



Note: Number pages sequentially (001, 002, 003) for each participant.

Page

MTN-011 (135)

CM-1 (423)

Participant ID

- -
 Protocol PTID Chk Cohort

Concomitant Medications Log

No medications taken at Screening/Enrollment. Staff Initials/Date: _____

No medications taken throughout study. Staff Initials/Date: _____

▶ End of form. Fax to SCHARP DataFax.

1.

Trade Name		Staff Initials/Log Entry Date
Indication		Taken for a reported AE? <input type="checkbox"/> yes <input type="checkbox"/> no
Date Started <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <i>dd MMM yy</i>	Date Stopped <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <i>dd MMM yy</i>	AE Log page(s): <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
OR <input type="checkbox"/> Continuing at end of study		
Frequency Mark only one. <i>prn qd tid qhs once bid qid other, specify:</i>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> _____	
Dose/Units	Route Mark only one. <i>PO IM IV TOP IHL VAG REC SC other, specify:</i>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> _____

2.

Trade Name		Staff Initials/Log Entry Date
Indication		Taken for a reported AE? <input type="checkbox"/> yes <input type="checkbox"/> no
Date Started <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <i>dd MMM yy</i>	Date Stopped <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <i>dd MMM yy</i>	AE Log page(s): <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
OR <input type="checkbox"/> Continuing at end of study		
Frequency Mark only one. <i>prn qd tid qhs once bid qid other, specify:</i>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> _____	
Dose/Units	Route Mark only one. <i>PO IM IV TOP IHL VAG REC SC other, specify:</i>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> _____

Concomitant Medications Log (CM-1)	
Purpose:	This form is used to document all medications taken by the participant starting at the Screening Visit. This form must be completed for each enrolled female and male participant. This includes, but is not limited to, prescription medications, non-prescription (i.e., over-the-counter) medications, contraceptive medications, intrauterine contraceptive devices, preventive medications and treatments (e.g., allergy shots, flu shots, and other vaccinations), herbal preparations, vitamin supplements, naturopathic preparations, and recreational drugs.
General Information/ Instructions:	When to fax this form: <ul style="list-style-type: none"> • once the participant has enrolled in the study; • when pages have been updated or additional Log pages have been completed (only fax updated or new pages); • when the participant has completed study participation; and/or • when instructed by SCHARP.
Item-specific Instructions:	
Page:	Number pages sequentially throughout the study, starting with 01. Do not repeat page numbers. Do not renumber any Concomitant Medications Log pages after faxing, unless instructed by SCHARP.
No medications taken at Screening/ Enrollment:	Mark this box if no medications were taken by the participant from Screening through the Enrollment Visit. This box should only be marked on Page 01.
No medications taken throughout study:	Mark this box at the Termination/Study Exit Visit if no medications were taken by the participant throughout the entire study.
Trade Name:	Record the trade name of the medication (not the generic name) whenever possible.
Indication:	For health supplements, such as multivitamins, record "general health." For preventive medications, record "prevention of [insert condition]" (e.g., for flu shot, record "prevention of influenza"). For recreational drugs, record "recreation."
Start Date:	If the participant is unable to recall the exact date of medication initiation, obtain participant's best estimate. At a minimum, the year is required. For injections, record each injection as a separate entry, with the same date used for start and stop date. For oral contraceptives, record the start date (and stop date) for each pill pack.
Stop Date:	At the participant's Termination/Study Exit Visit, the "Date Stopped" must be recorded for each medication OR the "Continuing at end of study" box must be marked. At a minimum, the month and year are required.
Frequency:	Below is a list of common frequency abbreviations: prn: as needed qd: every day tid: three times daily qhs: at bedtime once: one time bid: twice daily qid: four times daily other, specify: alternative dosing schedules
Dose/Units:	If the participant does not know the exact dose or units (for example, "250 mg"), you may record an estimate (such as "1 tablet"). If no information on dose or units is known, draw a single line through the blank response box and initial and date. For multivitamin tablets or liquids, record number of tablets or liquid measurement (e.g., one tablespoon).
Route:	Below is a list of common route abbreviations: IM: intramuscular TOP: topical VAG: vaginal SC: subcutaneous IV: intravenous IHL: inhaled REC: rectal other, specify: alternative routes