

Symptom Assessment

General Instructions

The Symptom Assessment form is a patient self-assessment questionnaire designed to capture the presence of symptoms that can occur in persons with liver disease. This Symptom Assessment form is completed at the Baseline visit and every treatment and follow-up visit.

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 will be available in multiple languages. For patients not fluent in English, a translated version of the questionnaire should be used if available or the information may be obtained via interview by a trained translator. If the patient is unable to understand the questions because of educational, cultural or language difficulties, and a trained translator is not available, help may be provided by 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.

The English version of the questionnaire is designed to be completed on-line via the HBRN web-based system. If the questionnaire is completed on paper, be sure to review both sections of 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 interpreter 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 each box to indicate who completed the form (patient, coordinator,

interpreter, family member/friend or other).

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For each symptom, check one response to indicate the level at which the patient was bothered by the symptom during the past month. If the patient did not experience the symptom during the past month, check "None at all".

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