

Section 11. Behavioral Assessments

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11 Introduction

This section contains information on behavioral research procedures performed in MTN-034; including ACASI assessments, behavioral case report forms (CRFs), in-depth interviews (IDIs), and focus group discussions (FGDs). All staff involved in administering behavioral assessments must read and understand the sub-sections that pertain to their responsibilities.

11.1 ACASI

11.1.1 Overview

The enrollment and follow-up behavioral questionnaires will be captured through Audio Computer Assisted Self-Interview (ACASI). All participants will complete the Enrollment ACASI at the Enrollment visit. Participants will also complete a follow-up ACASI questionnaire at each quarterly visit, unless they have permanently discontinued use of both study products. The ACASI Summary and ACASI Tracking CRFs must be completed at all study visits at which an ACASI questionnaire is scheduled or completed.

The enrollment behavioral questionnaire will evaluate past sexual behavior, partner and partnership characteristics, initial preference for ring or tablet, acceptability of the ring and the tablet, and social and behavioral factors that could influence adherence to the study products. Follow-up questionnaires will explore many of the same topics, plus adherence to the study product she is using during each phase.

11.1.2 Selecting the Appropriate ACASI Questionnaire

All participants must complete the Enrollment ACASI questionnaire at the study enrollment visit (Visit 2.0). During follow-up, ACASI questionnaires will be completed at all quarterly visits through Visit 23.0 (the scheduled PUEV). The appropriate questionnaire should be selected from the list below based on the participant's visit code and product use immediately prior to the visit:

- Visit 6/13/20 Ring
- Visit 6/13/20 Tablet
- Visit 9 Ring
- Visit 9 Tablet
- Visit 16 Ring
- Visit 16 Tablet
- Visit 20 No product
- Visit 23 Ring
- Visit 23 Tablet
- Visit 23 No product

11.1.3 ACASI Survey Schedule in Cases of Seroconversion, Pregnancy, Early Termination, and Permanent Product Hold.

Participants who discontinue use of both study products prior to the scheduled PUEV should be administered one of the three Early PUEV/Discontinuer ACASI questionnaires listed below. The survey selected should be based on the participant's product use immediately prior to the visit.

- Early PUEV/Discontinuer Ring
- Early PUEV/Discontinuer Tablet
- Early PUEV/Discontinuer No product

For participants who become infected with HIV, the Early PUEV/Discontinuer ACASI should be administered at the visit immediately following confirmation of an HIV infection, as described in protocol section 7.5.1. The visit code used in the ACASI survey selection will correspond to the code of the visit that seroconversion is confirmed (i.e. whole integer visit code and decimal visit interim code). The survey selected should be based on the product used immediately before the visit with the first positive rapid HIV test. If the participant chooses to remain in follow-up, no additional ACASI questionnaires will be administered for the duration of the study.

For participants who become pregnant, the Early PUEV/Discontinuer ACASI should be administered at the same visit as the positive pregnancy test. If the participant chooses to remain in follow-up, and resumes product use as described in protocol section 7.5.2, the standard ACASI schedule should be used once product use is resumed. If product use does not resume, no additional ACASI questionnaires will be administered for the duration of the study.

In Product Use Periods 1 and 2, participants who permanently discontinue both products prior to the scheduled PUEV (for reasons other than pregnancy or seroconversion) will be considered

terminated from the study, and the Early PUEV/Discontinuer ACASI questionnaire should be administered at the early termination visit. No additional ACASI questionnaires should be administered. During Product Use Period 3, participants may discontinue both products prior to the scheduled PUEV and be administered the No Product ACASI(s) thereon. Participants who withdraw early from the study for other reasons should complete the Early PUEV/Discontinuer ACASI questionnaire at the early termination visit.

Note: If an Early PUEV/Discontinuer ACASI is indicated at a quarterly visit, it should be administered instead of the regularly scheduled ACASI (not *in addition to* the regularly scheduled ACASI). As usual, only one ACASI Summary CRF and one ACASI Tracking CRF should be completed at the visit, with the Early PUEV/ Discontinuer questionnaire selected (there is no need to document that the regularly scheduled ACASI was not completed).

Participants who are on a temporary product hold for reasons other than pregnancy, or who permanently discontinue one but not both study products prior to the PUEV, should continue the regularly scheduled ACASI questionnaire and should not be administered the Early PUEV/Discontinuer questionnaire.

11.1.4 ACASI Administration Procedures

Detailed guidelines on ACASI equipment set-up, maintenance, trouble shooting and ACASI administration are addressed in the MTN 034 ACASI User's Manual, located on the [MTN-034 Study Implementation Materials Webpage](#). This section provides an overview of the procedures.

Each study site must have a tablet computer connected to the internet and a headset. The ACASI must be administered in a private room where participants will not be interrupted or overheard. Select a location in a room with a door that closes to allow privacy for the participant.

Once the participant has been welcomed, staff should introduce themselves and complete the following:

1. Explain the ACASI procedure.
 - a. Stress we are using ACASI to give as much privacy as possible.
 - b. Emphasize the responses are kept confidential.
 - c. Tell the participant what to expect during the ACASI interview.
2. Enter information into the Administrative Section.
3. Hand the tablet to the participant.
4. Demonstrate the use of the touch-screen and headphones.
5. Verify the participant's comfort using the touch-screen.
6. Allow the participant to complete the practice questions, assisting her, if needed, to make sure she understands how to answer questions and scroll through text.
7. Review the definitions of any terms that may be unknown or misunderstood by the participant.
8. Once the practice questions have been successfully completed, ensure the participant has read or heard and understands the statement encouraging her to respond to all questions as truthfully as possible.
9. Inform the participant that you will be just outside the interview room. Instruct her to let you know if she has questions. Ask her to alert you when she is finished with the questionnaire.
10. When ACASI is finished, thank the participant and make sure she returns the tablet.
11. Close out the ACASI and follow the procedures outlined in the next section (11.2.4) regarding additional counselling.
12. For ACASI questions or concerns, email: mtn034acasi@mtnstopshiv.org

11.1.5 Follow-up counseling

The ACASI questionnaires may bring up sensitive topics such as partner violence and alcohol abuse. The last question on the ACASI will ask the participant whether she would like to talk to someone about any of her answers. After closing out the ACASI, the study staff must run the Follow-Up Counseling Report to determine whether she has answered "Yes" to that question. Details for running

the report are provided in the ACASI manual. If the participant requested additional counseling, she will be directed to a study counselor who will address her worries or concerns, document the discussion according to good documentation procedures, and record any newly reported social harms, AEs, product holds, or other study data on the appropriate CRF.

11.1.6 Missed Questionnaires

Participants, who miss their scheduled visit and ACASI, may reschedule their visit, if within the visit window. If the ACASI is not done within the visit window for any reason, it is not made up at a later visit. The missing ACASI should be documented by marking “No” for the item “Was an ACASI questionnaire completed at this visit” on the ACASI Summary CRF, and the reason for the missed questionnaire should be documented in the “If “No”, please explain” field. This guidance applies to all visits where ACASI is required.

11.1.7 Interrupted Questionnaires

Site staff should ensure that ACASI questionnaires are always completed at the appropriate scheduled visit. If at a visit, an ACASI interview is begun, but not completed, every effort should be made to complete the entire ACASI questionnaire (starting from the beginning) on a day within the visit window as part of a split visit. If the ACASI questionnaire is not able to be completed in its entirety during the visit window, it should be documented as missed.

If participants need to briefly interrupt their ACASI sessions (i.e. attend to a call, go to the bathroom), at the discretion of the site staff, they can do so, first closing the app and then resuming the ACASI where they left off using the “Resume Incomplete Survey” option on the Admin Main Screen. If the interruption is any longer, (e.g. split visit) the participant should start a new survey rather than resume their incomplete one.

If duplicate ACASI questionnaires are present for the same PTID and date, the fully-completed ACASI questionnaire will be the one used in study analyses. These unique circumstances should be documented in the clinic chart notes and a brief description recorded on the ACASI Tracking CRF.

11.1.8 Wrong Questionnaires

If the wrong ACASI survey is administered to a participant and the error is caught during administration, the participant should stop and take the correct survey. If the error is caught after a participant completes the survey, site staff should use their discretion to decide whether the participant is able and willing to complete the correct survey, taking into account how far the participant has gone with the survey and the need to keep the visits short. In either case, site staff should email mtn034ACASI@mtncstopshiv.org to notify the team of the error, detailing which survey was administered and which was meant to be administered, as well as the decision that was made. The site should also document this as a protocol deviation indicating questionnaire administration deviation on the PD Log CRF. For guidance in making these decisions, email mtn034ACASI@mtncstopshiv.org.

