

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).

iRECIST 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)

iRECIST 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" and 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 Identification Method (m) 6922532 TUIDMETH	Text description of 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

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
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
Non-Target Lesion iRECIST Response Type (m) 6944826 RSNTIRSP	The disease response in a non-target lesion, using Immune Response Evaluation Criteria in Solid Tumors (iRECIST). CDASH: RSORRES (No CDE) where RSTEST (No CDE) = "Non-Target Response", RSCAT (No CDE) = "iRECIST"; SDTM: If RSNTIRSP (6941905) = "Not done", RSSTAT (6622054) = "NOT DONE" ELSE RSORRES (6642369) where RSTESTCD (6620609) = "NTRGRES" and RSTEST (6620604) = "Non-Target Response", RSCAT (6659633) = "iRECIST"	CHARACTER. Use choice list.
New Lesion Indicator (c) 6922023 TUNWLSNY	An indication of whether a new lesion is present. 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 on a combined RECISTv1.1 and iRECIST form. If order of new lesion required, use CDE 6944827.	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
New Lesion Identification iRECIST Type (c) 6944827 TUNLIRTP	The classification of a new lesion based upon common qualities based on Immune Response Evaluation Criteria in Solid Tumors (iRECIST). CDASH: No Match; SDTM: No Match, Can be a supplemental qualifier in SDTM; Conditionality Rule: This CDE is to be collected on a iRECIST form capturing ordering of new lesion.	CHARACTER. Use choice list.
Tumor Location ICD-O-3 Code (c) 6922526 TULOCICD	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

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
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 (6659635) where TRTESTCD (6659342) = "LDIAM", TRTEST (6659339) = "Longest Diameter"; Conditionality Rule: Collect 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: TRORRESU (No CDE); SDTM: TRORRESU (6619597); Conditionality Rule: Collect 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 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: Collect 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: Collect for Target or Index lesion form; Optional for Non-target or Non-index 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"; Conditionality Rule: Collect for Target or Index lesion form; Optional for Non-target or 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: TRORESU (No CDE); SDTM: TRORESU (6619597); Conditionality Rule: Collect for Target or Index lesion form; Optional for Non-target or Non-index lesion form.	CHARACTER. Use choice list.
Assessment Discontinuation iRECIST Reason (c) 6944831 RSDSCRSN	The reason the tumor assessment using Immune Response Evaluation Criteria in Solid Tumors (iRECIST) was stopped. CDASH: No Match; SDTM: No Match, Can be a supplemental qualifier in SDTM; Conditionality Rule: Use on iRECIST follow-up form.	CHARACTER. Use choice list.
Assessment Discontinuation Reason Text (c) 6944832 RSDRSTXT	Text specification of the reason the tumor assessment using Immune Response Evaluation Criteria in Solid Tumors (iRECIST) was stopped. CDASH: No Match; SDTM: No Match, Can be a supplemental qualifier in SDTM; Conditionality Rule: Use on iRECIST follow-up form.	CHARACTER

