

SEXUAL FUNCTION QUESTIONNAIRE: WOMEN (XF)

DATA SECTION	COMPLETION INSTRUCTIONS
GENERAL INFORMATION	<p>The Sexual Function Questionnaire (XF) is designed to measure sexual functioning in female patients.</p> <p>This questionnaire is to be administered at the Screen 2 visit, Treatment day 28, Treatment weeks 12, 24 and 48, and Follow-up week 24, or at the time of premature discontinuation during the treatment or follow-up period.</p> <p>This questionnaire is to be completed by the patient. If the patient is not able to complete the form without help, the coordinator may read the questions and answers to the patient.</p> <p>After completion of the survey:</p> <p style="padding-left: 40px;">Record whether the survey was completed by the patient alone or by the patient with assistance.</p> <p style="padding-left: 40px;">Review the form for any missing items. If there are any incomplete items ask the patient to provide a response.</p> <p style="padding-left: 40px;">Make sure that each item has a single response marked.</p> <p style="padding-left: 40px;">If the patient responds that he does not understand the question, a coordinator may read the question to him. Do not rephrase the question. If the respondent does not answer the question, indicate whether the response is unknown or the patient refused to answer the question.</p>
PATIENT ID	Record the patient's ID number on the cover page and in the top right hand corner of Page 1.
TIME POINT	<p>Indicate the time point that corresponds to the visit.</p> <p><u>Premature discontinuation:</u></p> <p>(1) Treatment is discontinued prior to 48 weeks other than for those determined to be non-responders at Treatment week 24. All forms required at Treatment week 48 must be completed at the time that study medication is discontinued.</p> <p>(2) Follow-up is discontinued during the first 24 weeks. All forms required at follow-up week 24 must be completed at the time of the discontinued follow-up.</p>
COMPLETED BY	<p>Indicate who completed the questionnaire: patient without assistance, patient with assistance from the coordinator, patient with assistance from family member.</p> <p>SPECIFIC INSTUCTIONS:</p> <p><u>Today's date:</u> Record the date (month/day/year) on which the patient filled out the questionnaire.</p> <p><u>Questions 2-4:</u> Each question refers to how often or how satisfied the patient has been <i>over the past month</i>.</p> <p><u>Question 5:</u> This question should not be asked at the Screen 2 visit. It should only be asked at the specified treatment and follow-up evaluations.</p>