

Section 8. Participant Retention

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This section presents information related to definitions, requirements, and procedures for participant retention in MTN-020.

8.1 Retention Definitions

The term “retention” refers to completion of required follow-up visit procedures at the time points specified in the protocol. This definition must be operationalized for any study, and operational definitions reflect the primary endpoints of the study. For MTN-020, retention will be measured in various ways depending on the statistical and study monitoring needs. During the study, retention data will be routinely provided to the Protocol Team in two ways: a per-visit retention rate (%) as well as an overall (cumulative) retention rate (%). These two measures are described below. Information on the reports containing retention data, including description of additional retention metrics, is provided in Section 17 of this manual (Study Reporting Plan).

Details of retention measures used in statistical analyses will be provided in the statistical analysis plan.

8.1.1 Per-Visit Retention

A per-visit retention rate (%) for each required follow-up visit will be calculated and provided in a monthly Retention Report. The per-visit retention percentage is calculated by taking the number of participants expected for a visit who complete the visit within the allowable time frame (the visit window) and dividing that by the number of participants expected for the visit. A participant is expected for every visit after she has enrolled until the study has reached its natural end and the participant is terminated or the participant has reached a primary study endpoint (HIV seroconversion).

8.1.2 Overall Retention

An overall (cumulative) retention rate (%) for each site will be calculated and provided in a monthly Data Summary Report. The overall retention percentage is calculated as the total number of completed study visits to-date (within the allowable time frame, i.e. the visit window) divided by the total number of expected study visits. For this calculation, “expected visits” is the number of visits expected to be completed assuming no missed visits or loss to follow-up.

8.2 Retention Requirements

For operational/study conduct assessment purposes during the study, MTN-020 will use a per-visit retention rate target of 95% for all required follow-up visits. Therefore each study site will target a retention rate of at least 95% for each required follow-up visit.

Low retention rates can have serious impacts on the HIV infection rates observed in study participants because we cannot know the HIV status of participants who do not return for required follow-up visits. In each group, the observed HIV infection rate could be higher or lower than the true rate, but it is not possible to determine the direction of the error. Low retention is also closely linked with low adherence to the study product. If a participant misses her regularly scheduled visit, she may not have access to the vaginal ring for the coming month. Poor adherence makes it harder to demonstrate whether or not the ring is effective at preventing HIV infection.

To avoid these problems, high participant retention rates must be maintained throughout the study. A retention check-in has been incorporated in the ASPIRE Counseling and Education (ACE) program to address participant challenges to high retention and is outlined in greater detail in the ACE Manual in SSP Section 12. If the 95% per-visit retention rate is not achieved from the start of the accrual period, the protocol team may request that accrual be slowed or stopped altogether until retention rates are brought to an acceptable level.

8.3 Retention SOPs

Site staff members are responsible for establishing a standard operating procedure (SOP) for participant retention, and for updating the SOP and retention efforts undertaken to meet the study retention goal of 95% per visit. This SOP should be re-evaluated and modified in response to lower than anticipated retention rates, or at any other time when retention strategies are modified. The SOP should minimally contain the following elements:

- Site-specific retention goals
- Methods for tracking actual retention versus retention goals
- Procedures for completing and updating participant locator information
- Site-specific definition of “adequate” locator information (for purposes of determining participant eligibility)
- Visit reminder methods and timeframes
- Methods and timeframes for identifying when a visit has been missed
- Planned retention methods, including what outreach/locator efforts are taken within various time intervals after a visit has been missed
- Inclusion of the definition of “chronic defaulter” (Section 8.5 below)
- Strategies for recovering participants considered to be chronic defaulters
- Methods for timely evaluation of the utility of retention methods
- Strategy for communicating retention challenges (particularly with respect to clinic-level challenges) that are discussed during Step 6 of the adherence counseling program back to designated members of the study team so that these can be discussed and change implemented as appropriate
- Ethical and human subjects considerations
- Staff responsibilities for all of the above (direct and supervisory)

- QC/QA procedures related to the above (if not specified elsewhere)
- #### 8.4 Obtaining and Updating Locator Information

Successful retention begins with collection of exhaustive locator information from each study participant. All study participants are asked to provide locator information during the study screening process, and to continually review/update this information during follow-up. Provision of "adequate" locator information during screening is a study eligibility requirement and each site must specify its definition of adequate locator information in its retention SOP.

