BE-DRI
Question by Question Specifications Guide
Form 233: Intervention Visits 3 and 4
Version 01/06/05 (B)

I. Purpose

The purpose of Form 233 is to capture selected information about intervention activities completed at the 3rd and 4th intervention visits.

II. Administration

A. Materials Needed

- Completed Visit 3 or 4 Encounter Form
- Any Interim Visit Encounter Forms completed between Visit 2 and 3 or between Visits 3 and 4
- Intervention Visits 3 and 4 Data Form (F233) with ID labels attached

B. Window for the Visits

- **Visit 3:** The target date for Intervention Visit 3 is 28 days following Randomization / Visit 1 with a visit window of ±7 days, i.e. the visit should be completed between 21 and 35 days following Visit 1. If unforeseen circumstances prevent the patient from completing Visit 3 prior to the close of o the window, Intervention Visit 3 activities will still be completed during her 3rd in-person visit with the BE-DRI Interventionist. These activities will be documented on the Visit 3 Encounter Form and abstracted onto F233.
- **Visit 4:** The target date for Intervention Visit 4 is 49 days following Randomization / Visit 1 with a visit window of ±7 days, i.e. the visit should be completed between 42 and 56 days following Visit 1. If unforeseen circumstances prevent the patient from completing Visit 4 prior to the close of the window, Intervention Visit 4 activities will still be completed during her 4th and last in-person visit with the BE-DRI Interventionist. In a worst case scenario, Visit 4 would be completed no later than Intervention Day 62 to allow the patient time to complete the 7-Day Evaluation Diary while still on drug treatment and prior to Visit 5. Visit 4 activities will be documented on the Visit 4 Encounter Form and abstracted onto F233.

C. Source, Timing and Method of Data Form Completion

The Visit 3 and Visit 4 Encounter Forms are considered the primary source document for BE-DRI intervention activities completed at the third and fourth intervention visits. Interim Visit Encounter Forms may also be used as source documents if the Interventionist is in contact with the patient between visits. These source documents will be used to complete F233. F233 should be completed by the Interventionist immediately after the visit or very soon thereafter, i.e. within 24 hours.

D. Maintaining Blinding for Evaluation Staff

Data recorded on F233 identify the patient's treatment assignment. Local procedures must be implemented to maintain blinding of Study Evaluation staff who may complete the post-intervention measurements including interviews, exams, Bladder Diary abstractions, or distribution and/or collection of the self-administered surveys.

III. Section by Section Review for Form 233

Section A. General Information

A1. **Study ID Number**: Affix the patient ID label in the space provided in the A1 field and at the top of each subsequent page of the Data Form. Avoid handwriting ID numbers. Check carefully to be sure the ID number matches that recorded on the patient's Visit Control Sheet.

A2. **Visit Number**: F233 will be completed at both Visit 3 and Visit 4. Circle the appropriate visit #. If you are abstracting Visit 3 activities on the form, circle INT3. If you are abstracting Visit 4 activities, circle INT4.

A3. **Date Intervention Visit Completed**: Record the date the visit was completed using the mm/dd/yyyy format.

A4. **Interventionist's Initials**: The certified Interventionist who completes the visit should record her initials in this data field. Enter first initial in the first space provided, middle initial in the second space provided, and last initial in the third space provided. If there is not a middle initial to record, strike a dash in the second space. If the last name is hyphenated or if there are 2 last names, enter the initials of the first last name in the third space.

A5. **Date Form Completed**: Enter the date that the form was completed. The Interventionist should complete F233 immediately after the visit is completed. An unblinded Evaluation staff member, e.g. Study Coordinator, Data Manager, etc s should receive the completed F233 within 24 hours after completion of the visit.

Section B: Summary of Key Elements of the Drug Intervention

Description: Questions in Section B pertain to all patients regardless of their treatment assignment.

'Need To Know' Medications

B1. **Does the patient report taking any 'Need To Know' drugs since her last visit?** If the patient has taken any 'Need to Know' medications, circle code 1 (Yes) and list them in B1a. If the patient denies taking any 'Need to Know' mediations, circle code 2 (No) and skip down to question B2.

