



# Bowel Control Scale (BWCS)

## 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
2013-12-05	1.0	Bowel Control Scale (BWCS) Draft
2013-12-18	1.0	Bowel Control Scale (BWCS)
2014-05-09	1.1	Bowel Control Scale (BWCS) Revised <ul style="list-style-type: none"><li>• Updated data example to include the rating scale anchor text in QSORRES when low or high anchor values are represented.</li><li>• Added SUPPQS records for the rating scale anchor text and values.</li></ul>

## 1 Introduction

This document describes the CDISC implementation of the Bowel Control Scale (BWCS) questionnaire, a standard questionnaire that is typically used in clinical trials to provide a brief assessment of bowel control and the extent to which bowel problems have an impact on everyday activities.

The BWCS 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 Bowel Control Scale (BWCS) 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 National Multiple Sclerosis Society for the agreement to include the Bowel Control Scale (BWCS) in the CDISC data standards.

The BWCS is one of ten scales that make up the Multiple Sclerosis Quality of Life Inventory (MSQLI). Details about the administration and scoring of the BWCS can be found in the following reference:

Ritvo PG, Fischer JS, Miller DM, Andrews H, Paty DW, LaRocca NG. Multiple Sclerosis Quality of Life Inventory (MSQLI): A User's Manual. New York: National Multiple Sclerosis Society; 1997.

## 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 Bowel Control Scale questionnaire are listed below.

**Bowel Control Scale (BWCS):** The BWCS is a self-report, multiple choice questionnaire that clinicians may use to provide an assessment of bowel control and the extent to which bowel problems have an impact on everyday activities. It consists of 5 items, of which 4 are rated on a 5-point scale and one is rated on an 11-point scale. Administration time is approximately 2-3 minutes.

1. 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.
2. The questionnaire evaluator should be stored in QSEVAL. For BWCS, the evaluator is usually defined as STUDY SUBJECT.
  3. The time period of evaluation for the BWCS is populated in the QSEVLINT field in ISO 8601 format when the evaluation interval can be precisely described as duration. The evaluation interval for BWCS is the past 4 weeks.
  4. 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 Bowel Control Scale (BWCS) QS Domain Model

The BWCS example below shows the terminology used to implement the questionnaire in the QS domain. This example shows the data for two subjects collected at the baseline visit for a BWCS questionnaire. The example uses CDISC controlled terminology for QSTESTCD, QSTEST, and QSCAT. This example is based on a questionnaire with an evaluation interval of the past 4 weeks, which is stored in QSEVLINT in ISO format. 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 1-5:** Show the questions from the BWCS form for USUBJID=P0001.

**Rows 6-10:** Show the questions from the BWCS form for USUBJID=P0002.

*qs.xpt*

Row	STUDYID	DOMAIN	USUBJID	QSSEQ	QSTESTCD	QSTEST	QSCAT	QSORRES	QSSTRESC	QSSTRESN
1	STUDYX	QS	P0001	1	BWCS0101	BWCS01-Been Constipated	BWCS	Not at all	0	0
2	STUDYX	QS	P0001	2	BWCS0102	BWCS01-Lost Control of Bowels	BWCS	Two to four times	2	2
3	STUDYX	QS	P0001	3	BWCS0103	BWCS01-Almost Lost Control of Bowels	BWCS	More than weekly but not daily	3	3
4	STUDYX	QS	P0001	4	BWCS0104	BWCS01-Altered Activity Because Bowels	BWCS	Two to four times	2	2
5	STUDYX	QS	P0001	5	BWCS0105	BWCS01-Bowels Restricted Lifestyle	BWCS	5	5	5
6	STUDYX	QS	P0002	1	BWCS0101	BWCS01-Been Constipated	BWCS	Once	1	1
7	STUDYX	QS	P0002	2	BWCS0102	BWCS01-Lost Control of Bowels	BWCS	More than weekly but not daily	3	3
8	STUDYX	QS	P0002	3	BWCS0103	BWCS01-Almost Lost Control of Bowels	BWCS	Daily	4	4
9	STUDYX	QS	P0002	4	BWCS0104	BWCS01-Altered Activity Because Bowels	BWCS	Daily	4	4
10	STUDYX	QS	P0002	5	BWCS0105	BWCS01-Bowels Restricted Lifestyle	BWCS	Severely	10	10