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Target Lesion iRECIST Response Type (o) 6944833 RSTGIRSP	The disease response in a target lesion using the Immune Response Evaluation Criteria in Solid Tumors (iRECIST). CDASH: RSORRES (No CDE) where RSTEST (No CDE) = "Target Response", RSCAT (No CDE) = "iRECIST"; SDTM: If RSTGIRSP = "Not done", RSSTAT = "NOT DONE" ELSE RSORRES (6642369) where RSTESTCD (6620609) = "TRGRES" and RSTEST (6620604) = "Target Response", RSCAT (6659633) = "iRECIST"	CHARACTER. Use choice list.
Lymph Node Indicator (o) 6941959 TRLMNDNY	An indication of whether a lymph node is present. CDASH: TRORRES (No CDE) where TRTEST (No CDE) = "Lymph Node Indicator", RSCAT (No CDE) = "iRECIST"; SDTM: TRORRES (6642371) where TRTESTCD (6659342) = "LYNDIND", RSCAT (6659633) = "iRECIST"	CHARACTER. Use choice list.
Lesion Overall Response irRECIST Type (o) 6944834 RSOVIRSP	The overall disease response in a target, non-target, or new lesion using the Immune Response Evaluation Criteria in Solid Tumors (iRECIST). CDASH: RSORRES (No CDE) where RSTEST (No CDE) = "Overall Response", RSCAT (No CDE) = "iRECIST"; SDTM: RSORRES (6642369) where RSTESTCD (6620609) = "OVRLRESP" and RSTEST (6620604) = "Overall Response", RSCAT (6659633) = "iRECIST"	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
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
Lesion Best Overall iRECIST Response Type (o) 6944835 RSTOIRSP	The best overall disease response recorded from the start of the study treatment until the end of treatment, using Immune Response Evaluation Criteria in Solid Tumors (iRECIST). CDASH: RSORRES (No CDE) where RSTEST (No CDE) = "Best Overall Response", RSCAT (No CDE) = "iRECIST"; SDTM: RSORRES (6642369) where RSTESTCD (6620609) = "BESTRESP", RSTEST (6620604) = "Best Overall Response", RSCAT (6659633) = "iRECIST"	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

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
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.
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: TRORES (No CDE); SDTM: TRORES (6642371) where TRTEST (6659339) = "Total Measured Tumor Burden Size" and TRTESTCD (6659342) = "TRTMTBRN"	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: TRORESU (No CDE); SDTM: TRORESU (6619597)	CHARACTER. Use choice list.
Date of Physical Examination (o) 6409603 PEDAT	The date when the physical examination was performed represented in an unambiguous date format (e.g., DD-MON-YYYY). CDASH: TUDAT (No CDE); SDTM: TUDTC (6651955)	DATE
Tumor Other Assessment Method Date (o) 6944836 TROMTHDT	The date of administration of the tumor identification assessment using another method not previously mentioned. CDASH: TRDAT (No CDE); SDTM: TRDTC (6651954)	DATE

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Lesion Quantity Result (o) 6944840 LESNUM	The number of lesions. CDASH: TRORESU (No CDE); SDTM: TRORES (6642371) where TRTEST (6659339) = "Number of lesions" and TRTESTCD (6659342)= "LESNUM"	CHARACTER
Non-Measurable Disease Indicator (o) 6944844 TRNMDSNY	An indication of whether non-measurable disease is present. CDASH: No Match; SDTM: No Match, Can be a supplemental qualifier in SDTM	CHARACTER. Use choice list.

Annotated CRF: iRECIST 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: iRECIST 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>Does the patient have 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" and 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 Identification (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>Specify other method (6922532) CDE Short Name: TUIDMETH</p> <p style="border: 1px solid blue; padding: 2px;">CDASH: TUMETHOD (No CDE)</p> <p style="border: 1px solid red; padding: 2px;">SDTM: TUMETHOD (6621680)</p>	<p>CHARACTER – Maximum Length = 200</p>
<p>Date of assessment (6922524) CDE Short Name: TRASMDAT</p> <p style="border: 1px solid blue; padding: 2px;">CDASH: TUDAT (No CDE)</p> <p style="border: 1px solid red; padding: 2px;">SDTM: TUDTC (6651955)</p>	<p>DATE – Maximum Length = 11</p>
<p>Site (6922525) CDE Short Name: TULOCDSC</p> <p style="border: 1px solid blue; padding: 2px;">CDASH: TULOC (No CDE)</p> <p style="border: 1px solid red; padding: 2px;">SDTM: TULOC (6621372)</p>	<p>CHARACTER – Maximum Length = 200</p>
<p>Non-target lesion (6944826) CDE Short Name: RSNTIRSP</p> <p style="border: 1px solid blue; padding: 2px;">CDASH: RSORRES (No CDE) where RSTEST (No CDE) = "Non-Target Response", RSCAT (No CDE) = "iRECIST"</p> <p style="border: 1px solid red; padding: 2px;">SDTM: If RSNTIRSP (6941905) = "Not done", RSSTAT (6622054) = "NOT DONE" ELSE RSORRES (6642369) where RSTESTCD (6620609) = "NTRGRES" and RSTEST (6620604) = "Non-Target Response", RSCAT (6659633) = "iRECIST"</p>	<p>CHARACTER – Maximum Length = 30</p> <ul style="list-style-type: none"> <input type="checkbox"/> iCPD – iRECIST Confirmed Progressive Disease <input type="checkbox"/> iCR – iRECIST Complete Response <input type="checkbox"/> iUPD – iRECIST Unconfirmed Progressive Disease <input type="checkbox"/> Non-iCR/Non-iUPD – Non iRECIST Complete Response-Non iRECIST Unconfirmed Progressive Disease <input type="checkbox"/> Not done – Not Done <input type="checkbox"/> Not evaluated – Negation Evaluation

