Section 14. DELIVER Qualitative Component

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14.1 Introduction

This section specifies the sources of procedural information available to DELIVER qualitative staff, including qualitative data collection and data management procedures, and the process by which each study site is approved to begin implementation of the DELIVER qualitative component.

Study implementation questions regarding the qualitative component that are not answered by the protocol or these operating procedures should be directed to the MTN-042 Qualitative Management Team (QMT). This group consists of representatives of the MTN LOC (FHI 360), RTI International (which acts as the qualitative data center), and the Protocol Chairs. This group can be reached using the following email address: mtn042qmt@mtnstopshiv.org

There is not a separate activation process for the qualitative component of DELIVER. However, prior to undertaking any study procedures for cohort 1, each site must receive notification of completion of all items on the DELIVER Qualitative Component Readiness Checklist from RTI. For subsequent cohorts, qualitative readiness items as outlined on the applicable cohort readiness checklist should be completed prior initiating study activities.

14.2 Documentation Requirements

Essential documents pertaining to the qualitative component, e.g. IRB correspondence related to approval of the IDI guide, this SSP section, Qualitative SOPs and SOP training, documentation of study specific qualitative training, signed DELIVER Qualitative Readiness Checklists, etc. should be filed in accordance with site specific procedures for other DELIVER Essential Documents (see SSP section 2). Study sites must maintain adequate and accurate participant file records containing all information pertinent to participation in the DELIVER qualitative component, for each study participant.

14.2.1 Participant File Contents

In addition to the file elements outlined in SSP Section 2, files for individuals participating in the qualitative component should contain:

- Documentation that the participant met the eligibility criteria to participate in the selected qualitative interview.
- Documentation that the participant provided written consent to participate in the qualitative component prior to the conduct of any study procedures.
  Note: Informed consent for participation is contained within the DELIVER enrollment informed consent form for all sites. A standalone ICF for the qualitative component can be developed as needed based on IRB/EC requirements.
- For purposively selected IDI participants: documentation that the participant fulfilled the designated recruitment criteria to receive an in-depth interview (IDI)
- For special cases: documentation of special case nomination and approval from the QMT
- Appropriate visit checklist (includes documentation that the participant meets eligibility criteria)
- A record of all contacts, and attempted contacts regarding qualitative research-related activities with the participant
- All source documents from each interview
  - Audio recording or documentation (e.g. chart note or note to file) indicating the location of the audio recording
  - Notes recorded during interview and/or additional materials used for IDIs.
  - English language transcript, once finalized
- The debrief report from each interview, once finalized
- 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 MTN-042 protocol, SSP, or the site Qualitative Component SOP.

14.2.2 Source Documentation

As noted in section 14.2.1, we consider the following three types of documents to be source documents in the qualitative component of DELIVER:

Audio files: Audio file recordings are considered to be source documentation for all IDIs, and will be removed from recording devices and ultimately transferred to CDs.

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

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

14.2.3 Record Retention Requirements

Please refer to Section 2 of this manual. The documents for DELIVER qualitative component must be maintained (at least) for the same timeframe as those for the DELIVER study. No documents may be moved to an off-site location or destroyed without written permission from DAIDS (see MOP section 18).

14.3 Participant Accrual

This section provides information on requirements and procedures for approaching participants for participation in the qualitative component. Target sample sizes for in-depth interviews are delineated by study Cohorts in Table 14-1 below. Informed consent considerations are provided in Section 14.5.

Table 14-1. Summary of target sample size for in-depth interviews

	Cohort 1	Cohort 2	Cohort 3	Total
# Enrolled Women (across sites)	150	150	250	550
VR	*100*	*100*	*200*	*400*
Truvada	*50*	*50*	*50*	*150*
Target # IDIs (across sites)	45* (30%)	32 (21%)	50 (20%)	127 (23%)
VR	*30*	*24*	*40*	*94*
Truvada	*15*	*8*	*10*	*33*

*****Note: Due to collaborative enrollment, sites may not enroll equally but a minimum of 4 IDIs should be targeted at each site for the vaginal ring

14.3.1 Study Accrual Plan and Site-Specific Accrual Targets (Cohort 2)

For Cohort 2, participants will be recruited through a purposive selection process to examine the potential role of any previous pregnancy, and previous pregnancy complications, on product acceptability and use. We intend to enroll 8 women at each site, 4 who have had only previous pregnancies with healthy outcomes (i.e., live births at term); and 4 who have no prior pregnancy or those who experienced a pregnancy loss prior to 20 weeks (i.e., nulliparous women or women with a history of miscarriages/abortions). Within each parity subgroup of 4 we will additionally aim to enroll by product using a 3:1 ratio (i.e., 3 who were randomized to the ring, 1 who was randomized to the tablet), as delineated in Table 14-3 below.

