



HPTN 052 (096)

ICM-1 (423)

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

Page

Index ID

- - - -

Site Number Index Number Partner Chk

Index Concomitant Medications Log

No medications taken throughout study. _____
 Staff Initials/Date

▶ End of form. Fax to SCHARP DataFax.

Medication (generic name)		Staff Initials/Log Entry Date
Indication		Taken for a reported AE? <input type="checkbox"/> yes <input type="checkbox"/> no ▶ Record AE Log page(s): <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Date Started <input type="text"/> <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"/> <input type="text"/> OR <input type="checkbox"/> Continuing at end of study	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

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Index Concomitant Medications Log (ICM-1)

All medication(s) that are used by the participant during the study, other than study product, must be documented on this form. This includes, but is not limited to, prescription medications, non-prescription (i.e., over-the-counter) medications, preventive medications and treatments (e.g., allergy shots, flu shots, and other vaccinations), herbal preparations, vitamin supplements, naturopathic preparations, and recreational drugs.

Fax this form to SCHARP whenever a change is made.

Page: Number pages sequentially throughout the study, starting with 001. Do not repeat page numbers. Do not renumber any Concomitant Medications Log pages after faxing, unless instructed by SCHARP.

No medications taken throughout study: Mark this box at the Termination visit if no medications were taken by the participant throughout the entire study. Record "Staff Initials/Date."

Medication: Record the generic name for all medications. For combination medications, record the generic names of the first three main active ingredients.

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."

Date Started: If the participant is unable to recall the exact date, obtain participant's best estimate. At a minimum, the year is required.

Date Stopped: At the participant's Termination visit, the "Date Stopped" must be recorded for each medication OR the "Continuing at end of study" box must be marked.

Taken for a reported AE? If the medication was not taken for a reported AE, mark the "no" box and leave the AE Log page boxes blank.