

Section 8. Participant Retention

This section presents information related to definitions, requirements, and procedures for participant retention in MTN-008.

8.1 Retention Definition

The term “retention” generally refers to completion of the subsequent evaluation visit and follow up and procedures as specified in a study protocol. This definition must be operationalized for any study, and operational definitions usually reflect the primary objectives and endpoints of a study.

During the study, retention will be defined based on whether participants complete required visits and follow-up procedures within the allowable visit windows. Women who complete their scheduled visits on Days 0 and 6, complete the Day 14 call, and who have received at least 4 doses of study product will be considered “retained” for those visits, for both Cohorts. Infants in the Lactation Cohort who complete their scheduled visits on Days 0 and 6, and complete the Day 14 call with the mother, within the allowable visit windows, will be considered “retained” for those visits. Infants in the Pregnancy Cohort are expected to complete a delivery visit, with successful cord blood collection, and post-delivery visit, to be considered retained. Please see SSP Section 6.4.1 for details regarding allowable visit windows for MTN-008.

As indicated above, participants who do not complete these visits within the allowable windows, will not be considered retained for the missed visit.

The target retention rate of this study is to have 95% of all enrolled mother-infant pairs contribute to the evaluable study population. Beyond that, striving for 100% adherence to study procedures and clinic visits among the evaluable mother-infant pairs will provide the highest quality data. Achieving a high retention rate begins with the recruitment stage. Site staff and clinician involvement during the screening process is an essential component and participant follow-up is equally as important. Each site will develop a retention SOP to define this process for their site. Please refer to the protocol section 10.5 for additional information.

MTN 008 must enroll an exact number of evaluable mother-infant pairs during the entire course of the study:

Pregnancy Cohort, Group 1 = 45 evaluable mother-infant pairs

Pregnancy Cohort, Group 2 = 45 evaluable mother-infant pairs

Lactation Cohort = 15 evaluable mother-infant pairs.

Additional participants must be enrolled if any of those previously enrolled have only incomplete exposure to study product. In order to be considered evaluable, the mother (of the mother-infant pair) must

- complete at least 4 and no more than 7 total doses of study gel
- complete the Day 6 visit

Participant follow-up is essential to a high retention rate. The Day 14 phone call is important to obtaining good quality data for both cohorts. And in particular, for the Pregnancy Cohort, the delivery day assessment of both the mother and the infant (and cord blood collection) provide important study data and sites should make every effort to capture this data.

The MTN Statistical and Data Management Center (SDMC) will generate reports during the study presenting retention rates for study visits. The SDMC also will generate a final end-of-study retention rate after the study is completed.

8.2 Retention Requirements

The study site will target retention of 95 percent of enrolled study participants at each required follow-up visit. Note: Retention will be reported separately for women and infants, and the 95 percent retention goal applies to both groups.

8.3 Retention SOPs

Site staff is 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 percent for every study visit. 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
- Visit timeframes
- Methods and timeframes for identifying when a visit has been missed
- Planned retention methods including, but not limited to,
 - what outreach/locator efforts are to be taken and when
 - those targeted toward maternal retention and toward infant retention
- Methods for timely evaluation of the utility of retention methods
- Ethical and human subjects considerations
- Staff responsibilities for all of the above (direct and supervisory)
- Staff training requirements (if not specified elsewhere)
- QC/QA procedures related to the above (if not specified elsewhere)

8.4 Obtaining and Updating Locator Information

Successful retention begins with collection of locator information from each study participant. All study participants will be asked to provide locator information during the study screening and enrollment process, and to continually review/update this information at every study visit.

Each study site is encouraged to develop an exhaustive locator form to maximize contact effectiveness and participant retention. Potential locator items include:

- Participant and/or parent/guardian 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.

- Transport directions and/or pictorial map to the participant's home, workplace, etc.
- 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 should also 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, rehabilitation provider, etc. For the infant, also helpful to obtain contact information on other care providers: grandmothers, aunts, siblings.

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.

8.5 Retention Tips

With the consent of the participant, study staff will obtain contact information from people who would be expected to know the whereabouts of the participant enrolled in this study. The need to follow up must be emphasized to each study participant/guardian. If a participant misses a scheduled study visit, the study site staff will try to establish communication with the participant through all possible means (e.g., telephone at least 4 different time periods on 3 different days), without breaching the participant's confidentiality. Study site staff is responsible for developing and implementing site-specific SOPs to achieve complete follow up.

Once participants are enrolled in this study, the study site staff will make every effort to ensure the participation of participants for the evaluation visits and follow up, in order to minimize possible bias associated with loss-to-follow-up. Each site will establish participant retention procedures to target an average retention rate of 95%. Study site staff is responsible for developing and implementing site-specific SOPs to target this goal.

Suggestions for such procedures include:

- Providing a thorough explanation of the study visit schedule and procedural requirements during the informed consent process and re-emphasizing this at every follow up visit.

- Collecting detailed locator information at the study Screening and Enrollment Visit, and actively reviewing and updating this information at follow up.
- Creating an environment to support the participant's needs during long visit days to ensure as much comfort and relaxation as possible.
- Schedule all follow-up visits at the participant's Screening Visit. Thereafter, at each follow-up visit, confirm the scheduling of the next visit and give the participant an appointment card with the scheduled day and time noted.
- Assigning adequate staff time and effort to retention efforts.
- Keeping participants and community members up-to-date on study progress to foster a sense of partnership and ownership of the study.
- Educating local service providers who interact with the local study population about the study, so that they also can express their support for the study.
- Emphasizing 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 commend their commitment, time, and effort devoted to the study.
- Scheduling all follow-up visits at the participant's Screening and Enrollment Visits. Thereafter, at each follow-up visit, confirm the scheduling of the next visit and give the participant an appointment card with the scheduled time noted.
- Preparing a calendar of scheduled visits for each enrolled participant, and noting the dates of all scheduled visits in the participant's file for easy reference.
- Paying close attention to the allowable visit window and prioritizing retention efforts for participants nearing the end of the window. Organizing daily caseloads and work assignments based on these priorities.
- Keeping locator information up-to-date and maintaining thorough documentation of all efforts to contact the participant. Keeping 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.
- Making use of all available contact methods (e.g. phone, , e-mail/internet). Also making use of other available locator information sources, such as phone and postal directories and other public registries.
- Attempting contact with the participant at different times during the day and the week, including evenings and weekends.