The sample per site will aim to be equal across sites, irrespective of enrollment at that site. Due to collaborative enrollment, this plan is subject to change. The QMT will provide additional guidance for the qualitative accrual targets at each site if needed.

Special case interviews are not required. However, approximately six special case interviews across all sites (identified by the site team and agreed upon by qualitative management team) **may** be invited (i.e., 6 total special case IDIs across sites for Cohort 2). Special case participants represent those with unexpected and/or interesting experiences related to behavioral endpoints (e.g., individuals who experience frequent VR expulsions or reported a social harm). Special case IDIs will not replace target numbers for purposefully selected IDIs based on parity.

Table 14-3. Target number of IDIs per parity subgroup, per product, per site for Cohort 2

Parity	Arm Assignment		TOTAL
	Ring	Tablet	
Only previous live birth(s) at term	3	1	4
Any pregnancy loss prior to 20 weeks or no prior pregnancies	3	1	4

TOTAL	6	2	8

Accrual Order & Timing for Cohort 2
Participants will be selected for IDIs at the Enrollment Visit by site staff in accordance with designated recruitment targets. All participants who enroll in DELIVER will be informed that about 20% of them will be invited to participate in an IDI at (or close to) their 4-week visit, and prior to participant study exit. Depending on the participant's gestational age at enrollment, women will be between 34-39 weeks at the time of their interview. IDIs may be scheduled any time between the 1st 4-week visit and the participant's study exit for cohorts 2 and 3. Special case IDIs may take place at any time point during study follow-up.

Purposive Selection for Cohort 2
Prior to the start of the qualitative component, RTI will provide a log indicating the number of participants who should be purposively selected within each set of criteria (combination of parity and product assignment as listed in Table 14-3).

- During enrollment, a participant will complete the Pregnancy History CRF and be randomly assigned to a study product. All participants' parity and product assignments will be recorded on a log. Sites will evaluate each participant's eligibility for an IDI sequentially in order of enrollment until all 8 slots (stratified by parity group and product) are filled.
- All details about participants who are purposively selected to participate in the qualitative component, including their eligibility and participation, will be documented in a Qualitative Participation Log (QPL, see Table 14-5).

14.3.2 Eligibility Criteria

Eligibility for participation in an IDI is contingent upon meeting the criteria described below.

- Participant is enrolled in DELIVER
- Cohort 2: Purposively selected by the site or have an approved nomination for a special case IDI from QMT
- If in Cohort 2, purposive (non-special cases) have at least 4 weeks since study product dispensed to participant

Note: Special Case participants in all cohorts have no product use requirement.

Eligible participants may be excluded from an IDI if they have any other condition that, in the opinion of the IoR/designee, would preclude informed consent, make study participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving study objectives.

If eligible, randomized participants may be invited to an interview. Participants must verbally confirm willingness to participate in the IDI and willingness to be audio-recorded during the interview. Note: Willingness to be recorded is not a requirement to proceed, but in situations where a participant declines being recorded, a notetaker is recommended.,

14.3.3 Qualitative Component Participation Logs

Data about participation in the qualitative component will not be recorded on the site's DELIVER Screening and Enrollment Log. However, sites should maintain a comprehensive record of all participants who are pre-selected, including tracking decisions regarding the participant's eligibility and participation. This information should be hand-recorded on the Qualitative Participation Log (QPL) at each site.

QPL templates will be provided to sites with recommendations for the information captured for each qualitative participant. A sample QPL for Cohort 2 is listed below in Table 14-5 below.

Sites should scan and send an up-to-date version of the QPL on a weekly basis to the QMT for cohort 1 and biweekly for cohort 2 (mtn042qmt@mtnstopshiv.org). 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.