11.2 Behavioral CRFs

11.2.1 Introduction

In addition to the ACASI questionnaires and ACASI Summary and Tracking CRFs outlined in the proceeding sections, all participants will complete the following case report forms (CRFs) as part of the MTN-034 behavioral assessments:

- Demographics*
- Tablet Assessment
- Ring Assessment
- Product Preference and Acceptability*
- Product Choice*
- Product Change*
- Social Benefits and Impacts*
- Social Impact Log
- Social Benefit Log
- COVID-19 Behavioral Assessment*

* CRFs marked with an asterisk (*) include at least some translated interviewer-administered

questions.

Instructions for completing each CRF are detailed in the CRF Completion Guidelines (CCGs) provided by SCHARP on the Atlas Portal. Instructions for documentation and follow-up of Social Impacts are described in SSP Section 8.9. This section provides general guidance on completion of behavioral CRFs and on data collection for Social Benefits.

11.2.2 Guidance on Completion of Behavioral CRFs

- All interviewer-administered CRFs (indicated with an asterisk above) should be administered in the preferred language of the participant. This may be different than the language she provided informed consent in, as long as fluency is confirmed/documented in both languages (e.g. on the IC coversheet and/or chart notes). Any deviation from this should be documented in the participant chart notes.
- In order to standardize behavioral data collection from site to site and to maximize quality, it is critical that behavioral CRFs be administered with a non-biased, non-judgmental approach. Study staff should help a participant feel comfortable sharing personal information and opinions while asking the study questions in a consistent manner from participant to participant.
- No counseling or correction of misinformation should ever be provided during the interview/data collection process. However, it is recognized that some information reported during the interview may prompt further action, in which case the guidance below should be followed:
 - If information reported during an interview relates **directly to participant’s safety and well-being**—specifically, if violence/abuse, sexual assault, social harms, food insecurity, or AEs are reported—the participant should be followed up on an individual level to collect additional information as needed and to provide referrals for the well-being of the participant. This should be done after the interview and by a separate staff member. See also SSP section 8 for further management of AEs, social harms, IPV, or sexual assault.
 - If information reported during the interview reflects **any other issue or misunderstanding** (e.g. misunderstanding of efficacy, worries about the ring, or unhealthy vaginal practices) the participant should not be counseled directly regarding these issues. Rather, to prevent future bias in her responses, these topics should be addressed at a group or site-level through generalized education or counseling.

11.2.3 Social Benefits

11.2.3.1 Definition

A social benefit is a positive change, event, or experience in the participant’s life related to her study participation, including as a result of her tablet or ring use. Social benefits may include events related to Personal, Medical/Health, and/or Community/Social (see Table 1 below for specific categories and examples). Social benefits are measured to understand how trial participation benefits women’s lives, and to understand the perceived benefits of product use above and beyond HIV prevention (for example, peace of mind or increased sexual pleasure).

Table 1: Social benefit categories

Personal
Pride about project participation: Feels pride about participation in REACH
Feeling better about oneself: Improved self-esteem or feeling of empowerment
Education: The study educated the participant or inspired /enabled participant to restart school or improve school performance.
Housing: The participant obtained better or improved her housing situation
Nutrition/food: The participant was able to improve nutrition or amount of food intake for self or family.
Improved communication: Participant learned more effective ways of communicating with family, friends, employers or others.
Work: Obtained or improved employment situation (includes informal work)
Income: Obtained or increased income (includes getting study reimbursement)
Medical/Health
HIV testing: The participant received regular HIV testing

Treatment of STIs: The participant was able to treat STIs
Treatment of other illnesses: The participant was able to treat/consult with a doctor about other illnesses (non-STIs)
Family Planning/Contraception: The participant was able to access contraception and family planning services
Preventative care services: The participant was able to receive preventative health care such as pap smears or vaccinations.
Staying HIV free: REACH provided more effective ways for the participant to avoid becoming infected with HIV; feelings of peace of mind, stress relief, fewer worries, etc. from product use.
Community/Social
Altruism: Participant helping community/others by participating in REACH
Activities: Participant became involved in community activities
Peer Support: Participant felt supported by or was able to provide support to peers
New relationships: Participant created new relationships

11.2.3.2 Assessment

At every quarterly visit, MTN-034 participants will be asked if “At any time during the past 3 months, have you experienced a positive change, event, or experience in your life related to your study participation?” on the Social Benefits and Impacts CRF. When administering this question, the staff member should read it verbatim in the participant’s preferred language and allow the participant to respond. If the participant needs help understanding the question about social benefits during the behavioral assessment, say something like, “Did something GOOD happen to you as a result of you being in REACH or getting the ring/tablets?” However, staff should avoid providing too many examples, as this may bias the participant’s responses (she may be more likely to say “yes” to the specific examples provided). It may help to reassure the participant that there are no right or wrong responses, to remind them that the information they provide is important to help us understand the benefits of study participation and study products, and to follow-up with the participant after they respond to make sure they understood the question.

In addition to responding to this standardized question each quarter, participants also may spontaneously report, at any study visit, that she or someone she knows has experienced a benefit from study participation or study product use.

11.2.3.3 Documentation on the Social Benefit CRF

A Social Benefit CRF should be completed for every social benefit reported either spontaneously or on the Social Benefit and Impact CRF. The Social Benefit CRF is similar to the Social Impact CRF, but it captures positive events due to study participation rather than negative events. One form should be completed for each social benefit experienced.

For each social benefit, staff should provide a brief description, designate which category the social benefit was related to (based on Table 2, above) and capture who else (up to 4 people) benefited from the event besides the participant using the appropriate relationship code. Use the other category for any other benefit, including increased sexual pleasure. Try not to use the “other” category if the benefit fits into another category. For all social benefits, ensure that the CRF description explains why the category was chosen. If there is any uncertainty on how to categorize a social benefit reported by a participant, contact the BRWG (mtn034brwg@mtnstopshiv.org) for additional guidance.

For social benefits, no follow-up is necessary once reported since these are positive events rather than harmful events (such as is captured on the Social Impact Log CRF).

11.3 Qualitative Data Collection Procedures

11.3.1 Participant Accrual

Approximately 48-60 participants per site will participate in the qualitative component of REACH, which includes serial in-depth interviews (IDIs), single IDIs, and focus group discussions (FGDs).

Table 2 summarizes the accrual targets and timing for each qualitative activity. The actual number of participants may vary, as some participants may be permitted to participate in more than one type of qualitative activity. All accrual activities will be documented on the Qualitative Participation Log (QPL).

Table 2: Accrual Targets and Timing for Qualitative Activities

Instrument	Number of Participants	Visit(s)
Serial IDI (SIDI)	6 per site (3 per arm)	Month 2, Month 8, and Month 14 (Visits 5, 12 and 19) (approximately)
Single IDI: Choice non-acceptors (NIDI)	Up to 12 NIDIs and CIDs combined per site	Month 12/Visit 16 (approximately)
Single IDI: Interesting cases (CID)		As needed, in consultation with RTI
"Early" FGDs (EFGD)	About 12 per site (2 FGDs)	2 Early FGDs around Month 2/Visit 5 for implementation/monitoring purposes only
"Late" FGDs (LFGD)	About 24 per site (4 FGDs)	4 Late FGDs around Month 18/Visit 23

11.3.1.1 Qualitative Activity Descriptions, Eligibility, Accrual, and Scheduling Process

Serial Interviews (SIDIs)

Description: SIDI participants will be interviewed at three time-points in the study – one in each study period. The goal of these interviews is to understand participants' experiences in the study and with the study products, and to assess shifts or changes in the participant's life and experience over the course of the study. Serial IDI participants will not be eligible to participate in any of the other qualitative activities.

Eligibility:

- Participant is enrolled in REACH
- Randomly selected by SCHARP and eligible for a serial IDI according to the Qualitative Participation Log (QPL)
- Participant verbally confirms willingness to participate in the serial IDI, including willingness to be audio-recorded during each interview

Accrual: A subset of 6 participants per site (24 overall) will participate in serial IDIs. Participants will be randomly selected for the IDI by SCHARP, and the site will use the following procedure during the Enrollment Visit to ensure equal numbers from each study arm and age group (16-17, 18-19, and 20-21):

1. Locate the participant's Randomization ID provided on the Randomization eCRF in the Enrollment Visit folder within the Medidata Rave study database.
2. Locate the participant's Randomization ID in the IDI Sampling List to determine whether or not this participant has been randomized to participate in the Serial IDI cohort.
3. If the participant is randomized for Serial IDIs, start filling in a row for the participant on the "Log 1 – SIDI all" page of the Qualitative Participation Log (QPL). See example in Table 3.

