

Section 3. Accrual and Eligibility Determination

3.	Introduction	3-1
3.1	Participant Accrual.....	3-1
3.1.1	Study Accrual Plan and SOP	3-1
3.1.2	Phase 1 Site-Specific Accrual Targets.....	3-1
3.1.3	Phase 2 Site-Specific Accrual Targets for Female Participants	3-2
3.1.4	Phase 2 Site-Specific Accrual Targets for Male Partners	3-3
3.1.5	Pre-Screening Definition for Phase 2 Participants	3-4
3.1.6	Screening Definition for Female Participants	3-4
3.1.7	Screening Definition for Male Partner Participants.....	3-4
3.1.8	Definition of Enrollment Procedures.....	3-5
3.1.9	Eligibility Determination and SOP	3-5
3.1.10	Assignment of Participant ID and FGD Numbers.....	3-7
3.1.11	Screening and Enrollment Timeframe.....	3-8
3.1.12	Screening and Enrollment Logs	3-9
3.1.13	MTN-032 Progress Reports	3-9
3.2	Participant Retention	3-10

3. Introduction

This section provides information on requirements and procedures for recruiting participants in MTN-032, Phases 1 and 2. This section also presents information related to definitions, requirements, and procedures for participant retention.

3.1 Participant Accrual

3.1.1 Study Accrual Plan and SOP

Each site is responsible for developing its own accrual plan for both Phase 1 and Phase 2 that can be described in the site Accrual SOP. However, as accrual is dependent on participation in the ASPIRE and HOPE studies, it is recommended that the section of the accrual plan addressing MTN-032 is developed in cooperation with these clinical staff, as available for consultation. Working in collaboration with the ASPIRE and HOPE clinical staff, the Community Working Group (CWG), and local Community Advisory Board (CAB) is encouraged. Please contact FHI 360 to help facilitate any of this process as needed.

The accrual plan should minimally contain the following elements:

- Site-specific accrual targets
- Methods for tracking actual accrual versus accrual targets
- Methods for maintaining participant confidentiality during the accrual process
- Staff responsibilities for all of the above (direct and supervisory)
- QC/QA procedures (if not specified elsewhere)

Study staff are responsible for updating this accrual plan if needed to meet site-specific accrual goals.

3.1.2 Phase 1 Site-Specific Accrual Targets

Approximately 32 former ASPIRE participants per site are targeted to be enrolled in MTN-032 Phase 1. The total accrual time anticipated for this study is 4-6 months. The participant subgroups and approximate enrollment targets are shown in Table 3-01, by interview modality. All participants will be selected from among those randomized to the active arm in ASPIRE. As seen in this table, participant selection will be stratified by age and level of dapivirine detected in plasma and/or residual rings.

Table 3-01: Phase 1 Approximate Enrollment Targets per Site

Participant Group	~Total No. of Participants/Site for IDI	~Total no. of participants/ site for FGD
Age 18-21		8
High level of drug detected	3	
Low level of drug detected	5	
Age 22-45		8
High level of drug detected	3	
Low level of drug detected	5	

All potentially eligible participants will be randomly pre-selected by SCHARP, based on several criteria: 1) all participants pre-selected will have been on product for a minimum of three months, 2) available data from plasma PK and/or residual ring, 3) IDI participants will be stratified by age and drug level detected, 4) FGD participants will be stratified by age.

Prior to the start of the study, Recruitment Lists (RL) will be generated by SCHARP and distributed to the sites. Recruitment of participants into the study from RL should occur **in sequential order within each sub-group**; however, sites may recruit from multiple sub-groups simultaneously. Enrollment status will be recorded on the RLs and Screening and Enrollment Log, and the outcome of each ASPIRE PTID considered for potential enrollment should be recorded on the Participant Status Form (PSF). Sites may choose to combine the RL with the Screening and Enrollment Log, provided that all necessary information is captured.

Note:

At sites where there are not enough participants on the RL in the younger (18-21) sub-group to meet targets for IDI, sites should: 1) prioritize recruiting for the younger age FGD first; 2) recruit those who do not or cannot participate in the FGD for an IDI; and 3) notify the MTN-032 Management Team of this change in interview assignment and document the outcome on the RL and/or the Screening and Enrollment Log.

