

# **MTN-020**

# **Data Communiqué #11**


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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 (HIV-infected or HIV-uninfected) once confirmatory testing has been completed.

3.	HIV RNA PCR	Go to item 4. ← <input type="checkbox"/>	Not done/ Not collected	> <input type="checkbox"/>	= <input checked="" type="checkbox"/>	< <input type="checkbox"/>	viral copies/mL	06173740	OR	target not detected <input type="checkbox"/>
3a.	RNA PCR kit lower limit of detection			20 <input type="checkbox"/>	40 <input checked="" type="checkbox"/>	OR	viral copies/mL			
4.	Absolute CD4+	Go to item 5. ← <input type="checkbox"/>	Not done/ Not collected	unable to analyze	<input type="checkbox"/>	OR		0172	cells/mm <sup>3</sup>	
4a.	CD4 %		not available		<input type="checkbox"/>	OR		15.0	%	
5.	Final HIV Status		HIV-uninfected <input type="checkbox"/>	HIV-infected <input checked="" type="checkbox"/>	pending <input checked="" type="checkbox"/>					



# 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 Log									
Trade Name <b>Microgynon</b>							Staff Initials/Log Entry Date		
Indication <b>Menorrhagia</b>							Taken for a reported AE? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no		
Date Started <b>02 MAR 14</b>			Date Stopped				AE Log page(s): <b>002</b>		
dd MM YY			dd MM YY OR <input type="checkbox"/> Continuing at end of study				[ ][ ][ ][ ][ ][ ]		
Frequency Mark only one: <input type="checkbox"/> prn <input type="checkbox"/> qd <input type="checkbox"/> bid <input type="checkbox"/> qhs <input type="checkbox"/> once <input checked="" type="checkbox"/> bid <input type="checkbox"/> qid <input type="checkbox"/> other, specify:									
Dose/Units <b>1 tablet</b>				Route Mark only one: <input checked="" type="checkbox"/> PO <input type="checkbox"/> IM <input type="checkbox"/> IV <input type="checkbox"/> TOP <input type="checkbox"/> IRL <input type="checkbox"/> VAG <input type="checkbox"/> REC <input type="checkbox"/> SC <input type="checkbox"/> other, specify:					
If contraceptive, was it dispensed at research center? <input type="checkbox"/> yes <input type="checkbox"/> no									

# 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	
Trade Name <b>Microgynon</b>	Staff Initials/Log Entry Date
Indication <b>Menorrhagia</b>	Taken for a reported AE? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no
Date Started <b>02 MAR 14</b> dd MONTH yy	Date Stopped OR <input type="checkbox"/> Continuing at end of study
Frequency Mark only one: <input type="checkbox"/> prn <input type="checkbox"/> qd <input type="checkbox"/> bid <input type="checkbox"/> qhs <input type="checkbox"/> once <input checked="" type="checkbox"/> tid <input type="checkbox"/> qid <input type="checkbox"/> other, specify:	AE Log page(s): <b>002</b>
Dose/Units <b>1 tablet</b>	Route Mark only one: <input checked="" type="checkbox"/> PO <input type="checkbox"/> IM <input type="checkbox"/> IV <input type="checkbox"/> TOP <input type="checkbox"/> IHL <input type="checkbox"/> VAG <input type="checkbox"/> REC <input type="checkbox"/> SC <input type="checkbox"/> other, specify:
If contraceptive, was it dispensed at research center? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no	

# 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 fumarate placebo pills should not be listed separately.

Concomitant Medications Log									
Trade Name Microgynon							Staff Initials/Log Entry Date		
Indication Family Planning							Taken for a reported AE? <input type="checkbox"/> yes <input checked="" type="checkbox"/> no		
Date Started 10 JUN 13			Date Stopped 01 JUL 13			OR <input type="checkbox"/> Continuing at end of study			
Frequency Mark only one <input type="checkbox"/> qd <input checked="" type="checkbox"/> bid <input type="checkbox"/> tid <input type="checkbox"/> qid <input type="checkbox"/> other specify:									
Dose/Units 0.18mg				Route Mark only one <input checked="" type="checkbox"/> PO <input type="checkbox"/> IM <input type="checkbox"/> IV <input type="checkbox"/> TOP <input type="checkbox"/> INJ <input type="checkbox"/> REC <input type="checkbox"/> SC <input type="checkbox"/> other specify:					
If contraceptive, was it dispensed at research center? <input type="checkbox"/> yes <input checked="" type="checkbox"/> no									
<del>Trade Name Ferrous Fumarate</del>									
<del>Indication Combination of Microgynon for Contraceptive</del>							<del>Taken for a reported AE? <input type="checkbox"/> yes <input checked="" type="checkbox"/> no</del>		
<del>Date Started 02 JUN 13</del>			<del>Date Stopped 08 JUL 13</del>			<del>OR <input type="checkbox"/> Continuing at end of study</del>			
<del>Frequency Mark only one <input type="checkbox"/> qd <input type="checkbox"/> bid <input type="checkbox"/> tid <input type="checkbox"/> qid <input checked="" type="checkbox"/> other specify:</del>									
<del>Dose/Units 75mg</del>				<del>Route Mark only one <input checked="" type="checkbox"/> PO <input type="checkbox"/> IM <input type="checkbox"/> IV <input type="checkbox"/> TOP <input type="checkbox"/> INJ <input type="checkbox"/> REC <input type="checkbox"/> SC <input type="checkbox"/> other specify:</del>					
<del>If contraceptive, was it dispensed at research center? <input checked="" type="checkbox"/> yes <input checked="" type="checkbox"/> no</del>									

# Questions?

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

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