Table 14-5: Sample Qualitative Participation Log (QPL) for Cohort 2, including IDI Slot List

	DELIVER PTID	Study Arm	Parity group	Slot available?	Accepted IDI?	If yes, Target IDI Date	I&D	IDI Completion Date	I&D	Postpartum IDI
	List of all participants	(Ring or Tablet)	(previous live births /no live births)	(Yes or No) If yes, invite participant to IDI	(Yes or No) If yes, add PTID to slot list	Or N/A if IDI was not accepted	Add initials and date	Or N/A with reason for no IDI)	Add initials and date	(Yes or No)
1										
2										
3										
4										
5										

IDI Slot List		
Ring IDIs		
#	Parity	Slots [add PTID]
1	Previous live birth outcomes	
2	Previous live birth outcomes	
3	Previous live birth outcomes	
4	No previous live birth outcomes	
5	No previous live birth outcomes	
6	No previous live birth outcomes	
Extra 1		
Extra 2		
Extra 3		
Use extra lines if participant(s) decline IDI after accepting invitation		
Tablet IDIs		
#	Parity	Slots [add PTID]
1	Previous live birth outcomes	
2	No previous live birth outcomes	
Extra 1		
Extra 2		
Extra 3		

Note: This is a sample QPL and not the final version, which will be released with other study materials prior to study activation, may include additional or different fields.

14.4 Informed Consent

Informed Consent for participation in the Qualitative Component follows the same guidelines and procedures as for DELIVER Enrollment IC. Please refer to Section 4 of this manual.

Before each IDI, key elements of informed consent should be reviewed with participants, and willingness to continue should be confirmed. This review/confirmation should be documented on visit checklist (as well as chart notes as needed).

14.5 Qualitative Visit Procedures

This section provides information on requirements and procedures for IDIs in DELIVER.

14.5.1 Participants who Withdraw Consent and are Selected for an IDI

Participants selected for an IDI may choose to withdraw consent at any point during the trial. If a participant selected for an IDI withdraws consent prior to her scheduled interview, she may still participate in the IDI, if willing, at her final visit. If she refuses the IDI or is deemed ineligible, study staff should document accordingly on the QPL.

14.5.2 Preparing for the Interview

Before each interview the following should occur:

1. Ensure a signed copy of the Mother Informed Consent Form is on file (or, for IRBs/ECs that require a standalone Qualitative ICF, confirm this ICF 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 the interviewing space has been reserved and is ready for use.
5. Ensure the correct version of the IDI guide is ready for use.
    - Gather needed supplies, e.g. pen and stationary for note-taking, IDI guide, refreshments (if applicable), and reimbursement.
6. Upon participant's arrival for the IDI, confirm participant identity per site SOPs.
7. Immediately before beginning the IDI, review key elements of informed consent and confirm willingness to participate verbally.

14.5.3 Data Collection Considerations

All interviewer-administered guides 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's file. The qualitative visit checklist should be used to guide the order of procedures for each IDI.

To maintain neutrality and promote an open/free environment, interviewers should be independent from (i.e. not involved in) any study procedures involving activities or topics (e.g. product adherence) that will be discussed during the IDI. No one other than the participant, interviewer and note-taker (when required) should be present during the IDI.

IDIs should be conducted in a confidential private location that allows for neutrality, which may be at the clinic, or another venue preferred by the participant. If requested or preferred by the participant, the IDI can be arranged at the participant's home, or at a different outside location if she has provided consent for off-site visits. If conducted at the clinic, please avoid the use of exam rooms, to demedicalize the conversation and allow for a more comfortable discussion space.

Interviews will follow an IDI guide, but will allow for probing and digression on relevant themes. IDIs will be audio-recorded and later transcribed and translated by site staff or outsourced to a transcription/ translation agency. If necessary, interviewers may request a note-taker to be present during the interview. Note-takers may only then be present if participants agree to be interviewed with them present.

Immediately following each IDI, the interviewer (or note-taker) should expand their notes and complete a debrief report using the Debrief Report template provided.

Further description of the management of the audio-files, interview notes, debriefing reports, visit checklists and transcripts of the IDIs is described in Section 14.9.

14.5.4 IDI and Qualitative Interview Techniques*

- **Maintain Confidentiality.** Respect confidentiality at all times. Be careful not to comment to other family members or neighbors about anything that you learned during the interview. This is especially important when interviewing participants about their sexual behaviors and intimate relationships.

