



BE-DRI

Question by Question Specifications Guide

Form 208: OAB-q Patient Survey

Version 06/01/04 (A)

I. Purpose

The OAB-q is a measure of quality of life specific for urge incontinence. These data will be collected at baseline and at each follow-up time point for comparison with other study measures, including other measures of quality of life. It is considered an extra measure for which patients will receive additional compensation.

II. Administration

All consent procedures must be completed prior to the completion of the OAB-q Patient Survey in accordance with local IRB requirements. The Patient Survey can be completed by the patient during a study visit, or at home and returned by mail or at the next study visit.

This questionnaire is designed to be self-administered (completed by the patient). Study staff can give minimal help or assistance to a patient who is completing this questionnaire (see details below). If a woman is unable to complete the questionnaire on her own, it should be administered as an interview, but then all follow-up OAB-q Patient Surveys must be administered in interview format to be comparable to baseline measure.

A. Window for Re-Screening of Patients:

The results of this measure expire 3 months following completion; therefore, if more than 3 months transpires between the date the Survey is completed and the date of randomization, all measures including this Survey must be repeated to ensure collection of 'current' baseline values that would be subject to change over a 3-month period.

B. Materials Needed

The following materials will be required:

- The OAB-q Patient Survey with ID labels attached, and
- QxQ Specifications Guide for the OAB-q Patient Survey.

III. Section by Section Review

Section A:

- A1. Study ID Number:** Affix the patient ID label in the space provided in the A1 field and in the upper right hand corner of each subsequent page of the Data Form. Do not handwrite ID numbers as transcription errors are common and handwritten numbers are often illegible.
- A2. Visit Number:** Circle the correct visit code for the event.
- A3. Date Form Distributed:** Enter the date that you give the form to the patient. All dates must be in the format of mm/dd/yyyy.

- A4. **Study Staff Initials:** Enter the initials of the person completing the form. Enter the first initial in the first space provided, middle initial in the second space provided and last initial in the third space provided. If you don't have middle initial, strike a dash in the second space. If your last name is hyphenated or if you have 2 last names, enter the initials of your first last name in the third space
- A5. **Mode:** Circle the code for the mode of completion of Form 07. This form is designed to be completed by the patient with only minimal assistance provided by study staff. In the case of extreme circumstances when the patient is unable to complete the form without assistance, it may be interviewer-administered.

Section B: OAB-q

Description: The OAB-q questionnaire asks about how much the patient has been bothered by selected bladder symptoms (B1-B33) during the past 4 weeks.

Instructions to Patients: Show the patient the first page of Section B. Briefly review the instructions with her; emphasize to her that the time period for these questions is the past 4 weeks. Instruct her to circle the number that best describes the extent to which she was bothered by each symptom during the past 4 weeks. Remind her that there are no right or wrong answers.