



MTN 015 Data Communiqué #2

April 19, 2010

This is official study documentation for MTN 015. Please circulate it among relevant staff for their review, print it, and place it in your MTN 015 SSP Manual in the Data Communiqués section. This document is considered part of the MTN 015 SSP manual.

UPDATES

1. Case Report Forms (CRFs) for site use now available on Atlas

The MTN 015 CRFs (non-Sample version) are now available for printing on the MTN 015 Atlas web page. SCHARP will continue to print and ship initial orders of CRFs to the sites as they begin 015, and will continue to print and ship CRFs for sites as requested during the study. However, since there may be times where only a few copies of a CRF are needed, we wanted to make all CRFs and CRF form packets available to the sites so that each site can easily obtain needed CRFs as quickly as possible.

You do not need an Atlas password to access the CRFs. Simply go to the MTN 015 Atlas web page (<https://atlas.scharp.org/cpas/project/MTN/015/begin.view?>) and scroll to the bottom of the page where you see the “CRFs” title bar. Click the “+” symbol to the left of “Visit Packets”, “Translated Visit Packet Supplements”, and “Individual CRFs” to see what CRF/packets/languages are available under that heading. Click on the “A4” in the page size column to bring up the pdf file with the selected CRF(s). For printing instructions, click on the “+” symbol to the left of “Other Documents”, and click on “CRF Printing Instructions”.

Please contact the SCHARP MTN 015 Project Manager with any questions about CRF printing/CRF supplies.

CLARIFICATIONS

1. Antiretroviral Medication Stop Codes 88 (Dose change), 89 (Completed therapy), and 72 (Pregnancy ended)

If a participant changes the dose or frequency of an ART (due to a PMTCT regimen, for example), please use “88 – Dose change” as the ART Medication Stop Code when documenting the stoppage of the ART at the original dose/frequency.

If a participant stops taking an ART medication because she has completed her PMTCT course of therapy, please use “72 – Pregnancy ended” as the stop code for all applicable ART medications.

Reserve the use of “89 – Completed therapy” for those cases where a participant was on ART as part of another research trial, and has completed her participation in that trial (or completed the ART therapy she was taking as a result of the trial).

REMINDERS

None.