- **Remaining Neutral.** It is especially important to be on guard against asking leading questions and influencing responses. Leading questions are those that imply a value judgment on your part. This can bias the responses that you will obtain because if the participant disagrees with you, they may be reluctant to state it.
    - *Biased question: "I know that most smart people in this community always use condoms, don't they?"*
    - *Better phrasing: "I have heard some people in this community say that most smart people use a condom, and others say that they know smart people who don't use condoms. What do you think?"*

- **Probe for Depth.** As much as possible ask follow up questions and probe for a deeper understanding of what the participant is saying. Examples of probing phrases might be: "Why?" "How did you feel when that happened?" "What did you do next?" "What do you think?" "What happened then?" "Can you tell me more?" "Could you describe X? I'm not sure I understand." Such probing also may require extra patience on the part of the interviewer.
    - *Example: Can you tell me more about why you didn't feel you could ask him to use a condom?*

- **If Uncertain, Verify Responses.** When you want to be sure that you have heard clearly what the participant said or that the information is accurate. You may ask them to repeat their response, or sometimes better, you can reflect the answer back to the participant.
    - *Example of reflecting back: So you told him that you think it's a sign of being responsible if you avoid sex while drinking?*

- **Do Not Respond to Questions.** If the participant asks you questions that are the focus of the interview, do not answer them. Your answers might influence how the participant will answer the rest of the questions. Instead, turn the question around and ask them what they think.
    - *Example: Well, I was hoping you could help me understand what people in this community say about how you get infected with the HIV virus.*

- **Be Patient.** It is not necessary to be asking questions every minute. Creating pauses and allowing silence can permit the participant to think more deeply about the topic. Don't be afraid to wait quietly while they think about a response or further probe but be reassuring in your body language, so the participant knows you are genuinely interested in what she/he has to say.

- **Do Not Interrupt Participant's Work.** The participant is doing a favor to answer the questions. If the participant must interrupt the interview to attend to a child, a customer, a neighbor, use this time productively to review your notes and think about what else you would like to ask and probe further upon their return.

- **Handle Time Wisely.** Always note the time when the interview begins and ends. As you begin the interview, evaluate how much time you may have with this participant and what are realistic goals for asking questions from the interview guide. Ideally, the interview will flow like a conversation rather than a series of questions and answers.

* The Qualitative Interview Techniques section is adapted from the following reference: Mack, Natasha, Cynthia Woodsong, Kathleen MacQueen, Greg Guest and Emily Namey. Qualitative Research Methods: A Data Collector's Field Guide. RTP, NC: Family Health International, 2005.

- **Be Truthful.** In obtaining informed consent or in responding to questions from participants during the interview, provide brief, truthful answers about the objectives of the study, the likely benefit to her or the community.

- **Moderate Tone of Voice.** During the interview, use a calm, moderate, friendly tone of voice.

- **Monitor Body Language.** Be sensitive to your participant's body language and aware of your own. Avoid body language that may send the signal that participants are giving "correct" answers, or that you approve of, or reciprocally, that you are wasting your time.

14.6 Visit Checklists

The qualitative section of the MTN-042 website contains a template qualitative component readiness checklist detailing the protocol-specified procedures that must be completed by each site before any qualitative activities are conducted in cohort 1. In addition, sites will be provided with a template cohort-specific qualitative visit checklist to be completed at all DELIVER qualitative study visits for each interviewed participant. These checklists should be modified as needed, then reviewed by RTI International for approval prior to implementation.

14.7 Reporting of Social Harms, Adverse Events, or Protocol Deviations and how to handle Participant Misunderstandings

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 DELIVER clinic/counseling staff as soon as possible and not more than 24 hours later to document and handle the AE, SH, or PD. Interview staff should document such notifications to clinic/counseling staff in the IDI debrief reports. If the issue is ongoing, ideally follow-up should occur after 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.

Important Note: Although the interviewer is required to share information about these events with other appropriate DELIVER staff, she should aim to maintain a sense of trust, discretion and rapport with the participant 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"*

Interviewers may also identify misunderstanding of key concepts that relate to study participant/informed consent during the interview (e.g. not understanding randomization, 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.

14.8 Data Collection

Only data collection issues unique to the qualitative data are covered in this section. For more information on DELIVER data collection procedures, see Section 11 of this manual.

For questions about this section or about general data collection policies, procedures, or materials for the DELIVER qualitative component, please email the qualitative data management team (mtn042qmt@mtnstopshiv.org).

14.8.1 Study Visit Timing

Women selected for participation in this qualitative component will receive a single in-depth interview. IDIs may be scheduled any time between the 1st bi-weekly visit and study exit for cohort 1, or any time between the 1st 4-week visit and the participant's study exit for cohorts 2 and 3, allowing to accommodate for participant availability. The ideal target date for IDIs with participants in cohort 1 will be the bi-weekly visit(s) after the 36th week of gestation, and at (or close to) the 4-week visit corresponding to the 36th week gestation for participants in cohort 2.