Table 3: Example QPL of all randomly selected participants for SIDIs

Log 1: Participants randomly selected for participation in serial in-depth interviews (SIDIs)						
A. PTID		C. Age group	D. Invited (Y/N) If "N," reason not invited	I & D	E. Agreed to participate (Y/N) If "N," reason for refusal	I & D
Enter all PTIDs randomized to SIDI at enrollment	Oral PrEP or DPV ring	16-17, 18-19, or 20-21	Check if product/age slot already filled in Log 2	Initials and date	If "Y" to D and E, enter PTID in appropriate line on Log 2	Initials and date
1 123-876543-2	Oral PrEP	16-17				
2						
3						
4						
5						

4. Then, take note of the participant’s age and randomization arm (i.e., which study product she was randomized to for study period 1) and refer to the “Log 2 – SIDI final” page of the QPL to determine whether a participant from the same randomization arm and age group has already agreed to participate in the Serial IDIs. See example in Table 4.
 - a. If another participant already has been randomized to Serial IDI from the same age group and randomization arm and has agreed to participate, the current participant will not be invited to participate. Site staff will return to the “Log 1 – SIDI all” page of the QPL and indicate that the participant was not invited and the reason.
 - b. If a participant has not yet been randomized to Serial IDI from the same age group and randomization arm:
 - i. Inform the current participant that she has been randomly selected to participate in the Serial IDIs and explain the IDI process and schedule. Obtain her verbal consent to participate in the IDIs.
 - ii. On the “Log 1 – SIDI all” of the QPL, document that the participant was invited and whether she agreed to participate. If she agrees to participate, fill out the corresponding row for randomization arm and age group in the “Log 2 – SIDI final” page of the QPL, including the PTID and date she accepted the invitation. See example in Table 5.

Table 4: Example QPL Log 2 of participants who are eligible for and accept participation in SIDIs

Log 2: Eligible and accepted participants for SIDIs							
A. Product for study period 1		C. PTID	D. Date accepted (dd/MMM/yy)	Initials and date	SIDI 1 Date (dd/MMM/yy)	SIDI 2 Date (dd/MMM/yy)	SIDI 3 Date (dd/MMM/yy)
1	DPV Ring	16-17					
2	DPV Ring	18-19	123-45678-9	16-Apr-18			
3	DPV Ring	20-21					
4	Oral PrEP	16-17					
5	Oral PrEP	18-19					
6	Oral PrEP	20-21					
7							
8							
9							

Table 5: Example QPL Log 1 of participants who are considered for participation in SIDIs

Log 1: Participants randomly selected for participation in serial in-depth interviews (SIDIs)							
A. PTID		C. Age group	D. Invited (Y/N) If "N," reason not invited	I & D	E. Agreed to participate (Y/N) If "N," reason for refusal	I & D	
Enter all PTIDs randomized to SIDI at enrollment	Oral PrEP or DPV ring	16-17, 18-19, or 20-21	Check if product/age slot already filled in Log 2	Initials and date	If "Y" to D and E, enter PTID in appropriate line on Log 2	Initials and date	
1	123-876543-2	Oral PrEP	16-17	Y	MKSQ, 26-Apr-18	Y	MKSQ 26-Apr-2018
2							
3							

- Document whether the participant is invited to participate in the Serial IDIs and whether the participant will participate in Serial IDIs on the Enrollment eCRF.
- Once all participants are selected for the Serial IDIs within a site, all new random assignments by SCHARP for that site will be documented on the Enrollment eCRF, indicating that the participant was not invited. No additional documentation on the QPL is required.

If a serial IDI participant seroconverts at any point before her SIDI3, inform the Qualitative Management Team (QMT) as soon as possible by emailing mtn034qmt@mtnstopshiv.org. The QMT may decide to discontinue her participation in the Serial IDIs and/or request that select questions from the CIDI guide be used in her last IDI. The QMT also may instruct the site to replace her with a new participant following the procedures described above.

If any serial IDI participant terminates the study early, notify the QMT as soon as possible. If the participant terminates the study before her second SIDI, the QMT may choose to replace her with a new participant who is eligible and able to complete all three serial IDIs. If a serial IDI participant terminates the study after her second SIDI (i.e. after Month 8), the QMT may choose not to replace the participant and allocate an extra CIDI to the site in replacement for the missed IDI.

Scheduling: Participants systematically selected to participate in serial IDIs will be informed of their selection at the Enrollment visit. Interviews should take place during or shortly after study visits at Month 2, Month 8, and Month 14 (Visits 5, 12 and 19; 2 months into each study period). If the

participant is not able to complete the IDI during the targeted visit or she misses the visit for any reason, the scheduled IDI should take place as soon as possible. If the participant has still not been interviewed by the end of the next visit window (i.e. Month 3, Month 9, or Month 15), sites should seek QMT guidance (mtn034qmt@mtnstopshiv.org) on whether to interview the participant or select a replacement.

Single Interviews: Choice non-acceptors (NIDIs)

Description: NIDIs will be conducted with participants who choose not to use either oral PrEP or the dapivirine ring at the Month 12 visit (Visit 16) or at a later point when a participant may switch to using neither product to understand reasons for this choice.

Eligibility:

- Participant is enrolled in REACH
- Participant is not selected for SIDIs
- Chooses to use neither the ring nor oral PrEP at the Month 12 visit (Visit 16)
- Verbally confirms her willingness to participate in the IDI, including willingness to be audio-recorded during the interview

Accrual: A total of 12 NIDIs and CIDIs may be conducted at each site. For the first 3 NIDIs, sites may invite any participant meeting the eligibility criteria for an interview without prior approval from the QMT. Sites seeking to interview more than 3 NIDIs should consult with the QMT prior to conducting additional interviews. For these additional NIDIs, site staff will document the reason for nomination and QMT approval or disapproval of the nomination in the QPL. All NIDI invitations or nominations will be documented in the QPL.

Scheduling: Participants who are selected for NIDIs may be interviewed on the same day as the study visit (when the choice is made) with the goal of understanding the reasons for not using a study product. If the participant cannot stay for the interview on the day of the visit, they may schedule a separate visit to complete the NIDI, taking place as soon as possible after that study visit.

Single Interviews: Interesting cases (CIDIs)

Description: This group will be made up of special cases identified by site staff in consultation with the QMT and may include participants who have seroconverted, experienced social harms or other challenges, had difficulty coming to study visits, admit to product sharing, or have emerged as champions of the study or the product(s). Other participants with unique experiences to share with the study team can also be included.

Eligibility:

- Participant is enrolled in REACH
- Participant is not selected for SIDIs
- Has a unique experience or event to share, as determined by the site team in conjunction with the QMT
- Verbally confirms her willingness to participate in the IDI, including willingness to be audio-recorded during the interview

Accrual: A total of 12 CIDIs and NIDIs may be conducted at each site. Interesting cases should be selected over the duration of the trial (early, mid-point, late) after the interesting experience or event has taken place. An email including the participant's PTID and a summary of what is unique about the participant should be communicated to the QMT via email (mtn034qmt@mtnstopshiv.org) and approval from the QMT should be obtained by email prior to conducting any CIDI. However, in cases where this is not possible (e.g. a participant is withdrawing from the study and the interview needs to be scheduled quickly), notification of the QMT can occur after the interview. All CIDI nominations will be documented in the QPL along with the reason for nomination and whether the nomination was approved by the QMT.

Scheduling: Participants who are selected for CIDs should be interviewed as soon as possible following their selection. Participants who are being interviewed because they have decided to withdraw consent from REACH should be approached about willingness to participate in a single IDI before the participant is terminated. If the participant agrees, it should be documented clearly in the chart notes that the participant is withdrawing consent, but is agreeing to participate in one final interview and when this interview will occur. All nominations for CIDs will be documented in QPL Log 3 – CID. If the participant declines, this will also be documented on the QPL and she should not be pursued further. As with all IDIs, CIDs must be completed prior to termination from the study.

Early FGDs (EFGDs)

Description: Early FGDs will be conducted for study monitoring purposes only; they will not be considered a research activity. The discussions will assess participants' early experiences in the study with the goal of providing feedback on study implementation to the sites and addressing any concerns early on. The debriefing reports from the EFGDs will be circulated to site teams and study leadership to provide a summary of the early experiences and feedback for implementation.

Eligibility:

- Participant is enrolled in REACH
- Participant is not selected for SIDs
- Has completed her Month 2 visit
- Verbally confirms her willingness to participate in the FGD, including willingness to be audio-recorded during the FGD

Accrual: Two Early FGDs will be conducted with participants who have been in the study for at least 2 months, with about 6-8 participants per FGD. Early FGDs will be commence as soon as enough participants have completed Visit 5 (Month 2).

Scheduling: Early FGDs should be scheduled when enough participants have completed their Month 2 visit to be able to invite 6-8 participants to join a discussion. Potential participants to be invited to an EFGD can be listed on QPL Log 5 – EFGD. Once a participant who is listed on this log has their Visit 5 date scheduled, this information should be added to Log 5 to assist with scheduling the EFGD. Participants selected to participate in Early FGDs should be informed of their selection at their Month 2 follow-up visit, invited, and documented in QPL Log 5 - EFGD. Should fewer than 4 participants arrive for a scheduled Early FGD, the FGD will be canceled and the staff will work with participants to reschedule the FGD.

Late FGDs (LFGDs)

Description: Unlike the Early FGDs, Late FGDs are a research activity. They will explore experiences with product use, and barriers and facilitators of use during study period 3. Based on REACH COVID-19 contingency planning guidelines, it may be necessary to conduct IDIs instead of FGDs. If this is necessary, the MTN-034 QMT will provide further guidance.

