

# 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).

## EQ-5D-5L (Version 1) CDISC Aligned NCI Standard Template Module Definitions

**Mapping to the CDASH:**

N/A

**Mapping to the SDTM:**

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

- QS – Questionnaires (v3.3)

## EQ-5D-5L (Version 1) 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
EQ-5D-5L Mobility 5 Point Scale (EQ-5D-5L descriptive system) 7074646 EQ5D0201	Persons' stated observation of their health state today as related to mobility (walking about), using a 5 point Likert scale.  CDASH: No Match; SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EQ5D0201, QSEVINTX (6659632) = TODAY and QSCAT (6648971) = EQ-5D-5L; Question #1 of 6	CHARACTER. Use choice list.
EQ-5D-5L Self Care 5 Point Scale (EQ-5D-5L descriptive system) 7074670 EQ5D0202	Persons' stated observation of their health state today as related to self-care (washing and dressing), using a 5 point Likert scale.  CDASH: No Match; SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EQ5D0202, QSEVINTX (6659632) = TODAY and QSCAT (6648971) = EQ-5D-5L; Question #2 of 6	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
EQ-5D-5L Usual Activities 5 Point Scale (EQ-5D-5L descriptive system) 7074687 EQ5D0203	Persons' stated observation of their health state today as related to their usual activities (work, study, housework, family or leisure activities), using a 5 point Likert scale.  CDASH: No Match; SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EQ5D0203, QSEVINTX (6659632) = TODAY and QSCAT (6648971) = EQ-5D- 5L; Question #3 of 6	CHARACTER. Use choice list.
EQ-5D-5L Pain/Discomfort 5 Point Scale (EQ-5D-5L descriptive system) 7074683 EQ5D0204	Persons' stated observation of their health state today as related to pain or discomfort, using a 5 point Likert scale.  CDASH: No Match; SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EQ5D0204, QSEVINTX (6659632) = TODAY and QSCAT (6648971) = EQ-5D- 5L; Question #4 of 6	CHARACTER. Use choice list.
EQ-5D-5L Anxiety/Depression 5 Point Scale (EQ-5D-5L descriptive system) 7074653 EQ5D0205	Persons' stated observation of their health state today as related to anxiety or depression, using a 5 point Likert scale.  CDASH: No Match; SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EQ5D0205, QSEVINTX (6659632) = TODAY and QSCAT (6648971) = EQ-5D- 5L; Question #5 of 6	CHARACTER. Use choice list.

<b>Field Name (Partition Status) CDE ID # Short Name</b>	<b>Definition CDISC Mapping and Instruction</b>	<b>Format</b>
EQ-5D-5L Your Health State Today (EQ visual Analogue scale (EQ VAS)) 7074660 EQ5D0206	Persons' stated observation of their health state today as related to anxiety or depression, using a 5 point Likert scale.  CDASH: No Match; SDTM: QSORRES (6659628) where QSTESTCD = EQ5D0206, QSEVINTX= TODAY and QSCAT = EQ-5D- 5L; Question #6 of 6	NUMBER

## Annotated CRF: EQ-5D-5L (Version 1) 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: EQ-5D-5L (Version 1) CDISC Aligned NCI Standard Template

EQ-5D-5L descriptive system

CRF Question	Value Domain
<p><b>MOBILITY (7074646)</b> CDE Short Name: EQ5D0201</p> <div style="border: 1px solid blue; padding: 5px; margin: 10px 0;">CDASH: No Match</div> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;">SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EQ5D0201, QSEVINTX (6659632) = TODAY and QSCAT (6648971) = EQ-5D-5L</div>	<p>CHARACTER – Maximum Length = 32</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> I am unable to walk – Unable to Walk</li> <li><input type="checkbox"/> I have moderate problems walking – Moderate Problems Walking</li> <li><input type="checkbox"/> I have no problems walking – No Problems Walking</li> <li><input type="checkbox"/> I have severe problems walking – Severe Problems Walking</li> <li><input type="checkbox"/> I have slight problems walking – Slight Problems Walking</li> </ul>
<p><b>SELF-CARE (7074670)</b> CDE Short Name: EQ5D0202</p> <div style="border: 1px solid blue; padding: 5px; margin: 10px 0;">CDASH: No Match</div> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;">SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EQ5D0202, QSEVINTX (6659632) = TODAY and QSCAT (6648971) = EQ-5D-5L</div>	<p>CHARACTER – Maximum Length = 51</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> I am unable to wash or dress myself – Unable to Wash or Dress</li> <li><input type="checkbox"/> I have moderate problems washing or dressing myself – Moderate Problems with Washing or Dressing</li> <li><input type="checkbox"/> I have no problems washing or dressing myself – No Problems with Self-Care</li> <li><input type="checkbox"/> I have severe problems washing or dressing myself – Severe Problems with Washing or Dressing</li> <li><input type="checkbox"/> I have slight problems washing or dressing myself – Slight Problems with Washing or Dressing</li> </ul>