If there are inadequate numbers of randomly selected individuals on the RL for any of the other target subgroups indicated above in Table 3-01, sites should contact the MTN-032 Management Team for guidance on how to fulfill targets. Any other changes to interview modality assignment or subgroup targets must first be approved by the MTN-032 Management Team, and documented on the Recruitment List and/ or the Screening and Enrollment Log.

The MTN-032 Study Coordinator at each site is responsible for updating the recruitment status on the RL regularly and communicating screening and enrollment progress with FHI 360 at a minimum of once per week (see section 3.1.9 below).

3.1.3 Phase 2 Site-Specific Accrual Targets for Female Participants

Up to 156 HOPE participants will be enrolled into Phase 2. The participant subgroups and approximate enrollment targets are shown in Table 3-02, by adherence (drug level) group.

Target sample for enrollment is approximately 10 HOPE participants enrolled at each of the following MTN-032 recruitment sites:

- Uganda (MU-JHU)
- MRC (Botha's Hill)
- CAPRISA (eThekwin)
- WRHI
- UZ-UCSF (Zengeza)
- UNC-Lilongwe

Within the 10 women selected for each location, we have enrollment targets for each of three adherence subgroups. Adherence subgroups are to be defined by HOPE drug feedback scores (0, 1,

2, 3) for the first available ring during HOPE. Enrollment targets, by subgroup, are outlined in Table 3-02.

Table 3-02. Female Participant Enrollment Targets by Adherence Group

Adherence group	Enrollment target
High (1st available ring = 3)	2
Inconsistent (1st available ring = 1 or 2)	6
Low (1st available ring = 0)	2

Prior to the start of the study, Recruitment Lists (RL will be generated by SCHARP and distributed to the sites. Recruitment of participants into the study from RL should occur in sequential order within each sub-group; however, sites may recruit from multiple sub-groups simultaneously. If there is a significant time gap between participants on one of the RL, sites should contact the management team to discuss.

Potentially eligible participants must meet protocol-specified eligibility criteria, as described in 3.1.8. Sites are required to determine enrollment eligibility based on inclusion criteria (particularly #4 and #5) and enroll participants as they exit from HOPE.

Enrollment status will be recorded on the RLs and Screening and Enrollment Log, and the outcome of each HOPE PTID considered for potential enrollment should be recorded on the Participant Status Form (PSF). Note that the HOPE PTID of women who do not enroll in MTN-032 should not be entered on the PSF per MTN-032 Data Communique #5. Sites may choose to combine the RL with the Screening and Enrollment Log, provided that all necessary information is captured and any information collected in the pre-screening/screening process from non-enrolled women is not connected to the HOPE PTID upon submission of RL to the management team. See Data Communique #5 for more information.

3.1.4 Phase 2 Site-Specific Accrual Targets for Male Partners

Up to 120 male partners of HOPE participants will be enrolled into Phase 2.

Target sample for enrollment is approximately 8-16 male partners of former HOPE participants per site for FGDs and, as necessary, up to 4 participants per site for IDIs. Per management team approval, the number of IDIs may increase if a site cannot enroll enough male partner participants into FGDs.

- o Uganda (MU-JHU)
- o MRC (Botha's Hill)
- o CAPRISA (eThekwin)
- o WRHI
- o UZ-UCSF (Zengeza)
- o UNC-Lilongwe

Prior to the start of the study, RL will be generated by SCHARP and distributed to the sites. Recruitment of participants into the study from RL should occur in sequential order within each sub-group. SCHARP will create two RLs for each site of female HOPE participants with unique PTIDs selected for each list.

- o 1st 50% of enrolled female HOPE participants for FGD 1
- o 2nd 50% of enrolled female HOPE participants for FGD 2

Table 3-03. Male Partner Enrollment Target by FGD group

	FGD 1	FGD 2
FGD participants	4-8 per site	4-8 per site

Potentially eligible participants must meet protocol-specified eligibility criteria, as described in 3.1.8. Sites are required to determine enrollment eligibility based on inclusion criteria (particularly #1 and #2) and sites with management team approval may enroll male participants only after their female partners have provided written permission to contact using the male partner PTC form. Sites will choose an FGD date that occurs after all HOPE participants in group 1 will have exited and recruit in order of SCHARP generated list, and will repeat the same process for group 2. The MTN-032 management team will provide specific guidance to sites with limited numbers of eligible male partner participants.

