

Instructions for Completing the Concurrent Medication Form

Concurrent medication information should be collected for **all** patients, including those assigned to CBI-only. **All** concurrent medications should be recorded, which would include over the counter medications and herbal supplements.

Week # (header of form)

The only week #s that should appear in the header of the forms are week 0, 16, 26, 52, and 68.

Week # /Sequence # (1st column)

The week # of each visit should be recorded. If there is more than one visit in the same week, a different sequence number should be recorded (01, 02, 03, etc.). If there is no change from visit to visit (i.e., person has not begun taking any new concomitant medications and has not stopped any concomitant medications), “**no change**” should be documented on the form.

Date (header of form)

Use the date of the week 16, 26, 52, and 68 visit.

Time Frame

Baseline (week 0) – At the baseline visit, ask about the use of concomitant medications for the past 90 days to be consistent with the time frame used for the Form 90 and the SAFTEE. Be sure to ask about the use of acamprosate or naltrexone during the last 30 days as this is one of the exclusion criteria listed in the protocol. The Concurrent Medication Form should be a continuous data collection form. Baseline (**week 0**) should include information collected during screening up through the randomization visit. If there is more than one baseline visit, use a different sequence number to indicate this. Note the date next to the Week 0 entry on the paper form, as you will need to enter this information into the DMS.

Within Treatment - Data for visits 1-16 can be recorded on one paper form but there will be different guidelines for entering the data. The form should be labeled **week 16**. Even if the participant discontinues treatment prematurely, the CRF should continue to be labeled Week 16. Although data will be collected at each treatment visit (1, 2, 4, 6, 8, 10, 12, and 16), staff should enter the information into the Data Management System by entering Week 16, Sequence 01 each time s/he wants to add more data or data can be entered all at once after the treatment phase is completed.

Post-Treatment Follow-up - Data for **weeks 26, 52, and 68** should be collected on separate Concurrent Medication Forms (one for each week), as data will be entered under these separate week numbers.

When collecting the follow-up data, go back to the date concurrent medication data was last collected (i.e., if the patient attended the week 16 visit, missed the week 26 visit, and then attended the week 52 visit, collect data from week 16 through 52 and enter data as week 52.

At week 26, capture information from week 16 (or since the last concurrent medication data was collected) through week 26. If a participant continues to take a medication that was recorded on the week 16 form, transcribe that medication to the week 26 form.

At week 52, capture information from week 26 (or since the last concurrent medication data was collected) through week 52. If a participant continues to take a medication that was recorded on the week 26 form, transcribe that medication to the week 52 form.

At week 68, capture information from week 52 (or since the last concurrent medication data was collected) through week 68. If a participant continues to take a medication that was recorded on the week 52 form, transcribe that medication to the week 68 form. .

Medication – document all concomitant medications being taken, including over the counter medications and herbal supplements.

Started Prior to Study

Yes/No

Date Started

Record the date the concomitant medication was started.

Ongoing at the End of Study?

End of study is defined as week 68. If, at week 16, the patient is still taking the concomitant medication, leave this item blank and transcribe the medication onto the week 26 form so staff will remember to ask about this medication at the next visit.

If a patient drops out and the last Concurrent Medication Form indicates that medications were not stopped, leave this item blank.

Date Stopped

If concomitant medication is stopped at any point during the trial, record the date the medication was stopped.

If the patient isn't sure about the month a medication was started or stopped, use bracketing (i.e., was it early 1997 or late 1997) to attempt to record a more accurate month. If the month or day is unknown, record this as permanently missing “=” on the paper form.

Data Entry - Although the month or the day might be recorded as permanently missing on the paper form, data entry staff should substitute data. If the only the year is known, enter “6” as the month and “15” as the day. Enter a note log to indicate that the month and/or day were arbitrarily selected.