Eligibility:

- Participant is enrolled in REACH
- Participant is not selected for SIDs
- Chooses to use either the ring or oral PrEP at Visit 16 (Month 12)
- Has been enrolled in the study for at least 60 weeks (i.e. has completed Visit 20)
- Verbally confirms her willingness to participate in the FGD, including willingness to be audio-recorded during the FGD

Accrual: Each site will conduct 4 Late FGDs in study period 3. During period 3, starting once 8 participants at a site have completed Visit 19, SCHARP will provide the site and the QMT with a monthly list of participants who are within the FGD window, with their product choice at Month 12, their age at enrollment, and their adherence levels during Period 3, if available, and any product switching after Month 12. SIDI participants will be noted so that they can be excluded. In the monthly qualitative meetings, site staff and RTI staff will discuss the SCHARP list and select 4 to 6 participants to invite for the FGD.

The decision will be primarily based on visit scheduling, inviting those who are scheduled to exit the study in the current or upcoming month first. Attempts will also be made to ensure a range of ages, product choices, and adherence levels among LFGD participants if possible.

Scheduling: Late FGDs should be scheduled between Visit 20 and study exit. Participants selected to participate in a Late FGD should be informed at the prior visit (e.g. Visit 22 if FGDs will occur around date of Visit 23). The target LFGD size is 4 to 6 participants. As described in REACH Qualitative Operational Guidance #1, the LFGD should be conducted as long as 2 participants are present. Should only 1 participant arrive for a scheduled LFGD, sites should conduct an IDI with the single participant, if she is willing. The LFGD guide should still be used to conduct the interview and sites should document the interview in the QPL- log 3 along with CIDs. At the conclusion of the IDI, sites should notify the QMT about the change in conducting the LFGD. Sites should work with participants, excluding the participant who took part in the IDI, to reschedule the missed LFGD for another time.

11.3.1.2 Visit Codes

Visit codes will not be used for REACH qualitative data collection activities. If a participant comes for her IDI/FGD interview at an interim visit, a REACH visit code will not be assigned unless a CRF is completed for other reasons (e.g. an AE or SH is reported). Participation in qualitative activities will be documented on the qualitative visit checklists and the QPL.

11.3.1.3 Qualitative Participation Logs and Reporting

Data about participation in the qualitative component will not be recorded on the site's REACH Screening and Enrollment Log. However, it is necessary for sites to maintain a comprehensive record of all participants who are pre-selected, those who participate in the qualitative component, and reasons for non-participation. This should be recorded on the Qualitative Participation Log.

An entry in the Qualitative Participation Log should be completed for each participant selected to participate in the qualitative component by SCHARP or site staff (depending on the type of activity). This log will include PTID, whether participant was invited, whether she agreed to participate, interview/discussion date(s), and reason for refusal (if applicable). Site staff should also use available space in the relevant participant's row (or space in the margins) to document any discontinuations or replacement selections for the qualitative sample. A Qualitative Participation Log template is available on the REACH website under Behavioral Assessment Tools.

Sites should send an up-to-date version of the QPL on the 15th of each month to the QMT (mtn034gmt@mtnstopshiv.org). If no updates for that month, sites should send the QMT an email saying there is no updates and the email will be saved as replacement for the QPL for that month. More frequent reporting requests may be made by the QMT, if deemed necessary. The person responsible for this report should be described in the site Qualitative Component SOP.

11.3.2 Qualitative Visit Procedures

11.3.2.1 Preparation for an IDI/FGD

Before each IDI, the following should occur:

1. Ensure a signed copy of the Enrollment Informed Consent Form is on file
2. Contact the participant to remind them of the visit at least one day before the interview: inform them of the time and location of the IDI
3. Ensure the audio-recorder(s) are ready: functioning, charged or has extra batteries, memory card or audio tape has sufficient space
4. Ensure interviewing space has been reserved and is ready for use
5. Ensure the correct version of the IDI guide and any other supplemental tools are ready for use.
 - a. Gather needed supplies, e.g., pen and stationery for note-taking, IDI guide, visual probes, refreshments (if applicable), and reimbursement
6. If a second or third serial IDI, review the debriefing report, notes and/ or transcripts from the previous IDI(s).
7. Upon participant's arrival for the IDI, confirm participant identity per site SOPs.

8. Immediately before beginning the IDI, review key elements of informed consent and confirm willingness to participate

Before each FGD, the following should occur:

1. Ensure a signed copy of the Enrollment Informed Consent Form is on file for each invited participant
2. Site staff should consider languages spoken by potential FGD participants and ensure at least one common language is spoken by all FGD participants.
3. Contact all participants to remind them of the visit at least one day before the FGD: inform them of the time and location of the IDI
4. Ensure an adequate number of audio-recorder(s) are ready: functioning, charged or has extra batteries, memory card or audio tape has sufficient space
5. Ensure FGD room has been reserved, is ready for use, and meets site-specific COVID-19 public health guidelines (for example size, ventilation).
6. Ensure the correct version of the FGD guide and any other supplemental tools are ready for use.
 - a. Gather needed supplies, e.g., pen and stationery for note-taking, IDI guide, refreshments (if applicable), reimbursements, name cards/tags, flip charts, sticky notes, markers
7. Ensure that a second staff member is available to take notes
8. Upon participants' arrival for the FGD, confirm participant identity per site SOPs.
9. Ensure site-specific COVID-19 public health guidelines are followed throughout the FGD (for example wearing masks, maintaining physical distancing, washing hands and sanitizing surfaces).
9. After confirming participant identity and before beginning the FGD, review key elements of informed consent and confirm willingness to participate.
10. Pseudonyms will be used in the context of all FGDs. These should be selected and documented per site SOPs.

11.3.2.2 Data Collection Considerations

1. Qualitative visit checklists: These checklists should be used to guide the order of procedures for each IDI. The qualitative section of the REACH website contains examples of checklists detailing the required procedures that must be completed for the IDIs and FGDs. These checklists should be modified as needed, then reviewed by the MTN LOC (FHI 360) and the QMT for approval prior to implementation.
2. Rooms for conducting IDIs and FGDs: The IDIs and FGDs will be conducted in private meeting rooms that are quiet enough for audio-recording. These should be located in a confidential private location that allows for neutrality. It is recommended to avoid the use of exam rooms to allow for a more comfortable discussion space.
3. Informed Consent for participation in the qualitative component: Consent is embedded within the REACH Enrollment ICF. Prior to the first IDI or FGD, key elements of informed consent should be reviewed with participants, as needed listed in the Pre-IDI/FGD Talking Points document, and willingness to continue with the interview should be confirmed. This review/confirmation must be documented on visit checklists (and chart notes as needed).
4. Language of IDI/FGD: All interviewer-administered guides should be administered in the preferred language of the participant(s). This may be different than the language she provided informed consent in, as long as fluency is confirmed/documented in both languages (e.g. on the IC coversheet and/or chart notes). Any deviation from this should be documented in the participant chart notes.
5. Interviewer expectations: All interviews will be conducted by a trained qualitative interviewer. To maintain neutrality and promote an open/free environment, interviewers should be independent from (i.e. not involved in) any study procedures that will be discussed during the IDI or FGD. For serial IDIs, it is recommended that, if possible, the same REACH interviewer be used for all 3 interviews in order to encourage greater rapport with the participant.
6. Length of qualitative activities: IDIs are anticipated to last approximately 45-60 minutes, and FGDs no more than 2 hours.
7. Flow of IDI/FGD: Both interview types will follow a semi-structured questionnaire guide which specifies topics that should be covered, but allows for iteration, probing, follow-up (if SIDI) and digression on relevant themes. The interviewer may start the discussion with an ice-breaker to

increase rapport as well as understanding of the context of participants' lives (e.g. asking about her home life, work, activities, family, friends).

8. **Audio recording:** IDIs and FGDs will be audio-recorded. The use of two or more audio recorders is recommended in case of malfunction or differing audio quality, and to ensure that all participants can be heard while maintaining physical distancing during LFGDs.

The expectation is that all REACH participants agree to being audio recorded, given that it is incorporated in the study informed consent. All FGD participants must agree with this study procedure, and all IDI participants should confirm that they agree to be audio recorded before being selected as an IDI participant.

In the case where an FGD participants declines to be audio recorded, they should not be included in the FGD. In the case where a NIDI, CIDI, or SIDI participant declines to be audio recorded at the time of the interview, a note-taker must be present during the interview. The QMT should be contacted immediately following the IDI (mtn034qmt@mtnstopshiv.org) to inform them that the participant did not agree to the audio recording.

