

## MTN-036/IPM 047 Data Communiqué #3- May 16, 2018

This is official study documentation for MTN-036/IPM 047. Please circulate it among relevant staff for their review, print it, and place it in your MTN-036/IPM 047 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-036/IPM 047 SSP manual.

### 1. REMINDERS

#### Relatedness of Adverse Events

A relationship category (related or not related) must be assigned to each Adverse Event reported. For each AE, study staff must also give a reason for their determination of the relationship to the AE to the study product. When an AE is assessed as “Not Related” to the study product, an alternative etiology, diagnosis, or explanation (for example, “not biologically plausible”) must be provided in the AE “Comments” field. When an AE is assessed as “Related” to the study product, a rationale must be provided in the “Comments” field. Note that recording “no other cause identified” is not adequate. Refer to SSP section 9.4 for additional information.

### 2. CLARIFICATIONS

#### Documenting contraceptives on the Concomitant Medications Log

Hormonal contraceptives (including copper IUD) that a participant uses during study follow-up must be documented on the Concomitant Medications Log CRF. The following guidance should be used when documenting contraceptives:

**Oral contraceptive birth control pills:** Record each pill pack confirmed by the participant to have been taken on a new log line. Indicate the start date as the date the first pill of the pack was taken and the stop date as the date the last pill of the pack was taken. If the participant is taking birth control pills at Screening, document this pill pack on the Concomitant Medications Log, as well as any other pill packs she begins during follow-up. If a participant misses a pill, this outage does not need to be recorded on the Concomitant Medications Log CRF.

**Implants/IUD:** Record each implant/IUD on a new log line. The start date should be the date of implant or insertion and the stop date should be the date the implant/IUD is removed. Indicate the frequency as “Other” and write “continuous” in the text field. For medical devices with no active medication, such as the copper IUD, indicate the dose as “1”, the dose unit as “Other”, and indicate “device” in the text field. For IUD route, select “Other” and write “intrauterine” in the text field. For Implant route, select “Other” and write “sub-dermal” in the text field. If the participant has an implant/IUD in place at Screening, document this on the Concomitant Medications Log, as well as any other implants or IUDs she receives during follow-up.

**Injectable contraceptive (Depo, NET-EN, Cyclofem, etc.):** Record each injection that the participant receives during study participation on a new log line. Enter both the start and stop dates as the date of injection. Indicate the frequency as “once”. Injections of contraceptive medications used before the Screening Visit are not recorded on the Concomitant Medications Log CRF. This CRF only captures medications used on or after the Screening Visit date.

### 3. UPDATES

None