MTN-016 Data Communiqué #4

1 May 2014

This is official study documentation for MTN-016. Please circulate it among relevant staff for their review, print it, and place it in your MTN-016 SSP Manual in the Data Communiqués section.
This document is considered part of the MTN-016 SSP manual.

UPDATES

1. **Infant Developmental Screening (IDS-1)**

   The developmental screening assessment has been eliminated from MTN-016 protocol version 2.0. Therefore, the Infant Developmental Screening form has been removed from the Schedule of Forms and the CRF visit packets on Atlas. This form should no longer be administered at the Month 6 Visit or the Month 12 Visit.

   However, please reference **MTN Operational Guidance 2**, which was distributed on 17MAR14. This Operational Guidance states that, "If MTN-008 sites submit protocol version 2.0 to their regulatory bodies and receive approval, they should continue to conduct the developmental screening assessment for any infants enrolled in the study under protocol version 1.0. This includes completing the Infant Developmental Screening form at the appropriate visits." So, for infants enrolled under version 1.0 of the protocol whose parent protocol is MTN-008, the Infant Developmental Screening form will still need to be completed at the Month 6 and Month 12 visits.

2. **Infant HIV Test Results (HTR-1)**

   Items 2b and 3b on the Infant HIV Test Results form have been updated to include revised lower limits of detection that better match current viral load platforms. In addition, items 2a and 3a have been revised to allow for viral load results of "target not detected" as well as "detected, under the limit of detection". The instructions below provide clarification on how to complete items 2a and 3a.

   A. **Viral Copies/mL Reported:** When the lab result is a number, record the number exactly as it appears on the report. Select the appropriate operator in item 2a or 3a and record the exact number in the adjacent boxes.

   Example of Local Lab Result from the Abbott M2000 Assay

Copies / mL:	Log Base 10 Value
4,914,478	6.69
Run comment:	
Sample comment:	
Reportable Range:	The Abbott RealTime HIV-1 RNA assay range of quantitation is 40 to 10,000,000 copies/mL.

Example of Completed HTR-1 using the Abbott M2000 Assay Results

Alternate Collection Date

Not done/
Not collected ☐   2. HIV RNA

dd	MMM	yy
2 4	A P R	1 4

2a. HIV RNA
PCR (plasma)

> ☐   = ☒   < ☐

viral copies/mL
| 0 | 4 | 9 | 1 | 4 | 4 | 7 | 8 |

OR *detected, under the limit of detection* ☐   OR *target not detected* ☐

2b. HIV RNA PCR
kit lower limit
of detection

20 ☐   40 ☒   OR *viral copies/mL* ☐☐☐

B. **Target Detected:** When the lab result says "<20, RNA target detected" or "<40, RNA target detected" but the reportable range further explains that "viral RNA was detected *but is below the lower limit of quantification*", mark "detected, under limit of detection" in item 2a or 3a.

Example of Local Lab Result from the Roche TaqMan Assay

Copies / mL:	Log Base10 Value
<20, HIV-1 RNA target detected.	<1.30

Run comment:

Sample comment:

Reportable Range: The COBAS TaqMan HIV-1, version 2.0 Test assay range of quantitation is 20 to 10,000,000 copies/mL. The result reported indicates viral RNA was detected but is below the lower limit of quantitation of the COBAS TaqMan HIV-1, version 2.0 Test assay.

Example of Completed HTR-1 using the Roche TaqMan Assay Results

Alternate Collection Date

Not done/
Not collected ☐   2. HIV RNA

dd	MMM	yy
2 4	A P R	1 4

2a. HIV RNA
PCR (plasma)

> ☐   = ☐   < ☐

viral copies/mL
| | | | | | | | |

OR *detected, under the limit of detection* ☒   OR *target not detected* ☐

2b. HIV RNA PCR
kit lower limit
of detection

20 ☒   40 ☐   OR *viral copies/mL* ☐☐☐

Example of Local Lab Result from the Abbott M2000 Assay

Copies / mL:	Log Base 10 Value
<40, HIV-1 RNA target detected.	<1.60

Run comment:

Sample comment:

Reportable Range: The Abbott RealTime HIV-1 RNA assay range of quantitation is 40 to 10,000,000 copies/mL. The result reported indicates viral RNA was detected but is below the lower limit of quantitation of the Abbott RealTime HIV-1 RNA assay.

