MTN-020
Data Communiqué #11

March 12, 2014
If Item 5 on the HCR-1 CRF is marked as ‘pending’, this item should be updated with the participant’s final serostatus (HIV-infected or HIV-uninfected) once confirmatory testing has been completed.
Concomitant Medications - Contraceptives

- All contraceptives dispensed to a participant, regardless of indication, should be recorded on CM-1 Log CRF with the item “If contraceptive, was it dispensed at the research center” completed.
Concomitant Medications - Contraceptives

- If a contraceptive was dispensed at the research center, the item "If contraceptive, was it dispensed at the research center" should be marked as ‘yes’ for this entry regardless of whether the contraceptive issued by the center is dispensed for contraception or another indication.
Concomitant Medications – OCPs

- 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.

Example:
If a participant is using Microgynon as her contraceptive method, only one entry per pill pack is required on the con meds log CRF. The ferrous fumerate placebo pills should not be listed separately.
Questions?

- Please contact Jen Berthiaume and Karen Patterson with any questions you have about this slide presentation or the Data Communiqué.

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