CONCOMITANT MEDICATION LOG (ML)

DATA SECTION	COMPLETION INSTRUCTIONS
PURPOSE	To record information on all concomitant medications (prescription, over the counter, herbals, and vitamins) currently taken by the patient.
PERSON(S) RESPONSIBLE	Study Coordinator/study physician
SOURCE(S) OF INFORMATION	Patient
WHEN TO ADMINISTER FORM:	Initiate at time of screening but update as needed throughout the course of the study.
GENERAL INFORMATION	The Medication Log is started at the Screening visit and captures all medications that the patient is currently taking as well as medications taken within the past 30 days. The log is updated as necessary through completion of the study. Record medications that are started or stopped during the course of the study. Do not record every change in dosing throughout the course of the study. If the patient begins taking a new medication during the course of the study, add the new medication to the Medication Log and enter a start date. If the patient stops taking a medication during the course of the study, record the stop date. If the total daily dose is changed but the patient remains on the medication, do not add a new line to capture the change in dosing. If the patient is taking a medication "as needed", do not record the information on a new line every time a dose is taken. Record the medication on the log sheet once and indicate that the medication is taken "as needed". If there are no concomitant medications to record, from 30 days prior to enrollment through completion of the study, make a note to file and keep the blank ML form in the patient folder so that it is available if needed. Do not record study drug information on this log. Make the patient aware of the necessity to record this information and ask them to bring either a list of all current medications taken or prescription pill bottles to each visit.
PATIENT ID	Record the Patient ID in the top left hand corner of each page.
PAGE	Record page number in the upper right hand corner. Each page of the log captures 25 medications. Begin with page 1 and add pages as needed.
	SPECIFIC INSTRUCTIONS: <u>Medication</u>: Record the name of the medication. The name of the medication should be copied as it appears on the label of the pill bottle, if provided. <u>Total daily dose</u>: Record the total daily dose, in the proper units, that the patient is taking. Do not record changes in dose during the study period.

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	Check the "As needed" checkbox if the patient takes the medication on an as needed basis. **Screening visit**: when you add a medication to the list for the first time, record the total daily dose that the patient is taking as of the screening visit, regardless of when they started taking the medication. **Other than Screening visit**: when you add a medication to the list, record the total daily dose that the patient is taking when they started the medication. Start date: Record the date that the patient took the medication for the first time, regardless of the starting dose or the number of times that the dose has changed since the patient began taking the medication. If any part of the date is unknown, record "Unk" in that field and complete the remaining fields. Stop date: Record the date that the patient stopped taking the medication. If any part of the date is unknown, record "Unk" in that field and complete the remaining fields. If the patient is currently taking the medication, leave this date field blank.