# MTN-020 Data Communiqué #11

March 12, 2014



## HIV Confirmatory Results CRF – Updating Final HIV Status

 If Item 5 on the HCR-1 CRF is marked as 'pending', this item should be updated with the participant's final serostatus (HIVinfected or HIV-uninfected) once confirmatory testing has been completed.

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	3a. RNA PCR ki	t lower limit of detection	
4.	Absolute CD4+	Go to Not collected smallyze ( item 5 OR OI 72 cells/mm <sup>3</sup>	
<u>0</u>	4a. CD4 %	not aveilable OR 15,0%	
5.	Final HIV Status	HIV-uninfected fHIV-infected pending	

A Study to Prevent Infection with a Ring for Extended Use

### **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.

> A Study to Prevent Infection with a Ring for Extended Use

Concomitant Medications Log		
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#### 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 Log		
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#### **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.

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# 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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