Ideally, IDIs will be completed in one session on the same day as a regular clinic visit. However, if there is not time to complete an interview during a regular clinic visit, IDIs can be scheduled on another day at the site's discretion. If an IDI participant starts an interview but is unable to complete it on the same day, she may be rescheduled to come back and complete the rest of the interview on another day. In the event that this occurs, the circumstances should be noted in the chart notes, the interview debriefing report and a comment included on the QPL.

14.8.2 Interview Guides and Materials: Supply and Storage

All guides and supplemental materials (e.g. checklists) needed for the qualitative component of DELIVER will be electronically supplied by RTI and should be printed locally. These materials will also be posted to the DELIVER website under *MTN-042 Qualitative.* The site is responsible for maintaining an adequate supply of the current version of these documents in all languages. One copy of previous versions of guides and materials should be maintained in an archive. The site is responsible for ensuring that previous versions are no longer implemented. Procedures for form storage should be detailed in each site's Qualitative Component SOP.

14.9 Qualitative Data Management

As a condition for initiation of the qualitative component, each study site must establish procedures for data management that should be described in the Qualitative Component SOP. The SOP minimally should contain the following elements:

1. Data collection, data back-up, transcription/translation procedures, and transmission procedures. This section should also include timeframes, and mechanisms for identifying when documents have been transmitted
2. Procedures and timeline for resolving data quality control notes from RTI on transcripts (reference section 14.9.6 below on Quality Control Procedures)
3. Storage locations for guides
4. Storage locations for securing sensitive documents
5. Confidentiality protections, including the procedure for destroying audio files
6. Other ethical and human subject considerations
7. Staff responsibilities for all of the above (direct and supervisory)
8. QC/QA procedures related to the above (if not specified elsewhere)

DELIVER qualitative data will be captured from the IDI that takes place at the site through audio recording and note-taking.

14.9.1 Audio Files

Following the IDI and before the end of the day, the audio file should be copied onto a password protected hard drive of a secure computer accessible only by the study staff 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 original audio recording, having all of the same attributes and information as the original (i.e. no editing occurred before transfer to CD), labeled with the PTID and stored per the site's Qualitative SOP. Audio files do not need to be sent to RTI.

Audio files of IDIs saved on computer hard drives should be stored in secure file locations accessible only by site study staff. Sites should refer to their Qualitative SOP for procedures on logging the file name and location of all audio files for future reference and destruction. The destruction process will be the responsibility of the IoR/designee and should be specified in the site Qualitative SOP. If required, sites may invite members of their community/CAB to observe the deletion. Once complete, deletion should be documented in the study files with signatures from the staff member responsible for the deletion and a witness and confirmed via email with RTI. The certified source audio files saved on CD must be kept 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 (see SSP section 2 on record retention requirements). No CDs or other documentation should be relocated offsite or destroyed without prior approval from DAIDS.

14.9.2 Interview Notes

Immediately following the IDI, all notes taken during the interview should be stapled together (if more than one page), with PTID and date of IDI listed on the front page and signed by the interviewer (or note-taker, if applicable). Notes should be filed per the site's qualitative SOP.

If the audio recording failed, 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 CRF.

If the participant refuses to be interviewed but agrees to participate in an interview, the interviewer should ask the participant's permission for a note-taker to be present in order to take more extensive notes.

14.9.3 Debrief Reports

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

14.9.4 Transcripts

IDIs should be translated and transcribed by someone other than the person who conducted the interview to ensure data integrity. While it is ideal to have a staff member different from the interviewer conduct the transcription-translation, it is recognized this may not be feasible. If the interviewer does conduct the transcription-translation, a separate staff member fluent in both languages must QC these documents. Sites should outline their QC process in their site SOP.

The site staff will conduct the translation-transcription process per their site Qualitative Component SOP. This may be done in-house or outsourced to an external agency. Regardless of whether this process is undertaken at the site or through an external agency, quality checks of the English transcript should be performed at the site and involve checks against the audio file. Transcripts can be simultaneously transcribed and translated (when conducted in a local language) and written up in English unless there are unique local language expressions that should be preserved. These expressions can be kept in the local language in italics, with explanatory notes provided in brackets to explain their meanings. All explanatory notes will be written in English.

An example of a formatted transcript is available in Appendix 14-2. When translating the audio files into English, staff should follow their site's Translation SOP or outline any variations from this in the DELIVER 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 before the transcript undergoes quality control procedures.