B1a. '**Need to Know' medications listed by name**: If the patient reports she has taken any 'Need to Know' medications, write them in this text field. Write or print legibly. Illegible entries will be returned to you for clarification in the form of an edit report.

Prescription of or recommendation to use a 'Need To Know' medication as well as the actual use of any 'Need To Know' medications must be reported to the MD Investigator immediately.

Drug Adherence

Description: Questions B2 and B3 aim to capture all drug adherence data.

Detrol LA 4mg capsules

B2. **Detrol LA 4mg capsules**

Record the number of 4 mg capsules taken since the previous visit. If the patient stopped taking Detrol LA 4mg at an earlier visit, record -00- in this data field and skip to B3.

If the patient stopped taking Detrol LA 4mg at an earlier visit but brings unused 4mg capsules to return today, code -6 (Capsules Recovered) in this data field and complete fields B2c-B2e.

If the patient took any 4mg capsules since the last visit or brings back 4mg capsules to return to you, you must complete B2c-B2e. Code this value based on your interview with the patient and your actual pill count. If the patient report does not agree with your actual pill count, probe carefully to resolve the discrepancy.

If the patient forgot to bring her medication bottle to this visit, B2 will be based on patient report alone. NOTE: B2c will be coded missing to indicate the pill count was not completed at this visit.

If you cannot complete an actual pill count, probe carefully. Review /discuss every day since the previous visit. Use a calendar as a prop to improve the patient's recall. To determine if her report of drug adherence is credible, ask the patient what strategies she employs to remember to take her medication. Were there any days that she forgot to take her capsule? Did she take her capsule yet today (day of the visit)?

B2a. **Start Date**: Record the date the patient started taking Detrol LA **4mg.** For most patients this date will match the date Visit 1 was completed. A date recorded in B2a that does not match the Visit 1 date will be considered an 'out of range' value. A rationale should be provided in the source document (Visit specific Encounter form or Interim Visit Encounter Form) for an out of range date. Record the date using the mm/dd/yyyy format.

B2b. **Stop Date**: Record the date the patient stopped taking Detrol LA **4mg**. If the patient is still taking Detrol LA **4mg**, record 01/01/0101 in this date field. If the patient stopped taking Detrol LA **4mg,** record the date of her last dose here. Record the date using the mm/dd/yyyy format.

B2c. **Number of Detrol LA 4mg capsules remaining**: Complete an actual count of the **4mg** capsules remaining in the medication bottle and record the actual number of Detrol LA **4mg** capsules remaining. If the patient forgot to bring in her medication bottle write the word '*missing'* in this data field. **Do not complete this data field based on patient report**. You must complete an actual count of the **4mg** capsules remaining in the medication bottle to code a numerical value here.

B2d. **Number of Detrol LA 4mg capsules recovered:** If you recover Detrol LA 4mg capsules, record the number in B2d. This value is based on your actual count of the **4mg** capsules recovered. If the patient stops taking Detrol LA **4mg**, you must recover all remaining/unused **4mg** capsules (# in B2c). In addition, the patient should never be holding more Detrol than she will be able to use through the end of Stage 1, i.e. Day 69*****. If the patient stopped taking Detrol **4mg** but forgot to

bring her medication bottle to the visit, write '*missing'* in this data field. But the capsules must be recovered at a subsequent visit. These 'recovered' capsules will be recorded on subsequent Intervention Visit data forms when they are actually recovered.

* All Detrol must be recovered at Visit 4 except for the exact number of capsules the patient will need to continue drug treatment to Day 69.

All unused Detrol must be recovered. If the Interventionist cannot recover the unused Detrol at an Intervention visit, the Evaluation staff will need to recover it at Visit 5. Be sure to alert the Evaluation staff to recover the correct # of 4mg capsules at Visit 5. See the Drug Adherence Worksheet attached.

B2e. **Number of Detrol LA 4mg capsules dispensed**: Record the number of Detrol LA **4mg** capsules dispensed at the visit. **Be certain to dispense only an amount that will be sufficient to last the patient to Day 69**.

