

MTN-027 Data Communiqué #1 – June 15, 2015

This is official study documentation for MTN-027. Please circulate it among relevant staff for their review, print it, and place it in your MTN-027 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-027 SSP manual.

UPDATES – none

CLARIFICATIONS –

1. Enrollment (ENR) CRF – Randomization date and time (Item 5)

The date and time of a participant's randomization should be completed using the FSTRF randomization confirmation email. The randomization time within this confirmation email is provided in Eastern Standard Time (EST). When completing item 5 on the Enrollment CRF, convert the time of randomization according to each site's local standard time zone, as needed.

2. Pelvic Exam Ring Assessment (PER) completion at Day 28

When completing the PER CRF at the Day 28 visit, mark 'yes' in item 2 if the vaginal ring was present at the start of the exam, as you will remove and collect the vaginal ring at this visit. The hour and minute boxes in item 2a should be lined through, initialed, and dated to indicate that this item is not applicable. Item 3 should be marked "not reinserted". For item 3a, record "Day 28 – end of product use" as the reason that the ring was not reinserted.

REMINDERS – none