



European Quality of Life Five Dimension Five Level Scale (EQ-5D-5L)

Questionnaire Supplement to the Study Data Tabulation Model Implementation Guide for Human Clinical Trials

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Notes to Readers

This supplement is intended to be used with other CDISC User Guides for specific Therapeutic/Disease Areas and follows the CDISC Study Data Tabulation Model Implementation Guide for Human Clinical trials.

Revision History

Date	Version	Summary of Changes
2014-02-10	1.0	European Quality of Life Five Dimension Five Level Scale (EQ-5D-5L) Draft
2014-03-05	1.0	European Quality of Life Five Dimension Five Level Scale (EQ-5D-5L)
2014-06-19	1.1	European Quality of Life Five Dimension Five Level Scale (EQ-5D-5L) Revised <ul style="list-style-type: none">Modified assumptions 2 and 3 so that the high and low range text for the EQ VAS is recorded in QSORRES.

1 Introduction

This document describes the CDISC implementation of the European Quality of Life Five Dimension Five Level Scale (EQ-5D-5L) questionnaire, a standardized instrument developed by the EuroQol Group for use as a measure of health status.

The EQ-5D-5L questionnaire preceded the CDISC CDASH CRF standards and based on its copyrighted status, cannot be modified to CDASH standards.

The representation of data collected for this questionnaire is based on the Study Data Tabulation Model Implementation Guide (SDTMIG) QS domain model, which can be found at the CDISC website at: (<http://www.cdisc.org/sdtm>).

These specific implementation details for this questionnaire are meant to be used in conjunction with the SDTMIG. All questionnaire documentation can be found on the CDISC web site at: (<http://www.cdisc.org/content2909>).

The CDISC Intellectual Property Policy can be found on the CDISC web site at: (<http://www.cdisc.org/bylaws-and-policies>).

1.1 Representations and Warranties, Limitations of Liability, and Disclaimers

This document is a supplement to the Study Data Tabulation Model Implementation Guide for Human Clinical Trials and is covered under Appendix F of that document, which describes representations, warranties, limitations of liability, and disclaimers. Please see Appendix F of the SDTMIG for a complete version of this material.

2 Copyright Status

This instrument is copyright approved. CDISC has included the European Quality of Life Five Dimension Five Level Scale (EQ-5D-5L) as part of CDISC Data Standards. Hence, CDISC developed QSTESTCD and QSTEST for each question based on the actual question text on the questionnaire. There may be many versions of this questionnaire in the public domain or copyright questionnaire. CDISC has chosen to use this version as the data standard.

The CDISC documentation of this instrument consists of: (1) controlled terminology, (2) standard database structure with examples, and (3) case report forms annotated with the CDISC SDTMIG submission values.

Note: CDISC controlled terminology is maintained by NCI EVS. The most recent version should be accessed through the CDISC website. (<http://www.cdisc.org/terminology>)

CDISC has developed this documentation at no cost to the copyright holder or any additional cost to users of the instrument beyond the normal licenses fees charged by the copyright holder.

CDISC acknowledges the EuroQol Group (copyright © 2009 EuroQol Group. EQ-5D™ is a trade mark of the EuroQol Group) for the agreement to include the European Quality of Life Five Dimension Five Level Scale (EQ-5D-5L) in the CDISC data standards.

3 The QS Domain Model

3.1 Assumptions for Questionnaire Domain Model

All assumptions and business rules described in the SDTMIG QS domain are applicable to this supplement. Additional assumptions specific to the European Quality of Life Five Dimension Five Level Scale questionnaire are listed below.

European Quality of Life Five Dimension Five Level Scale (EQ-5D-5L): The EQ-5D-5L is a self-report, multiple choice questionnaire that provides a simple descriptive profile and a single index value for health status. The EQ-5D-5L essentially consists of 2 pages – the EQ-5D descriptive system (page 2) and the EQ visual analogue scale (EQ VAS) (page 3). The descriptive system comprises the following 5 dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has 5 levels: no problems, slight problems, moderate problems, severe problems, and extreme problems. The EQ VAS records the respondent’s self-rated health on a vertical, visual analogue scale. The EQ-5D-5L takes only a few minutes to complete.

