

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).

Laboratory Test/Results 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 metadata table:

- LB – Laboratory Test Results (v2.0)
- 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:

- LB – Laboratory Test Results (v3.3)
- CO – Comments (v3.3)

Laboratory Test/Results 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
Date of Specimen Collection (m) 6401821 LBDAT	The date of specimen collection represented in an unambiguous date format (e.g., DD-MON-YYYY). CDASH: LBDAT (6401821); SDTM: LBDTC (No CDE)	DATE
Laboratory Test Name (c) 7275579 LBTESTNM	The name of the lab test or examination used to obtain the measurement or finding. Any test normally performed by a clinical laboratory is considered a lab test. CDASH: LBTEST (6343328); SDTM: LBTEST (No CDE); Conditionality Rule: Using a single CDE with a set of lab test names is recommended as a best practice. A set of individual test names may be substituted, especially if a single lab test is needed on a CRF.	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Lab Result Unit (c) 6409054 LBORRESU	The unit of the result as originally received or collected. CDASH: LBORRESU (6409054); SDTM: LBORRESU (No CDE); Conditionality Rule: Element needed if the Unit of Measure (UOM) is not part of the lab test name.	CHARACTER. Use choice list.
Lab Result (c) 6421484 LBORRES	Result of the measurement or finding as originally received or collected. CDASH: LBORRES (6421484); SDTM: LBORRES (No CDE); Conditionality Rule: Conditional based on type of lab results gathered (numeric vs. text descriptions).	CHARACTER
Laboratory Test Original Result Value (c) 6974972 LBORRESN	The description of the result of the measurement or finding as originally received or collected. CDASH: LBORRES (6421484); SDTM: LBORRES (No CDE); Conditionality Rule: Conditional based on type of lab results gathered (numeric vs. text descriptions).	NUMBER
Lab Performed (o) 6401829 LBPERF	An indication whether or not a planned laboratory measurement, test, observation or specimen was performed/collected. CDASH: No Match; SDTM: No Match	CHARACTER. Use choice list.
Time of Specimen Collection (o) 6402020 LBTIM	Time of specimen collection represented in an unambiguous time format (e.g., hh:mm:ss). CDASH: LBTIM (6402020); SDTM: LBDTC (No CDE)	CHARACTER

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Abnormal Reference Range Indicator (o) 6974973 LBABRRNY	The indication of whether or not the laboratory test result fell outside of the normal reference range. CDASH: LBNRIND (6401931); SDTM: If Yes, LBNRIND (No CDE) = 'ABNORMAL'	CHARACTER. Use choice list.
Vendor Name (o) 6411556 LBNAM	The name or identifier of the vendor (e.g., laboratory) that provided the test results. CDASH: LBNAM (6411556); SDTM: LBNAM (No CDE)	CHARACTER
Lab Reference ID (o) 6401975 LBREFID	An internal or external identifier such as specimen identifier. CDASH: LBREFID (6401975); SDTM: LBREFID (No CDE)	CHARACTER
Test Specimen Condition Type (o) 6974976 LBSPCNTP	The type of specimen condition submitted for laboratory tests. CDASH: LBSPCCND (6401918); SDTM: LBSPCCND (No CDE)	CHARACTER. Use choice list.
Lab Result Unit (o) 6409054 LBORRESU	The unit of the result as originally received or collected. CDASH: LBORRESU (6409054); SDTM: LBORRESU (No CDE)	CHARACTER. Use choice list.
Lab Normal Range Lower Limit- Original Unit (o) 6421482 LBORNRL0	The lower end of normal range or reference range for continuous results stored in LBORRES. CDASH: LBORNRL0 (6421482); SDTM: LBORNRL0 (No CDE)	CHARACTER

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Lab Normal Range Upper Limit- Original Unit (o) 6421483 LBORNHI	The upper end of normal range or reference range for continuous results stored in LBORRES. CDASH: LBORNHI (6421483); SDTM: LBORNHI (No CDE)	CHARACTER
Laboratory Test Comment Value Text (o) 7147758 LBCOVAL	A free text comment to describe laboratory test results. CDASH: COVAL (6355806); SDTM: COVAL (No CDE)	CHARACTER

Annotated CRF: Laboratory Test/Results 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: Laboratory Test/Results CDISC Aligned NCI Standard Template

Mandatory Questions

CRF Question	Value Domain
Sample Collection Date (6401821) CDE Short Name: LBDAT CDASH: LBDAT (6401821) SDTM: LBDTC (No CDE)	DATE – Maximum Length = 11

