



MTN-032 Data Communiqué #5 – 03 AUGUST 2018

This is official study documentation for MTN-032. Please circulate it among relevant staff for their review, print it, and file it in the Data Communiqués section of the MTN-032 SSP. This document is considered part of the MTN-032 SSP manual.

CRF CLARIFICATIONS

Participant Status Form (PSF) CRF Completion Clarifications

- 1. General Information/Instructions:** This form records essential administrative information about individuals who are randomly selected, screened and/or enrolled into MTN-032. This form will be completed for every HOPE participant/ HOPE participant's partner who is randomly selected for participation in MTN-032 Phase 2 until the point on the randomization list that the target number of enrollees for that subgroup is met.
- 2. Items 1 and 1a:** These should only be completed for former HOPE participants who enroll into MTN-032.
 - a. Do not complete* these items if a potential female participant **does not** enroll into MTN-032.
 - Do not complete* these items for male partners, regardless of whether they enroll into MTN-032.
- 3. Comments:** The Observation Number (outlined in Figure 1) on the SCHARP Recruitment List should be noted in PSF comments for all participants.

Previously Completed PSF CRF for Non-Enrolled Participants

- PSF CRFs previously completed should be updated by the site team to delete the HOPE PTID for male partners and for individuals who **did not** enroll into MTN-032 as follows:
 - The HOPE PTID should be crossed out with a single horizontal line through the entry, "DELETE per DC#5" should be written near the boxes, and the correction should be initialed and dated per SSP Appendix 7-5 and Good Clinical Practice (GCP).
 - The updated PSFs should then be re-submitted to RTI.
 - Previous electronic copies of the CRFs should be archived.

Clarifications regarding Recruitment List reporting to RTI

- Remove the HOPE PTID column from male and female Recruitment Lists prior to submitting accrual numbers to RTI.
 - If completing electronically, save a version of the list for submission and delete the HOPE PTID column from this version prior to submitting to RTI.
 - If completing by hand, follow the above guidance for deleting HOPE PTIDs prior to uploading and submitting to RTI.

2. For ALL individuals considered for enrollment into MTN-032, write the enrolled or non-enrolled PTID in the 'MTN-032 PTID' column per updated recruitment lists from SCHARP (see Figure 1. below). Write the date the participant was enrolled, deemed ineligible or declined participation in the 'Date Enrolled, Ineligible, or Declined' column'.
 - a. Complete these columns for all individuals considered for enrollment until accrual subgroup target enrollment is met.


Figure 1: Sample Completed Recruitment List for Accrual Reporting

**MTN 032 Participant Recruitment List - Female Participants
Malawi - Lilongwe Site
Generated 16JAN18
Middle Adherence Group
Enrollment Target = 6**

Obs	Seroconverter (Yes/No)	Adherence Group	Target Visit 9 visit date	Actual Visit 9 visit date	Confirmation of required product dispensation: yes or no (site to write in)	MTN032 PTID* (site to write in)	Date Enrolled, Ineligible, or Declined
1	No	Middle	04JUN2018	06JUN2018	Yes	7203	23JUNE2018
2	No	Middle	15AUG2018	19AUG2018	Yes	7204	30AUG2018
3	No	Middle	13MAR2018	20MAR2018	Yes	7801	01SEP2018
4	No	Middle	18JAN2018	16JAN2018	Yes	7205	01SEP2018
5	No	Middle	09MAY2018	10MAY2018	No	7802	03SEP2018
6	No	Middle	19JUN2018	19JUN2018	Yes	7206	04SEP2018
7	No	Middle	02FEB2018	26JAN2018	Yes	7207	05SEP2018
8	No	Middle	09APR2018	15APR2018	Yes	7803	05SEP2018
9	No	Middle	17JAN2018	20JAN2018	Yes	7208	10SEP2018
10	No	Middle	29JAN2018	12FEB2018	Yes		
11	Yes	Middle	03MAR2018	07MAR2018	Yes		

*Includes enrolled or non-enrolled PTID for all individuals considered until accrual subgroup target enrollment is met.

Ariana Katz, RTI International
Printed Name


Signature

03 Aug 2018
Date