



## MTN-025 Data Communiqué #4 - December 1, 2016

This is official study documentation for MTN- 025. Please circulate it among relevant staff for their review, print it, and place it in your MTN-025 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-025 SSP manual.

### UPDATES

#### **Family Planning Log CRF**

The Family Planning Log CRF has been updated to v3.0, dated 01 December 2016, to include an additional question, "*Reason(s) for changing or stopping the family planning method*". This item should be completed during follow-up in instances when a family planning/contraception method is changed or stopped (i.e., a date is provided for 'Date Regimen Stopped'). The existing item that asks for the reason(s) if a family planning method changed or stopped since a participant's last ASPIRE study or if there was a break in the family planning method should continue to be completed at the Enrollment Visit only.

The paper v3.0 Family Planning Log CRF has been added to the Enrollment Visit Packet on the MTN-025 ATLAS webpage.

#### **CRF Completion Guidelines (CCGs)**

The CRF Completion Guidelines have been updated to v.1.5 (dated 01 December 2016) and are posted onto the MTN-025 Atlas webpage for download. Updates to form completion have been made to the Family Planning log CRF.

### CLARIFICATIONS

CRF changes implemented as part of a clinical database migration will be incorporated on the eCRF within Rave. If a previous version of a paper CRF is completed at a study visit and data from that visit was not entered into Rave prior to the migration, the updated items on the paper CRF and eCRF will be discrepant. Complete a note to file to document any discrepancies between the paper CRF completed prior to database migration and the updated eCRF data entered into Rave post migration.

### REMINDERS

None