Sites should notify the management team if there is concern that there will not be enough men to fill an FGD, either because of few women giving PTC male partners, male partner refusals and/or scheduling conflicts. The management team will work with site management to develop an alternative plan.

IDI participants will be enrolled purposively according to special cases, or will be selected from among those that are chosen, but unwilling or unable to attend, FGD. IDIs may also be used in place of FGDs for special circumstances by site, per management team approval. No IDI-specific RLs are required.

3.1.5 Pre-Screening Definition for Phase 2 Participants

Pre-screening for Phase 2 of MTN-032 is primarily conducted by SCHARP in the generation of Phase 2 RLs. However, sites will conduct additional pre-screening activities that include review of HOPE charts for adequate residual drug feedback information and documentation of necessary permissions for contact, particularly with regards to eligibility criteria #4 and 5 for female participants and eligibility criteria #1 for male participants. Only those potential participants who have given permission to contact – or, those potential male participants whose partners have given written permission to contact – will be contacted to participate in MTN-032.

3.1.6 Screening Definition for Female Participants

Screening **female participants** for this study primarily refers to recruitment procedures undertaken by site staff to contact and obtain a verbal expression of willingness to join/enroll in the study, and to schedule the participant for her MTN-032 visit. Once pre-screening has been completed for potential female participants, including verification of a former ASPIRE or HOPE participant's permission to be contacted (PTC) a former ASPIRE or HOPE staff member will contact the potential participant using locator information provided during ASPIRE or HOPE. The staff member will follow the Screening/Recruitment Checklist, found on the MTN website, to describe the MTN-032 study. Note that, because potential participants who receive a call regarding their interest in MTN-032 have not yet completed the informed consent process, the "participant identifier" on the Screening/Recruitment Checklist should be the Obs. # listed on the SCHARP-generated Recruitment List. Potentially interested participants will then be scheduled for an enrollment visit, which may be the same date of the IDI/FGD in most cases. All contacts and contact attempts should be documented in Participant Contact Logs or File Notes in the participant's binder. A copy of the Screening/Recruitment Checklist should be maintained in Participant Files for all participants who are successfully enrolled. Completed Screening/Recruitment Checklists for participants who do not enroll in MTN-032 should be maintained separate from study documentation containing women's ASPIRE and/or HOPE PTIDs.

3.1.7 Screening Definition for Male Partner Participants

Screening **male partner participants** for this study primarily refers to recruitment procedures undertaken by site staff to contact and obtain a verbal expression of willingness to join/enroll in the study, and to schedule the participant for his MTN-032 visit. Note that only male partners of pre-selected participants who have given written permission to contact their partners using the MTN-032 Permission to Contact Male Partner form will be contacted.

Note:

After IRB approval of MTN-032 Protocol v2.0 LoA #01, sites should follow the below guidance:

1. HOPE participants who provided only verbal permission to contact male partners can be contacted to provide written permission on the IRB approved PTC form. Sites should only re-contact former HOPE participants: 1 – who provided verbal permission to contact their male partners **and** 2 - whose PTIDs appear on the SCHARP male partner recruitment list.
2. HOPE participants *who were not* asked to provide permission to contact male partners at HOPE PUEV or SEV can be contacted to provide written permission to contact male partners using the PTC form. Sites should only re-contact former HOPE participants: 1 – who provided permission to be contacted about future studies, including MTN-032 **and** 2 - whose PTIDs appear on the SCHARP male partner recruitment list.

Once pre-screening has been completed for potential male partner participants, including confirming PTC status, a HOPE staff member will contact the potential participant using locator information provided by the female partner on the PTC form. The staff member will follow the MP Screening/Recruitment Checklist, found on the MTN website, to describe the male partner aspects of the MTN-032 study. Note that, because potential male participants who receive a call regarding their interest in MTN-032 have not yet completed the informed consent process, and their partners who were enrolled in HOPE are not completing informed consent for MTN-032, the “participant identifier” on the Screening/Recruitment Checklist should be the Obs. # listed on the SCHARP-generated Recruitment List. Potentially interested participants will then be scheduled for an enrollment visit, which should be the same date of the IDI/ FGD in most cases. All contacts and contact attempts should be documented in Participant Contact Logs or File Notes in the participant’s binder. A copy of the MP Screening/Recruitment Checklist should be maintained in Participant Files for all participants who are successfully enrolled. Completed Screening/Recruitment Checklists for participants who do not enroll in MTN-032 should be maintained separate from study documentation containing the HOPE PTIDs related to these individuals.