Conditional Questions

CRF Question	Value Domain
<p>Lab Test (7275579) CDE Short Name: LBTESTNM</p> <p style="border: 1px solid blue; padding: 2px; margin: 5px 0;">CDASH: LBTEST (6343328)</p> <p style="border: 1px solid red; padding: 2px; margin: 5px 0;">SDTM: LBTEST (No CDE)</p>	<p>CHARACTER – Maximum Length = 200</p> <p>List of 861 PVs</p>
<p>Unit (6409054) CDE Short Name: LBORRESU</p> <p style="border: 1px solid blue; padding: 2px; margin: 5px 0;">CDASH: LBORRESU (6409054)</p> <p style="border: 1px solid red; padding: 2px; margin: 5px 0;">SDTM: LBORRESU (No CDE)</p>	<p>CHARACTER – Maximum Length = 100</p> <p>List of 750 PVs</p>
<p>Lab Value (6421484) CDE Short Name: LBORRES</p> <p style="border: 1px solid blue; padding: 2px; margin: 5px 0;">CDASH: LBORRES (6421484)</p> <p style="border: 1px solid red; padding: 2px; margin: 5px 0;">SDTM: LBORRES (No CDE)</p>	<p>CHARACTER – Maximum Length = 100</p>
<p>Lab Value (6974972) CDE Short Name: LBORRESN</p> <p style="border: 1px solid blue; padding: 2px; margin: 5px 0;">CDASH: LBORRES (6421484)</p> <p style="border: 1px solid red; padding: 2px; margin: 5px 0;">SDTM: LBORRES (No CDE)</p>	<p>NUMBER – Maximum Length = 5</p>

Optional Questions

CRF Question	Value Domain
<p>Was lab specimen collected? (6401829) CDE Short Name: LBPERF</p> <p>CDASH: No Match</p> <p>SDTM: No Match</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>Time (6402020) CDE Short Name: LBTIM</p> <p>CDASH: LBTIM (6402020)</p> <p>SDTM: LBDTC (No CDE)</p>	<p>CHARACTER – Maximum Length = 8</p>
<p>Abnormal Flag (6974973) CDE Short Name: LBABRRNY</p> <p>CDASH: LBNRIND (6401931)</p> <p>SDTM: If Yes, LBNRIND (No CDE) = 'ABNORMAL'</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>Performing Laboratory Name (6411556) CDE Short Name: LBNAM</p> <p>CDASH: LBNAM (6411556)</p> <p>SDTM: LBNAM (No CDE)</p>	<p>CHARACTER – Maximum Length = 200</p>
<p>Specimen Accession # (6401975) CDE Short Name: LBREFID</p> <p>CDASH: LBREFID (6401975)</p> <p>SDTM: LBREFID (No CDE)</p>	<p>CHARACTER – Maximum Length = 40</p>

CRF Question	Value Domain
<p>Lab Specimen Condition Type (6974976) CDE Short Name: LBSPCNTP</p> <p>CDASH: LBSPCCND (6401918)</p> <p>SDTM: LBSPCCND (No CDE)</p>	<p>CHARACTER – Maximum Length = 30</p> <ul style="list-style-type: none"> <input type="checkbox"/> Acceptable – Acceptable <input type="checkbox"/> Cauterized – Cauterize <input type="checkbox"/> Clotted – Clotted Specimen <input type="checkbox"/> Damaged – Damage <input type="checkbox"/> Frozen – Frozen Specimen <input type="checkbox"/> Hemolyzed – Hemolyzed <input type="checkbox"/> Hemorrhagic – Hemorrhagic Change <input type="checkbox"/> Lipemic – Lipemic <input type="checkbox"/> Not Specified – Unspecified <input type="checkbox"/> Quantity Not Sufficient – Not Sufficient Quantity <input type="checkbox"/> Thawed – Thaw <input type="checkbox"/> Unacceptable, Not Specified – Unacceptable
<p>Unit (6409054) CDE Short Name: LBORRESU</p> <p>CDASH: LBORRESU (6409054)</p> <p>SDTM: LBORRESU (No CDE)</p>	<p>CHARACTER – Maximum Length = 100</p> <p>List of 750 PVs</p>
<p>What was the lower limit of the reference range for this lab test? (6421482) CDE Short Name: LBORNRL0</p> <p>CDASH: LBORNRL0 (6421482)</p> <p>SDTM: LBORNRL0 (No CDE)</p>	<p>CHARACTER – Maximum Length = 200</p>
<p>What was the high limit of the reference range for this lab test? (6421483) CDE Short Name: LBORNRI</p> <p>CDASH: LBORNRI (6421483)</p> <p>SDTM: LBORNRI (No CDE)</p>	<p>CHARACTER – Maximum Length = 200</p>

CRF Question	Value Domain
<p>Comments (7147758) CDE Short Name: LBCOVAL</p> <p>CDASH: COVAL (6355806)</p> <p>SDTM: COVAL (No CDE)</p>	<p>CHARACTER – Maximum Length = 200</p>