

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-3L (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-3L (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-3L Mobility 3 Point Scale (EQ-5D descriptive system) 7074595 EQ5D0101	Persons' stated observation of their health state today as related to mobility (walking about), using a 3 point Likert scale. CDASH: No Match; SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EQ5D0101, QSEVINTX (6659632) = TODAY and QSCAT (6648971) = EQ-5D-3L; Question #1 of 6	CHARACTER. Use choice list.
EQ-5D-3L Self Care 3 Point Scale (EQ-5D descriptive system) 7074586 EQ5D0102	Persons' stated observation of their health state today as related to self-care (washing and dressing), using a 3 point Likert scale. CDASH: No Match; SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EQ5D0102, QSEVINTX (6659632) = TODAY and QSCAT (6648971) = EQ-5D-3L; Question #2 of 6	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
EQ-5D-3L Usual Activities 3 Point Scale (EQ-5D descriptive system) 7074632 EQ5D0103	Persons' stated observation of their health state today as related to their usual activities (work, study, housework, family, or leisure activities), using a 3 point Likert scale. CDASH: No Match; SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EQ5D0103, QSEVINTX (6659632) = TODAY and QSCAT (6648971) = EQ-5D- 3L; Question #3 of 6	CHARACTER. Use choice list.
EQ-5D-3L Pain/Discomfort 3 Point Scale (EQ-5D descriptive system) 7074618 EQ5D0104	Persons' stated observation of their health state today as related to pain or discomfort, using a 3 point Likert scale. CDASH: No Match; SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EQ5D0104, QSEVINTX (6659632) = TODAY and QSCAT (6648971) = EQ-5D- 3L; Question #4 of 6	CHARACTER. Use choice list.
EQ-5D-3L Anxiety/Depression 3 Point Scale (EQ-5D descriptive system) 7074602 EQ5D0105	Persons' stated observation of their health state today as related to anxiety or depression, using a 3 point Likert scale. CDASH: No Match; SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EQ5D0105, QSEVINTX (6659632) = TODAY and QSCAT (6648971) = EQ-5D- 3L; Question #5 of 6	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
EQ-5D-3L Your Health State Today (EQ visual analogue scale (EQ VAS)) 7074613 EQ5D0106	Persons' stated observation of their health state today, using a visual analogue scale (VAS) resembling a thermometer to assign a numeric value. CDASH: No Match; SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EQ5D0106, QSEVINTX (6659632) = TODAY and QSCAT (6648971) = EQ-5D- 3L; Question #6 of 6	NUMBER

Annotated CRF: EQ-5D-3L (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-3L (Version 1) CDISC Aligned NCI Standard Template

EQ-5D descriptive system

CRF Question	Value Domain
<p>Mobility (7074595) CDE Short Name: EQ5D0101</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) = EQ5D0101, QSEVINTX (6659632) = TODAY and QSCAT (6648971) = EQ-5D-3L</div>	<p>CHARACTER – Maximum Length = 37</p> <ul style="list-style-type: none"> <input type="checkbox"/> I am confined to bed – Confined to Bed <input type="checkbox"/> I have no problems in walking about – No Problems Walking <input type="checkbox"/> I have some problems in walking about – Some Problems Walking
<p>Self-Care (7074586) CDE Short Name: EQ5D0102</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) = EQ5D0102, QSEVINTX (6659632) = TODAY and QSCAT (6648971) = EQ-5D-3L</div>	<p>CHARACTER – Maximum Length = 47</p> <ul style="list-style-type: none"> <input type="checkbox"/> I am unable to wash or dress myself – Unable to Wash or Dress <input type="checkbox"/> I have no problems with self-care – No Problems with Self-Care <input type="checkbox"/> I have some problems washing or dressing myself – Some Problems with Washing and Dressing
<p>Usual Activities (e.g. work, study, housework, family or leisure activities) (7074632) CDE Short Name: EQ5D0103</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) = EQ5D0103, QSEVINTX (6659632) = TODAY and QSCAT (6648971) = EQ-5D-3L</div>	<p>CHARACTER – Maximum Length = 56</p> <ul style="list-style-type: none"> <input type="checkbox"/> I am unable to perform my usual activities – Unable to Perform Usual Activities <input type="checkbox"/> I have no problems with performing my usual activities – No Problems Performing Usual Activities <input type="checkbox"/> I have some problems with performing my usual activities – Some Problems Performing Usual Activities

CRF Question	Value Domain
<p>Pain/Discomfort (7074618) CDE Short Name: EQ5D0104</p> <div data-bbox="285 321 769 382" style="border: 1px solid blue; padding: 2px; margin: 10px 0;"> <p>CDASH: No Match</p> </div> <div data-bbox="285 422 769 596" style="border: 1px solid red; padding: 2px; margin: 10px 0;"> <p>SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EQ5D0104, QSEVINTX (6659632) = TODAY and QSCAT (6648971) = EQ-5D-3L; Question #4 of 6</p> </div>	<p>CHARACTER – Maximum Length = 34</p> <ul style="list-style-type: none"> <input type="checkbox"/> I have extreme pain or discomfort – Extreme Pain or Discomfort <input type="checkbox"/> I have moderate pain or discomfort – Moderate Pain or Discomfort <input type="checkbox"/> I have no pain or discomfort – No Pain or Discomfort
<p>Anxiety/Depression (7074602) CDE Short Name: EQ5D0105</p> <div data-bbox="285 737 769 798" style="border: 1px solid blue; padding: 2px; margin: 10px 0;"> <p>CDASH: No Match</p> </div> <div data-bbox="285 837 769 1012" style="border: 1px solid red; padding: 2px; margin: 10px 0;"> <p>SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EQ5D0105, QSEVINTX (6659632) = TODAY and QSCAT (6648971) = EQ-5D-3L; Question #5 of 6</p> </div>	<p>CHARACTER – Maximum Length = 36</p> <ul style="list-style-type: none"> <input type="checkbox"/> I am extremely anxious or depressed – Extremely Anxious or Depressed <input type="checkbox"/> I am moderately anxious or depressed – Moderately Anxious or Depressed <input type="checkbox"/> I am not anxious or depressed – Not Anxious or Depressed

EQ visual analogue scale (EQ VAS)

CRF Question	Value Domain
<p>YOUR HEALTH TODAY (7074613) CDE Short Name: EQ5D0106</p> <p>CDASH: No Match</p> <p>SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EQ5D0106, QSEVINTX (6659632) = TODAY and QSCAT (6648971) = EQ-5D-3L</p>	<p>NUMBER – Maximum Length = 3</p>