



# Overactive Bladder Questionnaire Short Form (OAB-Q SHORT FORM)

## 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
2014-11-05	1.0	Overactive Bladder Questionnaire Short Form (OAB-Q SHORT FORM) Draft
2014-11-20	1.0	Overactive Bladder Questionnaire Short Form (OAB-Q SHORT FORM)

## 1 Introduction

This document describes the CDISC implementation of Overactive Bladder Questionnaire Short Form (OAB-Q SHORT FORM) questionnaire, a standard self-report questionnaire that is typically used in clinical trials to provide a brief assessment of overactive bladder.

The OAB-Q SHORT FORM questionnaire preceded the CDISC CDASH CRF standards and based on its public domain 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 Overactive Bladder Questionnaire Short Form (OAB-Q SHORT FORM) 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 copyright holder or any additional cost to users of the instrument beyond the normal licenses fees charged by the copyright holder.

CDISC acknowledges: The Overactive Bladder Questionnaire Short Form (OAB-q Short Form) (Coyne KS, Lai JS, Zyczynski T, Kopp Z, Avery K, Abrams P. An overactive bladder symptom and quality-of-life short form: development of the Overactive Bladder Questionnaire (OAB-q)

short form (SF). Presented at the Joint Meeting of the International Continence Society and the International Urogynecological Association; August 23-27, 2004; Paris, France) for including the OAB-Q SHORT FORM 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 Overactive Bladder Questionnaire Short Form questionnaire are listed below.

Overactive Bladder Questionnaire Short Form (OAB-Q SHORT FORM): The OAB-Q SHORT FORM is a self-report questionnaire consisting of 19 items. Subjects rate the items on a scale of 1-6.

1. The time period of evaluation for the OAB-Q SHORT FORM is populated in the QSEVLINT field in ISO 8601 format when the evaluation interval can be precisely described as duration. Typically, the evaluation interval for OAB-Q SHORT FORM is the past 4 weeks.
2. The questionnaire evaluator is stored in QSEVAL. For OAB-Q SHORT FORM, the evaluator is defined as the STUDY SUBJECT since the instrument is self-administered.
3. 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 Overactive Bladder Questionnaire Short Form (OAB-Q SHORT FORM) QS Domain Model**

The OAB-Q SHORT FORM example below shows the terminology used to implement the questionnaire in the QS domain. This example shows the data for one subject collected at one visit for an OAB-Q SHORT FORM 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. QSBLFL is NULL based on VISITNUM=4. 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. The evaluation interval for OAB-Q SHORT FORM is the past 4 weeks, which is stored in QSEVLINT in ISO format.

**Rows 1-19:** Represent the questions from the OAB-Q SHORT FORM.

qs.xpt

Row	STUDYID	DOMAIN	USUBJID	QSSEQ	QSTESTCD	QSTEST	QSCAT	QSORRES	QSSTRESC
1	STUDYX	QS	P0001	1	OABQ0201	OABQ02-Uncomfortable Urge to Urinate	OAB-Q SHORT FORM	A little bit	2
2	STUDYX	QS	P0001	2	OABQ0202	OABQ02-Sudden Urge to Urinate No Warning	OAB-Q SHORT FORM	Not at all	1
3	STUDYX	QS	P0001	3	OABQ0203	OABQ02-Accidental Loss of Urine	OAB-Q SHORT FORM	A great deal	5
4	STUDYX	QS	P0001	4	OABQ0204	OABQ02-Nighttime Urination	OAB-Q SHORT FORM	Some what	3
5	STUDYX	QS	P0001	5	OABQ0205	OABQ02-Waking Up at Night had to Urinate	OAB-Q SHORT FORM	Quite a bit	4
6	STUDYX	QS	P0001	6	OABQ0206	OABQ02-Urine Loss Strong Desire Urinate	OAB-Q SHORT FORM	A great deal	5
7	STUDYX	QS	P0001	7	OABQ0207	OABQ02-Plan 'Escape Routes' to Restrooms	OAB-Q SHORT FORM	All of the time	6
8	STUDYX	QS	P0001	8	OABQ0208	OABQ02-Feel Something is Wrong with You	OAB-Q SHORT FORM	All of the time	6
9	STUDYX	QS	P0001	9	OABQ0209	OABQ02-Interfered with Good Night's Rest	OAB-Q SHORT FORM	A little of the time	2
10	STUDYX	QS	P0001	10	OABQ0210	OABQ02-Frustrated about Time in Restroom	OAB-Q SHORT FORM	Some of the time	3
11	STUDYX	QS	P0001	11	OABQ0211	OABQ02-Avoid Activ Away From Restroom	OAB-Q SHORT FORM	A good bit of the time	4
12	STUDYX	QS	P0001	12	OABQ0212	OABQ02-Awakened You During Sleep	OAB-Q SHORT FORM	A good bit of the time	4
13	STUDYX	QS	P0001	13	OABQ0213	OABQ02-Decrease Physical Activities	OAB-Q SHORT FORM	Most of the time	5
14	STUDYX	QS	P0001	14	OABQ0214	OABQ02-Caused Problems Partner/Spouse	OAB-Q SHORT FORM	A little of the time	2
15	STUDYX	QS	P0001	15	OABQ0215	OABQ02-Uncomfortable Travel with Others	OAB-Q SHORT FORM	Most of the time	5
16	STUDYX	QS	P0001	16	OABQ0216	OABQ02-Affected Relationships	OAB-Q SHORT FORM	A little of the time	2
17	STUDYX	QS	P0001	17	OABQ0217	OABQ02-Interfered with Getting Sleep	OAB-Q SHORT FORM	None of the time	1
18	STUDYX	QS	P0001	18	OABQ0218	OABQ02-Caused You Embarrassment	OAB-Q SHORT FORM	A little of the time	2
19	STUDYX	QS	P0001	19	OABQ0219	OABQ02-Locate Closest Restroom	OAB-Q SHORT FORM	A good bit of the time	4