Conditional Questions

CRF Question	Value Domain
<p>New target lesions present (6922023) CDE Short Name: TUNWLSNY</p> <div style="border: 1px solid blue; padding: 5px; margin: 10px 0;"> <p>CDASH: TUORRES (No CDE) where TUTEST (No CDE) = "New Lesion Indicator"</p> </div> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: TUORRES (6659635) where TUTESTCD (6659640) = "NEWLIND", TUTEST (6659638) = "New Lesion Indicator"</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>Have any new malignant lesions been identified since baseline (i.e. in a previous or current reporting period)? (6944827) CDE Short Name: TUNLIRTP</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 = 25</p> <ul style="list-style-type: none"> <input type="checkbox"/> No – No <input type="checkbox"/> Yes, first new lesion – First New Lesion Identification <input type="checkbox"/> Yes, subsequent new lesion – Next New Lesion Identification
<p>Site of disease (6922526) CDE Short Name: TULOCICD</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 = 7</p> <p>List of 409 PVs</p>
<p>Site of disease (6922527) CDE Short Name: TULOCSMD</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 = 100</p>

CRF Question	Value Domain
<p>Site of disease (6621372) CDE Short Name: TULOC</p> <div data-bbox="287 321 769 384" style="border: 1px solid blue; padding: 2px; margin-bottom: 10px;"> CDASH: TULOC (No CDE) </div> <div data-bbox="287 422 769 478" style="border: 1px solid red; padding: 2px;"> SDTM: TULOC (6621372) </div>	<p>CHARACTER – Maximum Length = 200</p> <p>List of 1113 PVs</p>
<p>Long axis (6922528) CDE Short Name: LDIAM</p> <div data-bbox="287 615 769 735" style="border: 1px solid blue; padding: 2px; margin-bottom: 10px;"> CDASH: TRORRES (No CDE) where TRTEST (No CDE) = "Longest Diameter" </div> <div data-bbox="287 772 769 919" style="border: 1px solid red; padding: 2px;"> SDTM: TRORRES (6659635) where TRTESTCD (6659342) = "LDIAM", TRTEST (6659339) = "Longest Diameter" </div>	<p>CHARACTER – Maximum Length = 100</p>
<p>Original Units (7044518) CDE Short Name: TRORUNIT</p> <div data-bbox="287 1056 769 1119" style="border: 1px solid blue; padding: 2px; margin-bottom: 10px;"> CDASH: TRORRESU (No CDE) </div> <div data-bbox="287 1157 769 1213" style="border: 1px solid red; padding: 2px;"> SDTM: TRORRESU (6619597) </div>	<p>CHARACTER – Maximum Length = 20</p> <p><input type="checkbox"/> cm – Centimeter</p> <p><input type="checkbox"/> mm – Millimeter</p>
<p>Short axis (6922529) CDE Short Name: TRSAXIS</p> <div data-bbox="287 1350 769 1470" style="border: 1px solid blue; padding: 2px; margin-bottom: 10px;"> CDASH: TRORRES (No CDE) where TRTEST (No CDE) = "Longest Perpendicular" </div> <div data-bbox="287 1507 769 1654" style="border: 1px solid red; padding: 2px;"> SDTM: TRORRES (6642371) where TRTESTCD (6659342) = "LPERP", TRTEST (6659339) = "Longest Perpendicular" </div>	<p>CHARACTER – Maximum Length = 100</p>

