
MTN-016 Data Communiqué #6

6 June 2017

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 End of Study Inventory and Woman End of Study Inventory (ESI-1)

The Infant End of Study Inventory and Woman End of Study Inventory CRFs will no longer be used in MTN-016, as they are outdated administrative forms and the information captured on these forms will not be analyzed. These case report forms have been removed from the Schedule of Forms in the Data Management SSP section as well as the CRF visit packets posted on Atlas. Sites should stop using these forms upon receipt of this data communiqué.

2. Infant Interim Visit (IV-1)

Item 2g of the Infant Interim Visit CRF was greyed out, as it listed the Infant End of Study Inventory CRF as a form that could be faxed in at an infant interim visit. The revised Infant Interim Visit CRF has been added to the Infant Individual CRFs posted to Atlas. Sites should use the revised version of this form upon receipt of this data communiqué.

3. Woman Follow-up Visit (WFU-1)

Item 1d of the Woman Follow-up Visit CRF was greyed out, as it listed the Woman End of Study Inventory CRF as a form that could be faxed in at a follow-up visit. The revised Woman Follow-up Visit CRF has been added to the Woman Individual CRFs and Woman CRF Packets posted on Atlas. Sites should use the revised version of this form upon receipt of this data communiqué.

4. Woman Interim Visit (IV-1), item 2e

Item 2e of the Woman Interim Visit CRF was greyed out, as it listed the Woman End of Study Inventory CRF as a form that could be faxed in at an interim visit. The revised Woman Interim Visit CRF has been added to the Woman Individual CRFs posted on Atlas. Sites should use the revised version of this form upon receipt of this data communiqué.

CLARIFICATIONS

1. Recording Parent Protocol Visit Codes on MTN-016 Case Report Forms

Item 2a on the Parent Protocol Participation CRF, item 2a on the Woman Follow-up Visit CRF, and item 3a on the Woman Interim Visit CRF ask you to record the visit code of a parent protocol visit if the participant completed an MTN-016 visit at the same time as a parent protocol visit. Visit codes (also known as visit numbers) in MTN-025/HOPE contain 2 digits to the right of the decimal point. For example, the visit number associated with the Month 1 Visit is 3.00. When recording an MTN-025/HOPE visit code on one of the aforementioned MTN-016 CRFs, remove the first 0 after the decimal point in the MTN-025/HOPE visit code before recording it onto the MTN-016 CRF. For example, when recording MTN-025/HOPE visit code 3.02 onto item 2a of the Woman Follow-up Visit CRF, remove the 0 after the

decimal point and write “3.2” onto the Woman Follow-up Visit CRF. If the parent protocol visit code that you need to record onto an MTN-016 CRF is higher than 3.09 (e.g. 3.10), contact the SDMC Clinical Data Manager for more information.

REMINDERS

1. Register New Fax Machines

If a site needs to register a new fax machine with SCHARP DataFax, please contact the SDMC Clinical Data Manager for the SCHARP DataFax Device Registration form and guidelines.