Row	QSSTRESN	QSBLFL	QSEVAL	VISITNUM	QSDTC	QSDY	QSEVLINT
1 (cont)	2		STUDY SUBJECT	4	2014-11-05	28	-P4W
2 (cont)	1		STUDY SUBJECT	4	2014-11-05	28	-P4W

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Row	QSSTRESN	QSBLFL	QSEVAL	VISITNUM	QSDTC	QSDY	QSEVLINT
3 (cont)	5		STUDY SUBJECT	4	2014-11-05	28	-P4W
4 (cont)	3		STUDY SUBJECT	4	2014-11-05	28	-P4W
5 (cont)	4		STUDY SUBJECT	4	2014-11-05	28	-P4W
6 (cont)	5		STUDY SUBJECT	4	2014-11-05	28	-P4W
7 (cont)	6		STUDY SUBJECT	4	2014-11-05	28	-P4W
8 (cont)	6		STUDY SUBJECT	4	2014-11-05	28	-P4W
9 (cont)	2		STUDY SUBJECT	4	2014-11-05	28	-P4W
10 (cont)	3		STUDY SUBJECT	4	2014-11-05	28	-P4W
11 (cont)	4		STUDY SUBJECT	4	2014-11-05	28	-P4W
12 (cont)	4		STUDY SUBJECT	4	2014-11-05	28	-P4W
13 (cont)	5		STUDY SUBJECT	4	2014-11-05	28	-P4W
14 (cont)	2		STUDY SUBJECT	4	2014-11-05	28	-P4W
15 (cont)	5		STUDY SUBJECT	4	2014-11-05	28	-P4W
16 (cont)	2		STUDY SUBJECT	4	2014-11-05	28	-P4W
17 (cont)	1		STUDY SUBJECT	4	2014-11-05	28	-P4W
18 (cont)	2		STUDY SUBJECT	4	2014-11-05	28	-P4W
19 (cont)	4		STUDY SUBJECT	4	2014-11-05	28	-P4W

## 4 SDTM Mapping Strategy

OAB-Q SHORT FORM 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. If a result variable is not included in the table for a questionnaire, it should not be populated.

**QSTESTCD=OABQ0201 QSTEST=OABQ02-Uncomfortable Urge to Urinate**  
**QSTESTCD=OABQ0202 QSTEST=OABQ02-Sudden Urge to Urinate No Warning**  
**QSTESTCD=OABQ0203 QSTEST=OABQ02-Accidental Loss of Urine**  
**QSTESTCD=OABQ0204 QSTEST=OABQ02-Nighttime Urination**  
**QSTESTCD=OABQ0205 QSTEST=OABQ02-Waking Up at Night had to Urinate**  
**QSTESTCD=OABQ0206 QSTEST=OABQ02-Urine Loss Strong Desire Urinate**

QSORRES	QSSTRESC	QSSTRESN
Not at all	1	1
A little bit	2	2
Some what	3	3
Quite a bit	4	4
A great deal	5	5
A very great deal	6	6

**QSTESTCD=OABQ0207 QSTEST=OABQ02-Plan 'Escape Routes' to Restrooms**  
**QSTESTCD=OABQ0208 QSTEST=OABQ02-Feel Something is Wrong with You**  
**QSTESTCD=OABQ0209 QSTEST=OABQ02-Interfered with Good Night's Rest**  
**QSTESTCD=OABQ0210 QSTEST=OABQ02-Frustrated about Time in Restroom**  
**QSTESTCD=OABQ0211 QSTEST=OABQ02-Avoid Activ Away From Restroom**  
**QSTESTCD=OABQ0212 QSTEST=OABQ02-Awakened You During Sleep**  
**QSTESTCD=OABQ0213 QSTEST=OABQ02-Decrease Physical Activities**  
**QSTESTCD=OABQ0214 QSTEST=OABQ02-Caused Problems Partner/Spouse**  
**QSTESTCD=OABQ0215 QSTEST=OABQ02-Uncomfortable Travel with Others**  
**QSTESTCD=OABQ0216 QSTEST=OABQ02-Affected Relationships**  
**QSTESTCD=OABQ0217 QSTEST=OABQ02-Interfered with Getting Sleep**  
**QSTESTCD=OABQ0218 QSTEST=OABQ02-Caused You Embarrassment**  
**QSTESTCD=OABQ0219 QSTEST=OABQ02-Locate Closest Restroom**

QSORRES	QSSTRESC	QSSTRESN
None of the time	1	1
A little of the time	2	2
Some of the time	3	3
A good bit of the time	4	4
Most of the time	5	5
All of the time	6	6

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