9. **Note-taking:** When an IDI or FGD is conducted, notes should be taken during each session to capture non-verbal communication and supplement the audio recording (or replace, if recording doesn't work or is refused). During FGDs, a note-taker should be present to take notes during the session. During IDIs, the interviewer will take brief notes as the interview is ongoing, unless the participant declines to be audio-recorded. If a participant declines to be audio-recorded, the interviewer will ask their permission to have a note-taker present instead.
10. **Misunderstandings of key concepts raised during IDIs/FGDs:** Interviewers may also identify misunderstanding of key concepts that relate to study participant/informed consent during the interview (e.g. required study procedures, confidentiality). While interviewers should probe to fully understand the issue, they should avoid departures into counseling or health education during the interview. Instead, it is recommended that interviewers summarize any concerns on the debrief report, so that designated staff may determine appropriate follow-up—for example, general review of key concepts may be addressed as part of ongoing informed consent, or during group/waiting room education sessions.

11.3.2.3 Reporting and Responding to Social Harms, Adverse Events, or Protocol Deviations

If any social harms (SH), adverse events (AEs), or protocol deviations (PDs) are reported by participants during qualitative interviews, interview staff should refer the issue to REACH clinic/counseling staff as soon as possible and not more than 24 hours later to document and handle the AE, SH, or PD. If the issue is ongoing, ideally follow-up should occur as soon as the interview is complete. However, if the issue is historical/resolved at the time of the interview, follow-up may occur at the next scheduled visit, per the discretion of the IoR. The site-specific procedure for referring and documenting these occurrences should be outlined in the site Qualitative Component SOP.

Although the interviewer is required to share information about these events with other appropriate REACH staff, she should aim to maintain a sense of trust, discretion and rapport with the participant during the interview by explaining this referral. Some sample language is provided below:

- *Thank you for sharing that issue with me. I want to reassure you that our conversations today will be kept private, but since this relates to your health, I need to pass this information along to [the nurse/doctor] so that they can follow-up with you [after our interview, during your next visit] and ensure you're okay. Are you okay with that?*
- *I appreciate your willingness to open up to me about that. I'm going to make a note for [the nurse/doctor, the counselor] to check in with you about that [after our interview, during your next visit] to make sure you're okay and all the necessary information is captured. This is the only part of our conversation I will share with them. Are you okay with that?*

11.3.3 Qualitative Documentation Procedures for IDIs and Late FGDs

This section provides guidance on documentation for the IDIs and the Late FGDs. Because the Early

FGDs are not a research activity, they will have different documentation procedures, which are described in section 11.3.4.

Essential documents pertaining to the qualitative behavioral assessments should be filed and managed in accordance with site SOPs for source documentation and data management. Study sites must maintain adequate and accurate participant file records containing all information pertinent to participation in qualitative assessments, for each study participant.

11.3.3.1 Source Documentation for Qualitative Activities

For the qualitative component of this study, we consider the following three types of documents to be source documents. All source documents must be stored according to the procedures outlined in section 11.3.5.1, 11.3.5.2, and 11.3.5.4 of this SSP and relevant site SOPs.

Audio files: CDs of audio file recordings are considered to be source documentation for all IDIs and FGDs.

IDI/FGD notes: Notes taken during IDIs and FGDs by the interviewer/facilitator or a designated note-taker are source documents, as well as any additional written/visual materials produced during the course of the IDI or FGD.

Transcripts: Final versions of the English transcripts from audio files are considered to be source documentation.

11.3.3.2 Documentation Requirements for Participation in Qualitative Activities

In addition to the documentation elements outlined in SSP Section 2, participant records for those participating in the qualitative component should contain a record of all qualitative research-related activities that take place during the conduct of the study. Details of storage of participant records will be in accordance with each site's relevant SOPs.

For participants in the IDIs, records of qualitative research-related activities will include:

- A record of all contacts, and attempted contacts, with the participant.
- Appropriate visit checklist (includes documentation that the participant meets eligibility criteria)
- For purposive selection (more than 3 choice non-acceptors and all special cases, per section 11.4.1.1), documentation of email approval from the QMT should be filed and logged on the QPL.
- For serial IDI participants, documentation of any change to series of IDIs due to product discontinuation events (i.e. seroconversion), operational challenges, or study design changes (and email approval from QMT/other relevant study communication).
- Referrals made (including for social harms or adverse events reported) as a result of information gathered during qualitative interviewing.
- Documentation of any deviation from procedures outlined in the REACH protocol, SSP, or the site Qualitative Component SOP.
- The debriefing report from each interview, once finalized
- All source documents from each interview (see section 11.3.3.1 for more detail):
 - The audio recording
 - Notes recorded on interview guides, separate sheets, and/or additional materials used for IDIs.
 - English language transcript, once finalized

For Late FGDs, this will include (reference the site's Qualitative SOP for details as to whether each document will be stored in the individual participant record or a separate record for the FGD):

- A record of all contacts, and attempted contacts, with the participant.
- Appropriate visit checklists (includes documentation that the participant meets eligibility criteria)
 - One checklist for each FGD, and an additional checklist for each individual participant in the Late FGDs
- Referrals made (including for social harms or adverse events reported) as a result of information gathered during the Late FGD.
- Documentation of any deviation from procedures outlined in the REACH protocol, SSP, or the site

Qualitative Component SOP.

- The debriefing report from each interview, once finalized
- All source documents from each Late FGD (see section 11.3.3.1 for more detail):
 - The audio recording
 - Notes recorded on FGD guides, separate sheets, and/or additional materials used for Late FGDs.
 - English language transcript, once finalized

11.3.4 Qualitative Documentation Procedures for Early FGDs

11.3.4.1 Documentation of Participation in Early FGDs

Because Early FGDs are not a research activity, documentation will be similar to that done in participant engagement activities and will be stored separately from the participant files. Details of where EFGD documentation is stored will be in accordance with each site's relevant SOPs.

Documentation for each EFGD will include:

- A record of whether the participant was invited to the EFGD, agreed to participate, and actually participated, recorded on the QPL.
- FGD Group Visit Checklist
- Documentation of any deviation from procedures outlined in the REACH protocol, SSP, or the site Qualitative Component SOP.
- The audio recording
- The debriefing report, once finalized
- Notes recorded on FGD guides, separate sheets, and/or additional materials used for Early FGDs.

Note: Early FGDs will not be transcribed, so there will be no transcript.

11.3.5 Qualitative Data Types and Management Procedures

As a condition for site specific study activation, each study site must establish procedures for data management that should be described in the Qualitative Component SOP.

All documents listed below must be stored and managed according to the procedures outlined in this section of this SSP and the site's relevant SOPs.

Timeline for data storage and/or transfer to RTI after each qualitative activity:

- Same day as IDI/FGD:
 - Audio file(s) and back-up version(s) saved
 - Notes filed in participant records per site SOP
 - Interviewer/facilitator completes the debriefing report (DR) for the IDI/FGD
- Within one week:
 - DR sent to RTI (See Section 11.3.5.6 and Appendix 11-2 for SFTP information)
 - RTI will respond within one week with queries. All further iterations of the DR with queries and responses to queries should happen within one week of the date of receipt
- Within four weeks:
 - Transcript sent to RTI (See Section 11.3.5.6 and Appendix 11-2 for SFTP information)
 - RTI will respond within two weeks with queries. All further iterations of the transcript with queries and responses to queries should happen within two week of the date of receipt

11.3.5.1 Audio Files

Following the IDI or FGD and before the end of the day, the audio file(s) should be copied onto a password protected hard drive of a computer at the site, and saved onto a CD as source documentation of the interview. If any site prefers a different method to save audio files, they must confer first with the QMT for guidance. Each CD should be signed and dated to show that the CD has been verified as an exact copy of the original audio recording(s), having all of the same attributes and

information as the original (i.e. no editing occurred before transfer to CD). For IDIs, the CD should be labeled with the study name, PTID and stored per the site's Qualitative SOP. For FGDs, the CDs should be labeled with the name of the audio file (e.g., **MTN-034_LFGD1_325_Audio_18NOV14**) and stored per the site's Qualitative SOP. Audio files do not need to be sent to RTI.

Computer audio files of IDIs and LFGDs will be destroyed following finalization of transcripts (transcript finalization process described below), only after notification by RTI. The destruction process will be the responsibility of the IoR or his/ her designee and should be specified in the site Qualitative Component SOP. If required, sites may invite members of their community/CAB to observe the destruction. Once complete, destruction should be documented in the study files with signatures from the staff member responsible for the destruction and a witness, and confirmed via email with the data center (RTI). Copies of the audio files saved on CD must be kept along with all other study records for at least two years after the vaginal ring is approved for marketing or two years after all developmental research on the vaginal ring is stopped. No CDs or other documentation should be destroyed without prior approval from the MTN.

11.3.5.2 Interview Notes

Immediately following the IDI or FGD, all notes taken during the activity should be stapled together (if more than one page), with PTID (IDI) or PTIDs (FGD) and date of IDI/FGD listed on front page, and filed per the site's qualitative SOP, along with any written/visual materials produced during the course of the activity.

If the audio recording did not work, the interviewer will review the guide and expand the notes they have taken during the discussion to serve as an alternate transcript, and a protocol deviation should be reported via a PD Log CRF.

