

## HALT-C Trial Symptoms Form

Form # 43 QxQ Version A: 06/15/2000

**Purpose of Form #43:** To assess symptoms that study participants may have been experiencing in the past week by using a brief, self-administrated instrument.

**When to complete Form #43:** Form #43 can be administered in either English or Spanish. The Symptoms Form should be completed by all patients at the following visits:

- **Lead-In Phase patients:** Baseline visit (W00), Week 8 (W08), and Week 20 (W20).
- **Express and Breakthrough/Relapse patients:** Randomization visit (R00).
- **Responder Phase patients:** every visit through Week 72 (W72).
- **Randomization Phase patients:** every visit through Month 54 (M54).

### **SECTION A: GENERAL INFORMATION**

- A1. Affix the patient ID label in the space provided.
- If the label is not available, record the ID number legibly.
- A2. Enter the patient's initials exactly as recorded on the Trial ID Assignment form.
- A3. Enter the three-digit code corresponding to this visit.
- A4. Record the date the form was completed using MM/DD/YYYY format.
- A5. Enter the initials of the person completing Section A of the form.

### **SECTION B: COMPLETING THE SYMPTOMS FORM**

Section B of this form should be self-administered by the patient. The patient should complete the form by marking with an "x" on the line next to each symptom that best describes how s/he has felt in the past week.

- If the patient has not experienced this particular symptom in the past week, s/he should mark an "x" on the left perpendicular line on the left side of the horizontal line under "None".
- If s/he has experienced this particular symptom, s/he will mark an "x" on the horizontal line corresponding to whether the symptom was a little more than "None" to "Worst ever".

The Symptoms Questionnaire should take approximately three minutes to complete.

If the patient is not able to complete this form by her/himself, the interviewer may read the question and have the patient point with a pen where s/he would make an "x" on the horizontal line. Please note in the margins of the form if the interviewer has completed the form and enter the initials of the person completing the forms as delineated above. The data entry person should add this written note as a form level comment in the DMS.

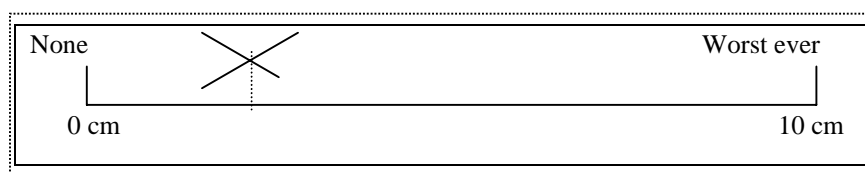
It is important that patients complete all of the items on the form.

- Review the form for any missing items.
- Make sure that each item has a single statement marked.
- Please ask the patient to complete any missing or doubly marked items.

**SECTION C: SCORING THE SYMPTOMS FORM**

The data managers should measure all scores to the nearest 0.1 cm in the following way:

- The horizontal line next to each symptom is 10 centimeters in length.
- Place a centimeter ruler on the horizontal line with the “0” of the ruler on the left-hand perpendicular mark (under “None”). The juncture of the “x” on the horizontal line measures the number of centimeters from the 0 cm (“None”) mark.
- This score should be placed in the gray box (Scoring: For Data Manager Use Only) next to the appropriate symptom.



- If the “x” is marked above the line, extend the juncture of the “x” perpendicularly down to the symptom line and then measure as delineated above, starting at the left hand perpendicular mark (“None”) up to the extended line from the juncture of the “x”.
- If for any reason the form was reproduced so that the horizontal line is slightly shorter or longer than 10 centimeters in length, the measurement should still be made from the left-hand perpendicular mark.