

## MTN-020 Data Communiqué #11- March 12, 2014

This is official study documentation for MTN-020. Please circulate it among relevant staff for their review, print it, and place it in your MTN-020 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-020 SSP manual.

### UPDATES

#### 1. HIV Confirmatory Test Results CRF (HCR-1)

If item 5 on the HCR-1 CRF is marked as 'pending', this item must subsequently be updated with the participant's final serostatus (HIV-infected or HIV-uninfected) once confirmatory testing has been completed. Review all HCR-1 CRFs that have been completed thus far during the study and update as needed.

Example: A participant's HIV rapid tests results are both positive at her Month 5 visit on 14February and her Western Blot is indeterminate. Item 5 on the HCR-1 CRF is marked as 'pending' while further testing is completed. On 10March, her repeat Western Blot result is positive and item 5 on a second HCR-1 is completed as 'HIV-infected'. At this point, Item 5 on the HCR-1 CRF, dated 14February, should be updated to "HIV-infected" and the 'pending' box should be lined through with all changes dated and initialed prior to refaxing to SCHARP.

### CLARIFICATIONS

#### 2. Concomitant Medications Log CRF (CM-1)

All contraceptives that are dispensed to a participant, regardless of indication, should be recorded on the CM-1 Log CRF with the item "If contraceptive, was it dispensed at the research center?" completed. This item should be completed if a contraceptive is dispensed to a participant even if it is for reasons other than family planning (e.g. to treat an AE) and marked 'yes' if dispensed at the research site.

Combined OCP pill packs that contain multiple ingredients should be recorded as one entry on the CM-1 Log CRF with the trade name provided, if possible. For example, if a participant is using Microgynon as her current contraceptive method, complete one entry per pill pack. Placebo ferrous fumarate pills should not be listed in a separate entry.

**REMINDERS** – None

**iDATAFAX CORNER** – No updates