



BE-DRI

Question by Question Specifications Guide

Form 205: Symptoms Checklist

Version 06/01/04 (A)

I. Purpose

The purpose of the **Symptoms Checklist (F205)** is to monitor the patient for potential side effects due to the study drug.

II. Administration

A. General Information

This form is to be completed at baseline to identify, and therefore control for, any symptoms that the patient might have prior to starting the study drug. Such symptoms would not be considered drug side effects. The form is also to be completed at all study visits to identify any newly developed symptoms that could be considered drug side effects.

B. Data Source

The patient is considered the source for data collected in Data Form 205; therefore, Data Form 205 is a source document.

C. Certification of Symptoms Checklist Coder

Section B of Data Form 205 requires coding. This coding can be performed only by a certified "Symptoms Checklist Coder."

III. Section by Section Review

Section A: General Study Information

- 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:** Please circle the correct visit number.
- A3. **Date Form Completed:** Record the date you complete the interview. Use the mm/dd/yyyy format.
- A4. **Coder's Initials:** The coder must be a certified Symptoms Checklist Coder. All coders must be certified by and registered with the BCC. Data submitted by non-certified individuals should not be data entered into the UITN BE-DRI DMS. The coder should record his/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.

Section B: Symptoms Checklist

Description: Each question has two parts. First, the patient is asked if she currently experiences the noted symptom. If the patient responds “Yes,” she must also indicate how bothersome that particular symptom is by drawing a line on the visual analog scale (VAS) in the box to the right. The patient should be instructed to draw a vertical line at the point on the VAS horizontal bar that best represents how bothersome the symptom is for her. The scale ranges from “Not at all Bothersome” on the left to “Extremely Bothersome” on the right. If the patient draws a vertical line towards the left of the VAS bar, it is considered less bothersome. Similarly, if a line is drawn closer to the right, the symptom is considered more bothersome.

The length of the VAS bar is 100 mm. Using the standardized metric rule provided by the BCC, the coder should measure the number of mms from the left of the bar to the vertical line drawn by the patient. This value should be recorded in the “Code” box for each item, i.e., B1a, B2a, B3a, etc.

Item by Item Review:

B1- B20. Each of these items consists of a symptom that has been reported previously by Pfizer as a potential side effect of the study drug, Detrol LA. Instruct the patient to record if she experiences the symptom, and if so, how to indicate the degree of bother experienced. As described above, she should be instructed to make a vertical line at the point on the VAS bar that best indicates how bothersome the symptom is for her.

B2. NOTE: Be sure the patient understands that this question is NOT asking about menstruation.

Section C: Everyday Memory

Description: The final section consists of 4 questions that ask the patient about her everyday memory. As with the list of symptoms in Section B, these questions have been included to determine if the study drug has a negative effect on memory.

Item by Item Review:

C1-C4. The patient should be instructed to circle one response to each question. The three response options include: *No, Not much worse* (1); *Yes, A bit worse* (2), and *Yes, A lot worse* (3).