
MTN-016 Data Communiqué #5

14 September 2015

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. Definition of Infant Enrollment

The MTN-016 management team, with the input of the MTN-016 statisticians and DAIDS Medical Officer, have re-defined infant enrollment as an infant that 1) is born alive, 2) was consented into the study, and 3) attended at least 1 study visit. This means that a) stillborn infants cannot be enrolled into the study; b) infants who die shortly after birth, before attending a study visit, cannot be enrolled into the study, and c) infants who are born alive but never attend a study visit cannot be enrolled in the study. If a site has already enrolled an infant into MTN-016 that falls into one of these 3 categories, that infant will need to be un-enrolled and the mother's Pregnancy Outcome CRF may need to be updated.

Specific form instructions are as follows:

- 1) Stillborn infants who were enrolled into the study:
 - Delete the Infant Enrollment CRF, Infant Termination CRF, and any other CRFs submitted for this infant, by drawing a single diagonal line across the form, writing "delete" above the diagonal line, and initialing and dating the correction.
 - Check to make sure the Mother's Pregnancy Outcome CRF lists the outcome, in item 5, as "stillbirth/intrauterine fetal demise (≥ 20 weeks)".
 - Check to also make sure a brief narrative of the pregnancy outcome was provided in item 6.
 - Record, in the site-specific Infant Enrollment Log (a non-DataFax form), that the infant was not enrolled into MTN-016 and the reason why.

- 2) Infants who were born alive but died shortly after birth (and did not attend a study visit) and were enrolled into the study:
 - Delete the Infant Enrollment CRF, Infant Termination CRF, and any other CRFs submitted for this infant, by drawing a single diagonal line across the form, writing "delete" above the diagonal line, and initialing and dating the correction.
 - Update the mother's Pregnancy Outcome form by recording, in item 6, "live birth but infant died X days after birth" (make sure to fill in the correct number of days for "X").
 - Record any additional information in item 6 about the cause of death and the date of the infant's death.
 - Item 5 on the Mother's Pregnancy Outcome form for this scenario does not need to be updated. It should still indicate that there was a "live birth". However, the skip pattern logic of the CRF indicates that, if "full-term live birth" or "premature live birth" are marked in item 5, item 6 should be skipped. For this scenario only, the skip pattern logic should be ignored and item 6 should be updated.
 - Record, on the site-specific Infant Enrollment Log (a non-DataFax form), that the infant was not enrolled into MTN-016 and the reason why.

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- 3) Infants who were born alive but never attended a study visit and were enrolled into the study:
- Delete the Infant Enrollment CRF, Infant Termination CRF, and any other CRFs submitted for this infant, by drawing a single diagonal line across the form, writing “delete” above the diagonal line, and initialing and dating the correction.
 - Record, on the site-specific Infant Enrollment Log (a non-DataFax form), that the infant was not enrolled into MTN-016 and the reason why.

SCHARP will confirm, using CRF data, if any infants fall into these categories and will provide specific sites a list of PTIDs that need to be addressed. Sites should also check their records to verify if they have any infants that fall into the above-mentioned categories that need to be un-enrolled.

CLARIFICATIONS

1. Infant Enrollment CRF (IEN-1)

Evaluation of gestational age using the Ballard pediatric assessment has been eliminated from MTN-016 protocol version 2.0. Therefore, item 4 on the IEN-1 should be marked as “not assessed” for all infants enrolled into MTN-016.

REMINDERS

1. None.