BE-DRI
Question by Question Specifications Guide
Form 244: End of Stage 1 Report
Version 10/20/04 (A)_revised 01/06/05

I. Purpose

Form 244 is the End of Stage 1 Report form. The purpose of Form 244 is two-fold.

- Section B is designed to capture information about seminal intervention activities that may occur between Visit 4 (the last Intervention Visit), and Visit 5 (the first post-intervention Evaluation visit).
- Section C is designed to capture 2 important end-of -intervention elements, specifically, the outcome of the final drug count completed by the Evaluation staff at Visit 5 and verification of the presence or absence of a urinary tract infection at the time the patient completed Visit 5 study measurements including the Evaluation Bladder Diary.

II. Administration

A. Materials Needed

- Any Interim Visit Encounter Forms completed since Visit 4.
- End of Stage 1 Report Data Form (F244) with ID labels attached

B. Visit 5 window

The target date for Visit 5 is 70 days following Randomization / Visit 1 with a visit window of +14 days, i.e. the visit should be completed between 70 and 84 days following randomization. NOTE: Visit 5 is an Evaluation Visit and it cannot occur at any time during Stage 1.

C. Source, Timing and Method of Data Form Completion

Any Interim Visit Encounter forms complete after Visit 4 will be the primary source documents for any intervention activities that may occur after Visit 4 through the end of Stage 1. Unlike any other BE-DRI Data Form, the End of Stage 1 Report form (F244) is completed by both an Interventionist and an Evaluator.

The Interventionist completes Section B at the end of Stage 1, immediately prior to Visit 5. Any seminal intervention activities that occur between the patient and the Interventionist through the last day of Stage 1, i.e. Day 69, must be captured on F244, hence it should be completed by the Interventionist as close to Day 70 as possible. This information must be available to the Evaluation staff at Visit 5.

An Evaluator completes Section C at Visit 5.

D. Maintaining Blinding for Evaluation Staff

The patient's treatment group is not recorded on F244 so BE-DRI Evaluation staff can review data recorded on this form.

III. Section by Section Review for Form 244

Section A. General Information

The Interventionist who completes the last Intervention visit should complete Section A and B of F244. If the last contact with the patient is an interim visit, the Interventionist who completes the last interim visit should complete Section B.

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 244 is pre-coded as Visit = VS0**5**.

Section B. Final Intervention Report

B1. **Did you complete any interim intervention visits with this patient since her last visit?** Code this item 'yes' or 'no' by circling the corresponding value. If no interim visits were conducted, code 'no' and skip to B9. Otherwise code 'yes' and continue with B2.

Drug Adherence

Description: Questions B2-B4 aim to capture drug adherence data for patients who have changed their Detrol dose since Visit 4. There are 3 possible dose change scenarios: You change the dose of Detrol from 4mg to a 2mg between Visits 4 and 5, the patient stops taking the 4mg dose and no other dose is substituted, or she stops taking her 2mg dose and no alternate dose of Detrol is substituted.

B2. **Since her last study visit, has the patient's Detrol dosage changed, i.e. switched to 2mg or stopped Detrol altogether?** Code this item 'yes' or 'no' by circling the corresponding value. If there has been no contact with the patient since her last study visit, code this item no. If there has been a dose change, complete B3 and B4. Otherwise skip to B5.

Detrol LA 4mg capsules

B3. **Detrol LA 4mg capsules**

Record the number of 4mg 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 B4. If the patient took any 4mg capsules since Visit 4, you must complete B3-B3d. Code B3 based on patient interview and an actual pill count at the time of the dosage change (day of interim visit). If the patient report does not agree with the pill count, probe carefully to resolve the discrepancy.

If you cannot complete a pill count, B3 will be based on patient report alone. 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 interim visit)?

NOTE: B3c will be coded missing to indicate the pill count was not completed at the interim visit.