3.1.8 Definition of Enrollment Procedures

MTN-032 staff will meet potential participants at the designated time and venue agreed by the participant during screening contact. This may be a community hall, the participant’s home (for IDIs), or another venue preferred by the participant that is quiet enough for audio-recording. The first step of the visit will be to undergo the informed consent process. After the administration of the informed consent and all participants’ questions have been addressed, but before signing the informed consent, site staff should administer the informed consent comprehension checklist. Participants will be considered enrolled in MTN-032 after they have provided written informed consent, and have met all eligibility criteria. At this point, they should be assigned a MTN-032 PTID. Individuals who do not enroll (i.e. do not sign informed consent, or do not meet all eligibility criteria) will be assigned a *non-enrolled PTID*. See section 3.1.10 for more information on the assignment of enrolled and non-enrolled PTIDs for MTN-032.

In-Depth Interviews should ideally be conducted the same day written informed consent is obtained. If it is not possible to conduct the IDI until a later date than IC administration, the IC should be reviewed again immediately prior to the IDI, and this should be documented in the participant file. In order to ensure completion of Focus Group Discussions, however, FGD participants can complete IC procedures 1-2 days prior to the discussion. Further information on the informed consent process is provided in Section 4.

3.1.9 Eligibility Determination and SOP

It is the responsibility of the site Investigator of Record (IoR) and other designated staff to ensure that only participants who meet the study eligibility criteria are enrolled in the study. Each study site must establish a standard operating procedure that describes how study staff will fulfill this responsibility. This SOP minimally should contain the following elements:

- Eligibility determination procedures, including:
 - Pre-visit eligibility assessment procedures
 - During-visit eligibility assessment procedures
 - Final confirmation and sign-off procedures prior to enrollment

- Documentation of each eligibility criteria (met or not met)
- Ethical and human subjects considerations
- Staff responsibilities for all of the above (direct and supervisory)
- QC/QA procedures (if not specified elsewhere)

Should study staff identify that an ineligible participant has inadvertently been enrolled in the study, the IoR or designee should contact the MTN-032 Management Team (mtn032mgmt@mtnstopshiv.org) immediately.

Prior to enrollment, eligibility for study participation must be confirmed and documented by designated staff. The visit checklists may be used to document eligibility, or sites may choose to create a site-specific MTN-032 Eligibility Checklist.

Each participant will be assessed for eligibility before/during the informed consent process, at which point study staff can verify inclusion and exclusion criteria are met, as listed in MTN-032 Protocol Section 5 and further discussed below.

NOTE: SCHARP will only select and randomly allocate participants who meet the product use criteria established below, as well as the PK or residual drug criteria. Therefore MTN-032 staff do not need to verify inclusion criteria 4-7 for Phase 1 participants (inclusion criteria 5 for Phase 2) in ASPIRE/HOPE files. **MTN-032 site staff must document verification of:** Phase 1 inclusion criteria 1-3; Phase 2 inclusion criteria 2-5; Phase 2 male partner inclusion criteria 1-5; and exclusion criteria 1 for all participants. Criteria requiring verification by staff are **bolded** below.

Inclusion criteria are as follows:

Phase 1: Former ASPIRE participants

1. **Participated in the ASPIRE protocol, randomized to active product and informed of their randomization assignment.**
2. **Able and willing to provide written informed consent in one of the study languages.**
3. **Able and willing to complete the required study procedures.**

For participants who did not acquire an HIV infection while taking part in ASPIRE:

4. Evidence of study product dispensation at a minimum of three consecutive ASPIRE scheduled clinic visits.
5. Have a minimum of three ASPIRE PK data measurement points available.

For participants who acquired HIV infection while taking part in ASPIRE:

6. Evidence of study product dispensation in the month prior to the participant's acquisition of HIV infection.
7. Have a minimum of one ASPIRE PK data measurement available.