1. For the EQ-5D descriptive system (QSTESTCD=EQ5D0201 - EQ5D0205), the numerical values of the response options are specified in the EQ-5D-5L User Guide (found on the EuroQol website at <http://www.euroqol.org/>) and are not printed on the CRF. These values are shown in the annotations on the annotated CRF and in Section 4: SDTM Mapping Strategy. The EQ-5D-5L User Guide should be used for analysis purposes.
2. For the EQ VAS question (QSTESTCD=EQ5D0206), QSMETHOD is populated with “VISUAL ANALOG SCALE (0-100)”.

3. Visual analog or numeric rating scales used within a questionnaire with a range of text and numeric values are indicated in the SUPPQS domain with:

QNAM=RNGTXTLO QNAM=RNGTXTHI
QNAM=RNGVALLO QNAM=RNGVALHI

By storing this information in SUPPQS, it is available for interpretation purposes. The SDS QS Team is researching alternative methods to handle this data in the future, but until a new method is identified, this will be the recommended approach.

- a. The low and high anchor text is stored in QSORRES with the numeric values stored in QSSTRESC and QSSTRESN. All other numeric values are stored in QSORRES, QSSTRESC and QSSTRESN.
4. The questionnaire evaluator should be stored in QSEVAL. For EQ-5D-5L, the evaluator is usually defined as STUDY SUBJECT.
5. The evaluation interval for the EQ-5D-5L is usually defined as TODAY. In this case the evaluation interval cannot be precisely described as an ISO 8601 duration, so the evaluation period for the EQ-5D-5L should be stored in QSEVINTX.
6. Terminology:
 - a. QSCAT, QSTESTCD and QSTEST are approved CDISC controlled terminology.
 - b. A full list of value sets for qualifier, timing, and result fields is provided in Section 4: SDTM Mapping Strategy.

3.2 Example for European Quality of Life Five Dimension Five Level Scale (EQ-5D-5L) QS Domain Model

The EQ-5D-5L example below shows the terminology used to implement the questionnaire in the QS domain. This example shows the data for one subject collected at the baseline visit for an EQ-5D-5L questionnaire. The example uses CDISC controlled terminology for QSTESTCD, QSTEST, and QSCAT. QSBLFL is Y based on VISITNUM=1. All original results are represented with preferred terminology in QSORRES. This result is then transformed into a standard numeric score in QSSTRESN and a character representation of the standard numeric score in QSSTRESC.

Rows 1-6: Show the questions from the EQ-5D-5L form for USUBJID=P0001.

qs.xpt

Row	STUDYID	DOMAIN	USUBJID	QSSEQ	QSTESTCD	QSTEST	QSCAT	QSORRES	QSSTRESC	QSSTRESN
1	STUDYX	QS	P0001	1	EQ5D0201	EQ5D02-Mobility	EQ-5D-5L	I have no problems walking	1	1
2	STUDYX	QS	P0001	2	EQ5D0202	EQ5D02-Self-Care	EQ-5D-5L	I have moderate problems washing or dressing myself	3	3
3	STUDYX	QS	P0001	3	EQ5D0203	EQ5D02-Usual Activities	EQ-5D-5L	I have slight problems doing my usual activities	2	2
4	STUDYX	QS	P0001	4	EQ5D0204	EQ5D02-Pain/Discomfort	EQ-5D-5L	I have extreme pain or discomfort	5	5
5	STUDYX	QS	P0001	5	EQ5D0205	EQ5D02-Anxiety/Depression	EQ-5D-5L	I am severely anxious or depressed	4	4
6	STUDYX	QS	P0001	6	EQ5D0206	EQ5D02-EQ VAS Score	EQ-5D-5L	33	33	33

qs.xpt (cont)

Row	QSMETHOD	QSBLFL	QSEVAL	VISITNUM	QSDTC	QSEVINTX
1 (cont)		Y	STUDY SUBJECT	1	2013-11-16	TODAY
2 (cont)		Y	STUDY SUBJECT	1	2013-11-16	TODAY
3 (cont)		Y	STUDY SUBJECT	1	2013-11-16	TODAY
4 (cont)		Y	STUDY SUBJECT	1	2013-11-16	TODAY
5 (cont)		Y	STUDY SUBJECT	1	2013-11-16	TODAY
6 (cont)	VISUAL ANALOG SCALE (0-100)	Y	STUDY SUBJECT	1	2013-11-16	TODAY

