



MTN-016 Data Communiqué #2

22 February 2013

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 Visit form (IFV-1), items 1 and 2

Sites will no longer document the growth percentiles on the Infant Visit CRF. Instead these must be recorded on the WHO growth charts (published by the Centers for Disease Control and Prevention, 1 November 2009, and found on the MTN-016 website) for each infant at each visit. Sites must use the updated version of the IFV-1 CRF (dated 21-FEB-13) beginning on 06-MAR-13. The new IFV-1 CRF has been emailed to each site, and has also been updated within all the Infant CRF Packets (i.e. Infant Newborn/Initial Visit 1 Packet, Infant Month 1 Visit 2 Packet, Infant Month 6 Visit 3 Packet, Infant Month 12 Visit 4 Packet), as well as within the "Infant Individual CRF" listing on the Atlas page. Please print the new version and replace any of the blank old versions in the unused packets.

2. Infant Physical Exam form (IPH-1), items 18 and 18a

Items 18 and 18a have been added to document any nutritional concerns which may be observed during the infant physical exam and whether the infant is referred for clinical follow-up. In order to make room for these new items, please note that some previous items have been merged (e.g. head/neck/scalp). Please review this form with your team to familiarize yourselves with the categories. Sites must use the updated version (dated 29-JAN-13) beginning on 06-MAR-13. The new IPH-1 CRF has been emailed to each site, and has also been updated within all the Infant CRF Packets (i.e. Infant Newborn/Initial Visit 1 Packet, Infant Month 1 Visit 2 Packet, Infant Month 6 Visit 3 Packet, Infant Month 12 Visit 4 Packet), as well as within the "Infant Individual CRF" listing on the Atlas page. Please print the new version and replace any of the blank old versions in the unused packets.

3. LDMS Specimen Tracking Sheet

The LDMS Specimen Tracking Sheet is now available on the MTN website http://www.mtnstopshiv.org/node/1584, under Section "III. Additional Forms and Worksheets". This sheet is no longer available on the MTN-016 Atlas webpage.

CLARIFICATIONS	CLA	RII	FICAT	TION	S
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REMINDERS

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