11.3.5.3 Debriefing Reports

On the same day as the IDI or FGD (or within 24 hours), the interviewer should complete a Debriefing Report (DR) (using the appropriate template for that interview type), which will list basic information about the session and provide a summary report of the interview that can be used in "real time."

Because Early FGDs will not be transcribed and coded, the facilitator and note taker will be asked to provide more detail in these reports, including quotes transcribed from the audio recording. After these reports are reviewed and approved by RTI, they will be circulated to the site and study management teams. The management teams may have queries or ask for more detail on issues raised in the FGDs. Once all queries are addressed, the reports will be finalized.

11.3.5.4 Transcripts

All IDIs and Late FGDs will be transcribed by someone other than the person who conducted the IDI/FGD. The site staff will conduct the translation-transcription process per their site Qualitative Component SOP. All transcripts will be simultaneously transcribed and translated (when conducted in a local language) and written up in English unless there are unique local language sayings that should be preserved. These sayings can be kept in the local language in italics, with explanatory notes provided in brackets to explain their meanings. All expanded notes will be written in English.

An example of a formatted transcript is available in Appendix 11-1. When translating the audio files into English, staff should follow their site's Translation SOP or outline any variations from this in the REACH Qualitative SOP. Qualitative transcripts must clearly document who was responsible for the translation by filling in the translation certification statement found in the transcript template at the top of the first page. This statement will be signed and dated by the transcriber once transcription is complete before undergoing quality control procedures.

Once the transcript has been finalized by RTI and the transcriber has updated the translation certification statement, certified paper copies of the electronic source documents will be created. The person making the copy will write a circled "C" on the copy, hand sign and hand-date.

- Documents may be printed as 2 pages per sheet, double-sided
- Documents consisting of more than one page may be certified by:
 - Writing a circled “C” on each page of the copy
 - Hand-signing, initialing and hand-dating the first page and
 - Initialing and hand-dating each subsequent page (marked with a circled “C”)
- A “Certified” stamp may be used in place of the circled “C”
- If printing double-sided, please certify each side of the page

11.3.5.5 File Naming Conventions

All data files should be named according to a standard naming format. The name will include the study name, interview mode, followed by the PTID for IDIs or 3-digit site number for FGDs, data type (audio file, debrief report, transcript), and the date the IDI/FGD was conducted.

Interview Modes:

- SIDI for serial IDI with a number to indicate the interview number (SIDI1, SIDI2, or SIDI3)
 - Example: **MTN-034_SIDI1_325-40008-1_Transcript_18NOV14”**
- NIDI for Choice Non-Acceptor IDI
 - Example: **MTN-034_NIDI_123-45678-9_Transcript_01JUL19**
- CIDI for Interesting Cases IDI
 - Example: **MTN-034_CIDI_123-56789-0_Transcript_15JUL19**
- EFGD for Early FGD with sequential numbers for each subsequent EFGD (EFGD1, EFGD2)
 - Example: **MTN-034_EFGD2_123_DR_01Aug19**
- LFGD for Late FGD with sequential numbers for each subsequent LFGD (LFGD1, LFGD2, LFGD3, LFGD4)
 - Example: **MTN-034_LFGD3_123_Transcript_15Aug19**

For LFGDs, if audio is not audible on a single audio recorder and an additional recorder is used to complete the transcript, then both recordings should be saved as source audio recordings. The letters “a” or “b” should be added after each interview mode to indicate each audio recording. For example, if two audio recorders were used to transcribe “LFGD4” and both are necessary for transcription, then the two CDs in the file should be labeled the following:

- **MTN-034_LFGD4a_123_Audio_20DEC20**
- **MTN-034_LFGD4b_123_Audio_20DEC20**

However, the transcribed transcript should use the normal file naming convention. For example: **MTN-034_LFGD4_123_Transcript_20DEC20**.

Each time a document is edited, the editor should add their initials to the filename without changing any other part of the filename. For the first iteration of the file that is sent to the QMT for review, there is no need to include the editor’s initials. It is only upon subsequent review (QCing) that this occurs.

For example, when reviewed for the first time, the IDI transcript:

File Naming Conventions:

IDI Initial format: [Study Name]_[Interview Mode]_[PTID]_[Data Type]_[Date of IDI]

Query format: [Study Name]_[Interview Mode]_[PTID]_[Data Type]_[Date of IDI]_[Initials]

Final format: [Study Name]_[Interview Mode]_[PTID]_[Data Type]_[Date of IDI]_v1.0

“MTN-034_SIDI1_325-40008-1_Transcript_18NOV14”

would become

“MTN-034_SIDI1_325-40008-1_Transcript_18NOV14_CM”

and

“MTN-034_SIDI1_325-40008-1_Transcript_18NOV14_CM_NM” for the second revision.

Once the document is finalized, all initials will be removed from the name and replaced with “v1.0,” like this: **“MTN-034_SIDI1_325-40008-1_Transcript_18NOV14_v1.0.”**

11.3.5.6 Data Transfer Procedures

Secure File Transfer Protocol (SFTP) is a highly secure file directory used to transfer files from one computer to another computer. Because the qualitative documents could contain personally identifiable information, an SFTP will be used to transfer **all qualitative data** to RTI (e.g. debrief reports and transcripts). Files with personally identified information **MUST** always be transferred in a secured way and should never be sent via email.

The purpose of SFTP is *only* for file **transfer**; files will not be stored for an indeterminate amount of time on SFTP and should be deleted typically after 24 hours. See appendix 11-2 for details of the use of the SFTP.

11.3.6 Quality Control Procedures for Qualitative Data

11.3.6.1 Initial Quality Control at Site

Initial quality control of interviewing skills at site:

1. A senior staff member or the qualitative lead should observe the first 2 IDIs or first FGD for each interviewer/facilitator to provide feedback on moderating and interviewing techniques (e.g. adequacy of probing, appropriate linking of topics, fidelity to the guide, etc.). This can be done directly (through observation of the IDI or FGD) or indirectly (through review of the audio file). Particularly for IDIs, it is recommended that this be done by listening to the audio recording to avoid outnumbering the interviewee with staff members. The feedback will serve to provide additional training to the interviewers/facilitators and also to improve on the quality of the data collected. Once the first 2 IDIs or first FGD has been completed and feedback has been given, the site leadership should decide whether an interviewer is ready to continue these interviews on his/her own. This should be documented in email to the QMT which specifies which IDI/FGDs were observed, and the decision as to whether the interviewer/facilitator is ready to continue activities on their own, or whether they require further training. Note-takers may serve this role for interviewers or facilitators. If a different staff member performs this function, participants must be asked if they are comfortable for additional staff to be present during an interview. All staff who sit-in or participate in interviews should be documented in the debrief report and transcript headings.
2. Sites should also conduct in-depth reviews of the first 2 transcripts from each interviewer to provide feedback on moderating and interviewing techniques (e.g. adequacy of probing, appropriate linking of topics, fidelity to the guide, etc.). The feedback will serve to provide additional training to the interviewers and also to improve on the quality of the data collected.

Initial quality control of the transcript at site: Quality checks of the transcription/translation should be performed at the site as described in the Qualitative Component SOP. This will include having a second staff member (i.e. one who did not translate the interview) who is fluent in the local language listen to the entire audio file while reading the English transcript. Preferably this will be the person who conducted the interview or FGD; if that person is not available, another staff member may review the audio and transcript together. The quality of at least the first three transcripts per transcriber/translator will be checked in this manner to determine that the quality of translation and transcription is sufficient. Specifically, the reviewer should ensure that:

- The translation accurately reflects the speakers' original words
- The translation is coherent and reflects the flow of the conversation in the original language
- Appropriate and sufficient punctuation is used throughout the transcript
- Formatting is consistent and conforms to the template in Appendix 11-1
- Pseudonyms are used in place of any names or other identifying information

These reviews will be continued until the quality is deemed acceptable for each transcriber. Once this is determined, the site leadership will email the QMT.

11.3.6.2 Ongoing Quality Control at Site

Quality control of debrief reports at site: After initial completion, DRs should undergo a site level quality review during which, at a minimum, all staff members who were present at the IDI/FGD review the report for accuracy and completeness. In addition, another layer of review should be done by the person who is managing the qualitative component of this study. Specifically, reviewers should ensure

that:

- Participant responses in the IDI/FGD are summarized accurately
- Summaries are provided for all main topics of interest as outlined in the DR template
- Information such as the context of the IDI/FGD, the demeanor/disposition of the respondent(s), and non-verbal cues that help the reader understand what the IDI/FGD are included
- Pseudonyms are used in place of any names or other identifying information

A DR template, provided by RTI, is posted on the [Study Implementation Materials webpage for MTN-034](#).

Quality control of transcripts at site: After the quality of the first three transcripts (or more, if needed) has been deemed acceptable, quality checks will continue and include listening to at least three 5-minute spots in the audio file and comparing those 5 minutes spots to the transcript. The text of each transcript will still be reviewed in its entirety even if the entire audio file is not reviewed. This process and staff responsible for this should be described in the Qualitative Component SOP.

