

General Instructions

The CES-D questionnaire is a research tool designed to measure the depressive symptoms through a series of questions that determine how the patient has felt during the past week. The CES-D will be administered throughout the course of the trial at the screening visit, the baseline visit, and weeks 12, 24, 36, 48, 96, 192, and 240 (follow-up week 48). Results of the CES-D should be used in conjunction with clinical judgment.

Per the study protocol, a score of >15 could result in a referral to a mental health provider, per the discretion of the physician investigator.

This version of the CES-D is available in English only.

The questionnaire is self-explanatory and the patient should be asked to complete it without additional instructions or assistance. The clinical coordinator should not attempt to interpret, elaborate upon, or rephrase questions. If the patient asks for assistance from the clinical coordinator, the coordinator should encourage the patient to do his/her best to complete the form on his/her own, stating that "there are no right or wrong answers".

The questionnaire is designed to be completed on-line via the HBRN web-based system. If completed on-line, the coordinator will initialize the session for the patient. The patient will complete the battery of questionnaires and then turn the session over to the coordinator. The coordinator will have the opportunity to review incomplete items with the patient before exiting the session. If the questionnaire is completed on paper, the coordinator should review the questionnaire for completeness while the patient is still present.

Specific Instructions

- Patient ID: Record the Patient ID in the top right hand corner.
- Date of Evaluation: Record the date (month/day/year) that the patient completed the questionnaire.
- Protocol visit: Record the protocol timepoint that corresponds to the visit.
- Form completed by: If the patient is unable to understand the questions because of educational, cultural or language difficulties help may be provided by a trained translator or the patient's next of kin or friend. In these situations the person helping the patient can read the questions to the patient and record the answers, or supply the answers to the best of his/her knowledge.

Check all that apply to indicate who completed the form (patient, coordinator, interpreter, family member/friend or other).

CES-D

Each statement refers to how often the patient has felt that way during the *past week*. A response should be recorded for each question.

The data system will generate the CES-D score once all responses are entered. The data system will not generate the CES-D score when one or more responses are missing.

The CES-D score can be calculated by summing the values associated with the responses. Remember that questions 4, 8, 12, and 16 are reverse scored. For these four questions a response of 0 should be counted as a 3, a response of 1 should be counted as a 2, a response of 2 should be counted as a 1, and a response of 3 should be counted as a 0.