Phase 2: HOPE participants

1. **Participated in the HOPE protocol.**
2. **Able and willing to provide written informed consent in one of the study languages.**
3. **Able and willing to complete the required study procedures.**

For participants who did not acquire an HIV infection while taking part in HOPE:

4. Evidence of study product dispensation for a minimum of three consecutive months.

For participants who acquired an HIV infection while taking part in HOPE:

5. Evidence of study product dispensation in the month prior to the participant's acquisition of an HIV infection.

Phase 2: Male partners of HOPE participants

1. Identifies as a male sexual partner of a HOPE participant for whom the HOPE participant has given permission to contact.
2. Was a male sexual partner of a HOPE participant during her participation in HOPE (regardless of whether she used the ring or not).
3. Able and willing to provide written informed consent in one of the study languages.
4. Able and willing to complete the required study procedures.
5. Is above the age of 18 at the time of study participation.

Exclusion criteria are as follows (**all participants**):

Phase 1 and Phase 2:

- 1) Has any condition that, in the opinion of the IoR/designee, would preclude informed consent, make study participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives.

NOTE: This exclusion criterion is standard across all MTN protocols and may be used to justify a range of reasons for participant exclusion from MTN-032. For example, if a participant is assigned to a FGD but refuses the audio recording, the IoR may decide to exclude her if s/he feels it might complicate interpretation of MTN-032 data.

3.1.10 Assignment of Participant ID and FGD Numbers

For all MTN-032 participants, RTI will assign a range of MTN-032 participant ID numbers (PTIDs). The site should assign one PTID to each participant after informed consent for the study has been obtained. PTIDs are assigned in sequential order within the range as participants are enrolled in the study. Staff should ensure that each PTID is assigned only once and may track this by using a Screening and Enrollment Log or PTID/ Name Link Log. Participants enrolled in Phase 1 were given the ranges showed in Table 3-04. Participants enrolling in Phase 2 will receive a new PTID even if they previously participated in Phase 1 (see Table 3-05). Explanation of the PTID assignments for Phase 2 can be found in Table 3-06. Sites should record the participants Phase 1 PTID on the Screening and Enrollment Log or PTID/ Name Link Log and the PSF P2 CRF for tracking purposes.

The Phase 1 and Phase 2 Participant Status Forms (PSF) will capture both the ASPIRE or HOPE PTID and Obs # on the SCHARP recruitment list for enrolled female participants, the Obs # on the SCHARP recruitment list for enrolled male partner participants, and the MTN-032 PTID of the female or male participant. For male participants as well as individuals on the Phase 2 Recruitment List who do not enroll, no HOPE PTID should be entered onto the PSF; see Data Communique #5 for guidance on completing the PSF for these individuals. The MTN-032 PTID should be used for all subsequent MTN-032 documentation. Anyone who was considered for participation in Phase 2 should receive a PTID, regardless of enrollment status, per Table 3-05.

MTN-032 PTID boxes are located near the upper left corner of each CRF page. The PTIDs used for this study are four digits long and are formatted as "XXXX".

Table 3-04: Range of PTIDs by Site for Phase 1

Site	PTID Range	FGD # Range
MRC Bothas Hill	1001-1099	101-199
WRHI	2001-2099	201-299
CAPRISA eThekwini	3001-3099	301-399

UZ-UCSF Zengeza	4001-4099	401-499
UZ-UCSF Spilhaus (Phase 1 only)	5001-5099	501-599
MUJHU	6001-6099	601-699
Lilongwe	7001-7099	701-799

Table 3-05: Range of PTIDs by Site for Phase 2

Site	PTID Range Female Participants	FGD # Range Female Participants (if needed)	PTID # Range Not-enrolled Females	PTID Range Male Partners	FGD # Range Male Partners	PTID # Range Not-enrolled Males
MRC Bothas Hill	1201-1299	121-129	1801-1899	1301-1399	131-139	1901-1999
WRHI	2201-2299	221-229	2801-2899	2301-2399	231-239	2901-2999
CAPRISA eThekweni	3201-3299	321-329	3801-3899	3301-3399	331-339	3901-3999
UZ-UCSF Zengeza	4201-4299	421-429	4801-4899	4301-4399	431-439	4901-4999
MUJHU	6201-6299	621-629	6801-6899	6301-6399	631-639	6901-6999
Lilongwe	7201-7299	721-729	7801-7899	7301-7399	731-739	7901-7999

Table 3-06: PTID breakdown for Phase 2

1st Digit	2nd Digit	3rd and 4th Digit
Site #	Female or Male Enrollment Status	Sequential counter for individual identification
MRC=1 WRHI = 2 CAPRISA = 3 Zengeza = 4 MUJHU=6 Lilongwe=7	2=female enrolled 8=female not enrolled	3=male enrolled 9=male not enrolled

All FGDs should be numbered in sequential order using the range of numbers assigned in Table 3-05. To distinguish the FGD numbers from the PTIDs, FGD numbers are three digits long and are formatted as “XXX”. Note that each participant included within an FGD will still receive a unique PTID per the specified PTID ranges.