Example of Completed HTR-1 using the Abbott M2000 Assay Results

C. **Target NOT Detected:** When the lab result says "target not detected" and there is no further explanation in the reportable range, mark "target not detected" in item 2a.

Example of Local Lab Result from the Abbott M2000 Assay

Copies / mL:	Log Base 10 Value
<40, HIV-1 RNA target not detected.	No log calculated

Run comment:

Sample comment:

Reportable Range: The Abbott RealTime HIV-1 RNA assay range of quantitation is 40 to 10,000,000 copies/mL.

Example of Completed HTR-1 Using the Abbott M2000 Assay Results

For more information about viral load testing, refer to MTN-016 Laboratory SSP Section 12.

The revised Infant HIV Test Results form has been added to the CRF visit packets posted on Atlas. **The revised version of the form with new plate number 136, dated 15APR14, must be used by 14MAY14**.

3. **Infant Safety Event Log (ISL-1)**

The Infant Safety Event Log is no longer required to be used in MTN-016. It has been removed from the CRF visit packets on Atlas.

4. **Woman Protocol Deviation Log (PDL-1)**

A new form, the Woman Protocol Deviation Log, has been added to the MTN-016 form set. This form documents all MTN-016-related protocol deviations for mothers. The completed form should be faxed to SCHARP DataFax in the same manner as all the other CRFs completed for this study. The use of iDataFax for this form is not supported at this time for MTN-016.

Missed Visits are counted as protocol deviations in MTN-016. However, a Woman Protocol Deviation Log does not need to be completed if a woman misses a visit. We will know that a protocol deviation due to a missed visit has occurred by the presence of the Woman Missed Visit CRF. Since sites are required to record a corrective action plan for a protocol deviation, sites should record this information in the comments section of the Woman Missed Visit CRF.

The new Woman Protocol Deviation Log has been added to the CRF visit packets posted on Atlas.

5. **Woman Missed Visit (MV-1)**

The instructions on the back of the Woman Missed Visit form have been updated to provide clarification that sites should record a corrective action plan for a missed visit protocol deviation in the comments section of the Woman Missed Visit CRF.

The revised Woman Missed Visit form has been added to the CRF visit packets posted on Atlas.

6. **Infant Protocol Deviation Log (PDL-1)**

A new form, the Infant Protocol Deviation Log, has been added to the MTN-016 form set. This form documents all MTN-016-related protocol deviations for infants. The completed form should be faxed to SCHARP DataFax in the same manner as all the other CRFs completed for this study. The use of iDataFax for this form is not supported at this time for MTN-016.

Missed Visits are counted as protocol deviations in MTN-016. However, an Infant Protocol Deviation Log does not need to be completed in an infant misses a visit. We will know that a protocol deviation due to a missed visit has occurred by the presence of the Infant Missed Visit CRF. Since sites are required to record a corrective action plan for a protocol deviation, sites should record this information in the comments section of the Infant Missed Visit CRF.

Please note that not all missed infant visits in MTN-016 count as protocol deviations. An infant can enroll into the study at any time point up until s/he is 1 year old (12 months). For DataFax reasons, sites are required to complete an Infant Missed Visit form for all infants that are enrolled after the Newborn/Initial Visit – one Infant Missed Visit form for every study visit the infant has missed prior to enrollment. For example, if the infant enrolls at the Month 6 Visit, the site would complete an Infant Missed Visit CRF for the Newborn/Initial Visit and another Infant Missed Visit CRF for the Month 1 Visit. In this scenario, the missed visits that occurred before the infant was enrolled will NOT count as

protocol deviations. For this scenario only, sites do not need to record a correction action plan on the Infant Missed Visit CRF.

The new Infant Protocol Deviation Log has been added to the CRF visit packets posted on Atlas.

7. **Infant Missed Visit (MV-1)**

The instructions on the back of the Infant Missed Visit form have been updated to provide clarification that sites should record a corrective action plan for a missed visit protocol deviation in the comments section of the Infant Missed Visit CRF.

The revised Infant Missed Visit form has been added to the CRF visit packets posted on Atlas.

CLARIFICATIONS

1. **Enrollment Reports**

MTN-016 Enrollment Reports have been revised to no longer include site-specific enrollment targets.

REMINDERS

1. **Do Not Print CRFs on Colored Paper**
Sites should no longer use colored paper to print CRFs. Certain colors of paper do not transmit well, thus making it difficult for DataFax to read the data from those CRFs into the database. Please use white paper only when printing CRFs.