



BE-DRI

Question by Question Specifications Guide

Form 211: Intervention Visit 1

Version 10/20/04 (A)_revised 01/06/05

I. Purpose

The purpose of the Intervention Visit 1 Data Form (F211) is to capture selected information about intervention activities completed at the 1st intervention visit.

II. Administration

A. Materials Needed

- Completed Visit 1 Encounter Form
- Intervention Visit 1 Data Form (F211) with ID labels attached

B. Window for Visit 1

Intervention Visit 1 should be completed on the same day the patient is randomized. Randomization / Visit 1 is completed on Day 0. There is no visit window for Visit 1.

C. Source, Timing and Method of Data Form Completion

The Visit 1 Encounter Form is considered the source document for BE-DRI intervention activities completed at the first intervention visit. Hence, the Visit 1 Encounter Form should be used as the source document to complete F211. F211 should be available to the UITN-certified BE-DRI Interventionist at the time of completion of Visit 1. The Data Form must 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 F211 identify the patient's treatment assignment. Local procedures must be implemented to maintain blinding of Evaluation staff that may complete post-intervention measurements including interviews, exams, Bladder Diary abstraction, or distribution and/or collection of the self-administered surveys.

III. Section by Section Review for Form 211

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:** The visit number for Form 211 is pre-coded as Visit = INT1.
- A3. **Date Intervention Visit 1 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 F211 immediately after Intervention Visit 1 is completed. An unblinded Evaluation staff member, e.g. Study Coordinator, Data Manager, etc should receive the completed F211 no later than 24 hours after the visit is completed.

Section B: Summary of Key Elements of the Drug Intervention

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

- B1. **Detrol LA 4mg dispensed:** Record the number of Detrol LA **4mg** capsules dispensed at Visit 1. Pfizer supplies Detrol LA **4mg** in bottles containing 30 capsules so the value recorded in B1 will be '30 capsules'. If less than 30 capsules are dispensed at Visit 1, a rationale should be available in the source document.
- B2. **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 1 Encounter Form. If you initiate an intervention for any of the symptoms on the Checklist (F205) circle code 1 (yes) and complete B3.
- 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 B3 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 B2 and write the symptom and the intervention and/or **assessment** in B3. 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 B2 and write the symptom and the intervention/assessment in B3.
 - The following actions alone would not necessitate recording a symptom in B3, "discussed (symptom) with the patient"; "will monitor at future visits"; "patient taking Rx from primary".
- B3. **Record the symptom(s) and code(s) and the intervention(s) and code(s) for each bothersome 'yes' symptom from the Symptoms Checklist:**
- i. **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.
 - ii. **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 F211 and attached here.

- iii. **Intervention:** Write or describe the intervention or treatment provided in this text field. Write legibly. Illegible entries will be returned to you for clarification in the form of an edit report.
- iv. **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 F211 and attached here.

Documentation for all interventions initiated 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.

- C1. **Number of leaks per week:** For Visit 1, we want to capture the number of leaks per week, which is actually the total # of leaks reported on the 7-Day Evaluation Diary returned by the patient at Visit 1. **Do not count leaks from invalid days.** Even if the # of valid days is less than 7, you should record the total # of leaks from all valid days from that valid Diary.
- C2. **Average # of voids per day (24 hour period):** Include all voids from all valid days in your calculation.
- 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.
- Do not count voids from invalid days.** Even if the total number of valid days is fewer than 7 for a given week, only count voids from valid days.

Record the average # of voids per days as a whole numbers. Follow common rounding rules at the very end of your calculations, i.e. round up to the next whole value for fractions equal to or greater than .5.

- C3. **Average urine output per day:** Patients are instructed to track intake and output for 2 days, consequently, for most patients, you will have 2 days of data to calculate this average. Calculate the voided volumes for each day separately, then add these 2 values and divide by 2 to determine average urine output per day. If the patient only provides output for one day, record the total volume for this single day in C3. If the patient tracks output for more than 2 complete days, you can include additional complete days in this calculation. Adjust your calculations accordingly. Follow common rounding rules to document volumes in whole numbers; i.e. round up to the next whole value for fractions equal to or greater than .5.

If there are no days for which the patient tracked output for the complete 24-hour period, write 'missing' in this data field.

- C3a. **Did the patient void >70oz / 24 hours?** Based on the value recorded in C3, code this item 'yes' or 'no' by circling the corresponding value.

When C3 is missing: Since 'average urine output per day' is used to determine if a patient in the combination arm should receive Fluid Management Counseling, and since this is the only time you will get output measurements on which to base your decision regarding Fluid Management Counseling, you will need to make use of the voided volume data in the Diary even if the output

data are incomplete. C3a should be coded 'yes' if the patient voids >70 oz in a day even if the patient tracked output for <24 hours. You can also code this item 'yes' if the patient voids <70 oz but in your clinical judgment you feel she would certainly have voided >70 oz if she had measured her output for the entire day (e.g. she voided 50oz by 12 noon and her measured intake was 60oz between 12 noon and midnight.) If the patient does such an incomplete job of recording her output that you cannot determine a code for this question, code this item as 'missing'.

- C4. **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 D5

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

Description: Questions D1-D4 pertain only to patients in combination treatment. D5 should be answered for patients in both treatment arms.

- D1. **Did the patient successfully identify pelvic floor muscles?** Circle code 1 if the patient was able to identify her pelvic floor muscles and only vaginal feedback was required. Circle code 2 if she was able to successfully identify her pelvic floor muscles but anal feedback was required. Circle code 3 if the patient was not able to identify her pelvic floor muscles.
- NOTE: Feedback is defined as digital feedback per manual palpation, not verbal feedback or verbal cues.
- D2. **Did she 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.
- D3. **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.
- D4. **Was Fluid Management counseling initiated?** Code this item 'yes' or 'not indicated' by circling the corresponding value. If C3a is >70 oz, Fluid Management Counseling is indicated and should be initiated and this item should be coded yes.
- D5. **How long did the visit last?** Record the actual number of minutes spent with the patient completing the intervention. Do not count waiting room wait time. Do not count time spent completing BE-DRI data forms at Visit 1. Time the patient spends completing her data forms will be counted in subsequent intervention visits but not at Visit 1.

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