CRF Question	Value Domain
<p><b>USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities) (7074687)</b>  <b>CDE Short Name:</b> EQ5D0203</p> <div data-bbox="289 384 769 443" style="border: 1px solid blue; padding: 5px; margin: 10px 0;"> <p>CDASH: No Match</p> </div> <div data-bbox="289 485 769 627" style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EQ5D0203, QSEVINTX (6659632) = TODAY and QSCAT (6648971) = EQ-5D-5L</p> </div>	<p>CHARACTER – Maximum Length = 50</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> I am unable to do my usual activities – Unable to Perform Usual Activities</li> <li><input type="checkbox"/> I have moderate problems doing my usual activities – Moderate Problems Performing Usual Activities</li> <li><input type="checkbox"/> I have no problems doing my usual activities – No Problems Performing Usual Activities</li> <li><input type="checkbox"/> I have severe problems doing my usual activities – Severe Problems Performing Usual Activities</li> <li><input type="checkbox"/> I have slight problems doing my usual activities – Slight Problems Performing Usual Activities</li> </ul>
<p><b>PAIN / DISCOMFORT (7074683)</b>  <b>CDE Short Name:</b> EQ5D0204</p> <div data-bbox="289 909 769 968" style="border: 1px solid blue; padding: 5px; margin: 10px 0;"> <p>CDASH: No Match</p> </div> <div data-bbox="289 1010 769 1152" style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EQ5D0204, QSEVINTX (6659632) = TODAY and QSCAT (6648971) = EQ-5D-5L</p> </div>	<p>CHARACTER – Maximum Length = 34</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> I have extreme pain or discomfort – Extreme Pain or Discomfort</li> <li><input type="checkbox"/> I have moderate pain or discomfort – Moderate Pain or Discomfort</li> <li><input type="checkbox"/> I have no pain or discomfort – No Pain or Discomfort</li> <li><input type="checkbox"/> I have severe pain or discomfort – Severe Pain or Discomfort</li> <li><input type="checkbox"/> I have slight pain or discomfort – Slight Pain or Discomfort</li> </ul>
<p><b>ANXIETY / DEPRESSION (7074653)</b>  <b>CDE Short Name:</b> EQ5D0205</p> <div data-bbox="289 1375 769 1434" style="border: 1px solid blue; padding: 5px; margin: 10px 0;"> <p>CDASH: No Match</p> </div> <div data-bbox="289 1476 769 1619" style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EQ5D0205, QSEVINTX (6659632) = TODAY and QSCAT (6648971) = EQ-5D-5L</p> </div>	<p>CHARACTER – Maximum Length = 36</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> I am extremely anxious or depressed – Extremely Anxious or Depressed</li> <li><input type="checkbox"/> I am moderately anxious or depressed – Moderately Anxious or Depressed</li> <li><input type="checkbox"/> I am not anxious or depressed – Not Anxious or Depressed</li> <li><input type="checkbox"/> I am severely anxious or depressed – Severely Anxious or Depressed</li> <li><input type="checkbox"/> I am slightly anxious or depressed – Slightly Anxious or Depressed</li> </ul>

EQ visual Analogue scale (EQ VAS)

CRF Question	Value Domain
<p><b>YOUR HEALTH TODAY (7074660)</b> <b>CDE Short Name:</b> EQ5D0206</p> <p>CDASH: No Match</p> <p>SDTM: QSORRES (6659628) where QSTESTCD = EQ5D0206, QSEVINTX= TODAY and QSCAT = EQ-5D-5L</p>	<p>NUMBER – Maximum Length = 3</p>