*qs.xpt (cont)*

Row	QSBLFL	QSEVAL	VISITNUM	QSDTC	QSEVLINT
1 (cont)	Y	STUDY SUBJECT	1	2012-11-16	-P4W
2 (cont)	Y	STUDY SUBJECT	1	2012-11-16	-P4W
3 (cont)	Y	STUDY SUBJECT	1	2012-11-16	-P4W
4 (cont)	Y	STUDY SUBJECT	1	2012-11-16	-P4W
5 (cont)	Y	STUDY SUBJECT	1	2012-11-16	-P4W
6 (cont)	Y	STUDY SUBJECT	1	2012-11-16	-P4W
7 (cont)	Y	STUDY SUBJECT	1	2012-11-16	-P4W
8 (cont)	Y	STUDY SUBJECT	1	2012-11-16	-P4W
9 (cont)	Y	STUDY SUBJECT	1	2012-11-16	-P4W
10 (cont)	Y	STUDY SUBJECT	1	2012-11-16	-P4W

The range text and numeric values for the QSTESTCD=BWCS0105 data collection values need to be populated in SUPPQS as follows. The standard terminology for QNAM and QLABEL are listed below.

*suppqs.xpt*

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
1	STUDYX	QS	P0001	QSTESTCD	BWCS0105	RNGTXTLO	Range Text Low	NOT AT ALL	CRF	
2	STUDYX	QS	P0001	QSTESTCD	BWCS0105	RNGTXTHI	Range Text High	SEVERELY	CRF	
3	STUDYX	QS	P0001	QSTESTCD	BWCS0105	RNGVALLO	Range Value Low	0	CRF	
4	STUDYX	QS	P0001	QSTESTCD	BWCS0105	RNGVALHI	Range Value High	10	CRF	
5	STUDYX	QS	P0002	QSTESTCD	BWCS0105	RNGTXTLO	Range Text Low	NOT AT ALL	CRF	
6	STUDYX	QS	P0002	QSTESTCD	BWCS0105	RNGTXTHI	Range Text High	SEVERELY	CRF	
7	STUDYX	QS	P0002	QSTESTCD	BWCS0105	RNGVALLO	Range Value Low	0	CRF	
8	STUDYX	QS	P0002	QSTESTCD	BWCS0105	RNGVALHI	Range Value High	10	CRF	

## 4 SDTM Mapping Strategy

BWCS 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.

**QSTESTCD=BWCS0101      QSTEST=BWCS01-Been Constipated**  
**QSTESTCD=BWCS0102      QSTEST=BWCS01-Lost Control of Bowels**  
**QSTESTCD=BWCS0103      QSTEST=BWCS01-Almost Lost Control of Bowels**  
**QSTESTCD=BWCS0104      QSTEST=BWCS01-Altered Activity Because Bowels**

QSORRES	QSSTRESC	QSSTRESN
Not at all	0	0
Once	1	1
Two to four times	2	2
More than weekly but not daily	3	3
Daily	4	4

**QSTESTCD=BWCS0105      QSTEST=BWCS01-Bowels Restricted Lifestyle**

QSORRES	QSSTRESC	QSSTRESN
Not at all	0	0
1	1	1
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6
7	7	7
8	8	8
9	9	9
Severely	10	10

## 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.

<b>QNAM</b>	<b>QLABEL</b>	<b>Applicable Domains</b>
RNGTXTLO	Range Text Low	QS
RNGTXTHI	Range Text High	QS
RNGVALLO	Range Value Low	FT, QS
RNGVALHI	Range Value High	FT, QS

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