CRF Question	Value Domain
<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>
<p>Measurement (6941900) CDE Short Name: SUMDIAM</p> <p>CDASH: TRORRES (No CDE) where TRTEST (No CDE) = "Sum of Diameter"</p> <p>SDTM: TRORRES (6642371) where TRTESTCD (6659342) = "SUMDIAM", TRTEST (6659339) = "Sum of Diameter"</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>
<p>Reason for iRECIST assessment discontinuation (6944831) CDE Short Name: RSDSCRSN</p> <p>CDASH: No Match</p> <p>SDTM: No Match, Can be a supplemental qualifier in SDTM</p>	<p>CHARACTER – Maximum Length = 40</p> <p><input type="checkbox"/> iCPD never occurred – iRECIST Confirmed Progressive Disease Never Occurrence</p> <p><input type="checkbox"/> Other – Other</p> <p><input type="checkbox"/> Patient's decision – Patient Decision</p> <p><input type="checkbox"/> Study treatment discontinuation – Treatment Study Discontinue</p> <p><input type="checkbox"/> Subject not clinically stable – Study Subject Negation Clinical Stable</p>

CRF Question	Value Domain
<p>Specify reason (6944832) CDE Short Name: RSDRSTXT</p> <p>CDASH: No Match</p> <p>SDTM: No Match, can be a supplemental qualifier in SDTM</p>	<p>CHARACTER – Maximum Length = 200</p>

Optional Questions

CRF Question	Value Domain
<p>Target lesion (6944833) CDE Short Name: RSTGIRSP</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) = "iRECIST"</p> </div> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: If RSTGIRSP = "Not done", RSSTAT = "NOT DONE" ELSE RSORRES (6642369) where RSTESTCD (6620609) = "TRGRES" and RSTEST (6620604) = "Target Response", RSCAT (6659633) = "iRECIST"</p> </div>	<p>CHARACTER – Maximum Length = 30</p> <ul style="list-style-type: none"> <input type="checkbox"/> iCPD – iRECIST Confirmed Progressive Disease <input type="checkbox"/> iCR – iRECIST Complete Response <input type="checkbox"/> iPR – iRECIST Partial Response <input type="checkbox"/> iSD – iRECIST Stable Disease <input type="checkbox"/> iUPD – iRECIST Unconfirmed Progressive Disease
<p>Lymph node (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) = "iRECIST"</p> </div> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: TRORRES (6642371) where TRTESTCD (6659342) = "LYNDIND", RSCAT (6659633) = "iRECIST"</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>Overall response (6944834) CDE Short Name: RSOVIRSP</p> <div style="border: 1px solid blue; padding: 5px; margin: 10px 0;"> <p>CDASH: RSORRES (No CDE) where RSTEST (No CDE) = "Overall Response", RSCAT (No CDE) = "iRECIST"</p> </div> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: RSORRES (6642369) where RSTESTCD (6620609) = "OVRLRESP" and RSTEST (6620604) = "Overall Response", RSCAT (6659633) = "iRECIST"</p> </div>	<p>CHARACTER – Maximum Length = 30</p> <ul style="list-style-type: none"> <input type="checkbox"/> iCPD – Progressive Disease, Confirmed <input type="checkbox"/> iCR – Complete Remission <input type="checkbox"/> iPR – Partial Remission <input type="checkbox"/> iSD – Stable Disease <input type="checkbox"/> iUPD – Unconfirmed Progressive Disease <input type="checkbox"/> NE – Unevaluable