B3a. **Start Date**: Record the date the patient started taking Detrol LA **4mg.** This date should match the date of Visit 1. Record the date using the mm/dd/yyyy format.

B3b. **Stop Date**: Record the date the patient stopped taking Detrol LA **4mg**. Record the date of her last dose of Detrol LA **4mg**. Record the date using the mm/dd/yyyy format.

B3c. **Number of Detrol LA 4mg capsules remaining**: Record the number of **4mg** capsules remaining at the time of the dose change. This value is based solely on an actual count of the capsules remaining in the medication bottle at the interim visit when you changed the patient's dose. 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.

B3d. **Number of Detrol LA 4mg capsules recovered:** Record the number of **4mg** capsules recovered at the time of the dose change. If the patient stops taking Detrol LA **4mg**, you must recover all the remaining capsules (# recorded for B3c). Record the # of capsules you recovered in B3d.

If the patient stopped taking Detrol **4mg** but forgot to bring her medication bottle to the visit, write '*missing'* in this data field. But Evaluation staff must recover all remaining Detrol capsules at Visit 5. Alert the Evaluation staff to recover the correct number of 4mg capsules. See the Drug Adherence Worksheet attached.

Alert the Evaluation staff to recover the correct number of 4mg capsules.

B3e. **Number of Detrol LA 4mg capsules dispensed**: In the unlikely event that you dispense Detrol 4mg capsules after Visit 4, record the number of Detrol LA **4mg** capsules dispensed in B3e. NOTE: The DMS is programmed to generate an edit for any value >0 for this data field. If **4mg** capsules are dispensed after Visit 4 you will need to provide a reason to override the edit that will result from a value >0. **Be certain to dispense only an amount that will be sufficient to last the patient through the end of Stage 1, i.e. Day 69**.

Detrol LA 2mg capsules

B4. **Detrol LA 2mg capsules**

Record the number of 2mg capsules taken since the previous visit. If the patient took any 2mg capsules since Visit 4, you must complete B4-B4d. Code B4 based on patient interview and an actual pill count. If the patient report does not agree with your actual pill count, probe carefully to resolve the discrepancy.

If you cannot complete a pill count, B4 will be based on patient reports alone. NOTE: B4c will be coded *missing* to indicate the pill count was not completed at the time of the interim visit. **If you cannot complete a 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 interim visit)?

B4a. **Start Date**: Record the date of the patient's first dose of Detrol LA **2mg**. Ideally, the date will match the date you dispensed Detrol LA **2mg**. Confirm with the patient she actually started taking the **2mg** capsules on the same date dispensed. Regardless, record the actual date of the patient's first dose of Detrol LA **2mg**.

B4b. **Stop Date**: If the patient stopped taking Detrol LA **2mg** since Visit 4, record the date of her last dose of Detrol LA **2mg**.

B4c. **Number of Detrol LA 2mg capsules remaining**: Record the number of **2mg** capsules remaining at the time of the dose change. Record the actual number of **2mg** capsules remaining in the medication bottle at the interim visit when you changed the patient's dose. 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.

B4d. **Number of Detrol LA 2mg capsules recovered:** Record the number of **2mg** capsules recovered at the time of the dose change. If the patient stops taking Detrol LA 2mg, you must recover all the remaining capsules (# recorded in B4c). Record the # of capsules you recovered in B4d.

If the patient stopped taking Detrol **2mg** but forgot to bring her medication bottle to the visit, write '*missing'* in this data field. But Evaluation staff must recover all remaining Detrol capsules at Visit 5. Alert the Evaluation staff to recover the correct number of 2mg capsules. See the Drug Adherence Worksheet attached.

Alert the Evaluation staff to recover the correct number of 2mg capsules.

B4e. **Number of Detrol LA 2mg capsules dispensed**: Record the number of Detrol LA **2mg** capsules dispensed at the interim visit. **Be certain to dispense only an amount that will be sufficient to last the patient through the end of Stage 1, i.e. Day 69**.