3.1.11 Screening and Enrollment Timeframe

Recruitment/screening, accrual, and enrollment procedures for Phase 1 in MTN-032 will begin upon study activation and continue for approximately four to six months at each site or until the site target accrual is reached. The screening and enrollment timeframe for Phase 2 will begin upon notification of site readiness. Female IDI participant accrual will be ongoing as HOPE participants complete their Study Exit Visits and continue until female IDI accrual targets are reached. Female FGD accrual, if necessary, will begin upon initial release of HOPE results, which is estimated to be during Q4 of 2018, and continue until female FGD accrual targets are reached. Male partner IDI & FGD accrual will begin as HOPE participants complete their Study Exit Visits and continue until accrual targets are reached.

3.1.12 Screening and Enrollment Logs

The DAIDS policy on Requirements for Essential Documents at Clinical Research Sites Conducting DAIDS Funded and/or Sponsored Clinical Trials requires study sites to document screening and enrollment activity on Screening and Enrollment Logs. Screening and Enrollment Logs will provide a comprehensive picture of all participants screened and enrolled in the study. Each participant that is screened for MTN-032 should be logged according to the Obs # on the SCHARP-generated RL, and should also have a completed Participant Status Form (PSF CRF), which will indicate enrollment into MTN-032 or reasons for ineligibility (including not providing Permission To Contact either herself or her male partner). Those individuals who do not enroll should be identified on the PSF by their Obs # and non-enrolled PTID, per Data Communique #5. Each person who provides informed consent is provided with the next chronological PTID; those who do not provide consent receive a non-enrolled MTN-032 PTID in chronological order as outlined above in Table 3-05.

An example of a Screening and Enrollment Log can be found on the MTN-032 website. Sites may choose to combine the RL with the Screening and Enrollment Log, provided that all necessary information is captured. This log will include ASPIRE or HOPE PTID for female participants, MTN-032 PTID if enrolled, screening date, and enrollment date or reason for non-enrollment (if applicable).

Sites are also expected to document the linkage between the participant's name and the MTN-032 PTID. This can be documented on a PTID/Name Link Log created by the site.

3.1.13 MTN-032 Progress Reports

Phase 1 Accrual Reporting:

Once MTN-032 accrual is initiated, study staff will report the total number of participants screened and enrolled to FHI 360 and RTI on a weekly basis, along with the date of the first, and final scheduled IDI and FGD, as well other key progress indicators, as requested. A Screening and Accrual Tracker template will be available on the MTN-032 website. RTI will send a Screening and Enrollment report to the MTN-032 Management Team on a weekly basis containing the information provided by sites.

Phase 2 Accrual Reporting:

Once MTN-032 Phase 2 accrual is initiated, study staff will report the total number of participants screened and enrolled to FHI 360 and RTI on a weekly basis by submitting an updated version of the site's Recruitment List as available on the Atlas website, including participant enrollment dates. The HOPE PTID column should be removed from the RL prior to its submission to RTI and FHI 360 per Data Communique #05. For all individuals considered for enrollment, the enrolled or non-enrolled PTID should be written in the 'MTN-032 PTID' column per updated RLs from SCHARP (see Figure 3-1 below). The date the participant was enrolled, deemed ineligible or declined participation should be written in the 'Date Enrolled, Ineligible, or Declined' column'. Complete these columns for all individuals considered for enrollment until accrual subgroup target enrollment is met. Other key progress indicators will be reported as requested by the management team. RTI will send a Screening and Enrollment report to the MTN-032 management team on a monthly basis containing the information provided by sites.

Figure 3-1: 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 to write in)	Confirmation of required product dispensation:	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.

3.2 Participant Retention

The majority of data collection activities for MTN-032 are one-time only events, thus participant retention is not applicable.