CRF Question	Value Domain
<p>Overall response duration (6941972) CDE Short Name: RSOVRDUR</p> <div data-bbox="289 321 769 384" style="border: 1px solid blue; padding: 2px; margin-bottom: 10px;"> <p>CDASH: No Match</p> </div> <div data-bbox="289 422 769 510" style="border: 1px solid red; padding: 2px;"> <p>SDTM: No Match, can be a supplemental qualifier in SDTM</p> </div>	<p>CHARACTER – Maximum Length = 200</p>
<p>Best overall response (6944835) CDE Short Name: RSTOIRSP</p> <div data-bbox="289 642 769 793" style="border: 1px solid blue; padding: 2px; margin-bottom: 10px;"> <p>CDASH: RSORRES (No CDE) where RSTEST (No CDE) = "Best Overall Response", RSCAT (No CDE) = "iRECIST"</p> </div> <div data-bbox="289 835 769 1010" style="border: 1px solid red; padding: 2px;"> <p>SDTM: RSORRES (6642369) where RSTESTCD (6620609) = "BESTRESP", RSTEST (6620604) = "Best Overall Response", RSCAT (6659633) = "iRECIST"</p> </div>	<p>CHARACTER – Maximum Length = 30</p> <ul style="list-style-type: none"> <input type="checkbox"/> iCPD – Progressive Disease, Confirmed <input type="checkbox"/> iCR – Complete Remission <input type="checkbox"/> iPR – Partial Remission <input type="checkbox"/> iSD – Stable Disease <input type="checkbox"/> iUPD – Unconfirmed Progressive Disease <input type="checkbox"/> NE – Unevaluable
<p>Please use the following fields to express any comment you might have on the data on this form (6355806) CDE Short Name: COVAL</p> <div data-bbox="289 1209 769 1272" style="border: 1px solid blue; padding: 2px; margin-bottom: 10px;"> <p>CDASH: COVAL (6355806)</p> </div> <div data-bbox="289 1310 769 1367" style="border: 1px solid red; padding: 2px;"> <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 1499 769 1562" style="border: 1px solid blue; padding: 2px; margin-bottom: 10px;"> <p>CDASH: No Match</p> </div> <div data-bbox="289 1600 769 1688" 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>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>Radiation given before protocol treatment started? (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"/> In field, but new lesion – Field of View New Lesion Identification</p> <p><input type="checkbox"/> In field, but PD since – Field of View Progressive Disease</p> <p><input type="checkbox"/> No – No</p> <p><input type="checkbox"/> Previously irradiated – Prior Irradiation</p> <p><input type="checkbox"/> Unknown – Unknown</p> <p><input type="checkbox"/> Yes – Yes</p>
<p>Sum (6944820) CDE Short Name: TOTBURDN</p> <p>CDASH: TRORRES (No CDE)</p> <p>SDTM: TRORRES (6642371) where TRTEST (6659339) = "Total Measured Tumor Burden Size" and TRTESTCD (6659342) = "TRTMTBRN"</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>
<p>Date of clinical exam (6409603) CDE Short Name: PEDAT</p> <p>CDASH: TUDAT (No CDE);</p> <p>SDTM: TUDTC (6651955)</p>	<p>DATE – Maximum Length = 11</p>

CRF Question	Value Domain
<p>Date of other method (6944836) CDE Short Name: TROMTHDT</p> <p>CDASH: TRDAT (No CDE)</p> <p>SDTM: TRDTC (6651954)</p>	<p>DATE – Maximum Length = 11</p>
<p>Number of lesions observed (6944840) CDE Short Name: LESNUM</p> <p>CDASH: TRORRESU (No CDE)</p> <p>SDTM: TRORRES (6642371) where TRTEST (6659339) = "Number of lesions" and TRTESTCD (6659342) = "LESNUM"</p>	<p>CHARACTER – Maximum Length = 100</p>
<p>Too small (6944844) CDE Short Name: TRNMDSNY</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>