Detrol LA 2mg capsules

B3. **Detrol LA 2mg capsules**

Record the number of 2 mg capsules taken since the last visit. Many patients will still be taking Detrol LA **4mg** at Visit 3 and 4. For these patients, write -00- in this data field and skip to B4. If the patient switched to Detrol LA **2mg** at or since the last visit, record the number of **2mg** capsules taken since the last visit.

If the patient changed from a 4mg capsule to a 2mg capsule between visits, source documentation for this change in dose must be recorded on an Encounter form. Record the number of Detrol LA **2mg** capsules taken since the last visit based on your interviews with the patient and your actual pill counts completed at an Interim Visit and/or today. If the patient report does not agree with your actual pill count, probe carefully to resolve the discrepancy.

If the patient stopped taking Detrol LA 2mg at an earlier visit but brings unused 2mg capsules to return today, code -6 (Capsules Recovered) in this data field and complete fields B2c-B2e.

If the patient took any 2mg capsules since the last visit or brings back 2mg capsules to return to you, you must complete B2c-B2e. Code this value based on your interview with the patient and your actual pill count. If the patient report does not agree with your actual pill count, probe carefully to resolve the discrepancy.

If the patient forgot to bring her medication bottle to this visit, the value recorded in B3 will be based solely on your interviews with the patient since an actual pill count cannot be completed. NOTE: B3c will be coded '*missing'* to indicate the pill count was not completed at this visit.

If you are dispensing Detrol LA 2mg on the day of this visit, code -1 (Dispensed Today) and continue to B3e.

If you cannot complete an actual pill count, be sure to probe carefully. Review /discuss every day since you dispensed Detrol LA **2mg**. Use a calendar as a prop to improve the patient's recall. To determine if her report of drug adherence is credible, ask the patient what strategies she

employs to remember to take her medication. Were there any days that she forgot to take her capsule? Did she take her capsule yet today?

B3a. **Start Date**: Record the date the patient actually started taking Detrol LA **2mg**. Ideally, the date will match the date you dispensed Detrol LA **2mg**. Confirm with the patient she started taking the **2mg** capsules on the same date dispensed. Record the actual day the patient first started taking Detrol LA 2mg.

B3b. **Stop Date**: If the patient stopped taking Detrol LA **2mg**, record the date of her last dose of Detrol LA 2mg. If a patient is still taking Detrol LA **2mg** at the time of Visit 2, record 01/01/0101 in this date field.

B3c. **Number of Detrol LA 2mg capsules remaining**: Complete an actual count of the **2mg** capsules remaining in the medication bottle and record the number in B3c. If the patient forgot to bring in her medication bottle write the word '*missing'* in this data field. **Do not complete this data field based on patient report**. You must complete an actual count of the **2mg** capsules remaining in the medication bottle to code a numerical value here.

B3d. **Number of Detrol LA 2mg capsules recovered**: If you recover Detrol LA 2mg capsules, record the number in B3d. This value is based on your actual count of the **2mg** capsules recovered. If the patient stops taking Detrol LA **2mg**, you must recover all unused **2mg** capsules. In addition, the patient should never be holding more Detrol than she will be able to use through the end of Stage 1, i.e. Day 69*****.

If the patient stopped taking Detrol **2mg** but forgot to bring her medication bottle to the visit, write '*missing'* in this data field. But the capsule must be recovered at a subsequent visit. Remind the patient to bring the unused capsules to her next visit. These 'recovered' capsules will be recorded on subsequent Intervention visit data forms.

***** All Detrol must be recovered at Visit 4 except for the exact number of capsules the patient will need to continue drug treatment to Day 69.

All unused Detrol must be recovered. If the Interventionist cannot recover the unused Detrol at an Intervention visit, the Evaluation staff will need to recover it at Visit 5. Be sure to alert the Evaluation staff to recover the correct # of 2mg capsules at Visit 5. See the Drug Adherence Worksheet attached.