Once the transcript has been finalized by RTI, 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

14.9.5 File Naming Conventions

All data files should be named according to a standard naming format. The name will include the study name, cohort number(i.e. C1 or C2),, interview mode abbreviation (SCIDI for special case IDI vs. IDI for parity (selected) IDI), PTID, data type abbreviation (audio file (AF), debrief report (DR) or transcript (TS)) and the date the IDI was conducted.

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 RTI for review, there is no need to include the editor’s initials. It is only upon subsequent review (QCing) that this occurs.

Finalized versions provided by RTI will redact the initials of reviewers and add a version number to the end of the file name.

File Naming Conventions:

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

For example, when reviewed for the first time, the IDI transcript:
“MTN-042_C2_IDI_325-40008-1_TS_18AUG2019”
would become
MTN-042_C2_IDI_325-40008-1_TS_18AUG2019_CM”
and
“**MTN-042_C2_IDI_325-40008-1_TS_18AUG2019_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-042_IDI_325-40008-1__TS_18AUG2019_v1.0”**

Any subsequent versions of the document will indicate a version change in the file name.

14.9.6 Quality Control Procedures for Qualitative Data

Initial Quality Control at Site

Initial quality control of interviewing skills at site:

1. A senior staff member or the qualitative lead should observe two mock IDIs for each interviewer to provide feedback on moderating and interviewing techniques (e.g. adequacy of probing, appropriate linking of topics, fidelity to the guide, etc.) before data collection begins. The feedback will serve to provide additional training to the interviewers and also to improve on the quality of the data collected.
2. Once the first 2 IDIs have been conducted, a senior staff member or qualitative lead should review the audio files from those IDIs and provide further feedback. Once 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 IDIs were observed, and the decision as to whether the interviewer is ready to continue activities on their own, or whether they require further training.

3. If any issues with interviewing procedures are flagged, sites should conduct in-depth reviews of the first 2 transcripts from each interviewer to provide feedback on 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; 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 accurate 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 14-2
- 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.

Ongoing Quality Control at Site

Quality control of debrief reports at site: After initial completion, DRs should undergo a detailed site level quality review during which, at a minimum, all staff members who were present at the IDI 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 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

For cohorts 2-3, DRs will be reviewed and distributed by RTI. DR's will not be queried unless clarification to DR descriptions is required. Interviewers should ensure that they provide a detailed and spell-checked version of their DR to the internal colleagues at their institution who review the DR to minimize the query review process. A DR template will be provided by RTI and will be posted on the DELIVER website under *MTN-042 Qualitative.*

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 reviewer 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 (if applicable).

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. Site teams should send DRs to RTI as soon as they become available and within **one week** of when an IDI occurs. Site teams should communicate with RTI if delays are anticipated. For cohort 1, DRs will undergo the following QC process: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 queries:
  - Problems such as typos that lead to ambiguous meaning (e.g. "sore the medication" vs. "store the medication"), confusing terms or missing /potentially incorrect data
  - Sentences that are unclear
  - Clarification of local terminology or context
- 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. Communication of the documents should happen via sFTP instructions found below.
- When the revised information is received by RTI, the Qualitative Data Manager or a designated data team member 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.
- Once RTI finds no additional issues, RTI will accept all changes, remove all comment bubbles and email the final clean report (now in PDF form so it is not an editable document) to the Qualitative Team. This final version of the DR should be printed and filed in the participant chart.

For cohorts 2-3, the original uploaded document should be of acceptable quality to be sent directly to the Qualitative Data Management Team (QMT). DRs will be reviewed by RTI and, if needed, requests for clarification of DR summary content will be provided to the site team. Once RTI finds no additional issues, RTI will accept all changes, remove all comment bubbles and email the final clean report (now in PDF form so it is not an editable document) to the Qualitative Team. This final version of the DR should be printed and filed in the participant chart

<u>For transcripts:</u>
After the site level QC process, the English language transcript will be uploaded to sFTP site for RTI to review. Site teams should send English language transcripts to RTI as soon as they become available and within **one month** of when IDI 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 sFTP site.

Appendix 14-1: Secure File Transfer Protocol (SFTP) Instructions

Overview

Secure File Transfer Protocol (SFTP) is a highly secure file directory used to transfer manually files from one computer to another computer. DELIVER will use SFTP to transfer **large files** (unable to attach to an email) and/or **files with personally identifiable information**. Files with personally identified information MUST always be transferred in a secured way and should never be sent via email.

Data needs may change throughout the study timeline and, as such, use-cases for SFTP and these instructions will evolve over time. Current (as of 8/20/19) use-cases for SFTP include:

1. Debrief Reports
2. Transcripts

The goal 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.