Each study site is encouraged to develop an exhaustive locator form to maximize contact effectiveness and participant retention. Sites also may wish to consider having outreach workers accompany participants to their homes or other community based locations to verify or further clarify their locator details. SMS and other means of communication with participants may be used throughout the ASPIRE trial assuming participant permission is provided (e.g. via the locator form, documentation in chart notes, or a site-specific tracking tool). All means of communication must be in line with local IRB guidelines.

Potential locator items include:

- Participant's full name, alias, and/or nickname; government-issued identification number; home address; home phone number; mobile phone number; pager number; work address; work phone number; fax number; e-mail address; daytime and nighttime locations, meeting places, hangouts.
- Walking/driving/public transport directions and/or pictorial map to the participant's home, workplace, etc; global positioning coordinates if available.
- Name, address, telephone number, and/or other contact information for stable community contacts (i.e., participant family members and friends) who typically know the whereabouts of the participant.

Note: Although contact information for a participant's current primary partner likely will be useful, contact information for other contacts also should be collected, since the participant's relationship with this partner could change during the course of the study.

- Name, address, telephone number, and/or other contact information for the participant's health care provider, school or training program; church or other place of worship; social service case worker; counselor, etc; participant's child's school and health care provider.
- Name, address, telephone number, and/or other contact information for support groups, shelters, food pantries, and other social service organizations used by the participant.

During the informed consent process and when collecting locator information, study participants must be informed that their locator sources will be contacted if study staff are unable to locate the participant directly. Study staff will negotiate with the participant how they will identify themselves when locator sources are contacted. Arrangements agreed upon with the participant should be documented on the locator form.

Study staff should view every participant contact as an opportunity to update the participant's locator information. When updating locator information, actively review each item on the locator form to determine whether the information is still current (i.e., rather than simply asking "Has any of your information changed since your last visit?"). Also probe for additional information that the participant was not able or willing to provide at previous visits.

Study staff should document in chart notes that they reviewed the locator information with the participant at every visit. Any updates to the locator form should use standard GCP corrections with initials and date of the staff member making the changes.

8.5 Chronic Defaulters

For the purposes of MTN-020 a 'chronic defaulter' will be someone who has missed three or more visits in a row. Sites should specify how chronic defaulters will be identified and how retention procedures will be modified for these participants (if at all) in their retention SOPs.

Chronic defaulters will remain in the study and will only be considered lost to follow up at study end. These participants will be terminated from the study at the natural end of the study, unless they wish to withdraw consent for their participation prior to this, or unless they are terminated per IoR discretion. Participant requests around visit tracking and follow-up from clinic staff will be honored and documented.

8.6 Use of a Participant Tracking System

Implementation of a participant tracking system is a requirement for study activation. This system may be paper-based, or an electronic database, such as the tool provided by the SDMC. The system chosen must be able to provide the site with a listing of all participants who have missed scheduled study visits, as well as a listing of "chronic defaulters" (participants who have missed three or more study visits in a row).

It is expected that each site has specific staff members designated to retention efforts and the maintenance of this system to track participant visits from the day that accrual starts. Adequate staffing for retention efforts will be a requirement for study activation.

The participant tracking system should be able to inform the site team of the following:

- Number of participants who are expected in the next week/day (to allow for visit reminders to be made in the timeframe specified in site Retention SOP).
- Participants who have missed their scheduled visit and are still within the visit window (ideally so that participants whose window is about to close can be prioritized for tracing).
- Participants who have missed their scheduled visit and study product needs to be replaced (for example, approaching 35 days on product).
- Participants who have missed their scheduled visit and the window has closed (and a missed visit CRF is needed).