The range text and numeric values for the EQ VAS data collection values need to be populated in SUPPQS as follows. The standard terminology for QNAM and QLABEL are listed below.

suppgs.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
1	STUDYX	QS	P0001	QSTESTCD	EQ5D0206	RNGTXTLO	Range Text Low	THE WORST HEALTH YOU CAN IMAGINE	CRF	
2	STUDYX	QS	P0001	QSTESTCD	EQ5D0206	RNGTXTHI	Range Text High	THE BEST HEALTH YOU CAN IMAGINE	CRF	
3	STUDYX	QS	P0001	QSTESTCD	EQ5D0206	RNGVALLO	Range Value Low	0	CRF	
4	STUDYX	QS	P0001	QSTESTCD	EQ5D0206	RNGVALHI	Range Value High	100	CRF	

4 SDTM Mapping Strategy

EQ-5D-5L specific mapping strategy: This section is used for reference with the annotated CRF for further details on the CRF data capture and to understand the alignment of the questionnaire to the SDTM QS domain. It also provides guidance on how the result variables (QSORRES, QSSTRESC, and QSSTRESN) should be populated for the questionnaire.

QSMETHOD
VISUAL ANALOG SCALE (0-100)

QSEVINTX
TODAY

QSTESTCD=EQ5D0201 QSTEST=EQ5D02-Mobility

QSORRES	QSSTRESC	QSSTRESN
I have no problems walking	1	1
I have slight problems walking	2	2
I have moderate problems walking	3	3
I have severe problems walking	4	4
I am unable to walk	5	5

QSTESTCD=EQ5D0202 QSTEST=EQ5D02-Self-Care

QSORRES	QSSTRESC	QSSTRESN
I have no problems washing or dressing myself	1	1
I have slight problems washing or dressing myself	2	2
I have moderate problems washing or dressing myself	3	3
I have severe problems washing or dressing myself	4	4
I am unable to wash or dress myself	5	5

QSTESTCD=EQ5D0203 QSTEST=EQ5D02-Usual Activities

QSORRES	QSSTRESC	QSSTRESN
I have no problems doing my usual activities	1	1
I have slight problems doing my usual activities	2	2
I have moderate problems doing my usual activities	3	3
I have severe problems doing my usual activities	4	4
I am unable to do my usual activities	5	5

QSTESTCD=EQ5D0204 QSTEST=EQ5D02-Pain/Discomfort

QSORRES	QSSTRESC	QSSTRESN
I have no pain or discomfort	1	1
I have slight pain or discomfort	2	2
I have moderate pain or discomfort	3	3
I have severe pain or discomfort	4	4
I have extreme pain or discomfort	5	5

QSTESTCD=EQ5D0205 QSTEST=EQ5D02-Anxiety/Depression

QSORRES	QSSTRESC	QSSTRESN
I am not anxious or depressed	1	1
I am slightly anxious or depressed	2	2
I am moderately anxious or depressed	3	3
I am severely anxious or depressed	4	4
I am extremely anxious or depressed	5	5

QSTESTCD=EQ5D0206 QSTEST=EQ5D02-EQ VAS Score

QSORRES	QSSTRESC	QSSTRESN
The worst health you can imagine	0	0
1	1	1
2	2	2
...
98	98	98
99	99	99
The best health you can imagine	100	100

If any value other than a whole number was recorded on the CRF, then that value should be represented in all three fields.

5 Supplemental Qualifier Name Codes

The following table contains an additional standard name codes for use in the Supplemental Qualifiers for Questionnaires (SUPPQS) special-purpose dataset.

QNAM	QLABEL	Applicable Domains
RNGTXTLO	Range Text Low	QS
RNGTXTHI	Range Text High	QS
RNGVALLO	Range Value Low	QS
RNGVALHI	Range Value High	QS

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