORRES (No CDE) where TRTEST (No CDE) = "Tumor burden", TRCAT = "irRC"</p> <p>SDTM: TRORRES (6642371) where TRTESTCD (6659342) = "TUMBDN", TRTEST (6659339) = "Tumor burden", TRCAT (No CDE) = "irRC"</p>	<p>CHARACTER – Maximum Length = 100</p>
<p>Original Units (6619597) CDE Short Name: TRORRESU</p> <p>CDASH: TRORRESU (No CDE)</p> <p>SDTM: TRORRESU (6619597)</p>	<p>CHARACTER – Maximum Length = 100</p> <p><input type="checkbox"/> % – Percentage</p>

CRF Question	Value Domain
<p>irRC tumor burden % change (6923722) CDE Short Name: TUMBDNC</p> <div data-bbox="289 321 769 436" style="border: 1px solid blue; padding: 5px; margin-bottom: 10px;"> <p>CDASH: TRORES (No CDE) where TRTEST (No CDE) = "Tumor burden change", TRCAT (No CDE) = "irRC"</p> </div> <div data-bbox="289 468 769 646" style="border: 1px solid red; padding: 5px;"> <p>SDTM: TRORES (6642371) where TRTESTCD (6659342) = "TUMBDNC", TRTEST (6659339) = "Tumor burden change", TRCAT (No CDE) = "irRC"</p> </div>	<p>CHARACTER – Maximum Length = 100</p>
<p>Original Units (6619597) CDE Short Name: TRORESU</p> <div data-bbox="289 772 769 825" style="border: 1px solid blue; padding: 5px; margin-bottom: 10px;"> <p>CDASH: TRORESU (No CDE)</p> </div> <div data-bbox="289 856 769 909" style="border: 1px solid red; padding: 5px;"> <p>SDTM: TRORESU (6619597)</p> </div>	<p>CHARACTER – Maximum Length = 100</p> <p><input type="checkbox"/> % – Percentage</p>
<p>Is the overall response confirmed? (6923723) CDE Short Name: RSOVRCNY</p> <div data-bbox="289 1077 769 1129" style="border: 1px solid blue; padding: 5px; margin-bottom: 10px;"> <p>CDASH: No Match</p> </div> <div data-bbox="289 1161 769 1245" style="border: 1px solid red; padding: 5px;"> <p>SDTM: No Match, Can be a supplemental qualifier in SDTM</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>