

## HALT-C Trial Q x Q

### CIDI-12 – Cognitive Effects AS

Form # 153 Version A: 06/15/2000 (Rev. 05/28/2002)

**Purpose of Form #153:** To identify recent psychiatric diagnoses using the CIDI-12 Auto 2.1 modules of DEMOGRAPHICS (A), ANXIETY (D), and DEPRESSION (E), in patients participating in the Cognitive Effects Ancillary Study.

**When to complete Form #153:** This form should be completed only at Site 17 (University of Southern California) and Site 18 (University of Michigan) as part of the Cognitive Effects of Long-term Peginterferon alfa-2a Ancillary Study. Express patients are not eligible for the Cognitive Effects Ancillary Study.

Form #153 should be completed after the 12-month version of the CIDI-12 Auto 2.1 program has been administered to study participants. Form #153 should be completed at the following study visits:

- **Lead-In Phase patients:** Week 24 (W24).
- **W20 Responder Phase patients:** Week 48 (W48) and Week 72 (W72).
- **Breakthrough/Relapser patients:** Randomization visit (R00) if it is more than one month after the most recent Neuropsychiatric Testing (Form #152).
- **Randomized patients:** Month 12 (M12), Month 24 (M24), Month 36 (M36), Month 48 (M48), and 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 the form.

#### **SECTION B: CIDI-12**

Administer the CIDI-12 Auto 2.1 12-month computerized interview per training manual and Manual of Operations instructions. Print out a hard copy of the patient's raw data from the file R[idnumber].ALL and store in patient notebook. Print out a hard copy of diagnostic data from the file R[idnumber].SCS and complete B1 through B7.

- B1. Record the date the CIDI-12 test was administered in MM/DD/YYYY format.
- B2. Record the seven-digit ID Code as follows:
  - The first digit starting at the left is a visit number as follows:  
W24 = 1, M12 = 2, M24 = 3, M36 = 4, M48 = 5, M54 = 6, W48 = 7, W72 = 8, R00 = 9
  - The last six digits are the patient ID number.

- B3. If the CIDI-12 was self-administered by the RESPONDENT, circle 1. If the INTERVIEWER administered the CIDI –12, circle 2.
- B4. If the CIDI-12 English version was administered, circle 1. If the CIDI-12 was administered in Spanish, circle 2.
- B5. If a subject has any DSM-IV diagnoses printed on the hard copy of file R[idnumber].SCS then circle 1 for YES and continue to B6. If there are no DSM-IV diagnoses listed, then circle 2 for NO. The form is complete.
- B6. Enter the number of DSM-IV diagnoses listed on the hard copy of file R[idnumber].SCS.

#### B7. CIDI-12 DSM-IV Diagnoses

This section provides important detailed information regarding the DSM-IV diagnoses generated from the CIDI-12 interview. All of the required information can be obtained from the file R[idnumber].SCS. Please note that the hard copy will have DSM-IV and ICD10 diagnostic scores printed. The DSM-IV will be only digits (e.g. 393.54) The ICD10 diagnostic score will start with a letter followed by digits (e.g. F41.0). Record **ONLY** the DSM-IV diagnostic score. Complete one row for each DSM-IV diagnosis present in the scoring file.

- B7a. DSM-IV 5-digit diagnostic code: Enter the five-digit DSM-IV code in this field.
- If a listed code only has four digits, add a zero to the right side of the decimal point. (e.g. 300.4 = Dysthymia would be entered as 300.40 )
- B7b. Diagnostic criteria met: Enter one of the following one-digit codes for diagnostic criteria.
- 0 = Indeterminate diagnosis
  - 1 = Criteria for diagnosis not met
  - 3 = The positive criteria for diagnosis are met but exclusion criteria not met
  - 5 = All diagnostic criteria are fulfilled
- B7c. Onset code: Enter one of the following one-digit codes identifying the diagnosis onset.
- 1 = within last 2 weeks
  - 2 = 2 weeks to less than 1 month ago
  - 3 = 1 month to less than 6 months ago
  - 4 = 6 months to less than 1 year ago
  - 5 = in the last 12 months, don't know when
  - 6 = more than 1 year ago
- B7d. Age of onset: If B7c onset is coded other than 0, enter the two-digit age of onset.
- B7e. Recency code: Enter one of the following one-digit codes identifying recency of the diagnosis.
- 1 = within last 2 weeks
  - 2 = 2 weeks to less than 1 month ago
  - 3 = 1 month to less than 6 months ago
  - 4 = 6 months to less than 1 year ago
  - 5 = in the last 12 months, don't know when
  - 6 = more than 1 year ago
- B7f. Age of recency: If B7e is coded other than 0, enter the two-digit age of diagnosis recency.
- B7g. DSM-IV diagnosis text: Type the DSM-IV diagnosis verbatim in this field.