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.**

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.

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.

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**.

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:

1. Open **FileZilla**

2. Enter the address of the server in the field **Host**, located in the **Quickconnect** bar
3. Enter your username, password, and port number
4. Click on **Quickconnect** or press **Enter** to connect to the server.
5. 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)

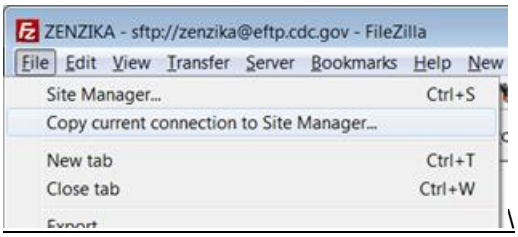
Each site will have a Username as follows:

- **Uganda:** MTN042-UGANDA
- **Blantyre:** MTN042-BLANTYRE
- **Zimbabwe:** MTN042-ZENGEZA
- **Wits RHI**: MTN042-SHANDUKANI

Passwords will be provided separately to the individual(s) at each site who are responsible for file transfer using SFTP.

Save a Connection with Site Manager

1. Perform Quick Connect
2. Click **File** and **Copy current connection to Site Manager…**



Now you are ready for file transfer!

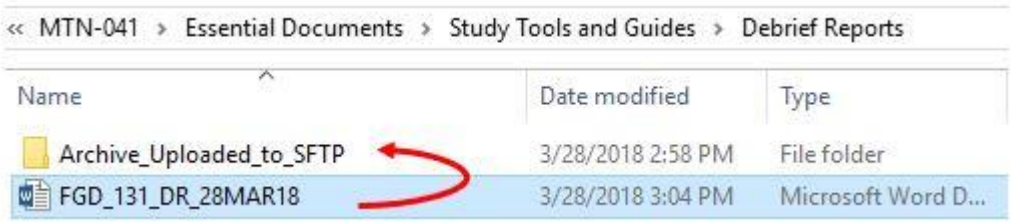
Transfer Files

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

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

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.