'Need To Know' Medications

B5. **Since her last study visit, did the patient report taking any 'Need To Know' drugs?** If the patient has taken any 'Need to Know' medications, circle code 1 (Yes) and list them in B5a. If the patient denies taking any 'Need to Know' mediations, circle code 2 (No) and skip to B6.

B5a. '**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.

B6. **Since her last study visit, did you initiate any interventions 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 an Interim Visit Encounter Form. If you initiate an intervention for any of the symptoms on the Checklist (F205) circle code 1 (yes) and complete B7.

- 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 B7 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. Circle code 1 (yes) to B6 and write the symptom and the intervention and/or assessment in B7. 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 B6 and write the symptom and the intervention/assessment in B7.
- The following actions alone would not necessitate recording a symptom in B7: "discussed (symptom) with the patient"; "will monitor at future visits"; "patient taking Rx from primary".

B7. **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 attached here.
iii. **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.
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 attached here.

Documentation for interventions initiated must be included on an Encounter Form or other source document for reference during a QA Site Visit.

B8. **Record the number of minutes spent with the patient since her last visits**. Count all time spent with the patient in phone contact or in-person since Visit 4. Each contact should be recorded on a separate Interim Visit Encounter Form. Do not count minutes spent making or rescheduling appointments.

B9. **Date of last Intervention contact:** Record the date of the last intervention contact. If this is the same as the date of Visit 4, record that date here. If you had any other contacts with the patient after Visit 4, record the date of the last contact here. Do not count a contact if you only spent time making or rescheduling an appointment. Use the mm/dd/yyyy format.

B10. **Date Section A and B Completed**: Enter the date you complete Section A and B. The Interventionist completes Section B at the end of the intervention stage, Stage 1, immediately prior to Visit 5. Any seminal intervention activities that occur between the patient and the interventionist through the end of Stage 1, i.e. Day 69, must be captured on F244, hence it should be completed by the interventionist on Day 70 or later.

B11. **Interventionist's Initials**: The certified Interventionist who completed the last intervention visit should complete Sections A and B and record her initials in this data field. If the last contact with the patient is an interim visit, the Interventionist who completes the interim visit should complete Section A and B and record her initials here. Follow conventions described in earlier QxQs.

Section C. Final Drug Accounting by Visit 05 Evaluation Staff

Description: Questions C1 and C2 aim to capture drug adherence data for patients at the end of the intervention. The Interventionist will need to summarize the patient's drug adherence history so the Evaluation staff know what to expect regarding the patient's drug adherence. See the Drug Adherence Worksheet attached. While referencing the Worksheet, the Evaluator should interview the patient and complete a pill count of any remaining Detrol capsules.

Detrol LA 4mg capsules

C1. **Detrol LA 4mg capsules**

Record the number of 4mg capsules taken since the patients last visit: If the patient stopped taking Detrol LA 4mg at an earlier visit, record -00- in this data field and skip to C2.

If the patient was still taking Detrol LA 4mg at Visit 4, C1-C1d must be completed. Code C1 based on information from the Interventionist as well as your own interview with the patient and an actual pill count. An empty medication bottle is equal to a zero pill count.

The number recorded in C1 should be equal to or less than the number of days between the date of Visit 4 and Day 69 inclusive. If the pill count doesn't corroborate the patient report, probe carefully to resolve the discrepancy.

If you cannot complete a pill count, C1 will be based on patient reports alone. **If you cannot complete an actual pill count**, be sure to 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?

NOTE: C1c will be coded missing to indicate the pill count was not completed at VS05.

C1b. **Stop Date**: Record the date the patient stopped taking Detrol LA **4mg**. Record the date of her last dose of Detrol LA **4mg** in C1b. This date should not exceed Day 69 (i.e. 1 day prior to VS05 target date). Record the date using the mm/dd/yyyy format.

