QUALITY OF LIFE (QL)

DATA SECTION	COMPLETION INSTRUCTIONS
PURPOSE	The Quality of Life questionnaire is designed to assess how the patient feels about their health and ability to perform usual activities.
PERSON(S) RESPONSIBLE	Patient
SOURCE(S) OF INFORMATION	Patient
WHEN TO ADMINISTER FORM:	Treatment Weeks 0, 4, 12 and 24 Follow-up Weeks 4 At the time of premature discontinuation of treatment or study
	SPECIFIC INSTRUCTIONS:
PATIENT ID	Record the Patient ID number in the top left hand corner of the page.
TIME POINT	Record the protocol time point for the evaluation.
DATE OF EVALUATION	Record the date (month/day/year) of the patient evaluation.
	GENERAL INSTRUCTIONS:
	Typically the patient is asked to complete the questionnaire without additional instructions. 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 answer the questions on his/her own.
	Help may be provided by the next of kin if the patient is confused or unable to understand the questions because of educational, cultural or language difficulties. In these situations the next of kin can read the questions to the patient and record the answers.
	After completing the questionnaire: Record whether the questionnaire was completed by the patient alone or by the patient with assistance.
	Review the form for any missing items. If there are any incomplete items ask the patient to provide a response. If the patient does not answer the question, indicate whether the response is unknown or the patient refused to answer the question.
	Do not review the completed questionnaire for consistency of responses.