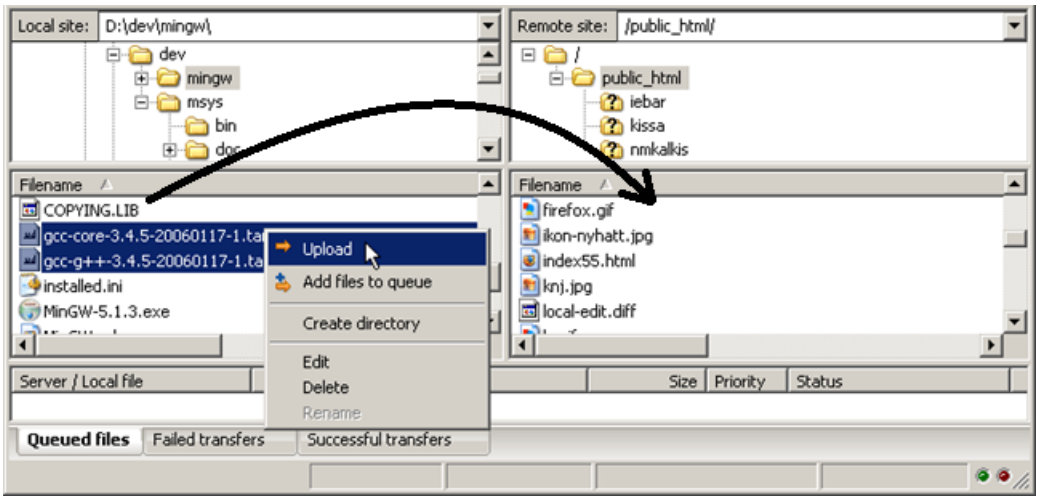


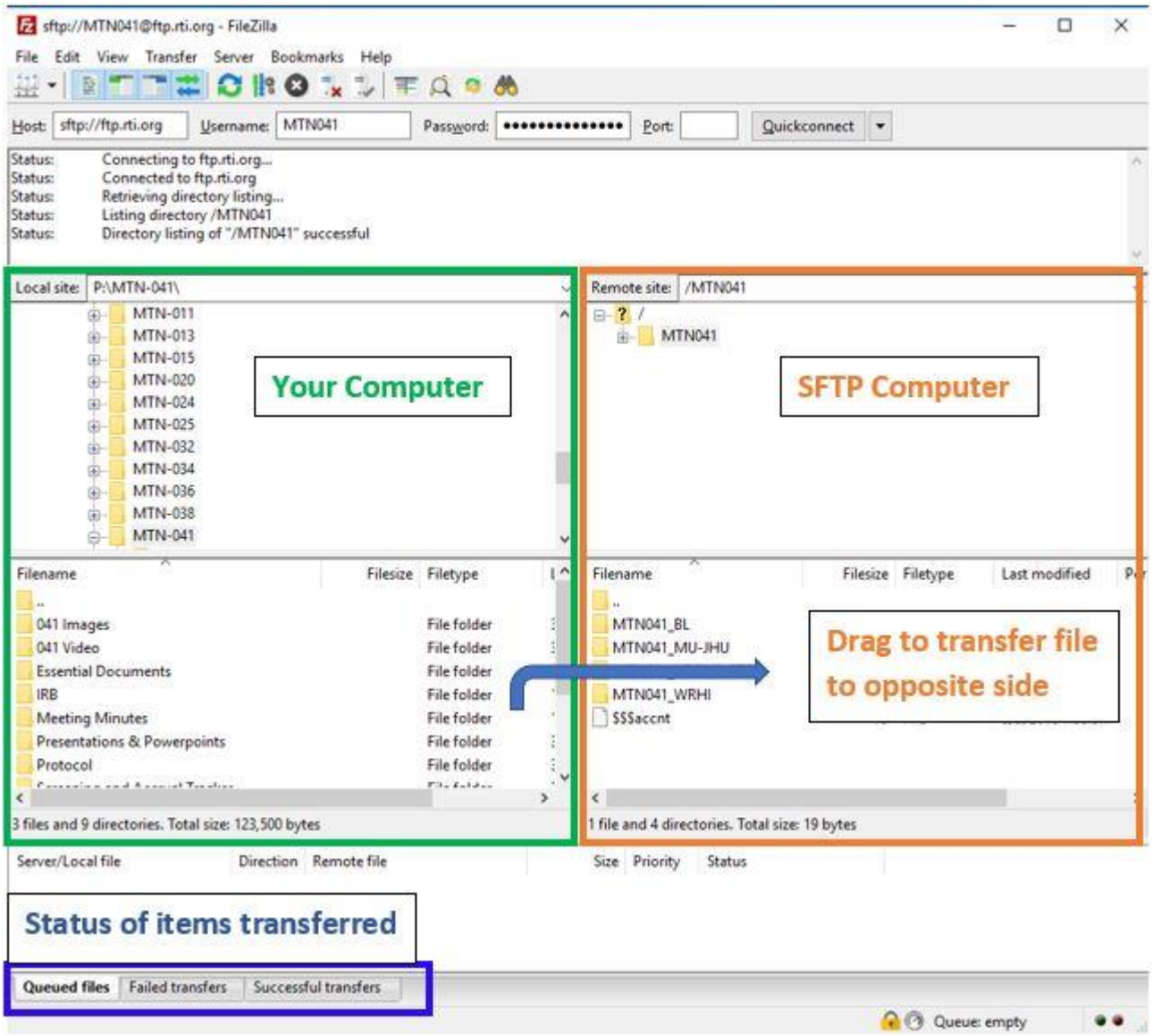
In the above photo, you can see that the upload is called IDI_131_DR_20AUG19.docx, which adopts the standard naming scheme for MTN-042. The name of the file tells us the file contains *a debrief report from IDI number 131* conducted on *August 20, 2019*. Please adopt the naming scheme for files uploaded to SFTP:

File	File Type	Name
Debrief Report or Transcript	MS Word Doc	IDI_2001_**DR**_20AUG19.docx IDI_2001_**TR**_20AUG19.docx

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.





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 STFP. 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>”

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 STFP 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.

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 one person who is the designated "deleter". It is the responsibility of the deleter to ensure the people who 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 (mtn042qmt@mtnstopshiv.org) with any questions about this process.

Appendix 14-2: Example of Formatted IDI Transcript

[MTN042_C2_IDI_TEMPLATE_TS_14MAY2021.docx]

HEADING INFORMATION REQUIRED FOR DELIVER IDI TRANSCRIPTS	
PTID:	[325-40008-1]
Interview date:	[DDMonYYYY]
Transcriber:	[Batman]
Translator:	[Wonder Woman]
Site reviewer:	☐No: [Reason] ☒Yes: [Initials]

I, [translator/transcriber], certify on [date of transcription], 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.
➢ 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