MTN-042 Data Communiqué #5 – January 26, 2021

This is official study documentation for MTN-042. Please circulate it among relevant staff for their review, print it, and place it in your MTN-042 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-042 SSP manual.

UPDATES

Discontinuation of Study Product CRF completion

Primary reason for ending study product use

Multiple response options for "Primary reason for ending study product use" align with scheduled discontinuation of study product:

- Scheduled study product use period completed
- Report of admission to care for labor and delivery management including induction of labor and cesarean delivery
- Pregnancy loss
- Labor or rupture of membranes is confirmed

Any participant with one of these reasons for discontinuation will be considered to have completed treatment.

The most specific option should be selected for each participant. It is expected that "Scheduled study product use period completed" will be selected primarily for participants who discontinue study product due to reaching 41 6/7 weeks gestation.

Date that study product use ended

The date of product use discontinuation should align with the reason selected for discontinuation. (e.g, if the reason for ending product use is admission for labor and delivery management, the date of product use discontinuation should match the date of admission).

Please follow this guidance in lieu of the guidance provided in Data Communiqué #3 (29-Oct-2020).

Example scenarios:

1. A participant presents to the hospital with signs of labor on 10-Jan. She is admitted to the hospital and the ring is removed. She gives birth on 12-Jan.
    - *Primary reason for ending study product use = Report of admission to care for labor and delivery management including induction of labor and cesarean delivery*
    - *Date that study product use ended = 10-Jan*

2. A participant suspects membranes have ruptured at home and removes the ring on 2-Feb but she does not have transportation to go to the hospital for confirmation until the next day, 3-Feb, when the rupture of membranes is confirmed. The participant gives birth on 5-Feb.
    - *Primary reason for ending study product use = Labor or rupture of membranes is confirmed*
    - *Date that study product use ended = 3-Feb*

3. A participant enrolls in the study on 1-Feb at 37 0/7 weeks gestation. She takes her last dose of Truvada on 6-Mar (41 6/7 weeks gestation) and gives birth on 9-Mar.
    - *Primary reason for ending study product use = Scheduled study product use period completed*
    - *Date that study product use ended = 6-Mar*

4. A participant experiences grade 1 nausea that she attributes to use of Truvada. She is evaluated at her biweekly visit on 22-Feb and determined clinically eligible to continue, however, she returns her unused tablets and declines receiving more. She is willing to continue her study visits.
    - *Primary reason for ending study product use = Participant refused further study product use*
    - *Date that study product use ended = 22 Feb*

5. *A participant experiences an allergic reaction after insertion of the ring on the day of her enrollment on 19-Mar.*
    - *Primary reason for ending study product use = adverse event*
    - *Date that study product use ended = 19 Mar*

Updates to completed Discontinuation of Study Product CRFs:

Sites should review previously completed Discontinuation of Study Product CRFs. If “Scheduled study product use period completed” was selected for a participant who discontinued study product before reaching 41 6/7 weeks gestation, the reason should be updated to the most accurate and specific option: “Report of admission to care for labor and delivery management including induction of labor and cesarean delivery”, “Pregnancy loss”, or “Labor or rupture of membranes is confirmed”. The “Date that study product use ended” should also be updated to align with the reason selected.