If at any time the site coordinator decides that the direct transcription from audio to English transcript is not consistently of high quality, he/she should consult the QMT to determine the corrective action, which may involve a temporary or permanent switch from a 1-step to a 2-step transcription/translation process for that translator.

11.3.6.3 Ongoing Quality Control with RTI

For debriefing reports:

After the site level QC process, the DR will be uploaded to SFTP site for RTI to review per SSP section 11.4.5.6. Site teams should send DRs to RTI as soon as they become available and within **one week** of when IDI/FGD occurs. Site teams should communicate with RTI if delays are anticipated. DRs will undergo the following QC process:

1. At RTI, the report will be read and reviewed by data team members and queries will be made on the report using MS Word's comment feature within **one week** of receipt of the file. The following are examples of types of queries:
 - Problems such as typos that lead to ambiguous meaning, confusing terms or missing/potentially incorrect data
 - Sentences that are unclear
 - Clarification of local terminology or context
 - Inclusion of name of person or place that would identify the participant
 - Requests for additional information
2. Within **one week**, the site is asked to correct or clarify any problems identified in the report directly in the report text using track changes and confirm the status (e.g. 'done', 'corrected', 'not needed', etc.) of each query within the comment bubble.
3. When the revised information is received by RTI, the Qualitative Data Team reviews the corrected areas and deems the issue resolved or further follows up with the site until all necessary changes are made on the report.

For transcripts:

After the site level QC process, the English language transcript will be uploaded to SFTP site for RTI to review per SSP section 11.4.5.6. Site teams should send English language transcripts to RTI as soon as they become available and within **four weeks** of when IDI/FGD occurs. Site teams should communicate with RTI if delays are anticipated. Transcripts will then undergo a similar QC process to that of the debriefing reports:

1. Each transcript will be reviewed by a member of RTI's data team and queries will be made on the transcript using comment bubbles (or track changes for smaller/straightforward typos). The QC may include the identification of the following:
 - Problems such as: typos that lead to ambiguous meaning, confusing terms or missing/potentially incorrect data, unclear sentences, clarification of terminology or context

- Issues identified by the protocol team requiring follow up, additional probing, or discussion with the interviewers. This could include general findings related to discussion facilitation techniques or specific issues that should be teased apart further in future IDIs.
2. RTI-reviewed transcripts will be emailed to the site within approximately **two weeks** of transcript receipt.
 3. The site must then respond to all comments within **two weeks** of receipt of the reviewed transcript. Responses will be made either through changes directly in the transcript using track changes or through using the comment box in the reviewing mode of MS Word, when in-text changes are unable to be made. When changes in the text reflect content that was not spoken verbatim by the participant or interviewer, they will be inserted in [brackets].
 4. After the revised transcript is received by RTI, a designated staff member will review the corrected areas and deem the issue resolved or else will follow up with the site until all necessary changes are made.
 5. Once RTI finds no additional issues, RTI will accept all changes, remove all comment bubbles, and finalize the transcript. RTI will notify sites of this finalization status via email and upload final transcripts to FTP site.

Appendix 11-1: Formatting for IDI and FGD transcripts

Example of Formatted IDI Transcript

SIDI2_123-45678-9_Transcript_12DEC2019

HEADING INFORMATION REQUIRED FOR REACH IDI TRANSCRIPTS	
PTID:	123-12345-1
Interview date:	12/12/2019
Transcriber:	Wonder Woman
Translator:	Wonder Woman
Site reviewer:	<input type="checkbox"/> No: If "no," reason why not <input checked="" type="checkbox"/> Yes: MKSQ

I, Wonder Woman, certify on 12/12/2019, that this transcript is an accurate and complete representation of the original audio file.

Note: certification statement completed before transcript undergoes quality control procedures.

Interview Text:

1. I: How is living in the new house?
2. R: *It's alright, but it is boring.*
3. I: Why?
4. R: *Everything is far away.*
5. I: Like?
6. R: *The shops, and the ATM [automatic teller machine] and most of the things are far away. If you do not have money you suffer [Laughing].*
7. I: Do you take taxis when you go to withdraw?
8. R: *I do not have money for the taxi. If I have money I can buy bread because there is a spaza shop [an informal shop operating from home]. A car is a necessity and we need to have it. It is alright at least I have my own space and privacy [Laughing].*
9. I: It is better. I was thinking about you and how the situation is in your new home? Are the children still there?

IDI Formatting Expectations

- Header should include filename of transcript. Every time the file name is updated, the header should be updated by right clicking the file name and selecting "Update Field."
- Use consistent Times New Roman or similar, 11 or 12-point font and 1.15 spacing.
- Heading within document includes: PTID, Interview Date, Transcriber Name, Translator Name, Site Reviewer initials
- A statement before the transcript from the translator and transcriber, including the date, that attests to the accuracy and completeness of the transcript before undergoing QC.
- After header, label next section "**Interview Text**," insert a hard return and begin transcribing the content of the audio file verbatim.
- Use "I:" before Interviewer remarks and "R:" before respondent remarks.
- Auto-number the transcript by paragraph so that each time the Interviewer or Respondent begins a new response, this should be indicated by a new number is this
- Replace all references to individual names or other identifying data with pseudonyms in brackets (to show that it has been modified from the original name)
- Any mumbling, laughing or silences recorded in transcript can be noted by [brackets]
- Explanation of unclear meanings, cultural terms, etc. can be noted by [brackets]
- Any words or phrases spoken in local language that do not translate well into English can be left in local language, in *italics*, and then the best translation can immediately follow the word or phrase in [brackets]
- Long pauses can be represented by use of an ellipsis "..."
- The footer contains the template date and version number and page X of X on right-hand side
- Spell check the transcript for any spelling and grammar errors

Example of Formatted Late FGD Transcript

LFGD1_123_Transcript_12DEC2019

HEADING INFORMATION REQUIRED FOR REACH LFGD TRANSCRIPTS	
FGD date:	12/12/2019
FGD #:	01
Transcriber:	Iron Man
Translator:	Iron Man
Site reviewer:	<input type="checkbox"/> No: If "no," reason why not <input checked="" type="checkbox"/> Yes: MKSQ

I, Iron Man, certify on 12 December 2019, that this transcript is an accurate and complete representation of the original audio file.

Note: certification statement completed before transcript undergoes quality control procedures.

FGD Text:

1. I: [Laughs]. Thanks for coming, we really appreciate this and we hope that we are going to use this hour fruitfully and to learn from you as we said before. All right, what can you tell us about the tablets? Anywhere you can start...
2. [Catwoman]: *Okay my name is [Catwoman]. I have been taking tablets but I had complications in the beginning. I used to feel dizzy, vomit, maybe my body was not used to them, but I came to the clinic and they told me that is the process I have to go through and it will eventually stop. I think I am now used to taking the tablets. I just want to ask that I am taking the tablets is there something happening in my bodies?*
3. I: Okay. Since you know; I'm not sure if some of you have similar concerns; as to what will happen to your bodies since you are no longer taking the tablet? But those are the questions that can be answered by the nurses and doctors because we [are] not nurses, so we don't want to give misinformation; information that is not appropriate. So, we will jot [write] that down and later on, we will call a nurse to explain. Okay
4. [Wonder Woman]: *I want to know that if the programme stops, I mean the ASPIRE, the MTN programmes, is there another programme or will it continue to maybe next year?*
5. I: If the MTN study stops?
6. [Wonder Woman]: *Yes... because they say my last day is the 28th.*

FGD Formatting Expectations

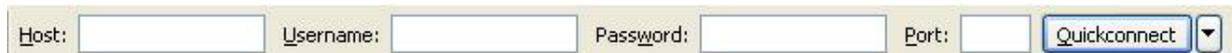
- Header should include filename of transcript. Every time the file name is updated, the header should be updated by right clicking the file name and selecting "Update Field."
- Use consistent Times New Roman or similar, 11 or 12-point font and 1.15 spacing.
- Header within document includes: FGD No., FGD Date, Transcriber Name, Translator Name, Site Reviewer initials
- A statement before the transcript from the translator and transcriber, including the date, that attests to the accuracy and completeness of the transcript before undergoing QC.
- After header, label next section "**FGD Text**," insert a hard return and begin transcribing the content of the audio file verbatim.
- Use "I:" before Interviewer remarks and insert the participant's pseudonym before respondent remarks.
- Auto-number the transcript by paragraph so that each time the Facilitator or a group member begins a new response, this should be indicated by a new number
- Replace all references to individual names or other identifying data with pseudonyms in [brackets] (to show that it has been modified from the original name)
- Any mumbling, laughing or silences recorded in transcript can be noted by [brackets]
- Explanation of unclear meanings, cultural terms, etc. can be noted by [brackets]
- Any words or phrases spoken in local language that do not translate well into English can be left in local language, in *italics*, and then the best translation can immediately follow the word or phrase in [brackets]
- Long pauses can be represented by use of an ellipsis "..."
- The footer contains the template date and version number and page X of X on right-hand side
- Spell check the transcript for any spelling and grammar errors