B3e. **Number of Detrol LA 2mg capsules dispensed**: Record the number of Detrol LA **2mg** capsules dispensed at the visit. **Be certain to dispense only an amount that will be sufficient to last the patient to Day 69**.

B4. **Did the patient take Detrol at the same time most days?** Code this item 'yes' or 'no' by circling the corresponding value. This information is gathered via patient interview.

B5. **Were any interventions initiated for bothersome 'yes' symptoms recorded on the Symptoms Checklist (F205)?** Code this item 'yes' or 'no' by circling the corresponding value. Source documentation must be available on the Visit or Interim Visit Encounter Form. If you initiate an intervention for any of the symptoms on the Checklist (F205) circle code 1 (yes) and complete B6.

- Do not write in symptoms if they are not included on the Checklist, even if an intervention is provided.
- Do not document 'yes' symptoms in B6 if interventions were not initiated for them but if the patient complains of pain and burning with urination, you should rule out the presence of a urinary tract infection (UTI) in accordance with your customary clinical practice and document your assessment in a source document. You should also circle code 1 (yes) to B5 and write the symptom and the intervention and/or **assessment** in B6. Likewise, if you complete an **assessment** to rule out a reportable adverse event, even if you do not initiate a clinical intervention, for the purposes of this study, you should treat such an assessment as an intervention, i.e. document your actions in a source document, code yes to B5 and write the symptom and the intervention/assessment in B6.
- The following actions alone would not necessitate recording a symptom in B5, "discussed (symptom) with the patient"; "will monitor at future visits"; "patient taking Rx from primary".

B6. **Record the symptom(s) and code(s) and the intervention(s) and code(s) for each bothersome 'yes' symptom from the Symptoms Checklist**:

1. **Symptom Name**: Write the 'yes' symptom name in this text field. Write or print legibly. Illegible entries will be returned to you for clarification in the form of an edit report.
2. **Symptom code**: Write in the code number of the 'yes' symptom written in the preceding text field. Use the codes from the Symptom and Intervention Codes Attachment provided on the back of F233 and attached here.
3. **Intervention**: Write or describe the intervention or treatment provided in this text field. Write or print legibly. Illegible entries will be returned to you for clarification in the form of an edit report.
4. **Intervention code**: Write in the code number of the intervention initiated for the 'yes' symptom recorded in the preceding text field. Use the codes from the Symptom and Intervention Codes Attachment provided on the back of F233 and attached here.

Documentation for all symptom complaints and interventions provided at a study visit must be included on an Encounter Form or other source document for reference during a QA Site Visit.

Section C: Abstraction of Key Elements from the Bladder Diary

Description: Questions in Section C pertain to all patients regardless of their treatment assignment. Use all the Blue Intervention Diaries completed by the patient since the last visit.

C1. **Average number of leaks per week:** Include all accidents from all valid days in your calculation. **Do not count leaks from invalid days.**

- First, determine the grand total of leaks from all valid days;
- Next, divide this number by the total # of valid days to get the average # of leaks per day;
- Finally, multiply this number by 7 to get the average number of leaks per week.

Record the average # of leaks per week as a whole numbers. Follow common rounding rules as the last step in your calculation, i.e. round up to the next whole value for fractions equal to or greater than .5.

C2. **Average # of voids per day (24 hour period):** Include all voids from all valid days in your calculation. **Do not count voids from invalid days.**

- First, determine the grand total of voids from all valid days,
- Next, divide this number by the total # of valid days to get the average # of voids per day.

Record the average # of voids per days as a whole numbers. Follow common rounding rules as the last step in your calculation, i.e. round up to the next whole value for fractions equal to or greater than **.**5.

C3. **What is the patient's treatment group assignment?** Circle the patient's treatment group assignment. If the patient is in the drug-only treatment arm, circle code 1 and skip to item D7.

Section D: Summary of Key Elements of the Behavioral Intervention (Combination Patients Only)

Description: Questions D1-D6 pertain only to patients receiving the combination treatment. D7 and D8 should be answered for patients in both treatment arms.