C1c. **Number of Detrol LA 4mg capsules remaining**: Record the number of 4mg capsules remaining at VS05. Record the actual number of **4mg** capsules remaining in the medication bottle. 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. An empty medication bottle is equal to a zero pill count.

C1d. **Number of Detrol LA 4mg capsules recovered:** Record the number of 4mg capsules recovered at VS05. All remaining capsules must be recovered at VS05. Record the # of capsules you recovered in C1d. If the patient forgot to bring her medication bottle to the visit, write '*missing'* in this data field. If there were any capsules remaining that were not retuned at VS05, every

effort should be employed to recover the remaining capsules. For example, you might give the patient a self-addressed-stamped envelope and ask her to mail the remaining capsules back to you today or tomorrow. Make a plan to call her if the package does not arrive within 3 days. You might go to her home to pick them up. You might send a courier to retrieve them.

Detrol LA 2mg capsules

C2. **Detrol LA 2mg capsules**

Record the number of 2mg capsules taken since the previous visit. If the patient never took Detrol LA **2mg** or stopped taking it at an earlier visit, record -00- in this data field and skip to C3.

If the patient was still taking Detrol LA **2mg** at Visit 4, C2b-C2d must be completed. Code C2 based on information from the Interventionist as well as your own interview with the patient and an actual pill count. An empty medication bottle is equal to a zero pill count.

The number recorded in C2 should be equal to or less than the number of days between the date of Visit 4 and Day 69 inclusive. If the pill count doesn't corroborate the patient report, probe carefully to resolve the discrepancy.

If you cannot complete a pill count, C2 will be based on patient reports alone. **If you cannot complete an actual pill count**, be sure to 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 (or non-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?

NOTE: C2c will be coded missing to indicate the pill count was not completed at VS05.

C2b. **Stop Date**: If the patient stopped taking Detrol LA **2mg** since Visit 4, record the date of her last dose of Detrol LA **2mg**. This date should not exceed Day 69 (the day prior to the V% target date). Record the date using the mm/dd/yyyy format.

C2c. **Number of Detrol LA 2mg capsules remaining**: Record the number of **2mg** capsules remaining at VS05. Record the actual number of **2mg** capsules remaining in the medication bottle. 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. An empty medication bottle is equal to a zero pill count.

C2d. **Number of Detrol LA 2mg capsules recovered:** Record the number of 2mg capsules recovered at VS05. All the remaining capsules must be recovered at VS05. Record the # of capsules you recovered in C2d. If the patient forgot to bring her medication bottle to the visit, write '*missing'* in this data field. If there were any capsules remaining that were not retuned at VS05, every effort should be employed to recover the remaining capsules. See example strategies described above in C1d.

C3. **Does the patient report or is there any evidence that she had a urinary tract infection during the completion of any Visit 05 study measures?** Review available documents (e.g. clinical records, Symptoms Checklist), interview the patient and complete appropriate

assessments as needed to determine if the patient had a UTI during completion of any of the VS05 study measures including he Evaluation Bladder Diary.

C4. **Date of visit 5:** Enter the date of Visit 5.

C5. **Date Section C completed**: Enter the date you complete Section C. The Evaluator completes Section C at the end of Visit 5.

C6. **Evaluator's Initials**: The Evaluator who completed VS05 should complete Sections C and record her initials in this data field. Follow conventions described in earlier QxQs.

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 Here

Tell the Evaluator what to expect regarding drug adherence and drug recovery at Visit 5?

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

4mg 2mg No drug

4mg

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

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

_____

2mg

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

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

_____

4. Are there any capsules from previous visits that must be recovered? Record the number of capsules that should be recovered in the space provided or circle, 'no capsules' if all capsules are accounted for.

4mg _____ 2mg _____ No drug

Describe the circumstances that resulted in unrecovered capsules: _____

_____

_____

_____

Interventionist ID: _____ Date: _____