Concomitant Medication Log (Adult)

General Instructions

The Concomitant Medication Log captures all **non-study prescription** medications that the patient reports taking from the time of the screening visit (latest screening visit up to 6 weeks prior to the randomization) through completion of the follow-up period or discontinuation from study. Prescription medications are defined as those medications prescribed by the patient's medical provider(s). Medications that the patient takes that are not prescribed by a medical provider (i.e. herbals, "natural" medicines, over the counter medicines) should not be included on the Concomitant Medication Log. Select over the counter and the use of "natural" or herbal medications will be captured on the Screening Evaluation and Visit Evaluation forms. The Concomitant Medication Log should be initiated at the screening visit and updated as needed throughout the course of the study.

Record prescription medications that are started or stopped during the course of the study.

Do not record a start/stop of medication to reflect a change in dose.

If the patient begins to take a medication that is not already recorded on the medication log, add the medication to the log, along with the start date.

If the patient stops taking a medication during the course of the study, record the stop date.

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".

Do not record study drug information on this log.

Ask the patient to bring either a list of all current medications taken or prescription pill bottles to each visit.

Specific Instructions

Patient ID**:**	Record the Patient ID in the top right hand corner.
Medication:	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.
Taken routinely:	Check if the patient takes the medication according to a set schedule, i.e. once a day, twice daily, thrice daily, or every other day, etc.
As needed:	Check if the patient does not take the medication according to a set schedule but takes it as needed.
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" [-3] 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" [-3] in that field and complete the remaining fields. If the patient is currently taking the medication, leave this date field blank.
System ID:	Record the system generated ID for the record.