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## MTN-016 Data Communiqué #1

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7 April 2011

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

None.

### CLARIFICATIONS

#### 1. Pregnancy Outcome form

Page 1, Item 6. Please be aware that there is a skip rule from item 5 if one of the first two response options is marked. If the pregnancy outcome is a “full-term live birth” or a “premature live birth” item 6 should not be completed. If your site has any outstanding QCs for this item, please make the appropriate corrections and re fax the form.

### REMINDERS

#### 1. Ultrasound Results form

The Ultrasound Results form must be completed at all required visits (i.e., Enrollment and all Quarterly Visits). If ultrasound exam results are not available at a particular required visit, mark the “no” response box for item 1. You must also mark a reason for item 1a. If results are not available, record the date of the required visit for the Exam Date (upper right corner). For example, if the first Quarterly Visit occurs on 23 June 2011, and there are no ultrasound results available at this visit, you will record “23JUN11” as the exam date and mark item 1 “no” and mark the appropriate reason for item 1a.

Please review SSP section 10.3 for more details.

#### 2. Exiting women from MTN-016

Women who have enrolled in MTN-016 should not be exited from the study when the pregnancy outcome is known. The Pregnancy Outcome Visit does not signify termination from the study, but does signify the end of follow-up until a subsequent pregnancy is reported or a valid reason for termination occurs.

See SSP section 13.3.2 for more details.