D1. **Did the patient perform 5 consecutive pelvic floor muscle contractions?** Based on your evaluation completed during the intervention, code this item 'yes' or 'no' by circling the corresponding value.

D2. **Was she able to minimize Valsalva and accessory muscle contractions?** Based on your evaluation completed during the intervention, code this item 'yes' or 'no' by circling the corresponding value.

D3. **Did the patient report she used the urge suppression strategies?** Code this item 'yes' or 'no' by circling the corresponding value. All patients in combination treatment receive urge strategies training, so this item should be coded yes or no for all patients in the combination treatment arm.

D3a. **Did she report it worked for her?** Code this item 'yes' or 'no' by circling the corresponding value.

D4. **Did the patient report she used the urge avoidance strategies?** Not all patients will receive urge avoidance training, and urge avoidance strategies are not taught until V3. Hence, this item should be coded NA (3) for all patients at V3. D4 should also be coded NA (3) at **V4** if the patient did not receive urge avoidance training at V3. If the patient received urge avoidance training at Visit 3, code D4 'yes' or 'no' at V4 by circling the corresponding value.

D4a. **Did she report it worked for her?** This item should be skipped (i.e. D4 coded "-1") for all patients at V3. If the patient received urge avoidance training at Visit 3, code D4a 'yes' or 'no' at V4 by circling the corresponding value.

D5. **Did the patient report she used the stress strategies?** Code this item 'yes.' 'no' or 'not receiving stress strategy training' by circling the corresponding value. This item will be coded 'no' if the patient is receiving stress strategies training but reports she had no occasion to use stress strategies since her last visit.

D5a. **Did she report it worked for her?** Code this item 'yes' or 'no' by circling the corresponding value.

D6. **Did the patient report she was able to delay voiding at least 10 minutes by using the urge strategies?** Code this item 'yes' or 'no' or 'not receiving bladder training' by circling the corresponding value.

D7. **How long did the visit last?** Record the actual number of minutes spent with the patient completing the intervention visit. In addition, count the time the patient spent completing the Symptoms Checklist and Exercise Adherence Questionnaire. Do not count any other waiting room wait time.

D8. **Record the number of minutes spent with the patient between visits**. Count all time spent with the patient in phone contact or in-person between study visits. Each contact should be recorded on a separate Interim Visit Encounter Form. Do not count any other minutes spent making or rescheduling appointments.

SYMPTOM AND INTERVENTION CODES ATTACHMENT

SYMPTOM CODES	
01	pain or burning with urination
02	blood in your urine
03	difficulty emptying your bladder
04	difficulty starting your urine stream
05	skin rash
06	nausea
07	heartburn
08	dizziness
09	confusion or difficulty thinking clearly
10	sore throat
11	dry mouth
12	blurred vision
13	abdominal pain
14	constipation
15	diarrhea
16	pelvic muscle soreness
17	insomnia
18	fever
19	drowsiness
20	headache

INTERVENTION	
120	Dry mouth handout
121	Constipation handout
122	Decrease study drug dose to 2 mg
123	Stopped study drug
999	Other

VISIT 05: DRUG ADHERENCE WORKSHEET

Affix ID Label

What should the Evaluator expect for Drug adherence and drug recovery for visit 5?

1. What dose of Detrol was the patient **taking** at Intervention Visit 4 or the last in-person intervention visit?

4mg 2mg No drug

2. How many **4mg** capsules was the patient holding at that visit? _____

   2a. How many **4mg** capsules should she take between her last visit and the last day of Stage 1 if she takes all the remaining prescribed 4mg capsules?

   _____

3. How many **2mg** capsules was the patient holding at that visit? _____

   3a. How many **2mg** capsules should she take between her last visit and the last day of Stage 1 if she takes all the remaining prescribed **2mg** capsules?

   _____

4. Are there any capsules from previous visits that must be recovered? Describe both dose and number of capsules that should be recovered. Record the number of capsules that should be recovered in the space provided or circle, 'no capsules'.

   # of 4mg: _____

   # of 2mg: _____

   No capsules:

Interventionist ID: _____ date: _____