Appendix 11-2: Use of the SFTP

Accessing the SFTP: Access to SFTP is based on folders, not individuals—a username and corresponding password will provide a connection to that folder, regardless of who is logging in. Because of this, username and password will be provided by the SFTP administrator to a specific individual and that individual shall not distribute that username and password to anyone beyond themselves. An individual wishing to receive access to a folder needs to send a request to RTI and may be granted access by the SFTP administrator through an email communication. **Any violation of this could be considered an ethics violation and a breach in study confidentiality.**

Using the SFTP:

1. **Download FileZilla:** FileZilla is a free, third-party program that allows access to an SFTP site. You must have this or a similar program to access SFTP.
 - a. Download FileZilla here (<https://filezilla-project.org/download.php>) and ensure in your download process that you are not downloading additional programs, bloatware, or viruses.
2. **Connect to SFTP with FileZilla:** Only connect to SFTP directories with the username and password provided to you by the SFTP administrator. Do not share your username or password information with **anyone**.
 - a. **Quick Connect:** To connect, you will need a **Host** (*sftp://ftp.rti.org*), **Username** and **Password** (provided via email from RTI staff), and **Port number** (22). Follow these instructions:
 - i. Open **FileZilla**

A screenshot of the FileZilla Quickconnect dialog box. It features four input fields: 'Host:', 'Username:', 'Password:', and 'Port:'. To the right of the 'Port:' field is a 'Quickconnect' button with a dropdown arrow. The fields are currently empty.

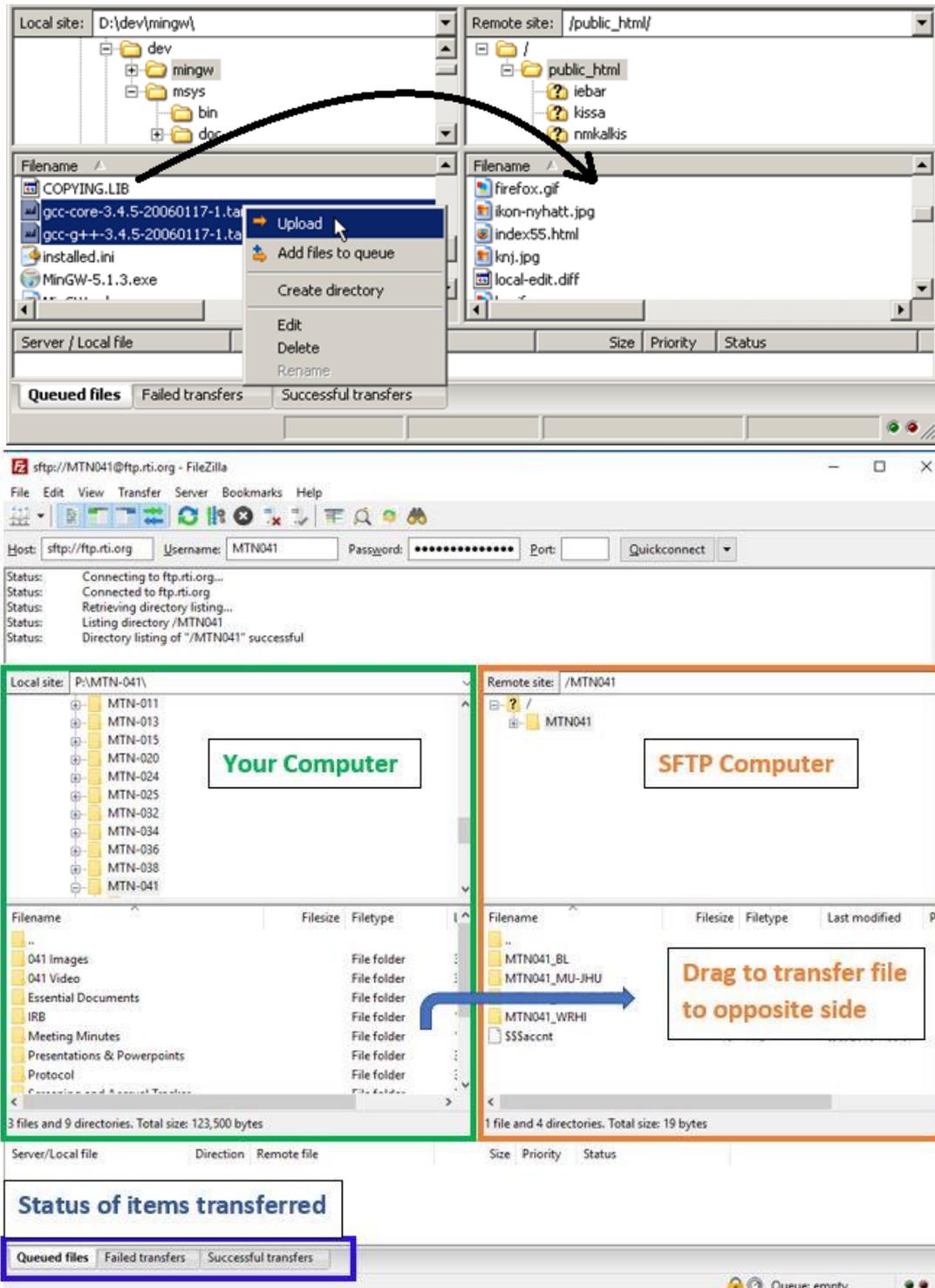
- ii. Enter the address of the server in the field **Host**, located in the **Quickconnect** bar
 - iii. Enter your username, password, and port number
 - iv. Click on **Quickconnect** or press **Enter** to connect to the server.
 - v. Click **OK** when you get a warning about an unknown host key. (The first time you connect to the FTP server you may be asked to verify that it is a trusted site. Check the “Always trust certificate in future sessions” box. Then click “OK” to continue)
 - b. Each site will have a Username as follows:
 - i. **MU-JHU:** MTN034-MUJHU
 - ii. **KEMRI-CDC:** MTN034-KEMRI
 - iii. **UZCHS-CTU:** MTN034-UZCHS
 - iv. **WRHI:** MTN034-WRHI
 - v. **DTHF:** MTN034-DTHF
 - c. Passwords will be provided separately to the individual(s) at each site who are responsible for file transfer using SFTP.
3. **Save a Connection with Site Manager**
 - a. Perform Quick Connect
 - b. Click **File** and **Copy current connection to Site Manager...**
 - c. Now you are ready for file transfer!

Transfer Files

Transferring files via SFTP requires administrative and technical actions. The process includes:

- Appropriately name and save the file using the naming convention described in SSP section 11.4.5.5 to be copied to SFTP for transfer; please save all of the files uploaded to SFTP on the original computer
- Upload the file via FileZilla (or other third party program) to SFTP
- Inform a specific group of people that it has been uploaded by email
- Download the file via FileZilla (or other third party program) to a secure location on another computer
- Delete the file on SFTP after a specific time frame

1. **Name and Save the Files to be Transferred:** Please keep a folder on your computer of all files uploaded to SFTP. This is very important. It provides a chronological history of your hard work, can be referenced by date, and these files can serve as backups, if needed.
2. **Upload the File:** You can upload a file by double-clicking on it, by right-clicking one or more file and selecting Upload, or by dragging one or more files from one side and drop them on the other side. Whichever method, the files will be added to the transfer queue and the transfer starts automatically.



3. **Inform Recipient(s):** STFP is a manual process. There are no automatic alerts when a file is added to a folder. Because of this, the person uploading a file must alert the recipients that a file has been uploaded.

- **Example Email**

“Hello [names of recipients],
I’ve just uploaded <name of file> to the <name of folder> on SFTP. Please download the file within the next <time frame, ~24 hours> before <name of designated deleter> removes the file. Please let me know if you have any questions.

Thank you,
<name of sender>
<sender affiliation>”

4. **Download the File:** Downloading a file is similar to uploading a file, only that the file is double-clicked, dragged, or right-clicked on the SFTP side of the navigation pane (i.e. the file directory on the right) and moved to your computer’s side. Ensure you know where you are saving a file when moving it to your computer; double-clicking will pick an automatic folder whereas dragging allows you to choose a folder with your mouse.
5. **Delete the File:** SFTP is designed for file transfer, *not* for file storage. It is important that files uploaded are deleted (do **not** delete the original file from your computer, instead leave this in the Uploads folder you created above) after an adequate amount of time (typically, 24 hours). Because of this, RTI and each site will have each one person who is the designated “deleter”. It is the responsibility of the deleter to ensure the people who most-need the file have received and downloaded the file before they delete.

REMINDER: Once you receive files from RTI, **please delete those files from the SFTP folder**. Only documents that are newly uploaded and waiting for RTI should be in the appropriate folders at any given time.

Please contact RTI (mtn034qmt@mtnstpshiv.org) with any questions about this process.