- Participants who are repeat defaulters and have missed ‘X’ number of visits (as determined by the site). Repeat defaulters are different from chronic defaulters (Section 8.5) in that the missed visits evaluated are in total, i.e., not necessarily sequential (as they are for chronic defaulters). These participants may require specific counseling approaches, and site flexibility in order to accommodate their schedules or concerns.

8.7 Retention Tips

Some general strategies for maximizing participant retention are presented in protocol Section 5.1.2. Additional tips for successful retention are as follows:

- Work with community members to identify the most applicable contact and retention strategies for the local study population, including the type and amount of participant incentives.
- Consider the comfort of the waiting rooms at the site. Ensure there is adequate room and comfortable seating. Depending on the population at the site consider television, refreshments, pamphlets and children’s play areas.
- Keep participants and community members up-to-date on study progress to foster a sense of partnership and ownership of the study (through the use of participant newsletters, for example). Note that all materials distributed to participants and within the community require IRB approval.
- Inform local service providers who interact with the local study population about the study, so that they also can express their support for the study.
- Actively review clinic flow to minimize participant waiting time.
- If possible, schedule the visit at the participant’s convenience, for example, after work hours or on Saturday morning. Reduced visit procedures or off-site visits can be held when necessary to ensure the participant is able to get the necessary safety tests conducted in order to remain on the study product. See section 6.4 for more information about conducting a visit with reduced procedures or conducting an off-site visit.
- Develop rapport and ensure participants feel welcome and comfortable during their visits. Visit adherence will be a key component of counseling for MTN-020. See Section 12 for more guidance on these counseling messages.
- Emphasize the value of the participant’s involvement in the study during the study informed consent process and subsequently at follow-up visits. When participants complete scheduled visits, acknowledge and compliment their commitment, time, and effort devoted to the study.
- Host gatherings, parties and/or other social events for participants.
- Host social, educational, and/or other “male involvement” events for participants’ partners.
- Schedule all monthly visits at the participant’s enrollment visit. Thereafter, at each monthly visit, confirm the scheduling of the next visit and give the participant an appointment card with the scheduled visit date and time noted.
- Prepare a calendar of scheduled visits for each enrolled participant, based on her enrollment date, or offer a planner/calendar as an incentive and note all study appointments in the planner/calendar. Note the dates of all scheduled visits in the participant’s file for easy reference.

- For participants who demonstrate a pattern of late or missed appointments, schedule follow-up visits for the beginning of the allowable visit window (i.e., up to two weeks before the actual target date) to allow maximum time for re-contact and re-scheduling if needed. Reference Section 14 of the ASPIRE SSP for visit window details and Section 9.4 regarding quantity of ring dispensation for instances of visits scheduled in excess of 35 days. Pay close attention to the allowable visit window and prioritize retention efforts for participants nearing the end of the window. Organize daily caseloads and work assignments based on these priorities.
- Follow-up on missed appointments with an attempt to re-contact/re-schedule within 24 hours (preferably on the same day). Continue these efforts per site retention SOPs until contact is made.
- Keep locator information up-to-date and maintain thorough documentation of all efforts to contact the participant. Keep all this information in an organized manner, so that different staff members can easily review the information and contribute to re-contact efforts when necessary.
- Make use of all information collected on the participant's locator form. Even if a locator source is not useful/ successful on one occasion, try it again later.
- Make use of all available contact methods (e.g. phone, mail, home visits, street outreach, newspapers, e-mail/ internet). Also make use of other available locator information sources, such as phone and postal directories and other public registries.
- Post outreach workers at other local service organizations utilized by the study population.
- Attempt contact with the participant at different times during the day and the week, including evenings and weekends.
- If a participant wishes to discontinue participation in the study, her wishes must be respected. See Section 6.9 for further information about procedures for participants that voluntarily withdraw from further participation in the study.